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Guidelines For Authors

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- 1 Learn how to use the Word features under the Tools/Autocorrect submenu. Some people turn off all autocorrection features because they are disconcerted by Word's default behaviour of adjusting capitalisation and reformatting type on the fly, but these features save a lot of time once you tune them in to match your expectations. In particular, if you have a long word like 'hypergammaglobulinaemia' that you need to type repeatedly, turn on 'Replace text as you type' and add it to the replacement list.
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- 3 Use styles and style tagging rather than formatting the article paragraph by paragraph. This makes it much easier to format an article as you write and easier again if you are asked to change the formatting later. For your level I headings, therefore, define a Heading I style, with the combination of font, spacing, and alignment that you want to use, and then apply this to each heading as you create it. To change all your level I headings later, simply redefine the style and all will be changed without having to select and manipulate each heading.
- 4 Format text as one continuous flow. Use a page break (Ctrl + Enter) to start a new page (e.g. after your title page) not a stream of hard returns. Put only one hard return between each paragraph. Do not break the article up with Word's section breaks.
- 5 Keep table formatting simple and consistent. A common error is to place a column of separate items into a single table cell, with each item separated by a hard return: instead each data item should have a table cell of its own. Sometimes tables are formatted with tabs instead of cells:

in this case, the key is to set the tab stops for the whole table so that one tab equals one column.

- 6 Image files should be sent as separate files. The same goes for Excel spreadsheets or charts. If you are embedding images in the file, it is probably best to do it at the end, after the text and references.
- 7 Be prepared to send the data used to generate graphs. Some publishers will use the data to regenerate the graphs according to their own style rules. In such a case, it helps if you send only the data that are actually shown in the graphs – not the spreadsheet with all of the data generated in the study.

What about PDF?

Send your Manuscript in a Word file. Don't send it as PDF or any other word processor format.

PDF files are not editable in the same way as word processor files. Some publishers will ask for, or even create, a pdf file of your manuscript for use during the peer review process, but a Word file will also be required for editing and production.

Tips for preparing images

Do not make electronic images too small. No effective way exists to increase the resolution of an image beyond its original size, and if an image is reduced in size and saved, picture data is permanently lost. Image files therefore have to be created and saved at high resolution. For a colour image that is to be printed as 4 X 4 in., the required size is (4 X 300) X (4 X 300) = 1200 X 1200 = 1440 000 dots. In many image formats (e.g. tagged image file format, or tiff), each dot will take eight bits (one byte) to store, so the image file will be 1.44 megabytes

Compression techniques can reduce the size of the image file. Zip compression is safe, because it uses an algorithm that packs the data tighter without throwing any of it away; In Compression during which files are saved in jpeg format, select the option for large file size (maximum picture quality).

Guidelines for Reviewers

Purpose of Peer Review

The purpose of peer review for *The Journal of the Egyptian Society of Cardio-Thoracic Surgery (JESCTS)* is twofold. One is to evaluate objectively the science of the submitted paper and the other is to provide a constructive critique indicating how the paper could be or could have been improved by the authors. Reviewers should respect the authors' efforts and avoid disparaging or unpleasant comments. Reviewers are not asked to copyedit papers, but should comment if language editing is needed.

Acceptance of a Manuscript for Review

Reviewers should accept assignments to review manuscripts that are within their sphere of expertise, which they plan to review within the 21 day deadline. Reviewers should decline assignments for which a conflict exists between the reviewer and authors or between the reviewer and commercial products that are integral to the content of the article.

Category of the Manuscript

The broad categories of papers for which peer review is undertaken are (1) original scientific articles; (2) new technology papers; (3) case reports, how to do it articles and images; and (4) review articles. The editor and/or associate editors review correspondence, invited commentaries, editorials, surgical heritage submissions and ethical and statistical papers.

General Requirements for Publication

The paper should conform to the format and restrictions for the category to which it belongs and be written in good, readable English. The paper should address an important or interesting subject and provide new and original information. Illustrative material should be well chosen and of good quality.

Original Scientific Article

Original scientific articles should provide new, reliable information that is relevant to the science and practice of cardiac and general thoracic surgery. The reviewer should assess the articles' interest to readers; strengths and weaknesses; originality; clarity of text, tables, illustrations and figure legends; presentation; analysis of results; credibility of results; importance of the findings; depth of scholarship; relationship of the results to the existing literature; and presence of marginally relevant or unnecessary archival material. Ethical issues, such as prior publication of all or part of the data; plagiarism; transgression of human or animal rights; or dishonesty should be noted, if detected.

Original scientific articles are usually one of three types: prospective, retrospective, or observational studies. For prospective studies the protocol of the study is planned

before data are collected. The most common form is the 'Prospective, randomized controlled trial', which is well suited for many experimental animal studies and some human trials. Retrospective studies use data recorded before the study protocol was designed. Most original scientific articles in clinical disciplines, particularly surgery, are retrospective, but modern statistical models are now available to analyze objectively retrospective data using a variety of statistical methods. Observational studies record observations of one or more groups of patients. These studies may record changes in various laboratory or biochemical tests in response to procedures or other therapy or determine the indications, efficacy and safety of a new procedure or laboratory or diagnostic test.

The following topics are offered to help guide the reviewer's assessment of an original scientific article. Not all topics are relevant to every article.

- 'Title' should reflect the content of the article and be concise and clear 'Abstract' should indicate the purpose of the study, subjects and methods used, most important results and the main conclusions supported by results.
- 'Introduction' should indicate the rationale and focus of the study and state the purpose or hypothesis.
- 'Methods' should present the design of the study, fully describe the number and subjects and exclusion and inclusion criteria; whether subjects were enrolled consecutively; methods used to gather data, including follow-up data; methods by which control and experimental groups were assembled; the primary outcome variable; secondary outcome variables; how outcome measurements were made and validated; the statistical design of the study; and the statistical methods used to analyze the study.
- 'Results' should concisely present the most important findings in text and relegate to tables data of lesser importance. Data should be reported as means or medians with appropriate indicators of variance and exact p values in tables and text. Figures should be well selected to highlight important findings and should not be used to present data of lesser significance. Survival and event curves should indicate specified confidence limits or subjects at risk. Regression diagrams should include the regression equations, regression coefficient and exact p value in the figure legend. Figure legends should adequately and clearly describe the important information illustrated.
- 'Comment' should not repeat results, but should point out the significance and conclusions of the new data, integrate the authors' new data with that in the prior literature, draw inferences and conclusions regarding the question or purpose addressed by the study and point out the limitations of the study. The 'Comment' section should not be a review of the literature.
- References should be properly cited, reasonably current, accurate, in proper format and selected. Important omissions should be noted.

New Technology

Articles describing new technology are necessarily descriptive and do not pose or test a hypothesis. These articles evaluate new devices, systems, machines, equipment, instruments, monitors, implantable material and similar technology designed for improving patient care and outcomes. The reviewer is asked to evaluate the efficacy, safety and indications of the new technology and the rigor, completeness and objectivity of the evaluation study.

Topics which the reviewer should consider include:

- Probable importance or usefulness of the technology.
- Problem or task that the technology addresses.
- Newness and innovation of the technology.
- How well the technology is described and illustrated.
- Protocol used for evaluation.
- Methods used to test the technology; and the results obtained.
- Reasons for selecting the methods of testing and evaluation.
- All studies used in the evaluation.
- Ease and difficulties in application including successes and failures.
- Advantages, complications and late adverse events of the new technology.
- Whether are included or should be included in the evaluation.

The conclusion section should summarize the indications, deficiencies and drawbacks. The article should have an objective, dispassionate tone and avoid the enthusiasm of an advertisement or endorsement.

The reviewer needs to inspect the 'Disclosure statement' after the text, before References. This statement should disclose the source of funds used for the evaluation study and whether or not the product was purchased, borrowed or donated by the manufacturer or inventor. Conflicts of interest statements for authors are managed by the editorial staff.

Case Reports, How to Do It, Images

Case reports describe interesting presentations of disease and innovative management of the patient's or patients' problem. *How to Do It* articles emphasize innovations in the operative

management of technical challenges and new ways of doing things. *Images*, which must fit on one printed page, are graphics of interesting presentations of disease within the chest.

Reviewers should evaluate the clarity and completeness of the case or procedure descriptions and the selection and quality of the illustrative material. Reviewers should also note whether or not the paper adheres to the format restrictions enumerated in "Information for Authors". The reference list should be selective rather than inclusive.

Review Article

Reviewers should assess the importance of the subject matter, need for the review and probable interest to readers. Reviews of very rare and unusual diseases are discouraged; subject matter should be sufficiently broad to have instructional and practical value for readers. Reviewers should note if authors have respected the format and restrictions of this category as stated in "Information for Authors".

The 'Introduction' should provide the rationale for reviewing the subject matter and provide the outlines of what is included and not included in the review. In the 'Methods' section reviewers should assess the methods used to search for articles, including search words and databases probed. The body of the review should be well organized with well chosen topical headings arranged in logical order. Within each topical heading the material should be presented in an integrated, comprehensive, objective manner. Statements should be referenced accurately. Reviewers should look for a "summing up" of the topical content before the author proceeds to the next topic. Reviewers should reject topical presentations consisting of "one sentence précis of referenced articles" arranged serially.

The review should provide a general overview of the subject matter assessing progress, pointing out deficiencies in present management and indicating opportunities and directions of future work. The reviewer should also assess the selection of references and note important absences or trivial inclusions.

Footnote.

This editor carefully reads all reviews and respects the time and effort that each reviewer has expended on behalf of the author and all readers. The reviewer remains anonymous; there is no reward beyond listing on the annual thank you list. The reviewer should direct his or her critique to the authors in the style and format that suits them best. The recommendation to the editor is made separately with or without additional comments.

EuroSCORE II as a Predictor of Need For Prolonged Mechanical Ventilation Following Valvular Heart Surgery in Egyptian Patients

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Objective: To Assess the usefulness of EuroSCORE II as a predictor of need for prolonged mechanical ventilation (PMV) in Egyptian patients undergoing heart valve surgery.

Patients and Methods: 255 consecutive adult Egyptian patients undergoing heart valve surgery, in Cairo University Hospital, in the period from February 2012 till August 2013. Risk factors needed to calculate EuroSCORE II were collected, as well as duration of mechanical ventilation and mortality.

Results: 255 patients were included. Overall mortality was 8 patients (3.8%), the mean EuroSCORE II was 2.02 and the area under receiver operating characteristic curve (AUROC) was 0.792, and a Hosmer-Lemeshow (HL) test for goodness of fit p value of 0.614. Ten patients (3.9%) required PMV more than 48 hour. HL test p value of 0.748, the AUROC was 0.564.

Conclusions: EuroSCORE II is a good predictive of mortality for Egyptian patients undergoing heart valve surgery, however, it couldn't properly predict the need for prolonged mechanical ventilation. A dedicated model for predicting the need for PMV is need.

KEY WORDS: EuroSCORE II, open heart, heart valve, cardiac surgery, prolonged mechanical ventilation, outcome, post-operative.

Standard EuroSCORE was first introduced in 1999. In the intervening decade, the EuroSCORE risk calculator[1] has continued to demonstrate itself as a well-established and validated tool[2], and since its validation in the Society of Thoracic Surgeons database[3] it has been increasingly adopted worldwide, because of its ease of calculation.[4]

In order to simplify the use of the system and to encourage risk assessment even in the absence of information technology, EuroSCORE was published as an additive system in which each risk factor is given a "weight" or a number of points which, when added, provide an estimate of the percent predicted operative mortality for a patient undergoing a particular procedure.[5] Nevertheless, because of its additive nature, the standard EuroSCORE has been found to underestimate risk in certain very high-risk patient groups [6]. The logistic model is a better risk predictor especially in high-risk patients and may be of interest to institutions engaged in the study and development of risk stratification[5].

However, the EuroSCORE is already outdated, as it was developed from data on patients operated on almost a decade and a half ago, and the results of surgery have improved significantly since, especially in the elderly. Also, because the data originated from only eight European countries and, from each one of these, only few centers contributed. So, a new model has been prepared from fresh data and is launched at the 2011 EACTS (European Association of Cardiothoracic Surgery) meeting in Lisbon. The model is called EuroSCORE II. The new model has been validated by the EuroSCORE Project Group and received validation by many users worldwide [7–13]. It was presented at EACTS in Lisbon on 3rd October 2011. [14]

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Codex : o3/01/1406

The EuroSCORE is often used to benchmark and predict hospital mortality after cardiac surgery. Based mainly upon coronary surgery patients.[15] The model is initially intended to measure mortality only. Many attempts were made to validate the EuroSCORE II outside Europe, and to assess its predictive value regarding other post-operative major complications including duration of post-operative mechanical ventilation.[7, 16]

In this study, we attempt to validate the EuroSCORE II as a predictor of need for prolonged mechanical ventilation (PMV) following valvular heart surgery.

Patients and Methods

This is a prospective study, in which 255 consecutive adult Egyptian patients undergoing valvular heart surgery are included. All adult Egyptian patients undergoing valvular cardiac surgery are included, in the period from February 2012 till August 2013, in Cairo University hospitals. Detailed data for EuroSCORE II risk factors are collected and in each patient, the score was calculated using the web-based calculators, available at <http://euroscore.org/>. the definition of disease conditions and risk factors was concordant with that described in the official website of EuroSCORE II mentioned above.

Prolonged mechanical ventilation

PMV was defined as the need for intubation and mechanical ventilation for >48 h, after completion of the operation (according to the society of thoracic surgeons definition) [19]. This includes both patients with early and persistent ventilator dependency who were not extubated within the initial 48 h and those who had one or more unsuccessful extubation attempts eventually accumulating >48 h of endotracheal intubation and mechanical ventilation.

Decision to extubate

The criteria for extubation were the following: (a) that the patients were haemodynamically stable, (b) drainage <50 ml/h, (c) fully awake and able to move all limbs to command (in cases of stroke the decision to extubate was individualized depending on the extent of neurological deficit), (d) partial pressure of oxygen >12 kPa on 0.5% fraction of inspired oxygen, (e) temperature >36°C, (f) base deficit <3, and (g) respiratory rate >10 min⁻¹. Primary extubation was nurse led according to the protocol and any deviation from the norm was assessed by the anaesthetist and appropriate intervention made to address individual patient's requirements. Patients who required PMV were assessed by the senior anaesthetist on a daily basis and a ventilation weaning protocol suggested.

Statistical analysis and method

Obtained data were presented as mean \pm SD, numbers,

percentages, and 95% confidence interval of the mean as appropriate. Associations between categorical predictor variables and outcomes were analyzed using Pearson Chi-Square (χ^2) test for Independence. Associations of continuous predictor variables and outcome were tested using binary logistic regression.

The model's validation was performed by assessing its calibration power and discriminatory power. Calibration power was assessed by goodness of fit testing using Hosmer–Lemeshow test. A P value >0.05 indicates that the model fits the data well and therefore accurately predicts mortality. Discriminatory power of a model pertains to its ability to discriminate between patients who died during hospitalization from those who did not and was assessed by calculating the area under the receiver operating characteristic curve (AUROC) or C-statistic. A value of 0.5 indicates that the model is not predictive and that the results are due to chance and a value of 1 indicates perfect discrimination.

Statistical analysis was performed using Microsoft® Office Excel 2013 (Microsoft Inc., 2013), MedCalc® (MedCalc Software bvba, Version 12.5.0.0, 2013), and IBM® SPSS® Statistics (Statistical Package for Social Sciences, IBM, Version 22.0.0.0, 2013). P value < 0.05 was considered statistically significant.

Results

This prospective observational analytic study enrolled 255 consecutive adult Egyptian patients who underwent surgery for valvular heart disease, in Cairo University Hospitals, in the period February 2012 till August 2013. Among 255 procedures included in the study, the overall mortality was 3.8% (8 patients), 95% CI: 1.2–5.1%. Table 1 summarizes the preoperative characteristics of the patients. The EuroSCORE II score ranged from 0.5% to 47.49%, (mean 2.02, 95% CI: 1.17–2.48) and a standard deviation of 3.89.

The area under receiver operating characteristics curve (AUROC) was 0.792 with a 95% confidence interval 0.73 to 0.84, and a Hosmer-Lemeshow test for goodness of fit statistic P value of 0.614. Error! Reference source not found. Figure 1 shows the ROC curve for EuroSCORE II performance regarding prediction of mortality in the study population.

In this study, 10 patients needed mechanical ventilation for periods longer than 48 hours, representing 3.9%, with 95% confidence interval 1.5–6.3%. Hosmer-Lemeshow test for correlation of EuroSCORE II with risk of prolonged mechanical ventilation showed a P value of 0.748, the AUROC for EuroSCORE II was 0.564, indicating poor discrimination, as presented in Figure 2.

Variable	Number of cases	Percentage to whole study (255 patients)	
Sex (Male)	132	51.8%	
Left atrial thrombus	10	3.9%	
NYHA class	Class I	7	2.7%
	Class II	121	47.5%
	Class III	118	46.3%
	Class IV	9	3.5%
CCS class	Class I	2	0.8%
	Class II	8	3.1%
	Class III	2	0.8%
	Class IV	1	0.4%
PAP categories	Moderate (30-55mmHg)	103	40.4%
	Severe (> 55mmHg)	63	24.7%
Previous cardiac surgery	22	8.2%	
Diabetes on insulin	6	2.4%	
Surgery on thoracic aorta	6	2.4%	
Hypertension	12	4.8%	
Impaired mobility	4	1.6%	
Chronic lung disease	3	1.2%	
Recent MI	2	0.8%	
Active endocarditis	7	2.7%	
Critical preoperative state	8	3.1%	
Arrhythmia	66	25.9%	
Emergency surgery	4	1.2%	
Planned Procedure	MVR	104	40.5%
	AVR	57	22.2%
	Mitral repair	6	2.4%
	MVR + CABG	5	2.1%
	CABG + Mitral repair	2	0.8%
	AVR + CABG	4	1.6%
	Other	78	30.4%

NYHA New York heart association, CCS Canadian cardiology society angina score, PAP pulmonary artery pressure, MI myocardial infarction, MVR mitral valve replacement, AVR aortic valve replacement, CABG coronary artery bypass grafting, Other: indicates non-STS applicable procedures

Table 1. Summary of preoperative variables

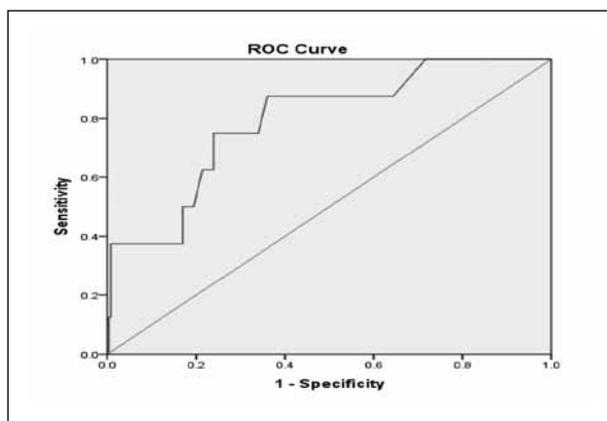


Fig. 1. Receiver operator curve for EuroSCORE II regarding prediction of mortality

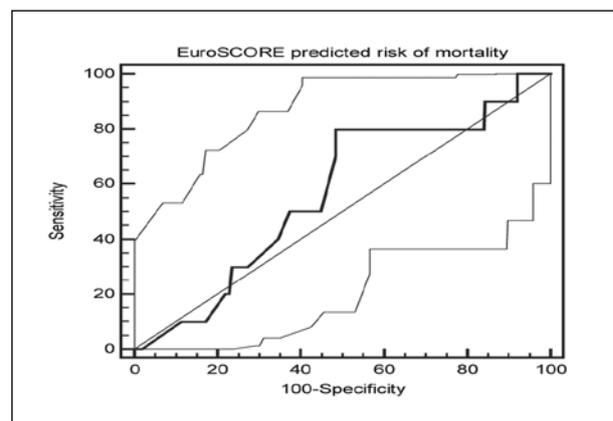


Fig. 2. ROC curve for EuroSCORE II regarding risk of prolonged ventilation

Discussion

Risk stratification models are increasingly important in the current clinical practice for two purposes, they can serve as a hospital performance benchmark, but can also be used to provide the surgeon and the patient with a quantitative estimate of the procedural risk, or to study the impact of particular risk factors on outcome.[20] Changes in cardiac surgery case mix, surgical techniques and clinical outcomes continuously lead investigators to improve and modify currently available risk-stratification systems. All improvements and modifications require further validation tests for different patient populations globally.[21] A European System for Cardiac Operative Risk Evaluation (EuroSCORE) additive (standard) model from eight European countries was developed between 1995 and 1999 [1, 22] and has gained wide acceptance in Europe, North America [23] and Asia [21, 24]. However, this model generally overestimates mortality in low-risk patients (EuroSCORE ≤ 6) and underestimates it in high-risk patient groups (EuroSCORE > 13). This poor calibration can be explained by the technical and technological advances in cardiac surgery, anaesthesiology and perfusion, which have resulted in a decrease in risk-adjusted mortality.

The investigators of the EuroSCORE have continued their work creating a new version called EuroSCORE II[25], [26], based on the surgical results observed in 22,381 consecutive patients undergoing major cardiac surgery in 154 hospitals in 43 countries over a 12-week period (May–July 2010) to compare with the original 1995 EuroSCORE database. Recently developed EuroSCORE II included additional surgical risk predictors such as poor mobility, diabetes on insulin, New York Heart Association, Canadian Cardiovascular Society Class 4 angina and weight of the intervention; and excluded neurological dysfunction, unstable angina and post-infarct septal rupture. They validated EuroSCORE II on a data subset of 5553 patients (actual mortality: 4.2% and predicted: 4.0%), and very good discrimination was maintained with an area under the ROC curve of 0.81. EuroSCORE II also improved on the original logistic EuroSCORE.[27]

After a score is developed, it should be validated outside the population in whom the score was developed, in order that, the score can be applied globally. Given the variation in patient care processes by surgeons and across institutions, one would expect that risk factor presence and strength of effect would also vary in models developed from different cohorts.

The accuracy of models can be assessed in several ways. Two major components are calibration and discrimination. Calibration is a measure of how well predicted probabilities agree with actual observed risk. When the average predicted risk within subgroups of a prospective cohort, for example, matches the proportion that actually develops disease, the model is considered well calibrated. The Hosmer-Lemeshow statistic[28] compares these proportions directly and is a popular means to assess model calibration.[28] Discrimination

is a measure of how well the model can separate those who do and do not have the disease of interest. If the predicted values for cases are all higher than for non-cases, it's considered that the model can discriminate perfectly, even if the predicted risk does not match the proportion with disease. Discrimination is of most interest when classification into groups with or without prevalent disease is the goal, such as in diagnostic testing. Discrimination is most often measured by the area under the receiver operating characteristic (ROC) curve, or c statistic.[29]

In the past decade many aspects of heart surgery have changed. First, as CABG volumes have decreased with the introduction of coronary stents, valve surgery as a proportion of overall heart surgery volume has increased in most practices. Thus, in assessing provider performance, it is no longer sufficient only to consider isolated CABG surgery. Second, during the same time period, the average mortality rate for isolated aortic or mitral surgery also decreased. Third, there is a substantially higher early mortality for heart valve surgery compared with isolated CABG, as well as considerable mortality variation across categories of valve operative site and concomitant CABG.[30]

Defining the predictors of postoperative PMV is a difficult task. Previous studies included heterogeneous groups of patients undergoing different cardiac or cardiovascular surgical procedures. We tried to include a relatively homogenous group of cardiac surgery patients, undergoing heart valve surgery.

To our knowledge, only one study was conducted to test the usability of EuroSCORE II as a predictor of post operative complications following heart valve surgery. This study was conducted in China, where Wang et al.[16] validated the EuroSCORE II in a total of 11,170 adult patients who underwent heart valve surgery from January 2008 to December 2011, comparing it to the original EuroSCORE II. The patients were divided into three subgroups according to the weight of the procedures, and the performance of EuroSCORE II for each group was assessed. They also assessed the relation between operative complications and EuroSCORE II. In-hospital mortality of this series was 2.02% (226 of 11,170), and the predicted mortality rate was $2.62 \pm 5.75\%$ by EuroSCORE II and $2.55 \pm 6.51\%$ by original EuroSCORE. The AUROC of EuroSCORE II and original EuroSCORE were 0.72 [95% confidence interval (CI) 0.69–0.75] and 0.67 (95% CI 0.63–0.70), respectively. Both models failed the Hosmer–Lemeshow goodness-of-fit test, with a $P < 0.05$. According to the weight of the procedure, the isolated non-CABG subgroup had the best discrimination (AUROC: 0.76 in the non-CABG group, 0.67 in the 2 procedures group and 0.73 in the 3+ procedures group). The complication ratio was strongly related to the EuroSCORE II-predicted mortality (Pearson correlation coefficient: 0.97 for prolonged ventilation and 0.94 for a prolonged ICU stay). This study showed that EuroSCORE II was an improvement upon its original model for Chinese patients who underwent

heart valve surgery, particularly for a single-valve procedure. The EuroSCORE II-predicted mortality correlated with the operative complications.

However, some studies were conducted on the original EuroSCORE II, in Finland [31, 32], both confirming that EuroSCORE can be used as a predictor for PMV, with an AUC of 0.77.

These results agree with ours regarding the ability of the EuroSCORE II to predict mortality, however, the study on Egyptian population showed that EuroSCORE II is not a good predictor of prolonged mechanical ventilation. This may be explained by the conclusion of Saleh et al, that the complexity of PMV as a clinical problem makes such models inadequate for the clinical use even in the lower risk elective patients. [33] this is also confirmed by a study conducted in Germany, [34] in which original EuroSCORE was compared to other 5 risk scores. For most risk factors, predictive values for morbidity were substantially different from predictive values for mortality. Therefore, the authors recommended development of specific morbidity risk scores to improve prediction of outcome and hospital cost. They proposed that due to the heterogeneity of morbidity events, that future score systems have to generate separate predictions for mortality and major morbidity events.

In conclusion, despite the good performance of the EuroSCORE II as a predictor of mortality in Egyptian patients undergoing heart valve surgery, its rule as a predictor of PMV is modest, and models dedicated for this purpose are needed.

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Simple Dental Extraction in Patients with Mechanical Heart Valves; Be Simple and Don't Stop Warfarin!

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Effective antithrombotic therapy in patients with mechanical heart valves is necessary; to replace warfarin with Low Molecular Weight Heparin (LMWH) or continue warfarin during dental extraction is a matter of debate in our daily practice.

Aim and methodology: to compare two different protocols in managing patients with mechanical heart valves on warfarin therapy during dental extraction, 160 patients were distributed to 2 equal groups, Group A (Bridging therapy) and Group B (NonBridging therapy), all relevant data were analyzed and compared in both groups including bleeding complications.

Results and conclusions: The 2 groups were homogenous. There were no significant difference between group A and group B as regard bleeding complications (3 cases in group A and 4 cases in group B) in spite of the significant difference in INR value at the day of extraction. On the other hand; group A had a mean cost of LMWH 985.5 Egyptian pounds, mean length of hospital stay 9.35 days, and a mean number of INR tests equals 8.15, we recommend the continuation of warfarin in patients with mechanical heart valves during simple dental extraction as it is safe, more simple and economic than bridging therapy and it avoids the potential risk of thromboembolic complications.

KEY WORDS (mechanical heart valves, warfarin and dental extraction)

Effective antithrombotic therapy in patients with mechanical heart valves requires continuous vitamin K antagonist (VKA) anticoagulation with an INR (International Normalization Ratio) in the target range; (2.5 ± 0.5) in mechanical aortic valve, (3 ± 0.5) in mechanical mitral or multiple valves.⁽¹⁾

When it is necessary to interrupt VKA therapy, VKA is stopped 2 to 5 days before the procedure (so the INR falls to <1.5) and restarted as soon as bleeding risk allows, typically 12 to 24 hours after surgery.⁽²⁾

During interruption of VKA therapy, the risk of an adverse event (thromboembolic complications) can be minimized by anticoagulation with alternative agents (such as subcutaneous Low Molecular Weight Heparin "LMWH") that can be stopped before and restarted after the surgical procedure what is called bridging therapy.⁽³⁾

Dental extraction in patients on anticoagulant therapy is still a matter of debate; with some clinicians favors the routine practice of withholding warfarin,⁽⁴⁾ while others found the risk of postoperative bleeding after tooth removal in patients on continued warfarin medication is low and prefer the continuation of anticoagulant therapy.^(5,6)

Aim of the work

The objective is to compare two different protocols in managing patients with mechanical heart valves on warfarin therapy during dental extraction.

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Patients and Methods

This study was conducted on 160 patients with mechanical heart valves on warfarin therapy that were referred to Cardiothoracic Surgery Department, Tanta university hospital to be prepared for dental extraction in the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Tanta University in the period from October 2010 to April 2014.

Inclusion criteria:

1. Extraction of a single maxillary or mandibular posterior tooth.
2. Anti-coagulation with warfarin (Marevan®, Glaxo, Egypt.)

Exclusion criteria:

1. Multiple extractions
2. Trans-alveolar extraction (removal of teeth that cannot be easily accessed, or impacted teeth, they almost always require an incision)
3. INR >3.5 on the day of extraction
4. History of liver disease or coagulopathy
5. History of bleeding or thromboembolic manifestations

Pre-procedure data

- Age and sex
- Type and duration of valve replacement
- Location of tooth (maxillary or mandibular)
- Dose of warfarin on referral
- INR value on the day of referral

Patients were randomly distributed into 2 equal groups:

Group A (80 patients): Bridging therapy where all patients were admitted to our department (in-patient), warfarin was stopped and daily INR was assessed, LMWH (enoxaparin) was given deep subcutaneously in a therapeutic dose (1mg/kg) every 12 hours till INR was less than 1.5, then enoxaparin last dose (50%) was given 24 hours before dental extraction and started again with warfarin after 12 hours if no late bleeding, then INR was checked daily till it returned to therapeutic range, when enoxaparin was stopped and patient was discharged.

Group B (80 patients): NonBridging therapy where all patients were managed as out-patients

- If INR was in the therapeutic range; warfarin was continued in same dose and patient was sent for dental extraction.
- If INR was more than therapeutic range; warfarin dose was decreased and INR was repeated till it reached the therapeutic range, then dental extraction was done.

- If INR was less than therapeutic range; dental extraction was done then warfarin was increased and INR was repeated till it reached the therapeutic range.

For all patients INR value on the day of extraction was assessed.

Dental procedure

All patients in both groups were managed as following:

- A full medical history, orthopantomogram, and clinical examination were performed.
- Antibiotics prophylaxis was given orally two days pre-operatively and 3 days post-operatively, in the form of 875 mg amoxicillin and 125 mg clavulanic acid twice daily.
- If acute infection was present, extraction was delayed until the infection had been treated. Antibiotic was given orally pre-operatively in the form of 875 mg amoxicillin and 125 mg clavulanic acid twice daily till the patient is free of acute infection the procedure had been done with as little trauma as possible and the same antibiotic was continued 3 days post-operatively.
- Local anaesthesia, 4% articaine 1.7 ml, with 1:100,000 epinephrine was injected in the buccal and palatal aspect of the teeth in case of posterior maxillary teeth; while in case of posterior mandibular teeth: inferior alveolar and lingual nerve block for extraction of mandibular premolars and inferior alveolar and lingual nerve block with local infiltration buccally of long buccal nerve for extraction of mandibular molars.
- Dental extractions were then performed with least trauma, using specific dental forceps.

For all patients, immediately following extraction, the bleeding was controlled by applying compression with gauze pack on the wound for 5 minutes, then the bleeding was controlled by applying local measures on the wound using gelatin sponges and the patients were instructed to bite on a pressure pack for 30 minutes and then checked for any early bleeding, and the patients were instructed to bite on a pressure pack again for 2 hours.

All patients were given appropriate post-operative instructions and were advised to immediately report the occurrence of any hemorrhagic problem and post extraction sites were checked for a week to assess bleeding complications and tissues healing.

Bleeding complications after dental procedure

The bleeding complications after dental extraction were classified according to the time of occurrence as:

- Early bleeding (occurring during extraction session at the dental clinic) that was defined by the need to stop bleeding

(either by suturing or any other intervention) when the blood extended beyond the tooth socket after 30 minutes of biting on a pressure pack with gelatin sponges.

- Late bleeding (occurring after leaving the dental clinic) was defined as significant bleeding that extended beyond 12 hours, made the patient call or return to the dental practitioner or to an emergency department or resulted in hematoma or ecchymosis within the oral soft tissues.

Number of INR tests and thromboembolic complications were assessed in both groups, while costs of LMWH and length of hospital stay were calculated in group A.

Statistical analysis

For qualitative data, comparison between the two groups; Chi-square test (X²) was used. For quantitative data, the range, mean and standard deviation were calculated, for comparison between means of two groups; student's t-test was used. A p-value of less than 0.05 was considered statistically significant.

Results

This study was conducted on 160 patients with mechanical heart valves on warfarin therapy, the mean age was 37 ± 10.61 years ranged from 20 to 63 years, 59 (36.9%) were males and 101 (63.1%) were females, the artificial valves were aortic in 47 cases (29.4%), mitral in 75 cases (46.9%), and multiple in 38 cases (23.7%), the mean duration of valve replacement was 9.2 ± 4.95 ranged from 1 to 25 years, the extracted tooth was in the maxilla in 72 cases (45%) and in the mandible in 88 cases (55%), mean dose of warfarin on referral was 5.37 ± 3.89 ranged from 1.5 to 12 mg, mean INR on the day of referral was 2.85 ± 0.46 ranged from 1.35 to 6.5, while mean INR on the day of extraction was 1.9 ± 0.71 ranged from 1 to 3.4, mean number of INR tests was 4.73 ± 2.83 ranged from 1 to 12 tests.

Group A and group B were homogenous groups; as there were no significant differences between the 2 groups as regard: age (table 1), sex (table 2), type of artificial valves (table 3), duration of valve replacement (table 4), location of tooth (maxillary or mandibular) (table 5), dose of warfarin on referral (table 6) and INR on the day of referral (table 7).

INR on the day extraction was significantly higher in group B (2.57 ± 0.5) than group A (1.23 ± 0.16) (p-value <0.00001) and total number of INR tests was significantly more in group A (8.15 ± 1.43) than group B (1.31 ± 0.69) (p-value <0.00001) (table 7).

Bleeding complications occurred in 7 cases (4.38%); early in 5 cases (3.13%) and late in 2 cases (1.25%), no cases needed modification of their anti-coagulation management or

hospitalization due to bleeding complications, they were treated conservatively except 3 cases of early bleeding (2 in group A and one in group B) who were simply sutured using vicryl 3/0.

There were no significant differences between group A and group B as regard bleeding (table 8); while no thromboembolic complications had occurred in both groups.

In group A; mean costs of LMWH were 985.5 ± 207.1 (ranged from 480 to 1440) Egyptian pounds, total costs of LMWH were 78840 Egyptian pounds, and mean length of hospital stay was 9.35 ± 1.9 (ranged from 5 to 13) days, total days of hospitalization was 748 days (table 9).

Age (years)	Group A (n=80)	Group B (n=80)	t-value	P
Range	20-63	23-53	1.021	0.31
Mean \pm SD	37.51 ± 7.59	36.34 ± 8.85		

Table (1) Distribution of patients regarding age

Sex	Group A (n=80)		Group B (n=80)		X ²	P
	n	%	n	%		
Male	31	38.75	28	35	0.24	0.623
Female	49	61.25	52	65		

Table (2) Distribution of patients regarding sex

Artificial valves	Group A (n=80)		Group B (n=80)		Total (n=160)	
	n	%	n	%	n	%
Aortic	25	53.2	22	46.8	47	29.4
Mitral	38	50.7	37	49.3	75	46.9
Multiple	17	44.7	21	55.3	38	23.7
X ²			0.626			
P			0.731			

Table (3) Distribution of patients regarding type of artificial valves

Duration of valve replacement (years)	Group A (n=80)	Group B (n=80)	t-value	P
Range	1-24	1-25	0.77	0.442
Mean \pm SD	8.80 ± 5.24	9.50 ± 4.64		

Table (4) Distribution of patients regarding duration of valve replacement

	Group A (n=80)		Group B (n=80)		X ²	P
	n	%	n	%		
Maxillary	35	43.75	37	46.25		
Mandibular	45	56.25	43	53.75	0.101	0.751

Table (5) Distribution of patients regarding location of tooth

Dose of Warfarin (mg) on referral	Group A (n=80)	Group B (n=80)	t-value	P
Range	1.5-12	2-10	0.448	0.655
Mean ± SD	5.40 ± 2.34	5.29 ± 2.08		

Table (6) Distribution of patients regarding dose of warfarin on referral

INR	Group A (n=80)	Group B (n=80)	t-value	P
On the day of referral	1.35-6.5	1.4-6	0.0374	0.970
Range	2.87 ± 0.97	2.85 ± 0.93		
Mean ± SD				
On the day of extraction	1-1.45	1.4-3.4	22.80	0.0001*
Range	1.23 ± 0.16	2.57 ± 0.5		
Mean ± SD				
Number of tests	5-12	1-4	38.3	0.0001*
Range	8.15 ± 1.43	1.31 ± 0.69		
Mean ± SD				

*Significant or P<0.05

Table (7) Distribution of patients regarding INR on the days of referral and extraction, and number on INR tests

Bleeding	Group A (n=80)		Group B (n=80)		X ²	P
	n	%	n	%		
Early	2	2.5%	3	3.75%	0.207	0.65
Late	1	1.25%	1	1.25%	0	1
Total	3	3.75%	4	5%	0.149	0.699

Table (8) Distribution of patients regarding bleeding complications

Group A (n=80)	Costs of LMWH (Egyptian pounds)	length of hospital stay (days)
Range	480-1440	5-13
Mean ± SD	985.5 ± 207.1	9.35 ± 1.9
Total	78840	748

Table (9) Costs of LMWH and length of hospital stay in group A

Discussion

The coagulation status (based on the International Normalized Ratio) in patients who are taking oral anticoagulation therapy must be evaluated before dental extraction. Any changes in anticoagulant therapy must be undertaken in collaboration with the patient's prescribing physician.⁽⁷⁾

Patients with mechanical heart valves on warfarin therapy were always referred to our cardio-thoracic surgery department, Tanta university hospital to be prepared for dental extraction in the Oral and Maxillofacial Surgery department

Patients in this study were managed by 2 different protocols during dental extraction: The first was (bridging therapy); where warfarin was stopped till INR was less than 1.5 and LMWH was given deep subcutaneously to prevent thromboembolic complications and was stopped shortly before dental procedure to avoid excessive bleeding during dental extraction, this protocol is supported by some authors that recommend interruption or reduction of oral anticoagulants in the days prior to the intervention to secure sub-therapeutic INR levels in a short period of time before the operation.^(8,9)

The second protocol (non-bridging therapy) was to proceed to dental extraction without interruption of anticoagulation therapy using local hemostatic measures based on the evidence that the benefit of preventing thrombo-embolism outweighs the risk of bleeding. This protocol is supported by many authors; Sacco et al. in 2007⁽¹⁰⁾ found no differences between reducing and maintaining the dose of the oral anticoagulant with the use of local hemostatic measures in case of dental extraction, and Jim et al. in 2008⁽¹¹⁾ recommended to avoid the interruption of anticoagulant therapy by working with therapeutic INR levels, and preventing hemorrhagic complications by application of local hemostatic measures.

In our study; most cases were young females, while in the majority of studies concerned with dental extraction in patients under anticoagulant therapy the mean age was over sixty with male predominance,^(12,13,14) this may be explained by knowing that we studied patients with mechanical heart valves that mostly in Egypt is a consequence of rheumatic heart disease that usually affects young females.

The 2 different protocols in this work were studied in 2 homogenous groups as regard age, sex, type of artificial valves,

duration of valve replacement, location of tooth (maxillary or mandibular), dose of warfarin on referral, and INR on the day of referral.

Bleeding complications were minimal and easily controlled in patients who continued warfarin therapy (5%) with mean INR on the day extraction (2.57 ± 0.5), this is consistent with Abdullah et al.⁽⁶⁾ who evaluated the risk of bleeding in a series of 35 patients on warfarin therapy following simple tooth extraction without modification of the warfarin dose, and found that simple teeth extraction in those patients can be performed safely without high risk of bleeding (11.4%) provided that the INR is equal or less than 3.5 at the day of extraction.

We found that the continuation or interruption of warfarin therapy did not affect the occurrence of early and late bleeding, this is consistent with the guidelines published by the British Committee for standards in Haematology (BCSH) together with British Dental Association and National Patient Safety Agency which stated that “patients, on warfarin with INR less than 4, have very small risk of significant bleeding”.⁽¹⁵⁾

We are in agreement with Bajkin BV et al.⁽¹⁶⁾ who evaluated postoperative bleeding and thromboembolic complications during dental extractions in anti-coagulated patients, where mild and easily controlled bleeding occurred in only 8 patients of 109 patients (7.34%) on continuous oral anticoagulation therapy, with a mean INR of 2.45, and in 5 patients of 105 patients (4.76%) who stopped oral anticoagulant and was given LMWH with a mean INR of 1.26 on the day of the procedure, with no thromboembolic complications in both groups, the difference between our and their studies was that we used local hemostatic measures (gelatin sponges) in both groups not only in cases who continued oral anticoagulation therapy, our rationale is the need for early starting of anticoagulants (after 12 hours) in patients who interrupted oral anticoagulation therapy and the very rare side effects of local hemostatic measures.

No thromboembolic complications occurred in our study in both groups despite different protocols in anticoagulation therapy, but we can't ignore the potential risk of developing cerebrovascular accidents during suspension of warfarin treatment in patients undergoing dental extractions.⁽¹⁷⁾

The overall cost for a LMWH bridging strategy was estimated to be 672 American dollars per case during temporary interruption of chronic anticoagulation.⁽¹⁸⁾ Similar findings were observed in a retrospective analysis of a health maintenance organization serving New Mexico.⁽¹⁹⁾ In our study; LMWH costs were near 1000 Egyptian pounds per case in patients managed with bridging therapy, but these category of patients with low socio-economic state were in need for hospitalization and so all costs must be considered and not just drug costs, mean length of hospital stay was 9.35 days with requirement of about eight INR tests per case, while patients who continued warfarin therapy did not need hospitalization and required less than two tests per case, that was socially and economically much better.

Conclusion

The continuation of warfarin in patients with mechanical heart valves during simple dental extraction is safe as regard bleeding, more simple and economic than bridging therapy and it avoids the potential risk of thromboembolic complications.

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Early Outcome of Tricuspid Repair For Functional Tricuspid Regurgitation Associated With Rheumatic Mitral Valve Disease; Modified Flexible Band Annuloplasty vs. Suture Annuloplasty

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Objectives: we investigated early outcome of flexible band as a piece of tube graft (PTFE) annuloplasty versus suture annuloplasty for functional tricuspid regurgitation associated with rheumatic mitral valve disease.

Methods: we prospectively reviewed patients who underwent our technique of band tricuspid annuloplasty (n=28) versus suture tricuspid annuloplasty (n=32) for functional tricuspid regurgitation concomitant with surgery for rheumatic valve disease with a mean follow up of 12 months.

Results: Thirty day mortality was zero in both groups. Tricuspid regurgitation grade was lower for band group at discharge and after 12 months follow-up by echocardiography, although the difference was not statistically significant. There was no need for reoperation or hospital readmission for right-sided heart failure for tricuspid regurgitation in both groups by the end of first year postoperatively.

Conclusion: tricuspid band annuloplasty using a piece of PTFE tube graft offered good outcome and tendency for improved durability than suture annuloplasty.

Key words: tricuspid regurgitation (TR) – band annuloplasty – suture annuloplasty – DeVega repair-rigid ring - flexible ring

Although some reports suggest that tricuspid regurgitation can resolve after diseased mitral valve has been replaced based on well known post-operative regression of pulmonary hypertension (1,2), others suggest that ignoring a diseased tricuspid valve at the time of surgery for left sided pathology can affect eventual outcome of the patient, and it may be associated with an increase in morbidity and mortality (3,4,5).

Both ring and band annuloplasty have been performed for treating TR. Many types of rings and bands rigid, semi-rigid or flexible were used with no clear evidence of superiority and durability of each type (6).

In this study we investigated early postoperative outcome up to 1 year after tricuspid annuloplasty for functional TR associated with rheumatic heart disease necessitating valve surgery. We compared modified flexible band using sized PTFE tube graft annuloplasty, to suture annuloplasty.

MATERIALS AND METHODS

Patient population:

From March 2012 to May 2013, sixty patients underwent tricuspid valve repair together with mitral and/or aortic valve surgery. We excluded patients with organic tricuspid valve disease. Patients undergoing concomitant CABG, aortic aneurysm and root surgery, infective endocarditis cases, low EF, together with redo cases were also excluded.

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Tricuspid regurgitation was scored as follows:

Grade 1: mild regurge

Grade 2: moderate regurge.

Grade 3: moderate-to-severe regurge.

Grade 4: severe regurge.

Significant regurge was defined as regurgitation equal or more than grade 3.

End points:

The primary end points were:

- Postoperative hospital mortality
- The degree of tricuspid regurgitation (TR) upon discharge, and at 12 months follow up.

Secondary end points were:

- One year survival
- Hospital readmission for right-sided heart failure
- Need for reoperation for severe TR

Surgical Technique:

Conventional median sternotomy, standard cardiopulmonary bypass using bicaval cannulation. Myocardial protection was achieved using antegrade intermittent cold cardioplegia. Mitral valve replacement was performed with preservation of posterior leaflet in all patients. Tricuspid valve annuloplasty was performed under cardiac arrest.

Saline infusion test was used to confirm adequate leaflet coaptation and competent valve. Postoperative transthoracic echocardiography was performed upon discharge and 1 year later.

1. Flexible Band

Twenty-eight patients had repair of their TR using a piece of flexible polytetrafluoroethylene (PTFE) tube graft commonly used for aortic root replacement (figure 1). The band annuloplasty was performed by a number of 2/0 Ethibond sutures starting from anteroseptal commissure to end at posteroseptal commissure. Interrupted 2/0 braided sutures without pledgets were placed circumferentially starting from anteroseptal commissure to posteroseptal commissure. Sutures were then passed through the band. The band size for all cases was pre-determined length of 3 cm and 3 mm width. The width is roughly 2 rings of the tube graft. The 3 cm length is measured

Over a 10 ml syringe. 3 cm length is equal to the distance between the zero mark and the 6 ml mark of the syringe (figure 2).

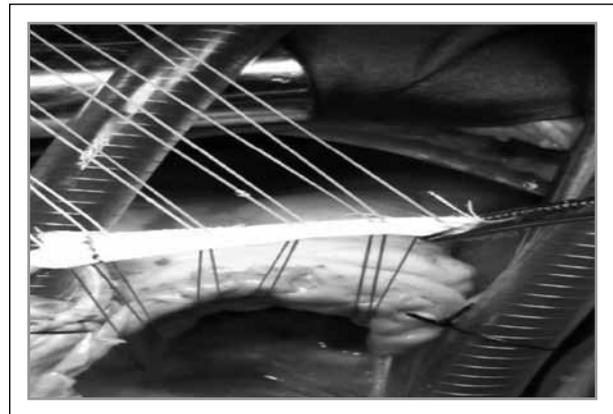


Fig. 1. Flexible PTFE band Sutures taken to plicate the annulus are passed through the flexible PTFE band

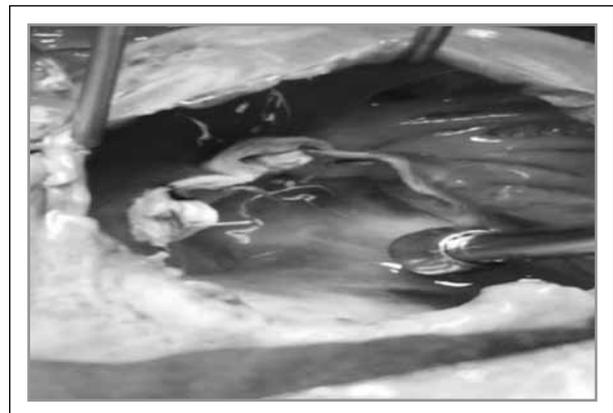


Fig. 2. Sutures tied down and band fixed in-place

2- Suture Annuloplasty

Standard DeVaga annuloplasty was performed in 18 patients, and segmental annuloplasty was performed in 14 patients. 2/0 Ethibond sutures were used in all cases of suture annuloplasty group.

Statistical Methods

Data were statistically described in terms of mean \pm standard deviation (\pm S.D), frequencies (number of cases) and percentages when appropriate. Comparison of numerical variables between the study groups was done using Student t test for independent samples. For comparing categorical data, Chi square (χ^2) test was performed. Exact test was used instead when the expected frequency is less than 5. p-values less than 0.05 was considered statistically significant. All statistical calculations were done using computer programs SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) version 15 for Microsoft Windows.

RESULTS

Preoperative characteristics

Preoperative demographics, NYHA class and echocardiography data showed no statistical difference between the 2 modalities of annuloplasty.

	Suture group (n=32)	Band group (n=28)	p Value
Age (yrs)	42±12	39±14	0.9
Gender			
Male	14 (44%)	13 (46%)	0.6
Female	18 (56%)	15 (54%)	
TR Grade	3.25±0.76	3.46±0.63	0.8
PAP (mmHg)	67 ± 18	62 ± 25	0.7
CPB Time (Min)	115± 37	110± 45	0.3
Cross-Clamp Time (Min)	64 ± 27	75 ± 23	0.9
NYHA Functional Class	3.2± 0.6	3.4± 0.8	0.6

Table 1. pre-operative patients characteristics

Endpoints:

Primary endpoints:

Hospital mortality:

- All patients in both groups were discharged from hospital in good condition with zero hospital mortality.

Postoperative TR grade:

- There was significant improvement of TR grade post-operatively compared to preoperative values in both groups (p=0.03 and 0.01 respectively). The mean preoperative TR for the suture group was 3.25±.76 and the mean preoperative TR for the band group was 3.46±.63 (table 1). At discharge the mean TR for the suture group was 1.88 ± .73 and the mean TR grade for the band group was 1.99 ± .53 (tables 1,2).

Suture group (n=32)		
TR grade	At discharge (n=32)	12 month post op (n=30)
1	9	2
2	20	13
3	1	12
4	2	3
Mean ± SD	1.88 ± 0.73*	2.5±0.8

*p value 0.03 compared to preoperative value

Table 2 postoperative TR grade for suture annuloplasty group

Table 3 below highlights TR grades at time of discharge and at 1 year for the PTFE band group.

Band group (n=28)		
TR grade	At discharge (n=28)	1 yr post op (n=27)
1	8	4
2	18	15
3	2	6
4	0	2
Mean ± SD	1.79 ± 0.53*	2.22 ± 0.79

* p value 0.01 compared to preoperative value.

Table 3

The mean TR grade for the suture group at 12 months was 2.5 ± 0.8, and for the band group was 2.2 ± 0.79 with no statistical difference between the 2 groups (p = 0.9). Tables 2 and 3 capture the detailed hospital discharge and 12 months TR grades for both groups.

Figure 3 compares the TR grade of the suture group to the band group at the three time points; preoperative, at discharge and at 12 months. The difference between the two groups was not statistically significant.

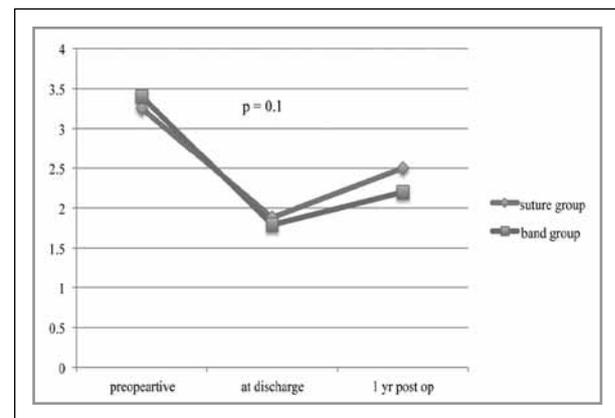


Fig. 1. mean TR grade of the suture group and band group

Secondary endpoints

12 months survival:

- 2 patients in the suture group died. One patient died due to cerebral hemorrhage complicating warfarin toxicity (5 weeks after discharge), and the other due to early infective endocarditis over the prosthetic mitral valve (10 weeks after discharge).

- In the band group one patient died almost 6 weeks after discharge. The patient was admitted in the ER suffering from cardiac tamponade and an INR of 8. The patient then rapidly went into cardiac arrest with failed attempts of resuscitation.

Hospital readmission for right-sided heart failure

Over the 12 months period of the study, none of the patients in both groups needed to be readmitted to the hospital to control right-sided heart failure.

Re-operation

After 1 year follow up and despite that some patients had tricuspid regurgitation grade 3 or 4 there was no need for re-operation and those patients were compensated on anti-failure measures.

DISCUSSION

Functional TR occurs primarily due to annular dilatation and subsequently failure of leaflet coaptation. Tricuspid annular dilatation occurs mainly in its anterior and posterior aspects, which can result in significant functional TR as a result of leaflet mal-coaptation⁽⁴⁾. Many authors suggest that tricuspid annular dilatation is an ongoing pathology that will eventually lead to severe TR. They advise early surgical correction regardless of the severity of TR. This is due to the fact that uncorrected TR even without severe annular dilatation may worsen or persist after mitral valve surgery, leading to progressive heart failure and poor survival^(1,2,3).

However, the use of concomitant TV annuloplasty for mild/moderate functional TR remains a controversial subject, because limited available data related to the long-term outcomes of concomitant TV annuloplasty exist (8). Yilmaz, et al. concluded that TV annuloplasty is rarely necessary for MV disease because TR progression after MV surgery is unlikely. They insisted that progression of TR was clinically insignificant and did not lead to the risk of further surgery (7). These patients often require substantial doses of diuretics to maintain Euvolemia (9).

Many studies report risk factors for recurrent TR following tricuspid annuloplasty. In one study the authors reported that regardless of the types of annuloplasty, recurrence of TR early after the procedure was associated with preoperative tethering of tricuspid valve leaflets, and postoperative left ventricular dysfunction. Those two factors especially predict mid-term outcome of tricuspid repair. Increased right ventricular pressure also results in worse TR during mid-term follow-up. However, the authors did not report on the difference between the types of annuloplasty as regards to better or worse outcome (6). The degree of tricuspid regurgitation observed postoperatively in our study is comparable with results obtained from other studies.

In our study we fixed functional TR in patients with moderate-to-severe or severe TR. This is consistent with most of the authors elsewhere. However, Murashita et al. recommends operating on patients with even mild TR if a patient has atrial fibrillation or pulmonary hypertension (10)

TV annuloplasty is mostly applicable to patients with functional TR. However, the incidences of residual and recurrent TR are reported to be high. McCarthy et al described 790 patients who underwent TV suture annuloplasty for functional TR and found that the incidence of residual TR was 15% one month after repair (11). Tang, et al. reported that there was a 30% TR recurrence (among 702 patients) at a mean follow-up of 5.9 years after TV annuloplasty (12).

In the current study tricuspid regurgitation grade was lower in the band annuloplasty group, although it didn't reach statistical significance, for all grades of regurgitation severity. The reason may be attributed to higher tensile strength of the PTFE graft compared to the suture material. One other reason may be the pre-determined band length (3 cm) causing more plication of the annulus as compared to the suture group. This under-sizing of the annulus may have contributed to the tendency of less residual/recurrent TR postoperatively in the band group vs. the suture group.

Although some patients suffered from late moderate TR in both groups, the clinical symptoms were not significant. More than 50% of patients who had moderate TR were in NYHA functional class I. The clinical condition was well controlled through medical treatment and none of the patients in both groups required re-operation for their residual TR.

There were no differences in survival and freedom from major cardiac/cerebrovascular adverse events between the two groups. However, freedom from moderate to severe TR was higher with band annuloplasty than with suture annuloplasty, albeit the difference was statistically insignificant.

Limitations

- 1- Small number of patients.
- 2- Short period of follow up.
- 3- Single institution experience.
- 4- We have not examined the geometry of the tricuspid annulus following annuloplasty with the two modalities by echocardiography. It would be interesting to see how the flexible PTFE band behaves and whether the annulus keeps 3-dimensional geometry.

CONCLUSION

Repair of functional TR by a piece of PTFE tube graft is a simple, safe and effective way to manage moderate-to-severe and severe incompetence. There is tendency for lower inci-

dence of residual TR with this technique compared to suture annuloplasty up to one year postoperatively. Longer follow up periods and larger number of patients is needed for better confirmation of earlier promising results.

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Evaluation of Moderate Ischemic Mitral Regurgitation Managed by Myocardial Revascularization With or Without Mitral Valve Surgery

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Background: The treatment of patients with ischemic heart disease (IHD) and concomitant chronic ischemic mitral regurgitation (cIMR) can be challenging and is associated with reduced long-term survival. It is unclear how mitral valve surgery with coronary artery bypass grafting (CABG) versus CABG alone affects subsequent outcome. We conducted this study to understand and to delineate the role of mitral valve surgery in this high-risk population.

Patients and methods: This study was done in Cardiac Surgery Unit, Nasser Institute for Research and Treatment, Cairo and in Mansoura University Hospitals and approved by Medical Research Ethical Committees. All patients provided informed consent for inclusion in the study.

Results: From June 2010 to December 2012, 70 patients (age range, 42-69 years) with IHD and moderate cIMR (>2) were identified. 35 patients underwent combined CABG and mitral valve surgery, mitral valve repair in 23 (78%) and mitral valve replacement in 12 (22%). On other hand 35 patients underwent CABG alone. Uni- and multivariate analyses were performed on the entire cohort; we specifically examined the impact of mitral valve surgery on their mortality rate and functional status. Follow-up was 96% complete (median, 6 months; range, 0-9 months). The observed in-hospital or approximately 30-day mortality was 8.6% for group A and 14.3% for group B. The overall reported early survival for the entire cohort was 88.58%. The overall reported early mortality for the entire cohort was 11.42%.

Conclusions: Survival after combined coronary artery bypass grafting and mitral valve surgery mostly influenced by factors related to the patient's condition at the time of surgery while specifics of mitral valve repair versus replacement did not seem to affect survival. Almost all patients remained in NYHA class I or II

KEY WORDS: CABG, ischemic regurge, mitral regurge, mitral annulus, papillary dysfunction.

The treatment of patients with ischemic heart disease (IHD) and concomitant chronic ischemic mitral regurgitation (cIMR) can be challenging and is associated with reduced long-term survival.¹ Giving the central role of myocardial infarction (MI) and the lack of mitral valve or chordal pathology, cIMR may more appropriately be termed left ventricular regurgitation. In these patients, improvement probably occurs as a result of restoration of blood flow to an area of hibernating myocardium; that is, ischemic but viable myocardium that does not function properly at rest, but does function with adequate blood flow.² cIMR has an incidence of approximately 10%, and it is higher in patients with previous inferior MI.³ It was often underrated because of low murmur intensity but with the use of echocardiography; this complication is observed between 15%-20%.⁴ Clinical studies of its role are somewhat confusing. On one hand, some studies suggest that moderate IMR has serious clinical consequences. On the other hand, several observational and retrospective studies suggested that treating IMR did not lead to reverse remodeling, nor did provide superior survival compared with CABG alone. Therefore, controlled

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Codex : o3/04/1407

studies are needed in which the only difference between cases is the surgical treatment of moderate cIMR.^{5,6}

Patients and methods

We conducted this study to understand and to delineate the role of mitral valve surgery in this high-risk population. This study was done between Cardiac Surgery Unit, Nasser Institute for Research and Treatment, Cairo and Cardiothoracic Department, Mansoura University Hospitals, Mansoura Faculty of Medicine and approved by both Medical Research Ethical Committees. All patients provided informed consent for inclusion in the study.

We included all patients with CAD associated with moderate cIMR. Excluding patients with acute IMR, recent infarction in the last month, unstable angina, structural abnormality of the mitral valve (e.g., calcification or thickening of valve annulus, leaflets, ruptured papillary muscle, ruptured chordae tendinae, mitral valve prolapse, mitral stenosis, mitral valve endocarditis), associate significant other valvular (aortic, tricuspid or pulmonary) diseases, associated aortic artery aneurysm or LV aneurysm, left atrial or LV thrombus, surgery on renal impairment, liver impairment, Low EF (Less than 35%), surgery on an emergency base, redo CABG, previous mitral valve surgery or other previous cardiac surgery. From June 2010 to December 2012, the 70 patients were randomly classified into 2 groups; each included 35 patients; the first group was subjected to CABG alone (group A); while the second group was subjected to CABG and MV surgery (group B).

Surgical technique

The surgical technique

After median sternotomy, conduits were harvested. Left internal mammary artery (LIMA) was used as a conduit to the left anterior descending artery (LAD) in 66/70 (94.28%) patients;

other territories received venous conduits primarily, because of the availability. After starting cardiopulmonary bypass, the procedure is the same as coronary bypass was performed to all major territories as long as there appeared to be viable myocardium and the coronary arteries were not too small or too heavily calcified. After completion of distal anastomoses of CABG, the LIMA was clamped. Antegrade cardioplegia was delivered to ascertain cardiac arrest. Both caevae were snared. MV surgery was done as mitral valve was exposed through a left atriotomy. In 14 patients, an annuloplasty was the sole procedure performed for the mitral valve and the surgical technique did not vary between different surgeons.

Ring size (Carpentier-Edwards Physioring; Edwards Lifesciences, Irving, CA) was determined after careful measurement of the height of the anterior leaflet, and then downsizing by two sizes (ie, size 26 when measuring 30). Rings were inserted using 14 to 16 deep U-shaped simple horizontal sutures using Ethibond 2-0 (Ethicon, Inc, Somerville, NJ) or Ti-Cron 2-0 (Syneture, Norwalk, CT). The stitches are crossed each other to enforce the stitches.

All patients had intraoperative transesophageal echocardiography assessment of LV and valve function. Mitral valve repair was considered successful if there was no or mild residual MR. When incomplete repair remains, more than grade 2-MR, by intra-operative echo examination, mitral valve was replaced, it was done in 12 cases.

Distal anastomoses were constructed with 8-0 and 7-0 proline sutures while proximal anastomoses were completed using a partial occluding aortic clamp with 6-0 proline suture. After routine and thorough de-airing of all cardiac chambers, aortic cross clamp was removed. CPB was gradually weaned off. Fifty one cases needed inotropes and others not. And 14 cases needed IABP, 6 in group A and 8 in group B. Conventional closure was done after hemostasis. Pacing wires was then inserted, and the sternotomy was closed.

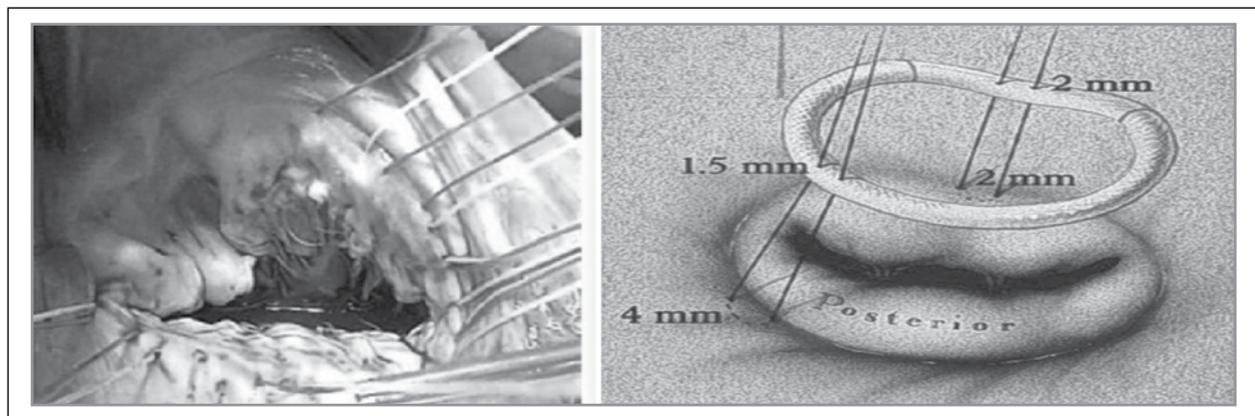


Fig. 1. A Showing the stitches are crossed each other to enforce the stitches. B The mitral annular diameter is reduced to improve the contour by using undersized Carpentier Edwards physiologic ring.

Results

From June 2010 to December 2012, 70 patients with IHD and moderate cIMR (> grade II) were identified. 35 patients underwent CABG alone, group A. On other hand, 35 patients underwent combined coronary artery bypass grafting and mitral valve surgery, group B, mitral valve repair in 23 (78%) and mitral valve replacement in 12 (22%). Uni- and multivariate analyses were performed on the entire cohort. We specifically examined the impact of mitral valve surgery on their left ventricular remodeling, as assessed by left ventricular end-systolic dimension (LVESD), LVEDD and EF. Also in hospital mortality rate and functional status assessed by NYHA. We assessed the surviving cases at time of discharge and 6 month later by clinical examination and echocardiography evaluation at rest.

Patients' preoperative characteristics

For the entire cohort, the male gender was 51 cases (72.9%), distributed as follow; 23 (65.7%) in group A and 28 (80.0%) in group B while females were 19 cases (27.1%), distributed as follow; 12 (34.3%) in group A and 7 (20.0%) in group B. The mean age at the time of surgery was 53.97 ± 8.82 years, range

was 42-69 years in group A. while it was 55.43 ± 7.76 for group B. (range was 45-67 years).

Our groups were near identical in preoperative variables, see table 1, propensity matched on 16 baseline characteristic variables (history of smoking, hypertension, diabetes, hyperlipidaemia, angina degree, preoperative New York Heart Association class (NYHA), site of previous MI, previous PCI, coronaries lesions distribution).

Operative Details

The mean cardiopulmonary bypass time was 85.03 ± 23.70 minutes (range, 47-123) for group A, and was 138.89 ± 37.97 minutes (range, 84-235) for group B. The mean aortic cross-clamp time was 49.63 ± 15.43 minutes (range, 30-82) for group A and 98.69 ± 15.43 minutes for group B (range, 60-195).

LIMA to LAD was used in 66 patients (98%), where only 1 patient (2.9%) did not need to revascularize in group B, while the other 3 patients (8.7%); 2 (5.8%) in group B and 1 in group A (2.9%); 2 (5.8%) received a venous conduits to LAD due to LIMA harvesting problems and one patient (2.9%) revascularized

		Group A	Group B	Total	P-value
Smoking	Positive	14 (40.0%)	24 (68.6%)	38 (54.3%)	0.016
Hypertension	Positive	25 (71.4%)	26 (74.3%)	51 (72.9%)	0.788
Hyperlipidemia	Positive	17 (48.6%)	13 (37.1%)	30 (42.9%)	0.334
DM	Positive	16 (45.7%)	14 (40.0%)	30 (42.9%)	0.629
Angina degree	Grade I	9 (25.7%)	1 (2.9%)	10 (14.3%)	0.006
	Grade II	26 (74.3%)	34 (97.1%)	60 (85.7%)	0.006
NYHA	Grade II	4 (11.4%)	14 (40.0%)	18 (25.7%)	0.012
	Grade III	31 (88.6%)	20 (57.1%)	51 (72.9%)	0.012
	Grade IV	0 (0%)	1 (2.9%)	1 (1.4%)	0.012
Previous PCI	Positive	18 (51.4%)	16 (45.7%)	34 (48.6%)	0.632
ECG	Anterior MI	14 (40.0%)	1 (2.9%)	15 (21.4%)	<0.001
	Inferior MI	13 (37.1%)	23 (65.7%)	36 (51.4%)	<0.001
	Mixed MI	8 (22.9%)	11 (31.4%)	19 (27.1%)	<0.001
LMCA	Positive	12 (34.3%)	5 (14.3%)	17 (24.3%)	0.051
LAD	Positive	35 (100.0%)	35 (100.0%)	70 (100.0%)	1
Diag1	Positive	10 (28.6%)	21 (60.0%)	31 (44.3%)	0.008
CX	Positive	26 (74.3%)	32 (91.4%)	58 (82.9%)	0.057
OM1	Positive	8 (22.9%)	9 (25.7%)	17 (24.3%)	0.780
OM2	Positive	7 (20.0%)	6 (17.1%)	13 (18.6%)	0.759
RCA	Positive	21 (60.0%)	26 (74.3%)	47 (67.1%)	0.203
PDA	Positive	12 (34.3%)	9 (25.7%)	21 (30.0%)	0.434

Table 1. the preoperative variables for both groups.

the LAD by LIMA and SVG distally due to distal lesion both in group A.

No. of distal anastomosis for group A were; 2 grafts in 17 patients(48.5%), 3 grafts in 10 patients(28.6%), 4 grafts in 5 patients(14.3%), 5 grafts in 3 patients (8.6%). The total number of grafts in this group was 95 grafts with the average number of grafts of 2.83 (± 0.98) with P value of 0.788.

No. of distal anastomosis for group B were; only 1 graft in 1 patient (2.8%), 2 grafts in 12 patients(34.3%), 3 grafts in 15 patients(42.8%), 4 grafts in 6 patients (17.1%) and only 1 patient had 5 grafts (2.8%). The total number of grafts in this group was 102 grafts with the average number of grafts of 2.77 (± 0.77).with P value of 0.788

MV Repair was performed in 23 patients (78%), and MVR was performed in 12 patients (22%). The type of mitral repair performed, categorized by the subtypes of repair, 14 (60.9%) had only ring annuloplasty (RMVA). The median size of the annuloplasty ring used was 28 mm (range 26 to 30 mm). 6 cases (40.0%) needed ring size 26, 7 cases (46.7%) needed ring size 28 and only 2 cases (13.3%) needed ring size 30. A nonflexible and complete ring was used in all 14 RMVA patients, while implanting a pericardial band or Gortex tube posterior annuloplasty only in 8 patients (34.8%). One patient (4.3%) required a more complex repair where RMVA ring was used and augmentation of PML by pericardial patch.

In patients who underwent MVR, 3 (54%) received a bio-prosthetic valve and 9 (46%) received a mechanical valve. Among patients who had a mechanical mitral valve replacement, 5 (55%) had preservation of the posterior mitral leaflet with excision of the anterior leaflet, and 4 (45%) had bileaflet preservation. The valve size was 27 in 3 cases (25.0%) and size 29 in 9 cases (75.0%).

Functional Results:

Mean NYHA functional class in the follow up visits for group A was 2.89 ± 0.32 with 9 surviving patients in NYHA

class I, 15 in NYHA class II, and 6 in class III. While the mean NYHA functional class for group B, was 1.82 ± 0.73 with 11 surviving patients in NYHA class I, 9 in NYHA class II, and 6 in class III. Notably, there were significant improvements in quality of life and effort tolerance at 6 months assessment; simply by questioning about if he can tolerate a 6-minutes' walk.

Postoperative Echocardiography:

Regarding group A, In group A, the mean preoperative LVEF was 50.29 ± 10.91 and reached 47.94 ± 9.99 in post-operative measurements decreased after surgery, in group A (Figure 3-a). Mean preoperative LVEDD was 59.86 ± 10.71 and reached 57.76 ± 8.87 in postoperative echocardiography (Figure 3-b). LVESD was decreased but did not reach statistical significance, mean preoperative LVESD was 43.80 ± 12.15 and reached 41.73 ± 10.68 in postoperative echocardiography (Figure 3-c).

For group B, combined surgery group, the mean preoperative LVEF was 45.37 ± 11.07 and reached 45.90 ± 8.71 in post-operative measurements after surgery (Figure 4-a). In group B, mean preoperative LVEDD was 48.27 ± 24.62 and reached 59.59 ± 7.89 in postoperative echocardiography (Figure 4-b). While the mean preoperative LVESD was 37.60 ± 18.60 and reached 44.59 ± 8.20 in postoperative echocardiography (Figure 4-c).

Overall Survival Analysis

We explored the mortality hazards for the entire cohort in 2 different riskphases (early phase, and late thereafter 6months after surgery). The Kaplan–Meier survival curvehad 2 different mortality phases: an acute phasecorresponding to the early period and a second latephase.The observed in-hospital or approximately 30-day mortality was 3/35 (8.6%) for group A and 5/35 (14.3%) for group B. The overall reported early survivalfor the entire cohort was 88.58%. The overall reported early mortality for the entire cohort was 8/70 (11.42%).

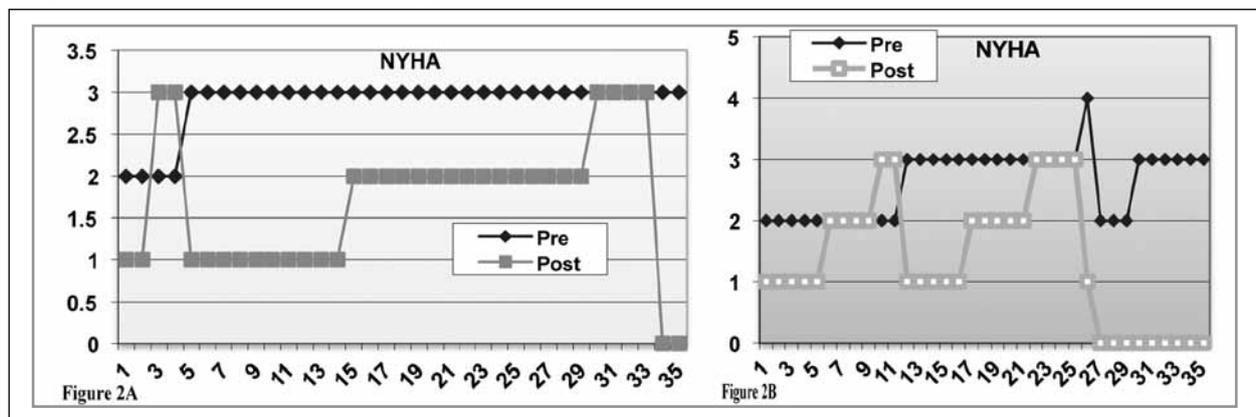


Figure 2A Paired preoperative and postoperative for group A.

Figure 2B Paired preoperative and postoperative for group B

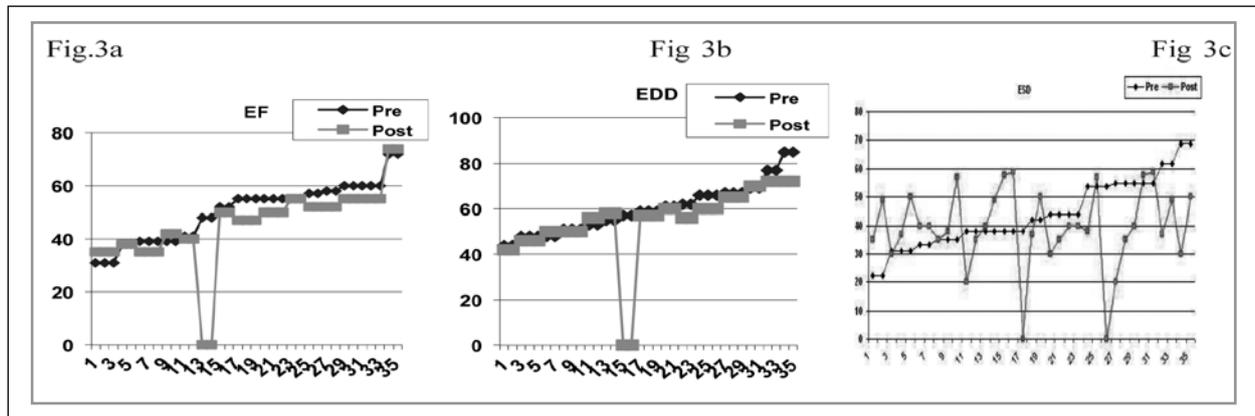


Fig. 3a Paired preoperative and postoperative EF for group A. Fig. 3b Paired preoperative and postoperative for LVEDD group A Fig. 3c Paired preoperative and postoperative LVESD for group A.

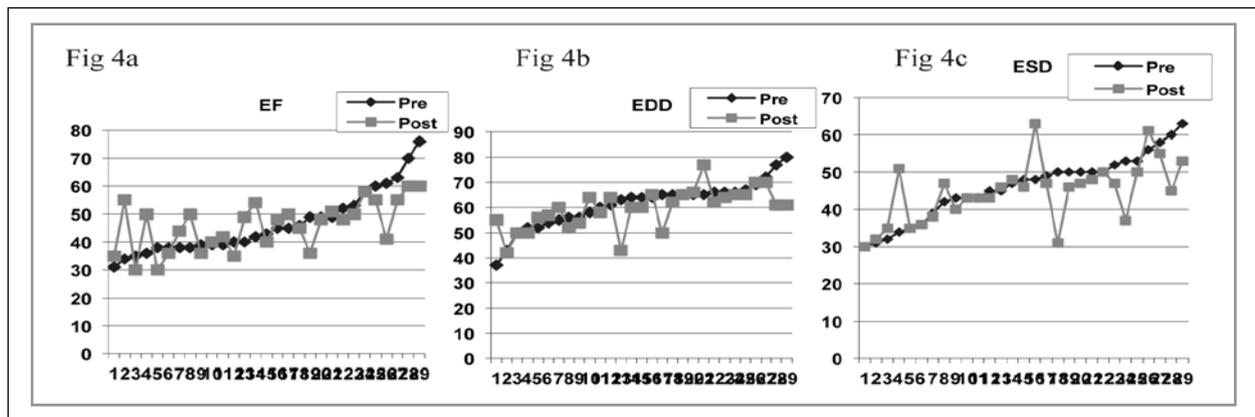


Fig. 4a Paired preoperative and postoperative for group B. Fig. 4b Paired preoperative and postoperative for group B Fig. 4c Paired preoperative and postoperative for group B.

The overall surviving cases after 6 months period of surveillance were 56/70 (80%) for the entire cohort and the overall mortality, after 6 months, was 15/70 (20%) for the entire cohort. But we better look for each group individually as 6 months survival was 6/35 (85.7%) for group A and it was 9/35 (74.3%) for group B. The 6 months mortality was 14.3% for group A and 25.7% for group B.

Discussion

There is general agreement that severe (grade 3, 4) cIMR should be corrected by mitral surgery at the time of CABG. However, the importance of moderate cIMR (grade 2) in such patients is controversial.^{7, 8} The pathophysiologic mechanisms for MR are: (a) asymmetric apical displacement of the posterior papillary muscle with tethering of both leaflets toward the left ventricular (LV) apex, Leaflet tethering usually prevails in the

posterior portion and results in asymmetric and restricted motion of the posterior mitral leaflet during systole and anterior leaflet pseudoprolapse,⁹ (b) mitral annular dilation.⁹ Our study presumed the cause of MR was to be ischemic based on our 70 patients echocardiography reports, electrocardiographic notes and operative notes which were reviewed to confirm that myocardial ischemia was primary mechanism for MR. All patients had a significant degree of mitral annular dilation and LV dysfunction due to prior MI. They were deemed to have IMR on the basis of leaflet tethering, papillary dysfunction, absence of any stenosis, thickening or calcification. Prior myocardial infarction was classified according to its site into patients with anterior or inferior or mixed.

In the presence of viable hibernating myocardium, adequate revascularization, lack of excessive atherosclerotic burden and preoperative therapy with beta-blockers and ACE inhibitors

perhaps a more conservative approach with CABG alone may be justified.¹¹ Mickleborough and colleagues proposed possible mechanisms for improvement, including decreased annular dilatation caused by decreased ventricular size, improved papillary muscle function owing to revascularization, and realignment of papillary muscles related to improved LV geometry.¹² In Calafiore and colleagues showed, in 2008, that in a large series of patients with a long mean follow-up, mild or moderate IMR impairs the long-term outcome of patients with an EF between 0.31 and 0.40, but not in patients with EF exceeding 0.40.¹⁶ Indeed, cIMR is a dynamic lesion, and its severity can vary over time, this may indicate that many patients who underwent CABG alone with residual mild-to-moderate MR at rest might have more severe MR during different loading conditions, which can contribute to symptoms appearance and an increase in systolic PAP and left atrial size.¹⁰ In the 10-years follow-up study by Grossi and colleagues, in 2001, there is clear evidence that CABG alone is not able to stabilize IMR, because its natural history seems to be independent from the revascularization¹³, the patient still has underlying CAD and is susceptible to plaque rupture and additional myocardial damage. However, there is no convincing evidence that mitral valve surgery for secondary MR improves survival, which is still poor, only about 50% at 5 years.^{14,15} In our study, 6 months survival was 6/35 (85.7%) for group A and it was 9/35 (74.3%) for group B. The 6 months mortality was 14.3% for group A and 25.7% for group B but our study was limited to 6 months follow up only.

In patients with posterior annular dilatation; this is corrected by ring annuloplasty. Current conservative surgical approaches to IMR mainly focus on annular reduction, with or without implantation of a prosthetic ring. Recently, mitral valve repair was shown to result in superior short- and mid-term outcome when compared with mitral valve replacement in certain patients with IMR.¹⁸ These data appear to have been accepted by the surgical community with the predominant form of valve repair, ring mitral annuloplasty, being performed in nearly 80% of patients with ischemic mitral regurgitation.¹¹ In our study, nonflexible and complete ring was used in all 14 RMVA patients, while implanting a pericardial band or Gortex tube posterior annuloplasty only in 8 patients (34.8%). One patient (4.3%) required a more complex repair where RMVA ring was used and augmentation of PML by pericardial patch.

However, because persisting regurgitation of varying degree is frequently observed with annuloplasty alone, a more sophisticated surgical approach to IMR appears to be indicated.⁹ The incidence of failure after RMVA can be as great as 30%, and it is believed to be due to the continual negative left ventricular (LV) remodeling with time.¹⁹ The resulting jet of mitral regurgitation is usually complex and is composed of a central and posteriorly directed jets of regurgitation (Carpentier types I and IIIb). Isolated annuloplasty principally addresses the central jet

of regurgitation (type I). It is therefore not surprising that many patients continue to suffer from significant mitral regurgitation after such repairs.²⁰ In our study, regarding group B, in our 23 patients who underwent repair, 12 patients had no mitral regurgitation, and 5 had mild mitral regurgitation. No patient had worsened mitral regurgitation grade. Regarding group A, 26 patients were discharged from the hospital with no residual mitral regurgitation; only 6 showed residual mitral regurgitation grade I, no case showed progression of mitral regurgitation.

That being said, one could argue that when a patient presents with a moderate to severe ischemic burden, one will be more inclined to repair the valve, compared with a patient who presents with an extremely dilated LV or lots of tethering, where surgeons might be more inclined to replace the valve. In our study where CABG was done only, we have 3 grafts in 10 patients (28.6%), 4 grafts in 5 patients (14.3%), 5 grafts in 3 patients (8.6%), which seems adequate revascularization that stabilized the decision toward CABG only as enough surgical solution for these patients.

We know the amount of recurrence of MR is approximately 20% to 30%. This can influence a surgeon's decision to replace or repair the valve initially according to the patient's symptoms. If the patient presents with severe angina symptoms, the most important thing is to perform CABG, but if the patient presents with long-term congestive heart failure symptoms, the most important thing was to replace the valve. This might influence the surgeon's decision.

Progression of cIMR was observed in lack of beta-blocker use, and presence of left bundle branch block, inadequate revascularization, especially in the area of the posterior descending artery, and in patients with 'natural progression of LV remodeling were found to be independent predictors of MR progression.²¹

Combined mitral valve surgery and coronary artery bypass grafting is associated with a reported hospital mortality of 7±18%,²² which is higher than the hospital mortality of 3% in isolated CABG and 4±7% in isolated mitral valve procedures.²³ Arcidi and colleagues reported on 58 patients with moderate MR and CAD treated with CABG alone between 1977 and 1983. The hospital mortality rate was 3.4%, and the initial 5-year survival estimate was 77%, with a mean follow-up 4.3±2.3 years. In contrast, 20 patients with moderate MR and CAD who had combined MVR and CABG during a similar time period had a hospital mortality rate of 25%, and 5-year survival was limited to approximately 31%. But many of those patients who did undergo a mitral procedure had more diffuse coronary artery disease, more severe LV dysfunction, and a greater degree of MR than those who did not have a mitral surgery.²⁴

Harris and colleagues reported on two groups of patients with the same degree of IMR (2/3) who had undergone either CABG alone (n=142; EF= 0.387) or CABG and MV surgery (n =34; EF=0.380). While in-hospital mortality was 9% ver-

sus 21%, the 5-year survival was similar (52% versus 58%).²⁵ These findings emphasize the continued need for improvement in operative and perioperative management of IMR patients, who appear to be at higher risk for early complications and mortality relative to the CABG-alone cohort.²⁶ Causes of death in our study within 6 month period were low output syndrome in 2, persistent arrhythmias in 2 and coagulopathy in 1 and he was re-explored. The cause of in-hospital death was cardiac-related event in 5 patients and IABP necessary to improve the postoperative cardiogenic shock in 3 patients in group B. In group A, 3 cases (8.6%) died during ICU stay, mainly from early postoperative ischemic changes in early ECG records, and the persistent low cardiac output condition despite the inotropic support and IABP used in 2 cases.

Total mortality, including hospital deaths, Anquita and colleagues, in 1993, correlated long-term survival with LVEF<30%, but with episodes of temporary cardiac decompensation.²⁷ Hausmann and colleagues, in 1997, did not find preoperative EF as risk factor for early death. One explanation for this finding is that preoperative ejection fraction does not take into account hibernating myocardium which will recover after revascularization.²⁸ It was predicted by preoperative LVEDD greater than 65 mm, LVESD greater than 50 mm proved to be the next significant predictor. For LVEDD of 65 mm or less, actuarial survival rates at 1, 3, and 5 years were 93%, 87%, and 80%, respectively, whereas for LVEDD greater than 65 mm these rates were 71%, 61%, and 49%, respectively.²⁹ Our study did extend for 6 months only.

Despite overall contradicting and poor long-term survival in patients with ischemic MR, the survival advantage seen with the surgical correction of cIMR is significant and well established and had demonstrated increasingly improved outcomes as survival rates and quality of life determined by New York Heart Association.¹⁷

Clinical Implications

We recently started to use, in these patients population, the RING plus STRING technique, which combines the annuloplasty with repositioning of the posterior papillary muscle toward the midseptal fibrous annulus (or saddle horn).

Study Limitations

The main limitations of the present study were mainly the lack of information on myocardial viability, the evaluations were based on 2-dimensional echocardiographic measurements and the recording of echocardiography data was deficient. More detailed information, such as coaptation height, tenting area, tethering height, sphericity index, and so forth, may shed better insight, control group wasn't included. The usage of multiple techniques is important, which will of course be biased toward the rigid ring annuloplasty subgroup that was carried out in the

majority of the study. The follow-up period may be too short to detect true survival differences. It included all the patients who underwent cIMR, independent of the location of MI, as it happens in the real world.

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Effect of Preservation of pleural Integrity during Internal Mammary Artery Harvesting on the Early Postoperative outcome of the Patients Undergoing CABG

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Background: Although there are many alternatives, the left internal mammary artery is widely used as the conduit of choice for myocardial revascularization. Pleurotomy during IMA harvesting may also impair respiratory functions during the postoperative period and may produce some postoperative complications as reported by several surgeons. Many studies have reported that pleural effusion, atelectasis, blood loss and pain were encountered less often in patients who did not receive IMA.

Objectives: This study was designed to compare the early postoperative course of two randomized groups of patients who underwent IMA harvesting with or without pleurotomy for myocardial revascularization as regard the early outcome including pulmonary functions, pulmonary complications and pain.

Patients and methods: This study was done in Cardiothoracic Surgery Department, Mansoura Faculty of Medicine, Cardiac Surgery Unit, Nasser Institute for Research and Treatment and Mahalla Heart Center and approved by Ethical Committee of Mansoura Faculty of Medicine. From June 2012 to September 2014, 100 patients with IHD prepared for elective first time CABG. 50 patients underwent LIMA harvesting without pleural preservation. On other hand 50 patients underwent LIMA harvesting with pleural preservation.

Results: There was statistically significant difference regarding mean blood loss after surgery, the duration of ventilation in hours and postoperative pain score. Regarding postoperative respiratory complications there was a statistically significant decrease in the incidence of atelectasis and pleural effusion on 5th postoperative day in group of closed pleura. Comparison of postoperative pulmonary function tests between both groups showed that FEV1, FEV1 % predicted, FVC, FVC % predicted and FEV1%/ FVC % predicted in the group of closed pleura was significantly higher than the corresponding values in the group of open pleura.

Conclusions: Preservation of pleural integrity has beneficial effects on the pulmonary functions, the blood loss, pain score and the duration of ventilation after coronary revascularization and has lesser pulmonary complications.

Key words: CABG, Pleural preservation, IMA harvesting, Pulmonary functions, Pulmonary complications.

In 2014, coronary artery bypass grafting (CABG) celebrates the 50th anniversary of the first successful procedure performed in 1964.¹ Although there are many alternatives, the left internal mammary artery (LIMA) is widely used as the conduit of choice for myocardial revascularization. Compared with the saphenous vein, the LIMA has superior graft patency and better long-term survival.² Many studies, as well as the clinical experience of cardiothoracic surgeons, have shown that respiratory problems are one of the major factors affecting morbidity and mortality after CABG.³ Anesthesia, poor preoperative pulmonary functions, cardiopulmonary bypass, and poorly executed surgical techniques are the most widely known reasons for respiratory complications after CABG.⁴ There is evidence that impairment of pulmonary functions in patients undergoing coronary artery bypass grafting is more pronounced when internal mammary artery (IMA) grafts are used.⁵ Pleurotomy during IMA harvesting may also impair respiratory functions during the postoperative period.²

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and may produce some postoperative complications as reported by several surgeons.⁶ Many studies have reported that pleural effusion, atelectasis, blood loss, the need for secondary thoracotomy, pain, and intercostal neuralgia were encountered less often in patients who did not receive IMA.⁷

Patients and methods

We conducted this study to compare the early postoperative course of two randomized groups of patients who underwent IMA harvesting with or without pleurotomy for myocardial revascularization. This study was done, between June 2012 and September 2014 in Cardiothoracic Surgery Department, Mansoura Faculty of Medicine, Cardiac Surgery Unit, Nasser Institute for Research and Treatment and Mahalla Heart Center. The study approved by Ethical Committee of Mansoura Faculty of Medicine. All patients provided informed consent for inclusion in the study.

We included all patients who underwent elective first time CABG with use of LIMA as a graft in addition to other grafts such as saphenous venous grafts and or the radial artery. Excluding patients over 65 years old, poor left ventricle (ejection fraction < 30%), redo or emergency or high risk CABG cases also patients with chronic pulmonary disease (e.g. COPD), patients with skeletal abnormalities of the chest that cause pulmonary restrictions and those who in need for concomitant cardiac or non-cardiac surgery.

The 100 patients were randomly classified into 2 groups; each included 50 patients; the first group was subjected to LIMA harvesting without preservation of the pleural integrity (open pleural technique) (OP group); while the second group was subjected to LIMA harvesting with preservation of the pleural integrity (closed pleural technique) (CP group).

Patients were evaluated with the aid of daily follow up. To monitor pulmonary complications including pleural effusion and atelectasis, chest radiography was performed routinely before surgery, immediately and on the first and 5th day postoperative. Pleural effusion was considered relevant when it passed the costophrenic angle, and atelectasis was recorded when there was a clear radiologic shadow exceeding 15 mm in width. Linear atelectasis was not recorded. Instances of sternal dehiscence and of mediastinal drainage of any kind were recorded. Such cases were accepted as mediastinitis in the event of positive serologic culture.

The preoperative, 1 hour postoperative, before extubation and after extubation values of ABGs including partial oxygen pressure (PaO₂), partial carbon dioxide pressure (PaCO₂), and oxygen (O₂) saturation were recorded for comparison, also preoperative and postoperative hemoglobin and hematocrit and preoperative and postoperative at day 5 pulmonary function tests (PFTs) including FEV₁, FVC and FEV₁/FVC.

Postoperative pain evaluation using visual analog scale (VAS) pain score. The pain quality and intensity were evaluated routinely by self-reporting using a VAS at fourth hour after extubation. VAS was a horizontal line, 10 cm in length, anchored by word descriptors at each end. The patients marked on the line the point that they feel represents their perception of their current state. The VAS score was determined by measuring in centimeters the distance from the left-hand end of the line to the point that the patient marks.

Surgical technique

The routine CABG technique was applied to all patients. Aortic and 2-stage venous cannulae were used to institute cardiopulmonary bypass (CPB) using a roller pump and membrane oxygenator, with identical priming solution. Distal anastomoses were performed during the cross clamp period. Proximal anastomoses were performed with a partial occluding clamp on the aorta. All the left anterior descending arteries received a pedicled non skeletonized LIMA graft. The other vessels received greater saphenous vein grafts, no one need radial artery graft.

In all patients, the LIMA was harvested using electrocautery and the side branches were occluded with hemoclips with its pedicle: the endothoracic fascia and surrounding fat and muscle tissue, accompanied by the vein. If its flow was adequate, the IMA was kept in a papaverine soaked sponge and anastomosed to the left anterior descending artery. If the pleura was opened accidentally the opening was widened and was included into the open pleural group which happened in 3 cases and another 2 cases the right pleura was opened during sternotomy. So we added them to open pleural group. The patients in the OP group received an additional left pleural tube for drainage.

Extrapleural Access

The endothoracic fascia was dissected along the chondrosternal cartilages without opening the pleura. The initial incision for the dissection of the endothoracic fascia without the pleura from the chest wall was performed at the level of the fourth rib. The anterior part of the IMA was freed throughout its length, and the surrounding fat was trimmed. The side arterial branches were divided between clips using gentle traction on the fascia. In this manner the IMA was separated from the chest wall, taking down the fascia and leaving the pleura. In a second stage the IMA with surrounding fat and veins was mobilized from the endothoracic fascia, clipping the branches. We decreased the tension of extrapleural harvested IMA by placing it in a groove formed by the thymus and the fatty tissue.

Statistical Analysis

Statistical analysis was performed using SPSS statistical software (SPSS, Inc., Chicago, IL, USA). Qualitative data were represented in the form of number and frequency, while quan-

titative data were represented in the form of mean ± standard deviation (mean±SD). Kolmogrov-smirnov test was used to test normality of quantitative data. Both chi square and McNemar tests were used to compare qualitative data. While, quantitative data were analyzed by both paired and unpaired student's t tests. Results were considered significant if p value is less than or equal 0.05.

Results

Preoperative Assessment

The study group consisted of 100 patients of these patients 89 were men, 47 of them in the OP group and 42 in the CP group. The mean age of the patients in the OP group was 57.22±7.20 years while 56.20±6.99 in CP group. Comparative preoperative clinical data on the patients regarding demographic data, risk factors, ejection fraction, ABG and hematocrit are shown in Table (1). The demographic and clinical data of the 2 groups were similar with no statistical significance.

Variables	Open Pleura (n=50)	Closed Pleura (n=50)	P-value
Age (years)	57.22±7.20	56.20±6.99	0.47
Sex (M/F)	47/3	42/8	0.11
Diabetes mellitus	19 (38%)	22 (44%)	0.54
Hyperlipidemia	6 (12%)	5 (10%)	0.75
Hypertension	26 (52%)	27 (54%)	0.84
Smoking	31 (62%)	26 (52%)	0.31
EF (%)	58.82±9.02	58.94±10.18	0.95
PaO ₂ (mmHg)	88.84±4.93	89.22±3.99	0.67
PaCO ₂ (mmHg)	34.34±1.94	35±1.98	0.9
O ₂ saturation (%)	98.94±0.42	98.92±0.48	0.82
Hematocrit (%)	41.65±4.15	41.87±4.16	0.78

Table 1. Preoperative demographic and clinical data

Intraoperative and Postoperative Assessment

Regarding intraoperative and postoperative analysis of the data; there were no statistical significant differences between groups as regard cross clamp time, cardiopulmonary bypass time(CPB), number of grafts, hematocrit level, ICU and hospital stay and postoperative complications such as rewiring, reintubation, re-exploration for bleeding, temponade, postoperative MI, wound infection and diaphragmatic paralysis Table (2). As regard temponading; In spite of that there is no statistically significance but the results may alarm us about this significant lethal complication.

There was statistically significant difference regarding mean blood loss after surgery in ml 840±252.99 in the OP group while 653±176.12 in the CP group, the duration of ventilation in hours with 14.22±4.17 in the OP group and 10.58±3.56 in the CP group and postoperative pain score with median pain score 5 in the OP group in contrast with 4 in CP group Table (2).

Regarding postoperative respiratory complications, in group of open pleura, the incidence of atelectasis was 2% on 2nd postoperative day (POD), and 10% on 5th POD, while there were no cases with atelectasis on 2nd and one case (2%) on the 5th POD in group of closed pleura. In group of open pleura, the incidence of pleural effusion was 8% on 2nd POD and 22% on 5th POD, while this incidence was 2% on 2nd POD and 6% on 5th POD in group of closed pleura. There was a statistically significant decrease in the incidence of atelectasis and pleural effusion on 5th POD in group of closed pleura Table (3).

Variables	Open Pleura (n=50)	Closed Pleura (n=50)	P-value
Cross clamp time (min.)	62.40±29.93	55.12±20.78	0.63
CPB time (min.)	87.08±33.61	83.82±34.68	0.64
Number of grafts:			
1 graft	3 (6%)	6 (12%)	0.29
2 grafts	13 (26%)	16 (32%)	0.50
3 grafts	27 (54%)	21 (42%)	0.22
4 grafts	7 (14%)	7 (14%)	1
Blood loss (mL)	840±252.99	653±176.12	0.02*
Hematocrit (%)	34.98±3.71	34.54±4.44	0.59
Duration of ventilation (hours)	14.22±4.17	10.58±3.56	0.012*
ICU stay (days)	2.44±1.26	1.51±0.88	0.08
Hospital stay (days)	7.98±1.75	7.44±1.31	0.16
Postoperative pain score	5(3-6)	4(3-6)	0.007*
Postoperative complications:			
Re-wiring	1 (2%)	0 (0%)	0.31
Re-intubation	3 (6%)	2 (4%)	0.64
Re-exploration for bleeding	5 (10%)	3 (6%)	0.46
Temponade	2 (4%)	6(12%)	0.14
Postoperative MI	2 (4%)	1 (2%)	0.55
Wound infection	6 (12%)	2 (4%)	0.14
Elevated diaphragm	1 (2%)	0 (0%)	0.31

*significant difference

Table 2. Intraoperative data and post-operative outcome

Postoperative day (POD)	Complication	Open Pleura (n=50)	Closed Pleura (n=50)	P-value
POD 2	Atelectasis	1 (2%)	0 (0%)	0.31
	Effusion	4 (8%)	1 (2%)	0.07
POD 5	Atelectasis	5 (10%)	1 (2%)	0.04*
	Effusion	11 (22%)	3 (6%)	0.005*

*significant difference

Table 3. Effect of pleural integrity on postoperative atelectasis and pleural effusion

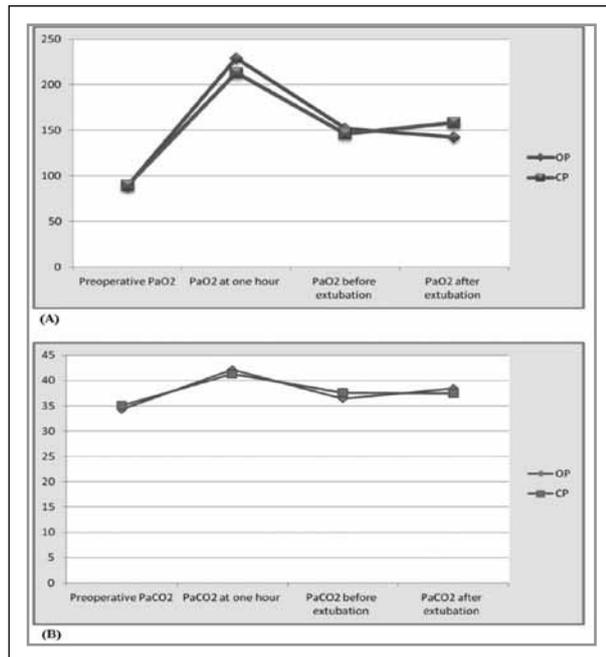


Fig. 1. Mean of preoperative and postoperative arterial blood gases in the studied groups: (A): PaO2. (B): PaCO2.

ABGs analysis demonstrates no significant differences between the studied groups regarding results of preoperative and postoperative ABGs with a significant increase in the mean PaO2 and PaCO2, one hour after surgery, before extubation and after extubation, in both groups of the study Fig. (1).

While in analysis of postoperative pulmonary function tests the mean FEV1 (L) was 1.72±0.37 with open pleura and 2.22±0.46 with closed pleura, the mean FEV1% predicted was 55.76±12.10 with open pleura and 71.34±9.16 with closed pleura, the mean FVC (L) was 1.99±0.51 with open pleura and 2.59±0.47 with closed pleura, the mean FVC% predicted was 58.16±11.14 with open pleura and 70.56±8.70 with closed pleura, the mean FEV1/ FVC (L) was 88.27±14.79 with open pleura and 86.12±11.62 with closed pleura and the mean FEV1%/ FVC% predicted was 96.05±10.95 with open pleura and 101.64±11.18 with closed pleura.

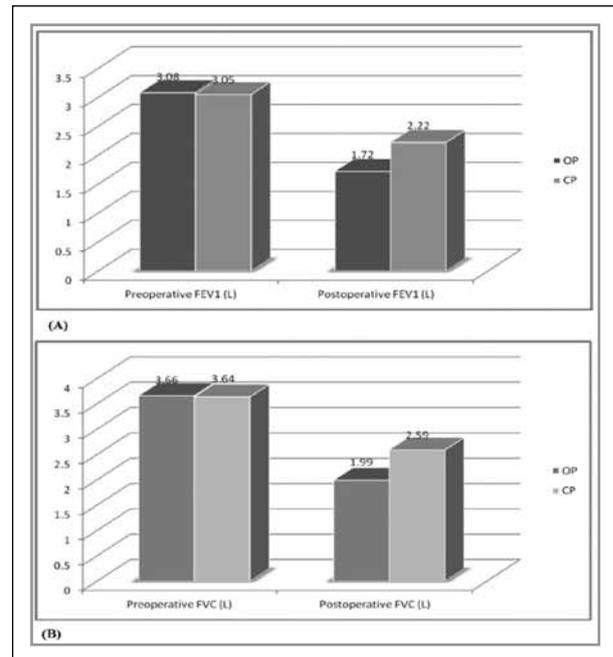


Fig. 2. Mean of preoperative and postoperative pulmonary function tests in the studied groups: (A):forced expiratory volume at one second (FEV1).(B):forced vital capacity (FVC).

In comparison of postoperative pulmonary function tests between both groups showed that FEV1, FEV1 % predicted, FVC, FVC % predicted and FEV1%/ FVC% predicted in group of closed pleura was significantly higher than the corresponding values in group of open pleura. Fig. (2).

Discussion

The IMA is the conduit of choice in CABG. Various techniques for IMA harvesting were described by several surgeons and extrapleural IMA harvesting is one of these methods.⁴ The respiratory problems in CABG patients are the critical issues influencing patient's early outcome. Most of the ischemic heart disease patients are current or ex-smokers. Additional negative effects of CPB on the respiratory protection system also led to excessive postoperative mucus secretion and atelectasis.⁸

Besides the graft patency, protection of extracardiac thoracic anatomy and nature may be an important issue particularly in the early postoperative temporary respiratory impairment period.⁹

Preservation of pleura was associated with significantly lower amount of blood loss when compared to group of open pleura p value = 0.02. Similar findings were reported in other studies in literature by Wimmer and associates⁸, Bonacchi and colleagues⁴, Goksin and co-workers¹⁰, Atay and colleagues¹¹, Iskesen and associates¹² who show significantly higher blood loss and blood transfusion requirements which was observed in group of open pleura than in group of closed pleura. The higher amount of blood loss with opened pleura might be attributed to the extensive dissection of the surrounding tissues, in addition to the “relatively-wider” surface area that needs to be secured as compared to patients with intact pleura which being “relatively smaller”, this area usually does not allow bleeding to skip the notice of the operating surgeon and hence provides more easy control of hemostasis, the narrower space in the mediastinum that will help compression on the minimal bleeding sites in the closed pleural group and the compression by the lung using the ventilator PEEP over the row area of IMA harvesting.

In this present study, there was significantly lower duration of mechanical ventilation in group of closed pleura (10.58 ± 9.06 versus 14.22 ± 10.17 hours; $p < 0.001$). There are controversial results in literature regarding the effect of pleural integrity on duration of mechanical ventilation after CABG. In the study by Bonacchi et al⁴, Ozkara et al⁹ and Atay et al¹¹, the mechanical ventilation stay was significantly higher in group of open pleura than in group of intact pleura. The most likely explanation of these results is that the pleurotomy may lead to collection in the pleural space which may cause atelectasis of a part of the lung; also this finding can be explained by disturbed alveolar stability due to changing the composition of alveolar surfactant which may be aggravated in patients with pleurotomy also the pleurotomy causing decrease in the pulmonary functions by 30%. In contrast with these findings, the study by Ali et al.¹³ showed insignificant difference between both groups (20.4 ± 1.4 hours in CP group versus 18.3 ± 1.2 in OP group). Iyem and co-workers² and Goksin et al¹⁰ reported no statistically significant difference between both groups. These results also may support our results and do not conflict with them.

There were no significant differences between both groups regarding results of Postoperative Blood Gases. In the study by Bonacchi et al.⁴ PaO₂ was significantly higher, and PaCO₂ and FiO₂ were significantly lower in group I (closed pleura) than groups II (opening of pleura) and III (incidentally opened pleura) at 1 and 4 h before extubation and at 1 and 4 h after extubation. Iyem et al.² reported that there were no significant differences between the groups in mean values of PaO₂, PaCO₂ and O₂ saturation after extubation or on the 1st postoperative

day. Oz and colleagues³ showed that on the fifth postoperative day, PaO₂ and O₂ saturation were significantly higher and the PaCO₂ was significantly lower in the closed pleura group. Ghavidel and co-authors¹⁴ found that postoperative PaO₂ and O₂ saturation were similar between the groups, but PaCO₂ pressure was significantly lower in group of open pleura. The most likely explanation for the difference in results between different studies is the difference in management of the anesthetic techniques used for intraoperative preservation of the both lungs like inflation for few minutes every hour, and the postoperative management in the form of lesser IV fluids, use of corticosteroids and nursing care.

There was a significant reduction of postoperative PFTs when compared to preoperative PFTs regardless the used technique. However, when compared to opened pleura, preservation of pleural integrity resulted in significantly higher results of PFTs.

Similar findings to ours regarding changes in PFTs were reported in literature. In the study by Wimmer-Greinecker et al.⁸, FEV₁ was significantly decreased in open pleura group than intact pleura group, 6 days after surgery ($p = 0.02$). The FEV₁ correlated to inspiratory vital capacity, which confirmed the advantage of the intact pleura ($p = 0.003$). Oz and co-authors³ reported that the FEV₁ showed a significant decrease five days postoperatively in the OP group (OP group: $61.2 \pm 3.6\%$; CP group: $76.1 \pm 6.2\%$; $P < 0.001$). VC was significantly more restricted in the OP group at 30 days postoperatively (OP group: $85.3 \pm 4.2\%$; CP group: $96.2 \pm 5.4\%$; $P < 0.001$). Ozkara & colleagues⁹ showed that, there were postoperative reductions in FEV₁ (0.17 ± 0.18 vs. 0.28 ± 0.14 , $p = 0.016$), FVC (0.18 ± 0.19 vs. 0.28 ± 0.13 , $p = 0.037$) with a significantly higher postoperative PFTs in group of preserved pleura. Gullu and associates⁵ demonstrated that FEV₁ (%) and FEV₁/FVC levels at the postoperative fifth day were significantly lower in group of opened pleura ($p < 0.05$).

In contrast with these findings confirming better effect of pleural integrity on PFTs, the study by Matsumoto et al.¹⁵, showed that pleurotomy does not affect postoperative FEV₁ at 20 to 30 days postoperatively. Also, the study by Iskesen et al.¹² showed that pleura preservation during coronary operation does not have any beneficial effect on respiratory functions. On the 7th postoperative day FVC did not show any significant difference between the groups (2.80 ± 0.6 in CP group and 2.75 ± 0.5 liter in OP group) ($P > 0.05$). Also, there was no significant difference between the postoperative FEV₁% values ($71.8 \pm 5.1\%$ and $73.4 \pm 6.3\%$ respectively) ($P > 0.05$).

The most likely explanation of these results is that the disturbed alveolar stability due to changing the composition of alveolar surfactant which may be aggravated in patients with pleurotomy, the pleurotomy causing decrease in the pulmonary functions by 30% and the presence of the ICT site in the open

pleural group which may add to the restrictive pattern of respiration in this group of patients.

Postoperative pain score measured via Visual Analogue Scale showed statistical significance difference in the median score between both groups ($p = 0.007$). There are some studies proved the superiority of pleural integrity regarding comparison of postoperative pain score. In the study by Wimmer-Greinecker et al.⁸ using a multidimensional pain score, patients in group A (IMA use with open pleura) experienced significantly sharper than group B (venoarterial intact pleura) (6 days: A, 6.7 ± 0.3 ; B, 3.3 ± 0.2 ; $p = 0.018$; 3 months: A, 3.5 ± 0.3 ; B, 1.4 ± 0.3 ; $p = 0.046$) and more annoying pain (6 days: A, 7.6 ± 0.2 ; B, 2.7 ± 0.1 ; $p = 0.036$; 3 months: A, 6.6 ± 0.3 ; B, 2.3 ± 0.2 ; $p = 0.040$). Bonacchi and associates⁴ reported that the pain score at 1-12 hours after awakening were significantly higher in OP groups and group of incidentally opened pleura versus CP group and becoming similar after the chest tubes were removed. In the study by Oz et al.³, patients suffering from sharper (stabbing) pain were more common in the OP group at five days and 30 days after surgery. More annoying (troublesome) pain was also more common in the OP group at five days and 30 days after surgery. Gullu and co-authors⁵ explain that the pain score was higher in the OP group at postoperative 5th day. This explained by the presence of separate pleural tube in the open pleural group which may cause severe postoperative pain due to the friction of the intercostal tube between ribs during breathing leading to irritation of intercostal nerves and costal periosteum.

Preserving of pleura was associated with a significant reduction in the incidence of atelectasis (2% versus 10%; $p = 0.04$) and pleural effusion (6% versus 22%; $p = 0.005$) when compared to opened pleura on the 5th day after surgery. In an early study by Noera et al.¹⁶, pleural effusion was infrequent or absent in group 2 patients (IMA used with intact pleura), whereas respiratory insufficiency was noted only in group 1 patients (open pleura technique). Ali and colleagues¹⁷ and Bonacchi and co-authors found that pleural effusion occurred more often in the patients who had opening of the pleura. Lim and his group¹⁸ found that patients with a left pleurotomy had a significantly higher incidence of left lung atelectasis (67.7% vs. 45.2%; $p = 0.007$), and insignificant incidence of pleural effusion (42.5% vs. 46.3%; $p = 0.66$). Iyem et al.² reported that atelectasis on the 5th and 7th postoperative days and pleural effusion on the 2nd, 5th, and 7th days were significantly less in the group with closed pleura. Goksin and associates¹⁰ showed that the incidence of postoperative pleural effusion and thoracocentesis were significantly lower in the group of intact pleura than the group of open pleura and other pulmonary complications such as pneumothorax, atelectasis and diaphragmatic paralysis were similar in both groups. In the study by Oz et al.³, Atay et al.¹¹, Ghavidel et al.¹⁴, Wimmer-Greinecker et al.⁸ and Gullu et al.⁵, the incidence of atelectasis and pleural effusion were also significantly higher in the open pleural group.

We suppose that the increase in atelectasis rate can be considered naturally due to the pressure of the hematoma in the pleural space. In patients with pleural integrity, as the hematoma volume is less, increase of the atelectatic lung segments will be limited, also the postoperative atelectasis may be due to pain related breath restriction which may cause cough restriction leading to mucous retention and atelectasis. Also as regard the pleural effusion it is increased in the open pleural group due to opening of the pleura itself, drainage of the bleeding points of the mammary bed and mediastinum into the pleural cavity which may cause minimal collection and irritation to the pleura with subsequent pleural effusion and the presence of the pleural tube which may cause also irritation to the pleura and then pleural effusion. As regard temponading; In spite of that there is no statistically significance but this complication may alarm us about this significant lethal complication which may be one of the serious disadvantages of the preservation of pleural integrity.

This study revealed that better results of pleural preservation regarding lower blood loss, shorter duration of mechanical ventilation, better postoperative pulmonary function tests, better pain score and lower rate of atelectasis and pleural effusion. Despite these results, the incidence of other postoperative complications, the ICU stay, the total postoperative hospital stay and postoperative ABG were similar between both groups. Temponading is a serious lethal complication which should be considered in our mind during the choice of IMA harvesting technique and the cost of negligence of expecting of this complication during the choice of the IMA harvesting technique is very high for both patients and surgeons.

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Topical use of Tranexamic Acid in on-pump and off-pump Coronary Artery Bypass Grafting

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Objective: Postoperative bleeding and the need for allogeneic transfusions are still one of the most common complications of cardiac surgery. Antifibrinolytic agents successfully reduce bleeding. The aim of this study was to evaluate the effect of topical tranexamic acid in reducing postoperative blood loss and transfusion requirements after coronary artery bypass Grafting.

Methods: In this prospective, double-blind, randomized, placebo controlled study, patients who were scheduled for elective coronary artery bypass grafting either on-pump or off-pump coronary artery bypass grafting were randomly divided to 4 groups according to administration of tranexamic acid locally into the pericardial cavity and mediastinum before the sternum was closed, Group I: 50 patients underwent onpump coronary artery bypass grafting (CABG) (ONCAB) and received tranxamic acid, Group II: 50 patients underwent onpump CABG and didn't receive tranxamic acid, Group III: 50 patients underwent off-pump CABG and received tranxamic acid and Group IV: 50 patients underwent off-pump CABG (OPCAB) and didn't receive tranxamic acid. We compared the volume of postoperative blood loss, transfusion requirments, and changes in laboratory variables of Hemoglobin between the 4 groups.

Results: postoperative blood losses were highly statistically significant between patients in group I versus group II (ONCAB Groups) and also between patients in group III versus group IV (OPCAB Groups) ($P < 0.0001$). The amount of packed red blood cell units transfused postoperatively were highly statistically significant between patients in group I versus group II (ONCAB Groups) and also between patients in group III versus group IV (OPCAB Groups) ($P < 0.0001$). Hemoglobin was highly statistically significant between patients in group I versus group II (ONCAB Groups) and also between patients in group III versus group IV (OPCAB Groups) ($P < 0.0001$) after one hour, 24 hour and on discharge.

Conclusions: this study indicates that topical use of tranexamic acid is effective and significantly reduces postoperative bleeding and the requirement for allogeneic transfusion both in off- and on-pump coronary artery bypass grafting.

KEYWORDS: Coronary artery bypass; Postoperative bleeding; Tranexamic acid.

Postoperative bleeding and coagulopathy are major complications of on-pump coronary artery bypass graft surgery. To reduce the morbidity associated with cardiopulmonary bypass (CPB), off-pump coronary artery bypass grafting (OPCAB) has gained popularity. Despite the avoidance of CPB, there is still activation of the fibrinolytic pathway during off-pump procedures because of the great surgical trauma (sternotomy, pericardiotomy, graft harvesting, and manipulation of the heart) and exposure to heparin and protamine [1].

Re-exploration for bleeding following cardiac surgery with CPB was reported to be in the range of 2–7%. Of these, 50–80% was found to be medical rather than surgical bleeding. Fibrinolysis was found to be responsible for 25–45% of significant post bypass bleeding [2].

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Codex : o3/06/1407

Many antifibrinolytic agents have been used to diminish post-bypass bleeding. These include ϵ Aminocaproic acid [3], aprotinin [4], and Tranexamic acid (TA) [5]. Systemic administration of antifibrinolytic agents has been commonly employed in the field of cardiac surgery, and many studies have reported their hemostatic effects. However, many cases of serious complications related to systemic administration have been reported. Intravenous tranexamic acid can increase risk of thromboembolism and early graft occlusion [6].

Local application of antifibrinolytic agent was first introduced by Tatar and colleagues who locally administered aprotinin into the pericardial cavity for the first time in 1993[7]. Since the withdrawal of aprotinin, many studies have reported the local administration of other antifibrinolytic agents as tranexamic acid and epsilon aminocaproic acid [1]. When used topically, TA was found effective in controlling bleeding in patients with hemorrhagic diathesis and in patients who were being treated with anticoagulants pre-operatively. Topical TA has also been successfully used in controlling bleeding in bladder, gynaecologic, oral, and otolaryngeal surgeries [8-10].

This aim of this prospective, double-blind, randomized, placebo controlled study was to evaluate the effect of topical TA in reducing postoperative blood loss and transfusion requirements after coronary artery bypass Grafting and to compare its effect in both on-pump and off pump CABG operations.

Materials and Methods

During the period January 2010 and January 2014, patients who were scheduled for elective CABG at Zagazig university hospital and Nasser Institute-Cairo were enrolled in this prospective, double-blind, placebo-controlled randomized study. The procedures were approved by the hospitals ethics committee and all patients signed an informed written consent. These patients fulfilled the following criteria: Elective patients, not redo operations, No other cardiac procedures other than CABG, No other advanced hepatic, renal, pulmonary, peripheral vascular or hematological disease, Preserved left ventricular function. No antiplatelet agent exposure within 7 days, preoperative heparin exposure within 48 hours, or non steroidal anti-inflammatory drugs (NSAIDS) use within 3 days. Any patient with postoperative morbidity other than those with bleeding or reexploration for bleeding, or mortality was excluded from this study.

After enrolled in this study, patients were randomly divided to 4 groups: Group I: 50 patients underwent onpump CABG (ONCAB) and received tranxamic acid, Group II: 50 patients underwent onpump CABG and didn't receive tranxamic acid, Group III: 50 patients underwent off-pump CABG (OPCAB) and received tranxamic acid and Group IV: 50 patients underwent off-pump CABG and didn't receive tranxamic acid.

Randomization was based on the chief nurse of the operating room who was the responsible personnel of preparing the test solution. None of the personnel in the operating room or in the ICU knew the type and nature of the solution.

All patients were standardized concerning premedication and anesthetic management. Patients stopped antiplatelet therapy 5 days before operation. All patients received 5mg Morphine 1 hour before operation. Induction of anesthesia started with fentanyl 2-5 μ g/kg, midazolam 0>1 mg/kg and Pancronium bromide 0.1 mg/kg. Endotracheal tube was inserted and mechanical ventilation started. Standard median sternotomy was carried out and harvesting of internal mammary artery (IMA) was started.

On-pump CABG

After finishing internal mammary artery (IMA) harvesting, full dose heparin (300 IU/kg) was administrated so as to keep ACT \geq 480 seconds although the operation. Aortocaval cannulation and initiation of CPB was done. After completing the distal anastomoses the cross-clamp was removed and proximal anaastmosis was done. After weaning of bypass reversal of heparin was done using protamine sulphate in the dose of 1 mg/100 IU.

Off-pump CABG

After finishing IMA harvesting half dose heparin(150 IU/kg) so as to keep ACT \geq 250 seconds although the operation. After completing all the anastmosis reversal of heparin was done using protamine sulphate in the dose of 1 mg/100 IU.

Hemostasis was done by only 2 surgeons for standardizing the procedure of hemostasis. For Group I and Group III Tranexamic acid 2 gram diluted in 25 ml of 0.9% normal saline was topically applied into the pericardial cavity just before closing the sternum while chest drains were clamped and clamps were released after closure of the chest is finished. For Group II and Group IV 25 ml of 0.9% normal saline was used.

Patients were transferred to ICU and put on mechanical ventilation. Calculation of drain was done every hour. Drains were removed when drain was less than 50 ml serous nature in the last 12 hours. Antiplatelet therapy and low molecular weight heparin were started the first postoperative day.

The transfusion protocol was as follow: Packed RPC's was transfused when hemoglobin was less than 8 gm/ml intraoperatively or 10 gm/ml postoperatively and/or hematocrit was less than 24 % intraoperatively or 30 % postoperatively. Plasma was transfused when PT more than 1.5 times the normal value and drain > 200 ml/hour. Platelet concentrate was transfused when platelet count was less than 75000/ml and drain > 200 ml/hour.

Patients were re-explored for bleeding if the mediastinal drain exceeded 500 ml/h in the first hour, 300ml/h for first 2 hours or 200 ml/h for 4 consecutive hours with accepted coagulation profile or when echocardiography documented the presence of cardiac tamponade.

Pre-operative demographic data and laboratory results (including hemoglobin, hematocrit, and platelet count and coagulation profile) were analyzed. Operative bypass time, crossclamp time and ACT were done. Postoperative laboratory results, 24 hours drain, Units of packed RBC's, plasma and platelets were recorded and ICU stay time and hospital stay time were also recorded and analyzed.

Statistical Analysis

Data are expressed as a mean value \pm standard deviation (means \pm SD) and as percentages (%). According to the type of data, the following tests were used to test differences for significance; normally distributed continuous variables were compared between the groups using the unpaired Student's *t* test, and abnormally distributed variables were compared using

Mann-Whitney U test. Chi-square test (χ^2) and Fischer exact test were used for comparison of ordinal and nominal data. Differences between frequencies (qualitative variables) in groups were compared by Chi-square test. Differences between means (quantitative variables) more than two groups were compared by ANOVA test. Statistical significance was defined as a *p* value of less than 0.05 ($p < 0.05$). Statistical analyses were performed with SPSS for Windows, version 11.5 statistical package (SPSS, Inc, Chicago, Ill, USA).

Results

Demographic and baseline characteristics of patients are shown in Tables 1. There were no significant differences for between surgical groups. Operative data are shown in Tables 2. There were no significant differences between patients assigned to ONCAB (Group I and Group II) and also between patients assigned to OPCAB (Group III and Group IV). Surgical time was significantly longer for ONCAB than for OPCAB ($P < 0.001$), and higher doses of heparin and protamine were used in ONCAB ($P < 0.0001$).

	Group				P	
	I	II	III	IV		
AGE	58.6 \pm 11.2	57.8 \pm 10.9	60.6 \pm 8.5	58.9 \pm 10.5	0.39	
SEX	F	21(42%)	19(38%)	22(44%)	20(40%)	0.78
	M	29(58%)	31(62%)	28(56%)	30(60%)	
Height (cm, mean \pm SD)	169 \pm 7	168 \pm 9	171 \pm 6	172 \pm 6	0.38	
Weight (kg, mean \pm SD)	73 \pm 10	71 \pm 12	77 \pm 9	77 \pm 12	0.09	
Hypertension	9 (18%)	6 (12%)	10 (20%)	7 (14%)	0.65	
Diabetes	8 (16%)	7 (14%)	5 (10%)	6 (12%)	0.98	

TABLE 1. Demographic and baseline characteristics of patients

	Group				P	
	I	II	III	IV		
No of grafts	1	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0.32
	2	7(14.3%)	5(10.2%)	2(4.1%)	5(10.2%)	
	3	25(51.0%)	26(53.1%)	28(57.1%)	24(49.0%)	
	4	14(28.6%)	17(34.7%)	16(32.7%)	18(36.7%)	
	5	2(4.1%)	1(2.0%)	3(6.1%)	2(4.1%)	
CPB time (min)	0 (0-0)	0 (0-0)	98 (67-123)	89 (65-98)	<0.0001	
Aortic crossclamp time (min)	0 (0-0)	0 (0-0)	69 (54-98)	65 (48-95)	<0.0001	
Surgical time (min)	179 (132-233)	198 (143-258)	254 (196-284)	237 (193-257)	<0.001	
Total heparin dose (mg)	90(80-110)	90(80-110)	260 (230-280)	250 (220-270)	<0.0001	
Total protamine dose (mg)	90(80-110)	90(80-110)	270 (250-310)	260 (230-310)	<0.0001	

TABLE 2 . Operative data

	Group				P
	I	II	III	IV	
Chest drainage	683.8 ±271.8	479.7 ±152.7	735.3 ±243.9	573.7 ±235.8	<0.001
Reexploration for bleeding	4 (8.2%)	2 (4.1%)	3 (6.1%)	2 (4.1%)	0.54

TABLE 3 . Postoperative drainage and reexploration for bleeding.

The extent of postoperative drainage and the requirement for reexploration for bleeding are shown in Table 3. The 24 hours total drain was significantly less in group I than in group II (on bypass CABG groups) and also was less in group III than in group IV (Off -bypass CABG groups) ($P<0.001$). As expected, postoperative blood losses were higher in patients undergoing ONCAB than in those undergoing OPCAB ($P<0.006$). Postoperative blood losses were highly statistically significant between patients in group I versus group II (ONCAB Groups) and also between patients in group III versus group IV (OPCAB Groups) ($P<0.001$). The requirement for reexploration for bleeding was insignificant between groups.

The postoperative requirements for allogeneic transfusions are shown in Table 4. The amount of packed red blood cell units transfused postoperatively was significantly higher in patients undergoing ONCAB than in those undergoing OPCAB ($P < 0.01$). The amount of packed red blood cell units transfused postoperatively were highly statistically significant between patients in group I versus group II (ONCAB Groups) and also between patients in group III versus group IV (OPCAB Groups) ($P<0.001$).

		Mean± Std. Deviation	P
Total packed red blood cells (units)	I	1.49 ±0.67	<0.001
	II	0.88 ±0.11	
	III	2.49 ±1.63	
	VI	1.12 ±0.43	
Total platelet concentrate (units)	I	0.65 ±0.49	0.87
	II	0.33 ±0.11	
	III	0.78 ±0.86	
	VI	0.49 ±0.32	
Total fresh-frozen plasma (units)	I	0.57 ±0.27	0.89
	II	0.45 ±0.23	
	III	0.73 ±0.32	
	VI	0.53 ±0.22	

TABLE 4. Perioperative allogeneic transfusions

Changes in laboratory variables of Hemoglobin are shown in Table 5. Hemoglobin was highly statistically significant between patients in group I versus group II (ONCAB Groups) and also between patients in group III versus group IV (OPCAB Groups) ($P<0.001$) after one hour, 24 hour and on discharge.

		Mean±Std. Deviation	P
Pre operative Hemoglobin (g/dL)	I	12.9±1.2	0.23
	II	12.9±1.4	
	III	12.8±1.3	
	VI	13±1.4	
Hemoglobin (g/dL) after one hour	I	11.5±1.2	<0.001
	II	10.4±1.3	
	III	9.5±1.2	
	VI	10±1.3	
Hemoglobin (g/dL) after 24 hours	I	11.5±1.1	<0.001
	II	11±0.8	
	III	10.1±0.9	
	VI	10.5±1	
On discharge Hemoglobin (g/dL)	I	11.6±1.2	<0.001
	II	11.4±0.9	
	III	10.6±0.8	
	VI	10.9±0.9	

TABLE 5. Changes in laboratory variables of Hemoglobin

No case showed postoperative thromboembolism in our study. The ICU stays and hospital stay was also less in patients receiving TA but the result was not statistically significant between groups ($p>0.05$).

Discussion

Bleeding is considered one of the most common complications after cardiac surgery. Excessive bleeding and need for blood transfusion have been associated with increased morbidity and mortality. Blood transfusion can cause infection and immunological reactions and increase hospital length stay

and cost, which justifies all efforts to reduce bleeding after CABG^[11,12].

Re-exploration for bleeding following cardiac surgery with CPB was reported to be in the range of 2–7%. Of these, 50%–80% were found to be of medical rather than surgical reasons and fibrinolysis was shown to be responsible for 25%–45% of significant post-bypass bleeding^[2]. Although the use of OPCAB technique has the advantage of avoiding exposure of blood to the nonendothelialized surface of CPB and hence less post-operative bleeding but it still has significant amount of bleeding^[11].

Skin incision, sternal opening, presence of blood in the pericardial cavity and exposure of blood to nonendothelialized materials in the extracorporeal circuit activate coagulation pathway and hence the fibrinolytic system^[13]. Aoki et al stated that after open heart surgery, surgical invasion activates the fibrinolytic system in the pericardial cavity in addition to tissue plasminogen activator secretion therefore; coagulation and fibrinolysis are repeated in response to oozing at the capillary level which may be responsible for postoperative hemorrhage. So, the use of antifibrinolytic agents emerged as a solution for this problem^[12]. Tranexamic acid is a lysine analogue that acts by forming reversible complex with plasminogen and plasmin through lysine binding sites. Saturation of these sites displaces plasminogen from the fibrin surface thus inhibiting fibrinolysis^[14].

Systemic use of antifibrinolytic agents such as aprotinin, ε-aminocaproic acid and Tranexamic acid have been proven to be beneficial in reducing post operative bleeding and transfusion requirements^[3-5]. Systemic uses of such agents have been reported to be associated with many complications such as thrombo-embolism that can result in early graft closure^[6]. After decline in the use of aprotinin (due to complications or the cost/effectiveness ratio), many studies discussed the use of tranexamic acid systemically in lower dose or locally^[15-19].

The first use of local administration of antifibrinolytic agent (aprotinin) was done by Tatar and colleagues in 1993 who demonstrated reduction of post-operative bleeding and need for blood transfusion^[7]. O' Regan and colleagues discussed the benefit of topical administration of aprotinin in cardiac surgery (CABG and valve replacement)^[15]. Çiçek et al also demonstrated the same results and found no trace of aprotinin in systemic blood sampling^[16]. These results encouraged De Bonis et al to begin the use of tranexamic acid topically and they found that it is effective in reducing post-operative bleeding but not the need for blood transfusion^[17].

Four randomized, double-blind, placebo-controlled trials have evaluated the efficacy of topical tranexamic acid following cardiac surgery^[2, 17-19]. When poured into the pericardial and mediastinal cavities prior to sternotomy closure, tranexamic acid consistently demonstrated a reduction in postoperative bleeding compared to placebo; however, only 1 study showed a reduction in packed red blood cell transfusion requirements,

with a decrease of about 2 units^[18]. Notably, the 22% to 32% reduction in blood loss with topical tranexamic acid in these studies is similar to the previously reported reduction of 30% after intravenous administration^[2, 17-19]. Tranexamic acid was associated with reduced length of ICU stay in 2 studies and a reduction in need for surgical re-exploration in 1 study, suggesting that there may be clinical and economic benefits with this strategy even if transfusion rates are not affected. All of these trials were conducted in patients undergoing elective, first-time cardiac procedures and excluded patients at higher risk for bleeding or those undergoing procedures associated with greater potential for postoperative bleeding (such as repeat operations). Several authors have suggested that the benefit of topical tranexamic acid may be greater in higher risk surgeries, particularly for reduction in transfusion requirements, but there are currently no published data to support this theory^[17-19].

None of the studies commented on the incidence of post-operative thromboembolism, but the risk for this complication appears to be low due to the lack of systemic absorption of tranexamic acid reported by De Bonis and colleagues^[17].

In our study we compared the effect of topical use of tranexamic acid in on-pump and off-pump CABG concerning post-operative bleeding and the need of blood transfusion. Each group had a control group to rationalize and facilitate statistical comparison.

In our study the 24 hours total drain and postoperative blood losses were significantly less in group I using tranexamic acid than in group II (on bypass CABG groups) and this is consistent with the results of Esfandiari et al^[20], Baric et al^[19], Nouraei et al^[11] and Fawzy et al^[2] and the 24 hours drain was less in group III using tranexamic acid than in group IV (Off-bypass CABG groups) and this is consistent with the results of Casati et al^[21], Mehr-Aein et al^[22], Aoki et al^[12] and Wang et al^[23].

The need for packed RBC's transfusion post-operatively was significantly less in the groups using tranexamic acid (group I and group III) than in the control groups (group II and group IV) and these results are consistent with the results of Wang et al^[23], Mehr-Aein et al^[22], Casati et al^[21] and Nouraei et al^[11] but discordant with the results of Aoki et al^[12], Baric et al^[19] and Fawzy et al^[2]. The discordance may be attributed to the protocol of Packed RBC's transfusion.

The transfusion of platelets and plasma was not significantly less in the groups receiving tranexamic acid than the control groups. This is consistent with the results of Casati et al^[21], Wang et al^[23] and Nouraei et al^[11] but not consistent with the results of Fawzy et al^[2] who found significant reduction in platelets transfusion only.

Although the reexploration for bleeding was more in groups not receiving TA but it was significant statistically. No case showed postoperative thromboembolism in our study and this is consistent with the report by De Bonis and colleagues^[17].

The ICU stays and hospital stay was also less in patients receiving TA but the result was not statistically significant and this is consistent with the results of Fawzy et al [2].

In conclusion, this study indicates that topical use of tranexamic acid is effective, safe and significantly reduces postoperative bleeding and the requirement for allogeneic transfusion both in off- and on-pump coronary artery bypass grafting.

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Concomitant management of thoracic aortic aneurysm with coronary artery disease; is it safe?

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40 patients (29 males and 11 females) undergoing elective repair of ascending thoracic aortic aneurysm between December 2011 and June 2014 were enrolled in the study. patients above 40 years and/or with clinical or laboratory suspicion on CAD underwent routine preoperative coronary angiography (CAG) and received coronary revascularization when lesion is significant. Based on the presence of coronary affection patients of the study classified to two groups ; group (A):20 patients in whom there was coronary affection and group (B):20 patients without affection. Patients with significant coronary stenosis underwent CABG concomitantly the other 20 patients underwent aneurysm repair only. Preoperative, operative and postoperative variables was statistically analyzed and compared for the 2 groups; there was no statistically significant differences in both groups; Overall mortality of patients undergoing aneurysm repair was 5% (1 patient in each group), the results of treating concomitant lesions was encouraging. The results of this study show the associated morbidity when combine CABG with aortic surgery but the benefit deserve to combine both; especially the mortality was equal.

KEY WORDS: Aortic aneurysm, Coronary artery bypass grafting, Coronary artery disease.

As the number of elderly people in the population has increased, as so as the number of patients with thoracic aortic aneurysm combined with ischemic heart disease because both diseases have the same predisposing and etiological factors this is atherosclerosis. The frequency of this combination of disease ranges from 16 to 30%.⁽¹⁻³⁾ Several risk factors for aneurysms have been labeled, male sex and cigarette smoking are the strongest factors in multivariate analysis. Two Other factors associated with higher prevalence include age, white race, family history, hypertension, peripheral arterial occlusive disease (PAOD) and hypercholesterolemia.⁽⁴⁾ The exact pathophysiology of MI is unidentified and this lack of understanding may limit the ability to predict and prevent perioperative MI.

Most would agree that operative candidates need some form of preoperative imaging in order to appropriately plan surgical intervention. Preoperative diagnostic imaging follows specific protocols designed to allocate patients with aortic aneurysms to the appropriate type of repair. Additive investigations is also essential to diagnose and treat CAD when suspicious.⁽⁵⁾

Concomitant CAD influences both the perioperative period and long-term survival such that cardiac complications are the leading cause of morbidity and mortality both early and late following aortic surgery.⁽⁶⁾

Materials and Methods

Study population

This is a prospective observational study conducted on 40 consecutive symptomatic patients with thoracic aortic aneurysm; 20 of them associated with significant coronary

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Codex : o3/07/1407

artery disease (group A), the other group were defined as (group B). The study is carried out during the period from December 2011 to June 2014.

Patients scheduled for elective repair of atherosclerotic thoracic were reviewed. Patient with organic valvular affection, recent stroke previous cardiac surgery and cardiomyopathy were excluded from the study.

There were 29 males and 11 females, with a mean age of 68.1 ± 5.3 years (range from 58 to 79 years) for group (A) and 62.9 ± 10.6 (range from 39-77 years) for group (B).

For patients with concomitant aneurysm and CAD; 19 were hypertensive on oral antihypertensive drugs; 17 were diabetic (11 on insulin therapy, 6 on oral hypoglycemic drugs), 2 of diabetic patients had diabetic foot lesions the two received frequent dressing ; All diabetic patients received insulin therapy 3 days before operation till 1 week postoperative and then back to previous regimen, 3 patients had previous MI , 1 patient had previous old stroke 10 years ago.

For patients with aneurysm only; 14 were hypertensive on medical treatment ; 11 were diabetic (5 on insulin ,6 on oral hypoglycemic drugs); no previous stroke or MI were found. Of group A 18 patient had high level of LDL, 13 patient had low HDL, 17 patients had high cholesterol level. Group B patients shows high LDL in 15 patient, high cholesterol in 8 patients and low HDL in 4 patients.

Patients scheduled for elective aneurysm repair (in addition to routine and specific aneurysm investigations) has routinely undergone preoperative coronary angiography when above 40 years or if they are suspicious to have CAD clinically or laboratory. In addition to CAG, all patients underwent a standard electrocardiogram and echocardiography for the assessment of myocardial ischemia and viability.

For group A patients the aneurysm size affecting the ascending aorta ranging from 5.7 cm – 6.6 cm, For group B the size of aneurysm ranging from 4.9cm – 6.5cm.

In our study the patient presented with significant CAD showing myocardial ischemia, the treatment option for the CAD was combined CABG and aneurysm repair simultaneously.

Informed consent was obtained before operation after full explanation. Operation was performed with the use of standard cardiopulmonary bypass (CPB) established with moderate hypothermia and antegrade (retrograde in some cases) blood cardioplegia.

Preoperative , operative and postoperative data was statistically analyzed and compared for the 2 groups of patients.

Surgical Technique

- Incision: median sternotomy, Left internal mammary artery LIMA and / or saphenous vein graft SVG is harvested (for ischemic group).
- Distal ascending aorta, femoral artery and axillary artery are used for arterial cannulation, depending on the distal extent of aneurismal disease; the right atrium is cannulated for venous drainage. Left ventricular vent catheter is inserted via the right superior pulmonary vein. Retrograde cardioplegia catheter is used in some patients.
- The aorta is cross-clamped; blood cardioplegia is used and administered directly into the coronary ostia. The infusion of cardioplegia is maintained throughout most of the procedure. Retrograde administration of cardioplegia via the coronary sinus was used alternatively in some cases.
- Distal coronary anastomoses (other than LIMA to LAD) are reconstructed using prolene 7/0 sutures (in ischemic group).
- **In cases with competent aortic valve or mild grade of regurge:** the proximal aortic anastomoses is reconstructed above the coronary ostia.
- **In cases with marked aortic regurge,** the aortic valve is inspected carefully to decide whether to replace or spare, to achieve a good long-term result, the valve leaflets should not be overstretched.
- **If the valve is not repairable** a valved conduit (or manually sewn valve to the graft) is sutured at the site of excised valve using ethibond 2/0 sutures.
- **If the valve is repairable** sparing technique is planned (usually David technique)
- Distal aortic anastomoses is reconstructed using prolene 3/0 sutures and pericardial strips
- LIMA to LAD anastomosis is reconstructed using 7/0 suture.
- Proximal anastomoses of SVG is reconstructed using prolene 6/0 sutures.

Statistical analysis

Data of the study was of both quantitative and qualitative types.

Preoperative, operative and post-operative data will be compared, tabulated, and statistically analyzed. Results were expressed as means \pm standard deviation (SD) or number (%).

Comparison between preoperative, operative and postoperative data of different parameters of the studied patients was performed using paired student t test; Comparison between categorical data was performed using Chi square test.

The data were considered significant if p values was ≤ 0.05 and highly significant if $p < 0.01$ (Riffenburyh, 2006)

Data was statistically analyzed using SPSS (statistical package for social science) program version 13 for windows for all the analysis. a p-value < 0.05 was considered statistically significant.

RESULTS

Preoperative data for the two groups is compared. The mean of Ef is 49.46 ± 4.26 in group (A) vs. 58.24 ± 5.82 in group (B). (Table 1)

Operative data is calculated and compared to each group. The mean number of the coronary grafts was 2.1 ± 0.8 . (Table 2)

Comparison of preoperative data			
	Group A (aneurysm+ CABG) 20 patients	Group B (aneurysm only) 20 patients	P- value
Age	68.1 \pm 5.3 (58-79)	62.9 \pm 10.6 (39-77)	0.086
Sex:			
Male	16 (80%)	13(65%)	0.07
Female	4 (20%)	7 (35%)	
Diabetes	17(85%)	13(65%)	0.088
Hypertension	19(95%)	14(70%)	0.17
Size of aneurysm	5.7cm-6.6cm	4.9cm-6.5cm	0.23
Previous MI	3(15%)	0	<0.0001
Old cerebral stroke	1(5%)	0	< 0.0001
Aortic Valve affection:			
incompetent	15 (75%)	14 (70%)	0.08
competent	5 (25%)	6 (30%)	
Ef	49.46 \pm 4.26	58.24 \pm 5.82	0.068

Values are expressed as mean \pm SD or number (%), MI:myocardial infarction, EF :ejection fraction

Table 1. comparison of preoperative data

Comparison of Operative data			
	Group A (aneurysm+ CABG) 20 patients	Group B (aneurysm only) 20 patients	p-value
Bypass Time	171.9 \pm 58.2	159.3 \pm 34.7	0.076
Ischaemic time	98.6 \pm 26.9	99.5 \pm 38.4	0.14
Mode of cannulation:			
Aortic	6(30%)	4(20%)	0.52
Femoral	11(55%)	13(65%)	
Axillary	3(15%)	3(15%)	
Technique of aneurysm repair :			
Supracoronary replacement	9(45%)	6(30%)	0.4
Root replacement	4(20%)	6(30%)	
Valve sparing	7(35%)	8(40%)	
Mode of coronary implantation:			
Cabrol	6(30%)	7(35%)	0.61
Direct	5(25%)	7(35%)	
Coronary Grafts	2.1 \pm 0.8	0	
Operative blood loss	2,435 \pm 1,560	2,930 \pm 1,580	0.09

Values are expressed as mean \pm SD or number (%), Circulatory arrest time:25 \pm 13 min, Graft diameter:30 \pm 4 mm

Table 2. Comparison of operative data

Post operative data is compared. the percentage of icu arrhythmia is 15% in group (A) vs 10% in group (B). There was 5% mortality in both groups.

Comparison of post operative data			
	Group A (aneurysm + CABG) 20 patients	Group B (aneurysm only) 20 patients	P- value
Icu stay (hours)	86 ± 9.5 hours	75 ± 9.1 hours	0.458
Postoperative ventilation	11 ± 3.6 hours	10 ± 5.2 hours	0.078
Inotropic support(dose of adrenaline)	0.085 ± 0.02 mg/Kg/min	0.07 ± 0.03 mg/Kg/min	0.092
icu arrythmias	3/20 (15%)	2/20 (10%)	0.82
Re- exploration	3/20 (15%)	2/20 (10%)	0.82
Post operative renal impairment	1/20 (5%)	0/20	
Hospital stay (days)	15.45 ± 6.59 days	13.92 ± 5.69 days	0.129
Deaths	1/20 (5%)	1/20 (5%)	1

Values are expressed as mean ± SD or number (%), ICU= intensive care unit

Table 3. comparison of post operative data

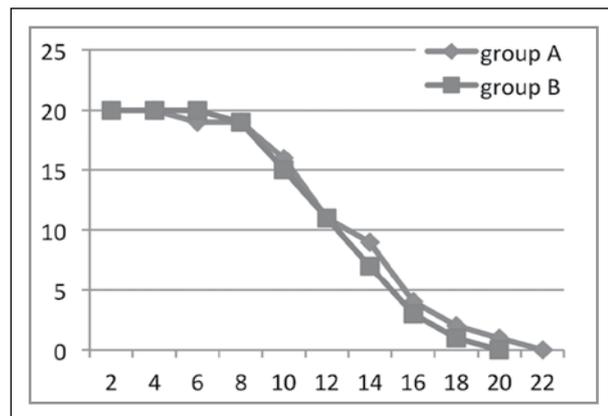


Fig. (1) relation between the mean hospital stay in both groups.

Discussion

Systematic approach of different diagnostic modalities should be planned to stratify the cardiac risk before aortic aneurysm repair is decided⁽⁷⁾.

In the preoperative period, risk stratification is used as a means of selecting patients who may benefit from a specific cardiac treatment, while escaping unnecessary, costly, and potentially dangerous cardiac evaluation^(8,11).

The preoperative cardiac evaluation of patients undergoing aortic surgery often presents a special challenge to surgical teams.

Concomitant coronary arteriosclerosis directly affects the perioperative morbidity and mortality of patients who will undergo aortic repair due to aneurysm^(9,10). Myocardial revascularization performed during or before surgical intervention for aortic aneurysm repair lessens perioperative cardiac complication rates substantially in patients who have coronary disease demanding revascularization.⁽¹²⁾

The limitations of cardiac risk scores and the physical impairment imposed by vascular disease have resulted in an excessive use of preoperative testing.⁽¹³⁾

Perioperative cardiac complication rates are noticeably elevated in patients whose coronary artery disease cannot be treated prior to or simultaneously with aortic repair; the extremely high cardiac-related mortality in patients with impending ruptured thoraco-abdominal aortic aneurysms is the most evident example of this phenomenon.⁽¹³⁾

In our study we compare the preoperative, operative, and postoperative data to delineate the safety of certain strategy for management of concomitant CAD with thoracic aortic aneurysm.

The question looking for answer is it beneficial and safe to manage both CAD and aortic aneurysm at the same sitting or the risk of this procedure signifies to manage each in separate sitting?

We have to state that the preoperative evaluation of our patients was an important topic in signifying the risk of the procedure; patients with marked COPD were accurately evaluated as regard respiratory and functional status, also diabetic patients underwent tight dietary and medical treatment.

The two cases with foot lesions received frequent dressing and treatment till the culture results became negative and this was mandatory to avoid contamination of the wound and operative infection which may be catastrophic, other medical problems was managed preoperatively.

Results of our study revealed that the comparison of the preoperative data is statistically insignificant of age this is due to the same pathology of both diseases also the male predominance signify male sex as risk factor, the low Ef noticed for group A (CAD and aortic aneurysm) denote the effect of ischemia on myocardium.

The results of analysis of operative data denote longer mean bypass time, longer ischemic time and higher mean of operative bleeding for group (A) (CAD with aneurysm) but still this risk is statistically non-significant; here we should denote that mean of coronary grafts operated was 2.1 ± 0.8 and this is very important as some literatures correlate the higher risk when mean of coronary grafts was three or more⁽¹⁴⁾.

Postoperative data analysis show higher mean of ICU and hospital stay for group (A), the number of patients developed ICU arrhythmias and ICU bleeding was higher in group (A) than group (B). The mortality was equal for both groups.

The results of this study show the associated morbidity when combine CABG with aortic surgery but the benefit deserve to combine both; especially the mortality was equal; so we agree with the previous opinion conclude correcting concomitant myocardial ischemia due to the safety of combined procedure.

Although literatures standard the benefit and safety of simultaneous correction of both aortic and coronary pathology⁽¹⁵⁾, we should consider that safety is relative issue, this is regard the associated morbidity due to additive procedure of coronary grafting.

In conclusion we document the it is relative safety to combine the management of both thoracic aortic aneurysm and coronary artery disease when possible.

Limitation of the study

The short period of post operative follow up and the small sample size of the studied group.

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Postoperative neurological complications following on-pump versus off-pump, with cavo-atrial temporary shunt, bidirectional Glenn procedure; early results

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Background: Neurological dysfunction is a significant problem after congenital heart surgery that may affect quality of life. Bidirectional Glenn shunt is a well-established procedure performed as a part of the single ventricle palliation pathway. Whether the bidirectional Glenn shunt is better performed without the support of cardiopulmonary bypass, is still a matter of debate. In this study, we report & compare early post operative neurological outcome after on-pump versus off-pump, with temporary cavo-atrial shunt, bidirectional Glenn procedure.

Methods: 50 patients indicated for Glenn procedure were divided into two groups. Group I (25 patients) where Glenn procedure was done with cardiopulmonary bypass and Group II (25 patients) where Glenn procedure was done without cardiopulmonary bypass with temporary cavo-atrial shunt. All patients were consented for the purpose of the study and scheduled for Glenn procedure. The study was done at Abu El-Rish children hospital in the period from July 2012 to July 2014. Preoperative evaluation to select patients according to inclusion and exclusion criteria & documenting different variables to make sure both groups are comparable. Operative monitoring documenting different variables of central venous pressure, oxygen saturation, operative time, shunt time, bypass time, hematocrite and creatinine for patients in both groups. Postoperative neurological evaluation using modified Glasgow coma scale to compare patients in both groups.

Results: In our study, there was no statistically significant difference in preoperative demographic data and clinical characteristics of the patients in both groups. Preoperative variables included age, sex, weight, oxygen saturation, hematocrite and diagnosis and association. All the patients completed the study. There was no mortality among the patients. Operative data didn't show any statistically significant difference between on-pump and off-pump groups regarding need for support, central venous pressure or oxygen saturation. Operative time was significantly longer in group I. Postoperative neurological outcome were similar in both groups. Other postoperative variables including mechanical ventilation, blood loss, need for support, central venous pressure, oxygen saturation, hematocrite, creatinine and intensive care unit and hospital stay were also similar in both groups and didn't reach statistical significance.

Conclusion: Bidirectional Glenn procedure may be done on pump or off pump with cavo-atrial temporary shunt with insignificant difference in the early postoperative neurological outcome, but we report that late complications and neurodevelopmental abnormalities should be traced in other long term studies. We also want to focus on better techniques of operative monitoring as near-infrared spectroscopy, transcranial Doppler & electroencephalogram should be adopted as standard of care, as it was not available during our study.

KEYWORDS: Glenn procedure, Partial cavopulmonary connection, Neurological complications.

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Codex : o3/08/1408

As there is a higher rate of survival after congenital heart surgery, there is a growing concern about quality of life. Discussing the issue of quality of life of children receiving cardiac surgery early in life, we found that neurological complications are the most important aspect that may affect them due to many reasons. Because of developments in surgical methods and preoperative and postoperative care, the prevalence of major acute neurological abnormalities has decreased to 1%-2%.⁽¹⁾

Patients with univentricular heart remain at increased risk of neurodevelopmental sequelae caused by several brain mechanisms. Thanks to a better perioperative care, adequate monitoring & better surgical technique, recent results are better than those of the first reports.⁽¹⁾

Bidirectional Glenn shunt is a well-established procedure performed as a part of the single ventricle palliation pathway. The bidirectional connection may also provide definitive palliation in certain patients. A major advantage of the cavopulmonary connection is that it diminishes the extent of the inevitable pulmonary recirculation, thereby resulting in a decrease in the workload of the functionally single ventricle. Other advantages include the avoidance of pulmonary vascular disease and, if carried out appropriately, of major pulmonary arterial distortion.⁽²⁾

Disadvantages of this type of connection emphasize the unpredictable duration of palliation observed following the cavopulmonary shunt, its limited application when there is an elevated pulmonary vascular resistance and the risk of development of pulmonary arteriovenous fistulas.⁽²⁾

Today, it seems that the surgeon and patient would dream to have all procedures done off of cardiopulmonary bypass, thereby ameliorating its perceived deleterious effects⁽³⁾. Because of difficulties with neurological and cognitive assessment in infants and children, accurate estimates of the long-term neurological impact of cardiopulmonary bypass in the pediatric population are difficult to obtain⁽⁴⁾. However, estimates of acute neurological morbidity approach 25%⁽⁵⁾.

Whether the bidirectional Glenn shunt is better performed with or without the support of cardiopulmonary bypass, is still a matter of debate. In this study, we report & compare early post operative neurological outcome after on-pump and off-pump, with use of temporary cavo-atrial shunt, bidirectional Glenn shunt.

Patients (Materials) & Methods

This was a comparative prospective clinical trial of 50 patients with univentricular hearts requiring Glenn procedure. Patients were randomly divided into two groups, Group 1 : 25 patients undergoing bidirectional Glenn, with cardiopulmonary

bypass support. and Group 2 : 25 patients undergoing bidirectional Glenn, without cardiopulmonary bypass support with temporary cavo-atrial shunt. All patients were consented for the purpose of the study and underwent Glenn procedure. This study compared between neurologic complications in patients undergoing Glenn procedure with cardiopulmonary bypass support vs without cardiopulmonary bypass support with temporary cavo-atrial shunt.

Contemplation pamphlet used for data collection, one pamphlet for each patient carry all variables. The collected data was statistically applied & entered into SPSS, EPI calc software programs to get the final results. The study was done at Cairo University Hospitals, in the period between July 2012 and Feb 2014.

Patients candidate for bidirectional Glenn shunts were included in the study. Exclusion criteria for the study included; patients with preoperative neurological deficits, patients with interrupted inferior vena cava requiring Kawashima procedure, patient requiring associated procedure (septectomy or atrioventricular valve repair), patient requiring emergency surgery due to marked hypoxia, also conversion group were operative events, like arrhythmias or persistent hypoxia mandated cardiopulmonary bypass and patients with redo cardiac surgery.

All patients went through preoperative, operative and early postoperative evaluation. Preoperative evaluation included: History taking, Clinical examination, Laboratory investigations (Complete blood count, Liver function tests, Prothrombin time and concentration, Kidney function tests, Fasting blood sugar and Serum electrolytes), Electrocardiogram, Plain chest x-ray and Echocardiography. Preoperative evaluation is of value for proper selection of cases according to inclusion and exclusion criteria.

Preoperative variables recorded: were demographic data, diagnosis, neurological evaluation, hematocrit and O₂ saturation.

Surgical procedure: Under general anesthesia, Glenn procedure was performed through median sternotomy. Operative monitoring will include upper body central venous pressure through temporary catheter "reflecting pulmonary pressure after Glenn shunt" that will be removed within 24 hours, lower body central venous pressure, transcutaneous O₂ sat., 3 or 5 lead ECG heart rate and invasive blood pressure. These parameters will be monitored before, during and after the procedure. Any arrhythmias all through the course of the procedure were reported. Patients were placed in a supine position with the arms placed by their side. A sandbag is put under the shoulders. The patient was then draped in the usual fashion with exposure of the sternum up to the mid clavicular line, and at least one groin. The sternal notch and the tip of the

xiphoid process were identified by palpation and the incision was begun and was extended with electrocautery down to the sternal periosteum. The linea alba was divided at the xiphoid. The sternum was then divided by electric saw. A sternal retractor with broad blades was placed and opened slowly. The sternum was opened only as wide as it was necessary to obtain adequate exposure. The pericardium was opened after dissecting the thymus gland and identifying the left innominate vein. Stay sutures by heavy silk and suturing the pericardium to the edges of the incision usually gave adequate exposure. The superior vena cava is dissected from the pericardial covering till the atrio-caval junction dissection is also extended to separate the superior vena cava from the right pulmonary artery. The lateral aspect of the superior vena cava is dissected with great carefulness to avoid injury of the right phrenic nerve. The azygous vein is identified and ligated. From that step, the 2 groups differed as follows :

Group 1 : The procedure will be on pump beating heart, After heparinization, routine aortic cannulation was done, high selective superior vena cava cannulation was done using a metal tip right-angled venous cannula thus keeping it away from site of anastomosis. The inferior vena cava was cannulated as usual by appropriate venous cannula according to body surface area. Snares were placed around the superior and inferior vena cavae cannulae.

Group 2 : The procedure will be off-pump, using cavoatrial shunt, where the superior vena cava is bypassed into the right atrium or the inferior vena cava using two right angled metal tip cannulae connected together, after full heparinization was achieved. Proper cannula selection is necessary to avoid higher superior vena cava pressure.

Anastomosis: After adequate mobilization of superior vena cava and right pulmonary artery, cavopulmonary anastomosis is carried out end to side using continuous 6/0 prolene sutures. The superior vena cava is transected about half a centimeter above the cavo-atrial junction to avoid the sino-atrial node.

Operative variables recorded: were operative time, bypass time [Group 1], superior vena cava clamp time – shunt time [Group 2], need for support, upper body central venous pressure after Glenn shunt, lower body central venous pressure and transcutaneous O₂ sat.: before and after Glenn shunt.

Postoperative variables recorded: were hematocrit, duration of postoperative mechanical ventilation, duration of intensive care unit stay, postoperative neurological evaluation after weaning from mechanical ventilation by Modified Glasgow Coma Score, neurological deficits like stroke or seizures, postoperative central venous pressure (“lower body”), postoperative O₂ sat., postoperative echocardiographic evaluation of the shunt.

Statistical Analysis: Data were statistically described in terms of mean \pm standard deviation (\pm SD), median and range, or frequencies (number of cases) and percentages when appropriate. Comparison of numerical variables between the study groups was done using Student t test for independent samples in normally distributed data and Mann Whitney U test for independent samples in non-normal data. For comparing categorical data, Chi square (χ^2) test was performed. Exact test was used instead when the expected frequency is less than 5. P values less than 0.05 was considered statistically significant. All statistical calculations were done using computer program SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) version 15 for Microsoft Windows.

Results

Our study was conducted on 50 patients with univentricular hearts scheduled for Glenn procedure. The patients were classified into two groups, each group includes 25 patients. All the patients completed the study. There was no mortality among the patients. This study is concerned with neurological complication following onpump vs offpump using temporary cavoatrial shunt Glenn procedure.

Preoperative evaluation

Age: The Mean \pm SD age of the patients was (36.26 \pm 19.149 month), in the range of 15 and 86 months. For Group I; was (38.8 \pm 20.052 month), in the range of 15 and 86 months. For Group II; was (36.26 \pm 18.25 month), in the range of 15 and 81 months. The difference in the mean age between both groups was statistically insignificant (P Value > 0.05).

Sex: Female gender was predominant; 26 females (52%) to 24 males (48%). For Group I; 15 females (60%) to 10 males (40%). For Group II; 11 females (44%) to 14 males (56%). The difference in gender distribution between both groups was statistically insignificant (P Value > 0.05).

Weight : The Mean \pm SD weight was (11.98 \pm 4.375 Kg), in the range of 7 and 26 kgs. For Group I; was (12.78 \pm 4.653Kg), in the range of 7 and 26 Kgs. For Group II; was (11.18 \pm 4.013Kg), in the range of 7 and 25 Kgs. The difference in the mean weight between both groups was statistically insignificant (P Value > 0.05).

Preoperative O₂ Saturation: The Mean \pm SD O₂ saturation was (70.000 \pm 1.7023 %). For Group I; was (70.400 \pm 1.9365 %), in the range of 68 and 75%. For Group II; was (69.600 \pm 1.3540 %), in the range of 68 and 72%. The difference in the preoperative O₂ saturation between both groups was statistically insignificant (P Value > 0.05).

Preoperative hematocrit: The Mean \pm SD hematocrit was (50.552 \pm 4.2258 %). For Group I; was (49.952 \pm 3.9363 %),

in the range of 56 and 44%. For Group II; was (51.152% \pm 4.4960 %), in the range of 57 and 43%. The difference in the preoperative hematocrit between both groups was statistically insignificant (P Value > 0.05).

Preoperative Main Diagnosis: Our study included many patients of different diagnoses distributed as following: Group I : included 10 Patients (40.0%) double outlet right ventricle, 2 Patients (8.0%) Ebstein anomaly, 3 Patients (12.0%) transposition of great arteries, 5 Patients (20.0%) tricuspid atresia, 1 Patient (4.0%) Fallot tetralogy and 4 Patients (16.0%) unbalanced atrio-ventricular canal. Group II : included 12 Patients (48.0%) double outlet right ventricle, 2 Patients (8.0%) Ebstein anomaly, 7 Patients (28.0%) tricuspid atresia, 1 Patient (4.0%) Fallot tetralogy and 3 patients (12.0%) unbalanced atrio-ventricular canal. The difference in the Main Disgnosis between both groups was statistically insignificant (P Value > 0.05).

Preoperative Associated Lesions: The traced lesions in our study were persistent left superior vena cava , stenotic proximal left main pulmonary artery and pulmonary atresia. All lesions that mandate cardiopulmonary bypass are in the exclusion criteria of patients in the proposal of the study.

The difference in the traced Associated lesions between both groups was statistically insignificant (P Value > 0.05).

	Group 1	Group 2	Total	P value
Persistent Left SVC	2 (8.0%)	2 (8.0%)	4 (8.0%)	1.000
Stenotic proximal left main pulmonary artery	3 (12.0%)	3 (12.0%)	2 (12.0%)	1.000
Pulmonary atresia	4 (16.0%)	2 (8.0%)	6 (12.0%)	0.384

Table 1. Showing The distribution of the traced associated lesions between both Groups

Operative evaluation

Operative Time: The Mean \pm SD operative time was (162.96 \pm 32.862 minute). For Group I; was (184.80 \pm 24.216

minute), in the range of 120 and 210 minutes. The Mean \pm SD cardiopulmonary bypass time of the patients was (46.04 \pm 11.631 minute), in the range of 38 and 70 minutes. For Group II; was (141.12 \pm 24.994 minute), in the range of 100 and 195 minutes. There was a significant decrease in operative time in group II (P Value < 0.05).

Superior vena cava Clamp Time : The Mean \pm SD superior vema cava Clamp time was (21.24 \pm 4.158 minute). For Group I; was (19.48 \pm 2.78 minute), in the range of 16 and 25 minutes. ForGroup II; was (23.00 \pm 4.592 minute), in the range of 16 and 35 minutes. The Mean \pm SD central venous pressure upper body during SVC Clamp of the patients in group II was (20.44 \pm 2.987 minute). There was a significant decrease in superior vema cava Clamp time in group I (P Value < 0.05).

Need For support: During our study only 7 patient was in need for support , 5 patients (20%) in group I and 2 patients (8%) in group II. The difference in the need for support between both groups was statistically insignificant (P Value > 0.05).

Central venous pressure Upper body after Glenn shunt: The Mean \pm SD central venous pressure upper body was (16.88 \pm 1.837 CmH₂O). For Group I; was (16.56 \pm 2.12 cm H₂O), in the range of 14 and 20cm H₂O. For Group II; was (17.20 \pm 1.47 cm H₂O), in the range of 14 and 22 cm H₂O. The difference in the central venous pressure upper body after Glenn shunt between both groups was statistically insignificant (P Value > 0.05).

O₂ saturation after Glenn shunt: The Mean \pm SD O₂ saturation was (86.50 \pm 3.01%). For Group I; was (86.92 \pm 2.99%), in the range of 83 and 95%. For Group II; was (86.08 \pm 3.02%), in the range of 83 and 92%. The difference in O₂ saturation after Glenn shunt between both groups was statistically insignificant (P Value > 0.05).

Postoperative evaluation:

Mechanical ventilation time: The Mean \pm SD time was (8.78 \pm 5.470 hour). For Group I; was (9.37 \pm 5.884 hour), in the range of 3.75 and 26.50 hours. For Group II; was (8.18 \pm 5.073hour), in the range of 3.75 and 18.30hours. The difference in the postoperative mechanical ventilation time between both groups was statistically insignificant (P Value > 0.05).

	(Group I)			(Group II)			P Value
	Mean	SD	Range	Mean	SD	Range	
Operative Time	184.80	\pm 24.216	120- 210 minute	141.12	\pm 24.994	100 – 195 minute	0.001
SVC Clamp Time	19.48	\pm 2.78	16-25 minute	23.00	\pm 4.592	16 – 35 minute	0.002

Table 2. Showing The difference in operative time and SVC clamp time between both groups.

Mechanical ventilation weaning: There were 3 patients with difficult weaning ,all of them were related to chest infection. The difference in number of patients with postoperative chest infection & experienced difficult weaning off mechanical ventilation between both groups was statistically insignificant (P Value > 0.05).

	Group 1	Group 2	Total	P value
Difficult weaning off mechanical ventilation	2 (8.0%)	1 (4.0%)	3 (6.0%)	0.5
Postoperative chest infection	2 (8.0%)	1 (4.0%)	3 (6.0%)	0.5

Table 3. Showing the difference number of patients experienced difficult weaning from mechanical ventilation

Postoperative Bleeding: The Mean ± SD amount for postoperative drainage in c³ was (141.10± 60.788 c³). For Group I; was (148.80 ± 64.82 c³). For Group II; was (133.40 ± 56.729 c³). The difference in postoperative drainage between both groups was statistically insignificant (P Value > 0.05).

Need for reopen for bleeding: From all the patients included in the study 2 patients were in need for exploration due to bleeding . Group I there were 1 patient (4.0%) , in group II there were 1 patient (4.0%),The difference in number of patient reopen for bleeding between both groups was statistically insignificant (P Value > 0.05).

Postoperative hematocrit: The Mean ± SD postoperative hematocrit was (45.54± 3.309). For Group I; was (44.76 ± 3.231). For Group II; was (46.32 ± 3.262). The difference in postoperative hematocrit between both groups was statistically insignificant (P Value > 0.05).

Postoperative serum creatinine: The Mean ± SD postoperative serum creatinine was(0.89± 1.38). For Group I; was (0.88 ± 0.143). For Group II; was (0.89 ± 0.13). The difference in postoperative serum creatinine between both groups was statistically insignificant (P Value > 0.05).

Postoperative central venous pressure “lower body” : The Mean ± SD postoperative central venous pressure “lower body” was (8.42± 1.29). For Group I; was (8.40±1.38). It is an important variable as in this group volume overload may be induced by cardiopulmonary bypass fluids and may affect the early postoperative neurological outcome , by increasing the number of patients suffering fits due to brain edema. For Group II; was (8.44±1.22). The difference in postoperative central venous pressure “lower body”between both groups was statistically insignificant (P Value > 0.05).

O₂ saturation during intensive care unit stay: The Mean ± SD O₂ saturation was (86.64% ± 2.34). For

Group I; was (86.32% ± 2.44). For Group II; was (86.96%± 2.24). The difference in O₂ saturation during intensive care unit stay between both groups was statistically insignificant (P Value > 0.05).

Neurological Outcome: Postoperative neurological outcome was satisfactory regarding both groups, there were no patients with major neurological insults, there were no patients with delayed recovery, all patients were evaluated to have 15/15 on modified Glasgow coma scale for infants and children.

Postoperative fits: Out of 50 patients included in the study, only 5 patients experienced fits , Group I 3 patients (12%) and Group II 2 Patients (8.0%). The difference in number of patient experienced postoperative fits between both groups was statistically insignificant (P Value > 0.05).

Surgical Outcome: We found no postoperative shunt failure, no heart failure and patent and well functioning Glenn shunt by 2D echocardiography. **Intensive care unit stay:** The Mean ± SD intensive care unit stay in hours was (74.00 ± 23.65). For Group I; was (79.60 ± 29.19), in the range of 28 and 154 hours. For Group II; was (68.40 ± 15.00), in the range of 48 and 85 hours. The difference in intensive care unit stay in hours between both groups was statistically insignificant (P Value > 0.05).

Hospital stay: The Mean ± SD hospital stay in days was (7.18 ± 2.51). For Group I; was (8.04 ± 3.08), in the range of 4 and 16 days. For Group II; was (6.32 ± 1.34), in the range of 5 and 10 days. The difference in hospital stay in days between both groups was statistically insignificant (P Value > 0.05).

Discussion

From the current study, performing bidirectional Glenn shunt on-pump vs off-pump, with use of temporary cavo-atrial shunt, don't carry any additional risks for early post operative neurological complication. Bidirectional Glenn shunt offers low mortality and an excellent clinical outcome for patients with univentricular heart whether performed with or without the support of cardiopulmonary bypass using temporary cavo-atrial shunt. Postoperative neurological outcome was satisfactory regarding both groups , there were no patients with major neurological insults , there were no patients with delayed recovery , all patients were evaluated to have 15/15 on modified Glasgow coma scale for infants and children and the difference in number of patients who experienced postoperative fits between both groups was statistically insignificant.

Preoperative data collected didn't show any statistical difference between both groups in preoperative risk factors so both groups were comparable. There was also insignificant difference between both groups in operative data except in operative time and superior vena cava clamp time which is expected. Postoperative evaluation was considering surgical

outcome of the procedure, We found no postoperative shunt failure, no heart failure and patent and well functioning Glenn shunt by echocardiography. Also there were insignificant difference between both groups regarding intensive care unit stay and hospital stay.

Preoperative data : As regard age, in a study performed by Jinfen et al ⁽⁶⁾ the mean age was 32.4 ± 31.2 month., with insignificant difference between this study & our study & between both groups in both studies. As regards *sex*, in study performed by Xin-Jin et al ⁽⁷⁾; 11 patients (30.5%) were females while 25 (69.4%) were males. In study performed by Liu J. et al ⁽⁸⁾; 10 patients were males and 10 patient were females. Accordingly, sex predominance was insignificant in most of studies. As regard weight, in a study performed by Liu J. et al ⁽⁸⁾, the mean weight was 11 ± 6 Kg . another study of Jinfen et al ⁽⁶⁾ the mean weight was 11 ± 6 Kg. with insignificant difference between these study & our study & between both groups in all studies. Previously discussed data revealed that our study met many other similar studies in the preoperative data.

Spectrum of cases included in study performed by John J. Lamberti et al ⁽⁹⁾, were distributed as double outlet right ventricle 34 (34%), tricuspid aresia 16 (16%), pulmonary atresia-ventricular septal defect 11 (11%), heterotaxy syndrome 15 (15%), hypoplastic left heart syndrome 8 (8%), transposition of great arteries 5(5%), tetralogy of Fallot 3 (3%), unbalanced atrioventricular canal 8 (8%). Our study met other similar studies except that our study did not include patients with hypoplastic left heart syndrome. This may affect the outcome studies that target long term neurological outcome as hypoplastic left heart syndrome has bad prognosis and we believe that it will not affect the immediate postoperative outcome.

In similar studies performed by Jinfen et al ⁽⁶⁾ and Liu J. et al ⁽⁸⁾, the mean O₂ saturation was 74.3 ± 5.7 % & 73.4 ± 5.0 % respectively. Another study performed by Bin Xie et al ⁽¹⁰⁾ revealed mean preoperative O₂ saturation as 78 ± 8.5 %. We found no statistical significant difference between both groups in all studies.

Excluded cases in our study were all patients with interrupted inferior vena cava. Also emergencies were excluded as in emergencies surgical outcome may be affected with higher incidence of complications including neurological complications. Also conversion group, were operative events, like arrhythmias or persistant hypoxia mandated cardiopulmonary bypass. Another category excluded were patients with associated intracardiac lesions, that mandate aorta cross clamp and cardioplegia. Last category that were excluded are any patient with preoperative neurological deficits, as preoperative neurological deficits may affect postoperative evaluation and itself considered as risk factor for postoperative neurological deficit, that may affect the results.

Operative data : In a study performed by Brain et al ⁽¹¹⁾, the mean cardiopulmonary bypass time was 74 ± 34 minute. The difference is in this study, they did not exclude cases with intracardiac repair, so cardioplegia and even circulatory arrest were used in some cases.

Regarding superior vena cava clamp time , in similar study performed by Jinfen et al ⁽⁶⁾, for 20 patients off pump Glenn shunt, superior vena cava clamp time was (24 ± 4.7 minute), meeting our result for the similar group of patients. We may get an important observation from these data, that cardiopulmonary bypass give us the benefit of bloodless and motionless field, enabling faster anastomosis time.

Regarding superior vena cava pressure after Glenn, in a similar study performed by Jinfen et al ⁽⁶⁾, for off pump procedure the mean SVC pressure after Glenn shunt was 14.1 ± 4.6 mm Hg. In another study performed by Brain et al ⁽¹¹⁾ for on pump Glenn shunt it was 13.6 ± 2.6 mm Hg.. These data illustrate that there were insignificant difference between both groups regarding SVC pressure after Glenn shunt.

Regarding O₂ saturation, in a study done by Jinfen et al ⁽⁶⁾, for off pump procedure, their Mean \pm SD O₂ saturation after Glenn shunt was 93.2 ± 2.2 % in patient where he used veno-atrial temporary shunt and 95.2 ± 4.1 in patients where he used veno-pulmonary temporary shunt. This study included 20 patients for both different type of temporary shunts.

Postoperative data : regarding intensive care unit stay period, in similar study perfrmed by Brain et al ⁽¹¹⁾, the mean intensive care unit stay was 50 hours. Another study for off pump Glenn by Jinfen et al ⁽⁶⁾, the mean intensive care unit stay was 86.4 ± 28.8 hours, meeting our results regarding results of similar groups.

Daniel et al ⁽¹²⁾ reported in a report published 2009, that there was no significant difference in postoperative success as determined by measurements of pressure gradients across the anastomosis, length of intensive care unit stay, intubation period, length of hospital stay and a 30 day mortality, there were no intraoperative mortality in both group. It was a single center experience, they also do off pump Glenn shunt using cavo-atrial temporary shunt, meeting the selected technique in our study and meeting our result regarding same issues.

Early postoperative neurological outcome, our result show that there were no significant difference between off pump and on pump Glenn shunt regarding early postoperative neurological complications. Meeting data from similar studies, like that performed by Jinfen et al ⁽⁶⁾, Daniel et al ⁽¹²⁾ and another Performed by Brain et al ⁽¹¹⁾. Also another study performed by Lamberti et al ⁽⁹⁾ reported that Glenn shunt may be done off pump with no significant difference in early postoperative neurological outcome.

In our study, all patient were evaluated to have 15 on modified Glasgow coma scale for infants and children. Out of 50 patients included in the study, only 5 patients experienced fits, Group I 3 patients (12%) , Group II 2 Patients (8.0%). The difference in number of patient experienced postoperative fits between both groups was statistically insignificant (P Value > 0.05).

Our study was limited, because of number of cases, unavailability of specific operative technique like transcranial doppler, electroencephalogram, near infrared spectroscopy or other operative monitoring modalities that may give data of value regarding cerebral perfusion. Transcranial doppler, electroencephalogram or near infrared spectroscopy, are the main monitoring techniques that may help to evaluate operative events that may affect cerebral perfusion. Adding single monitoring technique of above listed technique would give us lots of data that may guide toward better surgical technique.

We do recommend other long term studies, to evaluate long term neurological outcome, specially cognitive and neuropsychological states, to be sure about quality of life of these patients as members in our society. We also recommend adopting a more specific operative monitoring techniques, used regularly to trace any changes in cerebral perfusion, for both on pump and off pump technique. It will not affect immediate postoperative results significantly, but may have a great effect on long term outcome.

From our study we concluded that early postoperative neurological outcome didn't differ between on-pump vs off-pump, with use of temporary cavo-atrial shunt, bidirectional Glenn shunt. Both techniques had very good surgical and early neurological outcome.

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Concomitant Repair of Moderate Tricuspid Regurge in Patients Undergoing Mitral Valve Surgery

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Background: Moderate tricuspid regurge has a variable natural history as it may regress after mitral valve surgery without tricuspid repair, or may progress, so the decision to repair moderate functional tricuspid regurge in association with mitral valve surgery remains controversial.

Objectives: To compare the surgical results in patients with moderate tricuspid regurge who underwent mitral valve surgery with or without concomitant tricuspid repair, up to six months post surgery.

Methods: Fifty patients underwent mitral valve replacement for the first time with concomitant moderate tricuspid valve regurge divided into two groups. Group A (26 patients) who underwent mitral valve replacement alone and group B (24 patients) who underwent mitral valve replacement and tricuspid valve repair using DeVega annuloplasty technique .

Results: In group A there were 20 females (76%) and 6 males (23%). In group B there were 23 females (95%) and one male (4%). The age ranged from (20-53) in group A and (19-55) in group B. The mean age was 37.4 ± 9.4 in group A and 38.5 ± 10.5 in group B. There was no statistically significant difference between both groups regarding sex or age. There was no statistically significant difference between both group regarding mitral valve pathology or pre-operative NYHA class. Post-operatively, in group A there were 15 patients (57%) with no tricuspid regurge, 7 patients (26%) with grade (I) tricuspid regurge and 4 patients (15%) with grade (II) tricuspid regurge. In group B there were 21 patients (87%) with no tricuspid regurge, 2 patients (8%) with grade (I) tricuspid regurge and one patients (4%) with grade (II) tricuspid regurge. Group B was statistically significantly better than group A regarding post operative tricuspid regurge. There was no statistically significant difference between both groups regarding post operative NYHA class or post operative complications.

Conclusion: The results showed that the moderate tricuspid regurgitation has improved post-operatively, whether the repair was done or not. There is growing consciences to correct moderate TR to improve patient outcomes by preventing regurgitation progression and RV dysfunction.

KEYWORDS: Mitral valve surgery; Tricuspid regurge; Tricuspid repair.

Tricuspid regurgitation is a disorder in which the heart's tricuspid valve does not close properly, causing blood to flow backward into the atrium when the right ventricle contracts. The most common cause of tricuspid regurgitation is enlargement of the right ventricle [1], caused by left-sided valvular lesions. Mitral valve disease is often accompanied by concomitant tricuspid valve disease. The most common indication for tricuspid valve intervention is tricuspid regurgitation (TR), and the presence of significant TR has been reported to be an important prognostic indicator of outcomes following mitral valve surgery [2].

Surgical treatment of tricuspid valve regurgitation (TR) with left-sided valvular disease still remains a challenge for the cardiac surgeon. Uncorrected TR after repair of left-sided valvular lesion has been reported to have an adverse effect on early and

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late results. Thus, surgical management of moderate to severe TR is now widely recommended to achieve better early and late clinical outcome [3]. Moderate tricuspid regurgitation presents a surgical dilemma during mitral valve surgery as it may regress after successful mitral valve surgery without repair or may progress requiring repair with increasing risk of redo cardiac surgery [4].

This study was conducted to compare the surgical results in patients with moderate tricuspid regurgitation who underwent mitral valve surgery with or without concomitant tricuspid repair, up to six months post surgery.

Patients and methods

The study was a retrospective study conducted in Damietta Cardiology and Gastroenterology Centre between January 2010 and June 2013. A total of 50 patients with moderate tricuspid regurgitation associated with mitral valve disease underwent first time elective mitral valve surgery, included in the study. Patients with organic tricuspid valve disease were excluded from the study. Also, patients older than 60 years old, Left ventricular dysfunction (ejection fraction less than 50%), Redo mitral valve surgery, Ischaemic mitral valve regurgitation and patients with chronic pulmonary diseases were all excluded from the study.

Patients were divided into 2 groups: Group A (N= 26 patients) included patients underwent mitral valve replacement only. Group B (N= 24 patients) included patients underwent mitral valve replacement and tricuspid valve repair using DeVega annuloplasty technique.

Patients' clinical & echocardiographical data were collected from the patients database. Echocardiography was the cornerstone in evaluation of all patients pre-operatively and 6 months post-operatively. The degree of tricuspid regurgitation was evaluated using the apical four chamber view and graded as mild, moderate or severe when the distal jet area was; <5 cm², 5-10 cm² or >10 cm² respectively. Tricuspid regurgitation grading system as mild TR = grade I, moderate TR= grade II and III and severe TR= grade IV. In all patients ejection fraction, left ventricular end diastolic diameter, left ventricular end systolic diameter and left atrial dimension were obtained.

Surgical procedures:

All patients underwent mechanical mitral valve replacement through median sternotomy. This was followed by cannulation of the ascending aorta and both superior & inferior vanae cauae for cardiopulmonary bypass with moderate hypothermia (28°C - 32°C). Myocardial protection was achieved with intermittent cold or tepid ante-grade blood cardioplegia every 20-30 minutes. Tricuspid valve was assessed by haemodynamics and palpation for regurgitant thrill before the cardiopulmonary bypass.

All patients received a bi-leaflet mitral mechanical valve followed by closure of the left atrium, de-airing and removal of aortic cross-clamp. In group (B) the right atrium was opened obliquely and the TV was carefully explored on a beating heart. The tricuspid annulus was identified then DeVega annuloplasty was performed. Assessment of the tricuspid valve using water test for detection of any residual regurgitation was then performed.

After MVR only in group (A) or MVR and tricuspid valve repair in group (B), weaning from the cardiopulmonary bypass, haemostasis, placing chest drains was obtained followed by sternotomy closure as usual.

Follow-up:

All patients were followed-up in the out-patient clinic, after 2 months and 6 months. Colored Doppler echocardiography were done for all patients 6 months post operatively.

Statistical analysis:

Data was collected, verified tabulated then analyzed by SPSS (Statistical package for the social science), EPICalc software program to get the final results.

We used the following tests:

- Arithmetic mean, standard deviation and hypothesis "t" test (Student test) for quantitative values.
- The chi-square test (χ^2) for qualitative values expressed as proportions.

For all statistical comparisons, a P value of <0.05 was considered non significant and a P value of <0.05 was considered significant and a P value of <0.01 was considered highly significant.

Results

In group A there were 20 females (76%) and 6 males (23%). In group B there were 23 females (95%) and one male (4%) (table 1). The age of our patients ranged from (20-53) in group A and (19-55) in group B. The mean age was 37.4±9.4 in group A and 38.5±10.5 in group B (table 1). There was no statistically significant difference between both groups regarding sex or age (table 1).

In group A there were 4 patients with mitral regurgitation (15%), 20 patients with mitral stenosis (76%) and two patients with mixed mitral valve pathology. In group B there were 4 patients with mitral regurgitation (15%), 16 patients with mitral stenosis (66%) and 4 patients with mixed mitral valve pathology. There was no statistically significant difference between both groups regarding mitral valve pathology (table 2).

	Group A N: 26 patients	Group B N: 24 patients	p value
Sex			
Male *	6 (23.1%)	1 (4.2%)	0.054
Female *	20 (76.9%)	23 (95.8%)	
Age (years) ^	37.4 ± 9.4	38.5 ± 10.5	0.695

*: Number (%) ^: mean ± SD

Table 1. Demographic Data

Pre-operatively, In group A there were 19 patients grade (II) NYHA class (73%) and 7 patients with grade (III) NYHA class (27%). In group B there were 16 patients grade (II) NYHA class (67%) and 8 patients with grade (III) NYHA class (33%). There was no statistically significant difference between both group regarding pre-operative NYHA class (table 2).

	Group A N: 26 patients	Group B N: 24 patients	p value
Primary mitral valve pathology			
Mitral regurge *	4 (15.4%)	4 (16.7%)	0.597
Mitral stenosis *	20 (76.9%)	16 (66.7%)	
Mixed *	2 (7.7%)	4 (16.7%)	
NYHA class			
Class I *	0	0	0.621
Class II *	19 (73.1%)	16 (66.7%)	
Class III *	7 (26.9%)	8 (33.3%)	
Class IV *	0	0	
Pre-operative Echocardiogram			
Left atrial dimension ^	5.7 ± 0.6	6 ± 0.7	0.083
PASP ^	39.5 ± 6.2	46.7 ± 8.9	0.002
Right ventricular diameter ^	2.4 ± 0.7	2.6 ± 0.3	0.053
LVESD ^	3.5 ± 0.6	3.8 ± 0.4	0.085
LVEDD ^	5.5 ± 0.7	5.5 ± 0.6	0.987
Ejection fraction ^	63.3 ± 3.2	62.5 ± 3.5	0.427

*: Number (%) ^: mean ± SD

NYHA: New York Heart Association
PASP: Pulmonary Artery Systolic Pressure
LVESD: Left Ventricular End Systolic Diameter
LVEDD: Left Ventricular End Diastolic Diameter

Table 2. Pre-operative clinical & echocardiographic data

Coloured doppler echocardiography were done for all patients, pre-operatively. There was no statistically significant difference between both groups regarding, left atrial dimension, right ventricular dimension, left ventricular end systolic diameter (LVESD), left ventricular end diastolic diameter (LVEDD) or ejection fraction. Pulmonary artery systolic pressure was statistically higher in group B (table 2).

There was no statistically significant difference between both groups regarding, cardiopulmonary bypass time, aortic cross clamp time or post operative mechanical ventilation time (table 3). Intensive care unit stay duration was statistically significantly longer in group A than in group B (table 3). There was no statistically significant difference between both groups regarding post operative complications (table 3).

	Group A N: 26 patients	Group B N: 24 patients	p value
CPB time (minutes) ^	73.9 ± 10.0	72.9 ± 8.8	0.730
Aortic cross clamp time (minutes) ^	49.0 ± 9.0	50.8 ± 9.3	0.490
Ventilation time (minutes) ^	206.8 ± 37.8	186.8 ± 41.7	0.081
ICU stay (hours) ^	36.9 ± 15.5	29.0 ± 10.0	0.039
Post operative complications			
None *	13 (50.0%)	16 (66.7%)	0.383
Arrhythmia *	7 (26.9%)	4 (16.7%)	
Low cardiac output *	4 (15.4%)	1 (4.2%)	
Bleeding *	2 (7.7%)	3 (12.5%)	

*: Number (%) ^: mean ± SD

CPB: Cardio-pulmonary Bypass
ICU: Intensive Care Unit

Table 3. Peri-operative details

Post-operatively, in group A there were 15 patients (57%) with no tricuspid regurge, 7 patients (26%) with grade (I) tricuspid regurge and 4 patients (15%) with grade (II) tricuspid regurge. In group B there were 21 patients (87%) with no tricuspid regurge, 2 patients (8%) with grade (I) tricuspid regurge and one patients (4%) with grade (II) tricuspid regurge (table 4). Group B was statistically significantly better than group A regarding post operative tricuspid regurge (table 4)

The postoperative improvement (after 6 months) of functional classes of dyspnea were statistically significant. In group A there were 19 patients (73%) with no dyspnea, 5 patients (19%) with NYHA grade (II) and two patients (7%) with NYHA grade (III). In group B there were 21 patients (88%) with no dyspnea, two patients (7%) with NYHA grade (II) and one patient with NYHA grade (III). There was no statistically significant difference between both groups regarding NYHA class (table 4).

The degree of pulmonary hypertension has been shown by echocardiography to be moderately predictive to the severity of secondary tricuspid regurgitation. At least theoretically, reduction in degree of pulmonary hypertension (for example by mitral valve surgery) Could result in less tricuspid regurgitation after remodelling of previously dilated right ventricle [8].

DeVaga annuloplasty was the technique of choice for tricuspid repair in our study as it offers a readily available, technically less demanding, quick and cheap alternative to annuloplasty ring, further more it is associated with good postoperative result as believed by many authors [4, 9]

There was no statistically significant difference between the two groups as regards the aortic cross clamp time and the cardiopulmonary bypass time. All patients in both groups required post-operative mechanical ventilation and no patients were extubated in the operating theatre. The ventilation time was slightly longer in group (A) than in group (B) with no statistically significant difference between both groups. The intensive care unit (ICU) stay, on the other hand was significantly longer in group A than in group B.

As regarding the post operative echocardiographic assessment, in group A, there were 15 patients (57.7%) with no tricuspid regurge, 7 patients (26.9%) with grade I tricuspid regurge and 4 patients (15.4%) with grade II tricuspid regurge. In group B, there were 21 patients (87.6%) with no tricuspid regurge, 2 patients (8.3%) with grade I tricuspid regurge and only one patients (4.2%) with grade II tricuspid regurge. the difference between both group was statistically non-significant.

According to porter A et al., although repair of left sided valve dysfunction may reduce the severity of tricuspid regurgitation, a substantial proportion of patients will go on to develop moderate or severe TR. In their study, 43% of patients had severe TR at a mean follow up of 11 years after isolated MV replacement [10].

Duran MG et al., reported that in their experience among patients with functional MR submitted to mitral repair, the presence of significant functional TR was 30% before surgery. In more than half (57%) of patients, the TR was ignored by the surgeon and at follow up close to 50% of the patients showed significant TR despite successful mitral repair [11].

Maysuyama K et al. also clearly reported that 16% of the patients who underwent non ischaemic mitral valve surgery without concomitant tricuspid valve surgery developed grade 3 to 4 TR at 8 years follow up [12].

Similar results were reported by Musharaf M et al., 2013 [13] in a study of 77 patients divided into two groups. Group (A): 51 patient who had MVR only; and group (B): 26 patients who had MVR and TVR. Echocardiographic assessment of the tricuspid valve postoperative revealed, in group (A) 22 patients

had moderate TR and 29 patients had mild TR while in group (B) 9 patients had mild TR and 17 patients had no TR [13].

Kim et al., 2011 [4] reported a follow up of 225 out of 256 patients with mild to moderate functional TR who underwent first-time isolated mechanical MV replacement with (123 patients repaired group) and (133 patients non-repaired group) with a median follow-up of 48.7 months, during which time 991 echocardiographic assessments were done. Freedom from moderate-to-severe TR at 5 years was $92.9 \pm 2.9\%$ in the repair group and $60.8 \pm 6.9\%$ in the non-repair group [4].

In our study there were significant decrease in systolic pulmonary artery pressure in both groups but more significant in group (B) than group (A). Pulmonary artery pressure is known to be associated with the development of secondary tricuspid regurgitation, however not all patients with pulmonary hypertension develop significant tricuspid regurgitation.

No complications occurred in 50% in group (A) and in 66% of group (B) in our study. The arrhythmia and low cardiac output were more in group A with no statistically significant difference between the two groups regarding the post operative complications. There was no mortality in either group.

CONCLUSION

The results showed that the moderate tricuspid regurgitation has improved post-operatively, whether the repair was done or not. There is growing consciences to correct moderate TR to improve patient outcomes by preventing regurgitation progression and RV dysfunction .

More study need to be done with bigger number of cases and longer post operative follow up period

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Wound complications of endoscopic versus open vein-graft harvesting in patients undergoing C.A.B.G.

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Background: Coronary artery bypass grafting (CABG) is still the most commonly performed procedure in cardiac surgery. In most CABG procedures, a greater saphenous vein (GSV) is used in addition to internal mammary artery. GSV harvest from lower extremity for CABG requires the longest wound of any surgical procedure. In the mid 90s, surgeons began using endoscopic vein-graft harvesting techniques as an alternative to large incision-based open vein-graft harvesting to improve postoperative discomfort and incision-site complications. Our study aim to compare wound complications in patients undergoing CABG procedure attended to GSV harvesting by traditional open vs endoscopic technique.

Methods: In this study, 50 patients with ischaemic heart disease requiring CABG were included. 25 patients attended to do endoscopic vein-graft harvesting, other half to do open vein-graft harvesting. All patients were consented for the purpose of the study & scheduled for CABG. The study was done at the armed forces hospitals (mainly El Galaa & El Maadi armed forces hospitals) in the period between May 2013 and May 2014. We assessed both groups preoperatively to make sure that they were comparable groups. Study then compared early outcomes, including leg wound complications including infection, seroma, haematoma or dehiscence and pain in patients undergoing CABG surgery with endoscopic vs open vein-graft harvesting. Also mobility, hospital stay & financial burden were evaluated & compared between both groups.

Results: There was no statistically significant difference in preoperatively demographic data and clinical characteristics of the patients in both groups. This included risk factors for wound complication including age, sex, obesity, diabetes, hemoglobin & kidney function. All the patients completed the study. There was no mortality among the patients. Post-operative pain score using the visual analogue scale and wound complications including fever, wound dehiscence & infection were less in group with endoscopic vein-graft harvesting, with highly statistically significant difference. Also hospital stay and readmission due to leg wound complications was less in group with endoscopic vein-graft harvesting. Mobility, patients satisfaction and cosmesis were more in group with endoscopic vein-graft harvesting.

Conclusion: It is obvious that not only cosmetic reasons drive surgeons to perform less invasive surgery procedures but also to minimize harm to patients by reducing pain, reducing the danger of infection by minimizing wound dimensions, thereby shortening the patient's hospital stay and decreasing costs. In our less invasive study group, we achieved less pain level, so that the patients become more mobile. The hospital stay was significantly shorter in the study group, and there were less incidences of wound complications. Endoscopic vein harvesting provide more cosmetic and satisfactory leg wound.

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Codex : o3/10/1408

Coronary artery bypass grafting (CABG) is still the most commonly performed procedure in cardiac surgery. CABG is one of the most intensely studied of surgical procedures. The choice of conduit, whether arterial or venous, is one of the many factors that have been shown to influence patient outcomes in both short and long term settings. Although

surgical revascularization exclusively using both internal mammary arteries is associated with the best long-term patency, in most CABG procedures either a greater saphenous vein graft (GSV) or the radial artery are used in addition (Kempfert et al., 2011). Of necessity, GSV continue to be a frequent choice of conduit during CABG (Dacey et al., 2011).

During the last few decades, minimally invasive techniques have dramatically changed clinical practice in cardiac surgery. Driven by the idea of providing less invasive techniques to improve outcome and patient satisfaction, a variety of new techniques have been suggested. At that time, the term minimally invasive summarized surgery through limited or alternative skin incisions or the use of endoscopic or videoscopic support, as well as to perform cardiac surgery procedures without cardiopulmonary bypass support (Kempfert et al., 2011).

One of the major changes in surgery during the past decade has been the movement toward "less invasive" access to the human body with minimization of incision length. GSV harvest from lower extremity for CABG requires the longest wound of any surgical procedure (Illig et al., 2003). In the mid 90s, surgeons began using endoscopic vein-graft harvesting techniques as an alternative to large, incision-based open vein-graft harvesting to improve postoperative discomfort and incision-site complications (Williams et al., 2012).

The aim of our work is to compare wound complications in patients undergoing CABG procedure attended to do vein harvesting by traditional open vs endoscopic technique.

Patients (Materials) & Methods

This was a comparative prospective clinical trial of 50 patients with ischemic heart disease requiring CABG. Patients were randomly divided into two groups, Group "A", included 25 patients who underwent endoscopic GSV harvesting and Group "B", included 25 patients who underwent GSV harvesting by open method. All patients were consented for the purpose of the study and underwent CABG operation. This study compared between wound complications in patients undergoing CABG surgery and had endoscopic vs open vein-graft harvesting.

Data from medical records and patient structure interview were collected using checklist and data compilation form as research tools. The collected data was statistically applied & entered into SPSS, EPI calc software programs to get the final results. The study was done at the armed forces hospitals (mainly El Galaa & El Maadi armed forces hospitals). The cases studied dated over 1 year from May 2013 to May 2014.

Inclusion criteria for the study included patients with ischemic heart disease undergoing CABG using GSV as conduit. Patient undergoing CABG surgery using arterial graft only were excluded from the study. Patients with associated valvular

or congenital lesions were also excluded from the study.

Preoperative assessment included : History taking, Clinical examination, Laboratory investigations (Complete blood count, Liver function tests, Prothrombin time and concentration, Kidney function tests, Fasting blood sugar and Serum electrolytes), Electrocardiogram, Plain chest x-ray, Echocardiography and diagnostic coronary angiography.

Preoperative counseling in the preoperative visit prior to surgery, a brief explanation of the steps of the operation, the post-operative events and the intensive care stay. The visual analogue scale for pain assessment in the post-operative period was instructed to the patients in the preoperative visit.

Preoperative data recorded; was demographic data included age, sex and body mass index; clinical characteristics included diabetes mellitus and smoking and laboratory data included hemoglobin and creatinine. These data recorded as preoperative risk factors for wound complications.

Preoperative preparation included : a morning dose of cardiac medications. Intramuscular 10 mg morphine sulphate before transfer to the operating theatre was given to all patients.

Anesthetic techniques : After arrival in the preparation room a 14 gauge peripheral intravenous cannula was inserted using local anesthesia. Sedation was optimized using 0.03-0.07 mg/Kg midazolam. The intraoperative anesthetic technique was the same for all patients and consisted of a 20 gauge radial artery cannula was inserted using local anesthesia. Two blood samples were withdrawn from the arterial line, the 1st for preoperative baseline activated clotting time and the 2nd for baseline arterial blood gas analysis. Monitoring started using three or five leads ECG, pulse oxymetry and invasive B.P.. The induction of anesthesia was achieved with Fentanyl citrate (5 to 10 µg/kg), Thiopental (3 to 5 mg/kg) or Propofol infusion (3 to 4 mg/kg/hour) and Vecuronium bromide (0.1 mg/kg) or Pancuronium (0.02 mg/Kg). A supplemented hypnotic does of propofol 0.5-1 mg/Kg or additional dose of Fentanyl 100-200 µg was given in an on need bases. After full muscle relaxation, the trachea was intubated orally with an appropriate sized endotracheal tube. Anesthesia in all patients was maintained with inhalational Isufloane 0.5-1.0 %. After induction, a triple lumen central venous catheter was inserted into the right internal jugular vein. A urinary catheter was also inserted. Anticoagulation was achieved with heparin (3-4 mg/kg) after the conduits were harvested. The activated clotting time was maintained at 300 seconds or greater. Heparin was reversed with protamine after completion of the anastomosis and weaning from cardiopulmonary bypass. Standard intraoperative monitoring techniques were used.

Cardiopulmonary bypass : Membrane oxygenators were used. Hematocrite was kept around 28% during cardiopulmonary bypass. Myocardial protection was carried out through

systemic cooling to 28 °C, topical iced saline bath to keep myocardial temperature at 15°C and most important by antegrade crystalloid cardioplegia. Induced cardiac standstill was usually achieved within one minute. Cardioplegia was given in a dose of 15-20 ml/Kg every 30-40 minutes.

Surgical technique

For Group “A” (Endoscopic vein harvesting)

All patients were positioned supine with positioning of the leg the same as it would be for a traditional vein harvest. Externally rotate the leg with the knee flexed and with support behind the knee and the thigh. The incision is placed just below the knee which is the most commonly used site. Palpate along the tibia until reaching the medial tibial condyle 2-cm incision along the posterior border of the tibial condyle. Dissection of the subcutaneous tissue, exposing the adventitial layer of the vein. A small self-retaining retractor may help in finding the vein. A vessel loop may be placed around the isolated vein. Under direct visualization dissection of the anterior surface of the vein in the direction of planned harvesting. The endoscope with attachable conical tip is used to dissect surrounding subcutaneous and connective tissue from the saphenous vein and to dissect the branches. The atraumatic conical tip performs the blunt dissection and therefore must be in focus at all times. CO₂ insufflation aids the dissection by enabling constant visualization, reduces bleeding and helps maintain a working space. The harvesting cannula is used for branch cauterization and division. The integrated instrument aims the endoscope, cautery tool and C-Ring (vessel cradle) in one direction, allowing easy branch division and vein retraction. Once all branches have been cauterized and divided, running the C-Ring (vessel cradle) along the entire length of the vein to ensure that all branches have been divided. Make a second pass with the C-Ring in the opposite orientation to ensure that all branches and connective tissue are free from the vessel. Identifying and dividing any connective tissue or branches that are still adhered to the vein. Distal ligation can be performed in various ways. A “stab and grab” approach is used to pull the vein through a puncture site, where it is then externally divided. The saphenous vein is removed through the incision. It is measured to assure adequate length for the bypass grafting. If additional length is needed, further dissection can be carried out through the same incision, harvesting in the opposite direction. Flush and prepare the vein according to standard protocol.

For Group “B” (open vein harvesting)

All patients were positioned supine with externally rotate the leg with the knee flexed and with support behind the knee and the thigh. Open dissection was started at the ankle; just

above the medial malleolus. An incision overlying the vein and extended directly over the trajectory of the vein is made, taking care not to create skin flaps. Sharp dissection is then used to free the vein from the surrounding tissue with all side branches ligated and divided in situ. Side branches on the vein should be left long and should be ligated flush with the vein, taking care to avoid narrowing of the conduit. In the lower leg, care should be taken to avoid trauma to the saphenous nerve, which is in close proximity to the vein. Once dissection is completed the vein is ligated and divided proximally and distally. The vein is then gently flushed with heparinized blood solution. A blunt tipped cannula is placed in the distal end and the conduit stored in heparinized blood solution. The vein should not be grasped with forceps, stretched, or over distended, since patency rates may be related to endothelial damage induced during harvest and preparation. When using a bridged technique, two or three step incisions are performed over the course of the vein. Dissection of the vein is carried out in a similar fashion except that branches are divided in situ and ligated once the vein is explanted.

Postoperative data collection; included blood loss, total intensive care unit stay and morbidities (fever and other morbidities). Hospital stay evaluation one week after surgery included pain score, other leg wound complications e.g. wound infection, seroma, dehiscence and total hospital stay. Outpatient follows up for wound sequalea, pain, patient satisfaction, cosmesis and cost effectiveness.

Statistical analysis ; Data was collected, verified and edited on a personal computer, then analyzed by SPSS (Statistical package for the social science), EPICAL software program to get the final results. These results will be presented in tables & chart & parameters accordingly. The following tests were used:

- Arithmetic mean, standard deviation and hypothesis “t” test (Student test) for quantitative values.
- The chi-square test (χ^2) for qualitative values expressed as proportions.
- For all statistical comparisons, a P value of <0.05 was considered significant and a P value of <0.01 was considered highly significant.

Results

This study was conducted on 50 patients. All patients underwent CABG. 25 patients had vein harvested endoscopically and 25 patients had vein harvested by open method. All the patients completed the study. There was no mortality among the patients. This study compares wound complications in the standard open versus the new endoscopic saphenous vein harvesting for CABG surgery.

In group "A", age ranged from 38-70 years with a mean of 58.36 ± 8.28 , while in group "B", age ranged from 39-74 years with a mean of 59.68 ± 7.08 and there was no statistical significance (P value >0.05). In group "A", there was 21 males (84%) and 4 females (16%) and in group "B" there was 21 males (84%) and 4 females (16%) with no statistical significance (P value >0.05). The mean body mass index in group "A" was 30.11 ± 4.39 Kg/ m2 and in group "B" it was 31.11 ± 5.53 Kg/ m2 and a P value >0.05 .

Preoperative risk factors for wound complication including diabetes, smoking, hemoglobin and kidney function were compared between group A and B in Table 1.

	Group "A"	Group "B"	"P" value	Sig.
Diabetic	14(56%)	13(52%)	>0.05	NS
Smoker	15(60%)	12(48%)	>0.05	NS
Hemoglobin (g/dl)	13.09 ± 1.05	13.34 ± 1.42	>0.05	NS
Creatinine (mg /dl)	1.10 ± 0.27	1.11 ± 0.24	>0.05	NS

Table 1. Preoperative clinical and laboratory classification (Number & %).

Post-operative pain score using the visual analogue scale was compared in the two groups. In group "A", the mean pain score was 2.24 ± 1.53 while in group "B" was 4.56 ± 2.18 during the fifth post-operative day. This data shows that pain was less in group "A", with highly statistically significant difference.

Post-operative complications in group "A", was 2 patients (8%) with complications. Two patient (8%) developed post-operative fever. There was no infection in leg wound of this group, also all the patients in this group was mobile well. In group "B", 12 cases (48%) suffered from post-operative complications. Twelve patients (48%) developed post-operative fever. Seven patients (28%) had superficial wound infection involving only the skin and responded to frequent dressing and antibiotics. Eight patient become immobile due to leg wound complications. This data shows that post-operative complications was less in group "A", with highly statistically significant difference. All the patients of the group "A" was mobile after endoscopic vein harvesting while in group "B" only seventeen patient was mobile after open vein harvesting.

The total hospital stay was comparable in the two groups, the range of hospital stay in group "A" was 6-13 days with a

mean of 8.76 ± 1.48 days, while in group "B" the range was 7-21 days with a mean of 11.08 ± 4.04 days. This shows that the total hospital stay in the endoscopically vein harvesting group was less than open vein harvesting group and this difference has statistical significance.

No patients of the group "A" was readmitted to the hospital due to leg wound complication while in in group "B", two patients were readmitted to be managed by suction set and combined parenteral antibiotics.

Also group (A) patients were more satisfied by the leg wound and the leg wound was also cosmetic than group (B) with highly statistically significant difference.

Summary of postoperative differences between group A and B is shown in Table 2.

	Group "A"	Group "B"	"P" value	Sig.
Postoperative pain (by cm)	2.24 ± 1.53	4.56 ± 2.18	<0.01	HS
Complications	2(8%)	12(48%)	<0.01	HS
Fever	2(8%)	12(48%)	<0.01	HS
Infection	0(0%)	7(28%)	<0.01	HS
Leg wound complication	0(0%)	11(44%)	<0.01	HS
Mobility	25(100%)	17(68%)	<0.01	HS
Hospital Stay				
Range (days)	6-13	7-21		
Mean \pm SD (days)	8.76 ± 1.48	11.08 ± 4.04	<0.01	HS
Readmission	0(0%)	2(8%)	<0.01	HS
Satisfaction	25(100%)	2(8%)	<0.01	HS
Cosmosis	25(100%)	2(8%)	<0.01	HS

Table 2. Postoperative differences between groups.

Comments (Discussion)

From this study, we concluded that endoscopic GSV harvesting is better than traditional open GSV harvesting. Endoscopic GSV harvesting is associated with less wound complications, pain and hospital stay and more mobility, satisfaction and cosmosis.

In our less invasive study group, we achieved less pain level, so that the patients become more mobile. The hospital stay was significantly shorter and there were less incidences of wound complications in less invasive study group. Endoscopic GSV harvesting provide excellent cosmetic results and satisfactory leg wound, and is almost as safe as open GSV harvesting.

Preoperative data collected didn't show any statistical difference between both groups in preoperative risk factors for leg wound complication so both groups were comparable. There was no statistically significant difference as regards the age, sex, body mass index, preoperative smoking and diabetes. Also preoperative hemoglobin level and serum creatinine done revealed no statistical significant difference. The age groups in our study are relatively younger than the age groups in other studies as Allen et al, 2000 & Bitondo et al, 2002. However, there was no statistically significant difference between mean ages in both groups in our study & other studies as Allen et al, 2000 & Bitondo et al, 2002. Regarding the sex, the male affection is more than the female affection. There was no statistically significant difference between sex distributions in our study groups. Preoperative history of diabetes mellitus and smoking was higher than other studies like Allen et al, 2000 study. This can be attributed to the high incidence of diabetes mellitus and smoking in Egypt and developing countries.

Regarding post-operative comparison, post-operative pain score using the visual analogue scale was compared in the two groups. The study data shows that pain was less in group "A", with highly statistically significant difference. Ouzounian et al, 2010 found that there was reduction in postoperative pain at the harvest site with endoscopic compared with traditional open GSV harvest. Also Kiaii et al, 2002 found that at hospital discharge there were important differences in the degrees of the patients pain and cosmosis favoring endoscopic GSV harvesting .

The prevalence of infection varies widely in the literature (from 1%-20%), depending to some degree on the definition of leg-wound complications, as well as the intensity of follow-up. The Society of Thoracic Surgeons National Cardiac Database in 1998 noted a prevalence of leg-wound infection of only 1.5%, but observation may be limited to the hospital stay. Thus this may significantly underestimate the true prevalence of infections because our study, as well as those of others, have shown that the mean time to diagnosis is about 2 to 3 weeks after surgery (Carpino et al, 2000).

The study data shows that post-operative complications was less in group "A", with highly statistically significant difference. Raja et al, 2012 validates that endoscopic GSV harvesting is associated with a reduced incidence of leg wound infections. Kiaii et al, 2002 stated that the difference in the incidence of leg

infection between the conventional group and the endoscopic group was highly statistically significant. The result of readmission due to leg wound complications was almost similar to Crouch et al, 1999 as it was zero and 16.4 % respectively.

Kiaii et al, 2002 found that at the time of discharge, the patient's subjective ability to mobilize was significantly higher with endoscopic as compared with conventional GSV harvesting. Endoscopic GSV harvesting may enable patients to ambulate earlier in their postoperative course, which may help improve pulmonary function (Patel et al, 2001).

Leg wound complications after CABG are an underappreciated source of patient morbidity. They may prolong the hospital stay or necessitate readmission for intravenous antibiotics and debridement, both of which will increase hospital costs (Carpino et al, 2000). This study shows that the total hospital stay in the endoscopically GSV harvesting group was less than open GSV harvesting group, and this difference has statistical significance

This data shows that group (A) patients were more satisfied by the leg wound and the leg wound was also cosmetic than group (B) with highly statistically significant difference.

Although an economic analysis was not part of this study, outpatient resource utilization for the care of leg wound complications following endoscopic vein harvesting was found to be reduced when compared to traditional longitudinal saphenectomy. The need for additional operative time and the higher expense for endoscopic instrumentation can be balanced against reduced patient morbidity and improved patient satisfaction (Allen et al, 2000). It is evident that endoscopic GSV harvesting is considerably more expensive than open GSV harvesting. It is a complex issue in this era of healthcare constraints to justify this increased expense. However, the reduction in pain, leg wound infections, and hospital stay may put both techniques at financial parity. Additional studies are warranted to improve our understanding of the mechanism by which endoscopic GSV harvesting influences long-term outcomes, as well as how clinical teams can maximize the utility of this technique.

It is obvious that not only cosmetic reasons drive surgeons to perform less invasive heart surgery procedures. The less invasive procedures are also intended to minimize harm to patients by reducing pain, reducing the danger of infection by minimizing wound dimensions, thereby shortening the patient's hospital stay and decreasing costs.

Endoscopic vein harvesting is a desirable procedure and will very likely become the vein harvest procedure of choice. It is less painful for the patient; it carries fewer morbidities; it is likely to be much less costly overall, and it accomplishes the

goal of adequate vein harvest for coronary bypass in a reasonable time by a single operator. It is effective, safe, and financially prudent.

Compared with open, endoscopic technique eliminates the need for a long incision, reduces pain and most important, eliminates serious wound infections. Consequently, the length of hospital stay is reduced and the need for multiple hospital readmissions is eliminated .

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A Prospective study to assess the effectiveness of topical application of tranexamic acid in reducing post operative bleeding following elective coronary artery bypass grafting .

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Background: Generalized microvascular bleeding is common following coronary artery bypass operations. Systemic use of tranexamic acid has proven efficacy in reducing post operative blood loss following cardiac surgery.

Our study aims to assess the benefit of adjunctive topical application of tranexamic acid in reducing post operative blood loss.

Methods: 40 patients scheduled for elective primary isolated coronary artery bypass grafting were included. Systemic plus topical tranexamic acid group (20 patients) received 2 grams tranexamic acid diluted in 200 cc normal saline and poured in the mediastinal cavity prior to sternal closure, in addition to 2 grams of tranexamic acid administered intravenously once arrived in cardiac intensive care unit. Systemic only tranexamic acid group (20 patients) only received 2 grams tranexamic acid intravenously in the cardiac intensive care unit.

Results : Both groups are comparable in their baseline demographic and surgical characteristics.

Cumulative blood loss 24 hours post operatively was significantly less in the topical plus systemic administration group (median 500 ml) than in the systemic administration only group (median 1000ml) (P value less than or equal 0.001). Allogenic blood transfusion requirements were significantly less in the topical plus systemic administration group (median 2 units) than in the systemic only group (median 5 units) (P value less than or equal 0.001).

No significant difference in fresh frozen plasma requirements or platelets requirements between both groups.

No significant difference in rate of reexploration for bleeding between both groups. No other differences found in terms of morbidity and mortality between both groups.

Conclusion : Topical application of the cheap readily available tranexamic acid augments its systemic administration in reducing blood loss and transfusion requirements post coronary artery bypass grafting operations.

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A history of preventive application of fibrinolytic inhibitors in cardiac surgery is older than 30 years (8). This pharmacological strategy is frequently used to reduce postoperative blood loss, transfusion requirements and the frequency of early revisions for bleeding.

Lysine analogues (tranexamic acid, e-aminocaproic acid) is an important part of blood saving programs in many cardiac surgery centers (6).

The use of tranexamic acid is more common in Canada and Europe (4).

Tranexamic acid exerts its clinical effects by competitively binding to lysine – binding sites of plasmin and plasminogen (9).

Tranexamic acid is generally well tolerated but few adverse events were reported as theoretically increased risk of thromboembolic events.(3).

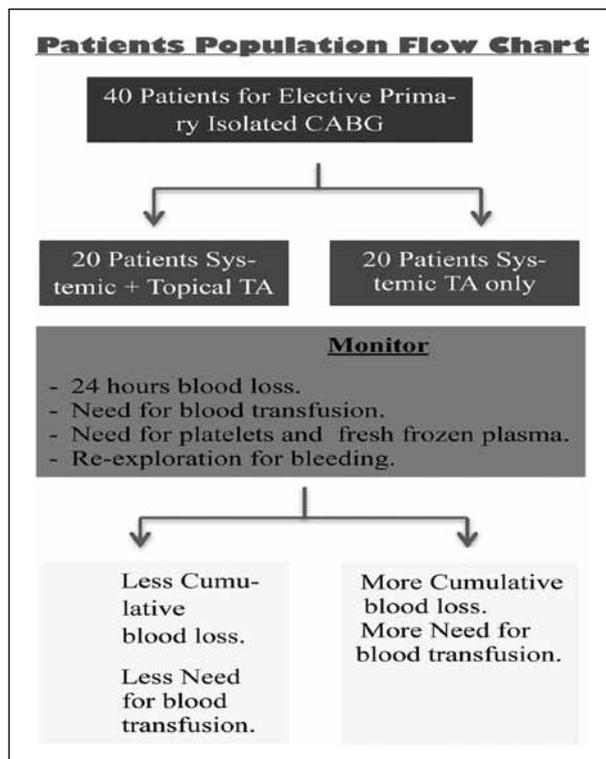
The systemic application of TA is the most common approach in cardiac surgery.

The topical application of TA into the pericardial cavity is not so frequent in comparison with its systemic use, a dose of TA varying from 1 g to 2.5 g in 100-250 ml of normal saline was poured into the pericardial cavity or the end of procedures prior to sternal closure (5).

In all these trials, the topical application of TA significantly reduced postoperative blood loss in 24 hours, But the tendency towards re- duced transfusion requirements (packed red blood cells), reached statistical significance in only one study with the highest concetra- tion of TA. (7).

In our study we tested a possible augmentation of systemic admin- stration of TA (2 gm) slowly IV by the additional topical application 2gm TA diluted in 200 cc normal saline poured in mediastinal cavity prior to sternal closure in patients undergoing on pump coronary artery by pass grafting.

Patients and Methods



The protocol was approved by our institutional review board of Ain Shams university, this prospective randomised study was performed in department of cardiothoracic surgery , Ain Shams university be- tween 2013 and 2014 and all patients signed written informed con- sent to participate in this study.

40 patients scheduled for elective isolated coronary artery by pass grafting were eligible to participate.

TA(IV plus topical application) group n=20 received 2 gm TA dilut- ed in 200 cc normal saline poured in the pericardial cavity prior to sternal closure in addition to 2gm TA slowly IV once arrived at car- diac care unit.

TA(IV only) group n=20 received 2 gm TA slowly IV once arrived at cardiac intensive care unit.

Patients were excluded if they had a preoperative coagulopathy that included thrombocytopenia (platelet count <100.000/mm³) uremic thrombocytopeny and inherited or acquired coagulopathy as hemo- phyliaA.

Patients receiving inotropic therapy or intraaortic balloon counter pulsation were excluded as well.

Patients receiving preoperative heparin infusions were not excluded from the study.

Prior to induction of anesthesia a baseline laboratory evaluation was obtained including prothrombin time, haemoglobin (Hb), hematocrit (HCT) and fibrinogen level.

A subset of these tests were repeated 24h postoperatively.

The anesthetic protocol consisted of intravenous thiopental, fentanyl citrate, midazolam and pcuronium bromide in body wt re- lated doses .

Maintenance of anesthesia was with isoflurane 1.2%, fentanyl, and proposal with standard monitoring in the form of 5 lead electrocardiogram with ST segment monitoring, pulse oximetry, end tidal CO₂, nasopharyngeal and skin temperatures, urine output, in- vasive arterial pressure.

Cardiopulmonary bypass was instituted with 1500 ml crystal- loid priming volume and mild hypothermia (32 C) with a trillium affinity NT oxygenator and a sarns CPB machine at a flow rate of 2.6 l .min -1.m-2.

Myocardial protection was achieved with cardioplegia at 20 C . During CPB ,homologous donor packed RBCs were transfused if HB was below 6 g.dl -1. Systemic heparinisation was carried out be- fore CPB with unfractionated heparin at an initial dose of 300 IU .Kg -1. A elite activated clotting time (ACT) above 400 was tar- geted .This was achieved with additional heparin doses of 100 IU.Kg-1 if necessary. The effect of heparin was reversed at the end of CPB with protamine 1 mg for every 100 U of heparin administered

The anesthesiologist administered the protamine into the central line by continuous infusion over a period of 15 min. one additional dose of protamine 50 mg was administered if the ACT remained at more than 150 sec.

CPB time, aortic cross clamp time were recorded .ACT was measured before and after heparin administration, every 30 minutes, during CPB and after protamine infusion.

TA(IV plus topical application) group received 2 gm TA diluted in 200 cc normal saline poured in the pericardial cavity prior to sternal closure in addition to 2gm TA slowly IV once arrived at cardiac care unit.

TA(IV only) group received 2 gm TA slowly IV once arrived at cardiac intensive care unit.

Immediately on reaching the post-cardiac surgical unit , the coagulation assessment was repeated.

Mediastinal tube drainage was recorded at 1,3,6,12,24 h post-operatively, all packed red blood cells are transfused for HCT <25% before and after CPB, fresh frozen plasma was administered for a PT>150% of control.

Platelet concentrates were transfused for a platelet count <100.000 per mm³

The rate of reexploration for bleeding was also recorded in on interval of 24h postoperatively. It was performed when bleeding exceeds 200 ml/hr for 6 hrs consecutively or above 400 ml during the first hour .

Statistical analysis

All analysis was performed with SPSS version 20 the minimal sample size was less than or equal 40 by type I error 5% and type II error 10% with power of test 90% by Med.Calc. 7.2.

Demographic characteristics and clinical factors were compared between groups using t/x^2 test and p-value ≤ 0.05 was considered statistically significant .

Age, weight and LVF were shown as mean \pm SD.

While sex and clinical factors as DM, HTN, COPD, RF, PVD and previous MI were shown as percentage variables as number of RBCS, PLT and FFP units were shown as mean \pm SD and they were compared between groups using t-test and p-value ≤ 0.05 was considered statistically significant .

The amount of postoperative bleeding were shown as mean \pm SD and it was compared between group using t-test and p-value ≤ 0.05 was considered statistically significant.

The intraoperative data as the number of grafts and cross clamp time and TBT were shown as mean \pm SD and they were

compared between groups using t-test and p-value ≤ 0.05 was considered statistically significant.

The rate of re-exploration for bleeding was shown as percent-age and it was compared between groups using Chi-square test and p-value ≤ 0.05 was considered statistically significant.

The postoperative hematological profile was shown as mean \pm SD and it was compared between groups using test and p-value ≤ 0.05 was considered statistically significant.

Results

Forty patients participated in the study who were scheduled for elective primary isolated coronary artery bypass grafting, demographic characteristics and clinical factors are similar among the 2 study groups as shown in table(1) (Fig1) (Fig 2)

As regards the preoperative hematological profile there was insignificant difference between the study groups as shown in table(2) fig.(3).

Intraoperative variables such as the number of grafts , the duration of extracorporeal circulation and the aortic cross clamp time were similar between the 2 study groups as shown in table(3)fig(4) .

The amount of postoperative blood loss (mediastinal tube drainage) was significantly reduced in TA(IV plus local application) group compared with TA(IV only) group (p<0.001) at 1,3,6,12,24 hours postoperatively as shown in table (4) fig. (5) .

As regards postoperative hematological profile (HB, HCT, INR and PTT) there was insignificant difference between the study groups as shown in table(5) fig.(6) .

There was significant difference in fibrinogen level between the study group (p<0.016) as shown in table (5) fig.(6).

The number of RBCS units required were significantly lower in TA (IV plus local application) group compared with TA(IV only) group at all time points (p<0.001) as shown in table (6) fig.(7) .

There was insignificant difference in the number of platelets or FFP units in TA(IV plus local application) group compared with TA(IV only) group at all time points (p= 0.061) as shown in table(6) fig.(7).

We demonstrated that patients receiving TA (IV plus local application) group had insignificantly less incidence of re exploration for bleeding compared with TA (IV only) group (p=0.235) as shown in table(7) fig.(8).

		Groups		Test	
		TA(local plus IV)Group	IV only Group	t/X ²	P-value
Age	Mean±SD	65.45±10.12	65.92±11.54	0.137	0.891
Sex	Female	7(35%)	3(15%)	1.200	0.273
	Male	13(65%)	17(85%)		
Weight	Mean±SD	80.33±12.75	82.64±10.7	0.621	0.538
Smoking		7(35)	8(40%)	0.000	1.000
Diabetes mellitus		4(20%)	5(25%)	0.000	1.000
Hypertension		7(35%)	8(40%)	0.000	1.000
Chronic obstructive Airway disease		1(5)	1(5)	0.526	0.468
Renal failure		0(0%)	0(0%)	0.025	0.874
Peripheral vascular Diseases		1(5)	1(5)	0.526	0.468
Preview myocardial infarction		2(10)	3(16.7%)	0.000	1.000
LVEF	Mean±SD	51.61±16.08	50.13±14.67	0.304	0.762

LVEF: left ventricular ejection fraction

Table (1) Demographic characteristics and clinical factors among the two study groups TA (local plus IV)group and TA(IV only) group

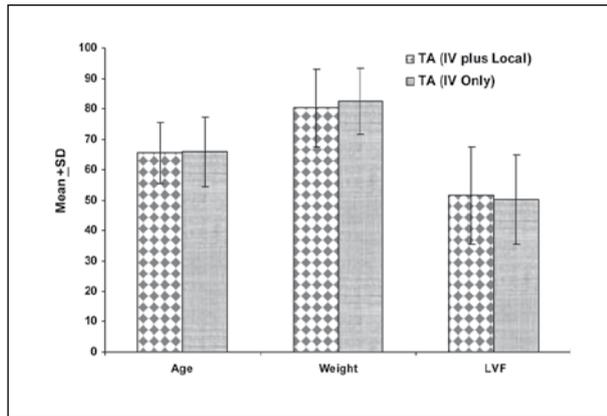


Fig 1. Demographic characteristics and clinical factors among the two study groups Group I TA (local plus IV) and group II (TA IV only)

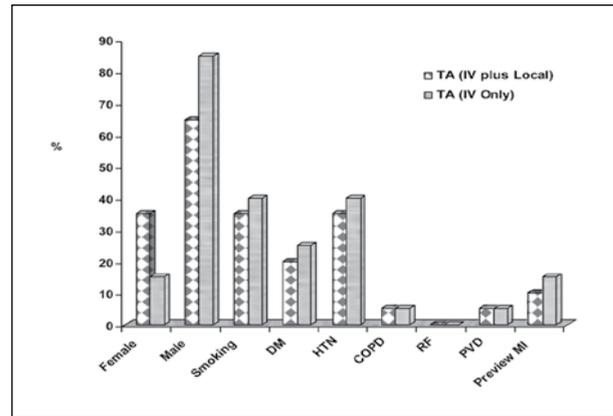


Fig 2. Demographic characteristics and clinical factors are similar among the 2 study groups.

After CPB hematological profile		Groups		T-Test	
		TA(local plus IV)Group	IV onlyGroup	t	P-value
Platelets	Mean±SD	265.4±129.5	194.8±92.5	1.984	0.055
Haemoglobin level	Mean±SD	15.1±2.1	13.8±2.7	1.700	0.097
HCT	Mean±SD	38.4±3.7	40.7±4.2	1.838	0.074
INR	Mean±SD	1.1±0.45	1.4±0.53	1.930	0.061
PPT	Mean±SD	32.1±5.2	35.8±6.5	2.007	0.053
Fibrinogen	Mean±SD	358.6±130.7	435.2±165.7	1.623	0.112

Table (2) Preoperative hematological profile of local plus IV tranxamic acid group and IV tranxamic acid only group .

Intra-operative data		Groups		T-Test	
		TA(local plus IV)Group	IV only Group	t	P-value
Number of Grafts	Mean±SD	2.7±1.3	2.8±1.2	0.253	0.801
Cross clamp time	Mean±SD	73.4±19.5	74.6±20.4	0.190	0.850
Total bypass time	Mean±SD	98.63±27.9	96.02±26.8	0.302	0.764

Table (3) Comparison between local plus IV tranxamic group and IV tranexamic only group as regards number of grafts, cross clamptime and TBT.

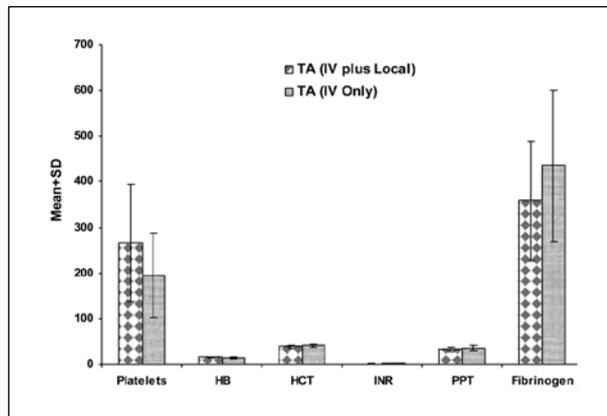


Fig. 3. Preoperative hematological profile of local plus IV tranxamic acid group and IV tranexamic acid only group .

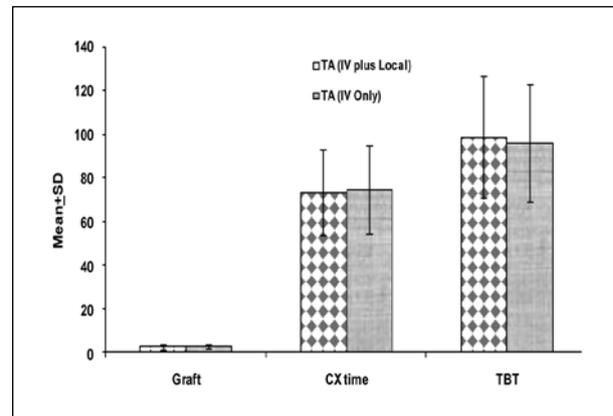


Fig. 4. Comparison between local plus IV tranxamic group and IV tranexamic only group as regards number of grafts, cross clamptime and TBT.

Post operative bleeding		Groups		T-Test	
		Group I	Group II	t	P-value
After 1 hr.	Mean±SD	100.23±50.42	250.7±84.7	6.827	<0.001*
After 3 hr.	Mean±SD	200.74±54.9	350.8±104.5	5.685	<0.001*
After 6 hr.	Mean±SD	350.21±56.7	600.2±115.4	8.695	<0.001*
After 12 hr.	Mean±SD	400.01±74.1	850.6±246.7	7.823	<0.001*
After 24 hr.	Mean±SD	500.74±80.6	1000.9±427.6	5.140	<0.001*

Table (4) Comparison between tranxmiac acid (local plus IV) and IA IV only group as regards postoperative bleeding.

Post operative hematological profile		Groups		T-Test	
		TA(local plus IV)Group	IV onlyGroup	t	P-value
Platelets	Mean±SD	194.7±62.8	197.6±66.4	0.142	0.887
Haemoglobin level	Mean±SD	10.2±1.2	10.3±1.4	0.243	0.809
Hematocrit level	Mean±SD	28.7±4.2	31.2±4.2	1.117	0.067
INR	Mean±SD	1.4±0.4	1.2±0.3	1.431	0.160
Partial thromboplastin time	Mean±SD	42.5±6.6	44.8±6.8	1.085	0.284
Fibrinogen	Mean±SD	361.4±212.2	238.7±53.3	-2.508	0.016*

Table (5): Comparison between the study groups as regards postoperative hematological profile:

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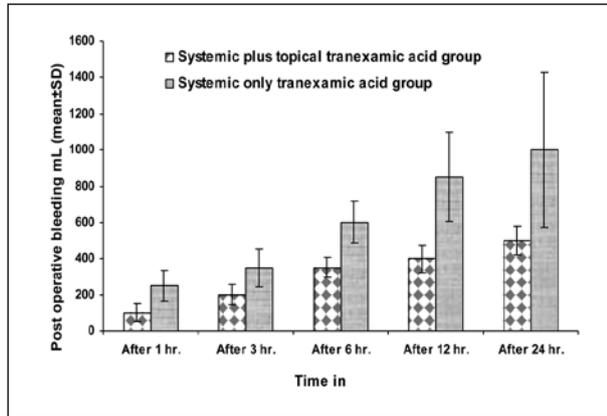


Fig. 5. Comparison between tranexamic acid (local plus IV) and TA IV only group as regards postoperative bleeding.

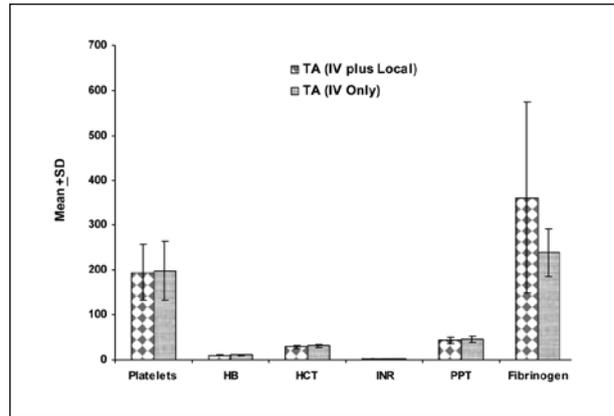


Fig. 6. Comparison between the study groups as regards postoperative hematological profile

		Groups		T-Test	
		TA(local plus IV)Group	IV onlyGroup	T	P-value
RBC	Mean±SD	2.2±1.5	5.15±2.4	4.661	<0.001*
PLT	Mean±SD	0.92±0.61	1.3±0.63	1.938	0.061
FFP	Mean±SD	3.1±1.9	4.4±2.8	1.718	0.094

RBCS: red blood cells PLT: platelets FFP: fresh frozen plasma

Table (6) Comparison between the study groups as regards number of RBCS, PLT and FFP units required:

Re exploration for bleeding	Groups			Chi-Square	
	TA(local plus IV)Group	TA(IV only)Group	Total	X ²	P-value
Yes	2(10%)	6(30%)	8(20%)	1.406	0.235
No	18(90%)	14(70%)	32(80%)		

Table (7) Comparison between Systemic plus topical tranexamic acid group and Systemic only tranexamic acid group as regard re-exploration for bleeding

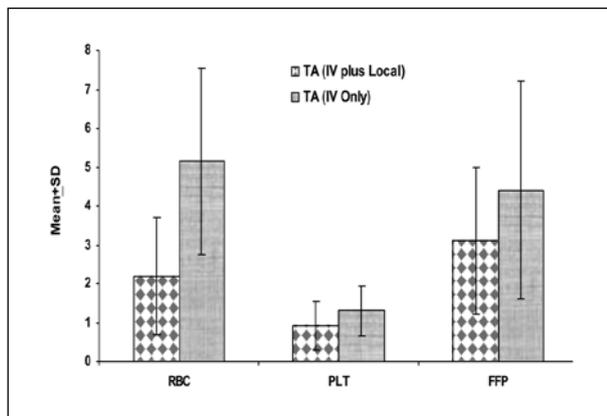


Fig 7. Comparison between the study groups as regards number of RBCS, PLT and FFP units required

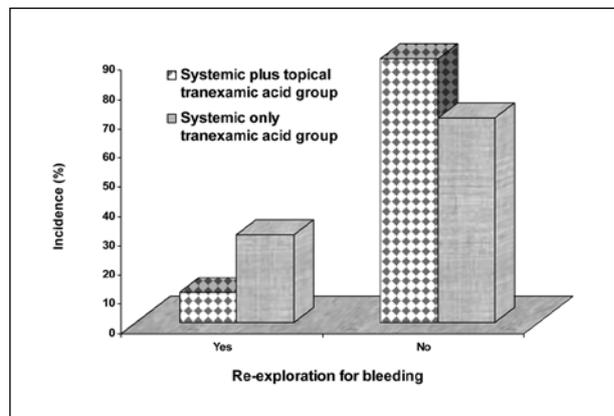


Fig. 8. Comparison between Systemic plus topical tranexamic acid group and Systemic only tranexamic acid group as regards re-exploration for bleeding

Discussion

The hemostatic defects associated with extracorporeal circulation are a result of the activation of the coagulations, kallikrein and complement 8.

Contact activation caused the generation of thrombin and stimulates the endothelial cells to produce tissue-plasminogen activator (13).

This results in the cleavage of plasminogen into plasmin and fibrinolysis leading to bleeding after CPB which has been described previously

Prophylactic administration of antifibrinolytic drugs can reduce perioperative bleeding and minimize transfusion requirements further more antifibrinolytic therapy can minimize the platelet defect that is mediated by plasmin(14).

We demonstrated that patients receiving TA (local plus systemic application) had significantly less need for blood transfusion. Several studies have demonstrated that TA reduces bleeding in cardiac surgical patients when administered according to a variety of dosing scheme.

Bakhtiar et al. Showed that the use of low dose tranexamic acid can significantly reduce blood loss and need for transfusion with no increase in complication, which agrees with our study(2).

Tomas et al. showed that topical use of tranexamic acid is a promising, interesting and effective method for significant reduction of postoperative bloodloss in patients undergoing cardiac surgery(1).

Linda et al. showed that tranexamic acid was effective in reducing postoperative mediastinal tube drainage and incidence of transfusion by 33% in patients undergoing repeat cardiac surgery(10).

The plasma concentration required to suppress fibrinolysis in vitro is 10 mg/kg and to suppress plasmin-induced platelet activation is 16 mg/kg so a study by Horrow and colleagues on the dose-response association showed a plateau effect on drainage losses with a total dose of 3 g of TA, while no effect on transfusion was seen so in our study we chose the dose of 2 g TA to study its effects on blood loss and transfusion requirements(11).

It's different from our study that it was done on patients undergoing repeat cardiac surgeries.

Conclusion

Topical application of cheap readily available tranexamic acid augments its systemic administration in reducing blood loss and transfusion requirement post coronary artery bypass grafting operations.

Acknowledgements

This work was supported by both, the department of Cardiothoracic surgery and the department of Anesthesiology at Ain Shams university, Cairo, Egypt.

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Radial Artery versus Free Right Internal Thoracic Artery for Coronary Artery Bypass Surgery

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Background: Utilizing the left internal thoracic artery (LITA) to graft the left anterior descending artery is the standard of care in coronary artery bypass surgery (CABG). Despite displaying similar characteristics, widespread utilization of the right internal thoracic artery (RITA) was limited by its association with higher rates of sternal wound complications. When compared to RITA, radial arteries avoid increasing the risk of sternal wound complications. On the other hand, RA has a higher propensity to vasospasm and its long term patency has been questioned.

Methods: Between May 2008 and December 2011, 60 patients underwent CABG using either the RA or free RITA as the second arterial conduit (on the left coronary system) in Cairo University hospitals. Patients were followed up throughout their hospital stay and for 3 months after discharge.

Results: 30 patients received RA and 30 patients received RITA as the conduit of choice for the second best target after the LAD on the left coronary system. There was single in-hospital mortality in RA group (3.3%) but no mortality in RITA group. Two patients (6.7%) developed postoperative myocardial ischemia in the RA group versus none in the RITA group. Re-exploration for bleeding and the rate of prolonged mechanical ventilation was higher (double) in the RITA group (6.7% versus 3.3%). Sternal wound complications were encountered only in one patient in the RITA group (3.3%).

Conclusion: Both RA and RITA can be used with comparable safety for coronary artery revascularization. Differences in long term patency still to be determined.

Today, patients undergoing coronary artery bypass grafting have multiple risk factors, higher atherosclerotic burden, are older and commonly have undergone multiple percutaneous coronary interventions. Under these circumstances the use of SVGs might be associated with a significantly higher risk of graft occlusion. This means that the effect of arterial revascularization on the outcome of patients undergoing CABG might be more evident than previously reported^{1,2}.

The left internal thoracic artery (LITA) to left anterior descending artery (LAD) graft has become the standard of care in coronary artery bypass graft surgery (CABG) after the long-term survival benefit demonstrated in the mid 1980s³.

The internal thoracic artery (ITA) is unquestionably associated with significantly better patency, survival and re-intervention rates compared to other bypass conduits^{2,4,5}. However, most patients who undergo CABG have disease in more than one artery, necessitating the use of additional arteries or saphenous vein grafts.

Consequently, remarkable attention was paid to explore other arterial conduits searching for an equivalent patency. This resulted in increased utilization of the radial artery (RA) and the right internal thoracic or mammary artery (RITA or RIMA)^{6,7}.

The first arterial conduit that was added to the LIMA was the right internal mammary artery (RIMA) which presented characteristics similar to the LIMA^{8,9}.

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Codex : o3/12/1409

However, some drawbacks limited the widespread utilization of the RITA including its limited length, that limited its use as an in-situ graft, low patency when grafted to the RCA, increased rate of sternal wound complications and longer operative time¹⁰.

In an attempt to maximize use of arterial conduits on the presumption that these might yield a better outcome than vein grafts, Acar and colleagues revived the technique of coronary artery grafting using the radial artery (RA), which had originally been used in the 1970s by Carpentier and colleagues¹¹.

In comparison with RITA, radial arteries are larger and easier to work with; are more straight forward to prepare; are harvested concomitantly with LITA, reducing operative time, more amenable to revascularize remote branches than the RITA; and avoid the risk of sternal wound infections caused by bilateral ITA dissection^{12,13}.

The major disadvantages of the RA are its propensity to spasm and possibly inferior long term patency^{2,13}.

In this study we compared 30 patients receiving free RITA (right internal thoracic artery) versus 30 patients receiving RA (radial artery) as the second arterial conduit, in an attempt to identify the second best arterial conduit.

Methods

Between May 2008 and December 2011, 60 patients who underwent coronary artery bypass grafting (CABG) surgery utilizing either the radial artery (RA) or free right internal thoracic artery (RITA) as the second arterial conduit (on the left coronary system) in the Department of Cardiothoracic Surgery, Faculty of Medicine, Cairo University were included in this study. This was designed as a prospective non randomized observational study.

The left internal thoracic artery (LITA) was uniformly used to bypass the left anterior descending artery (LAD). Revascularization was completed using saphenous vein grafts, as needed. The second target had to have an inflow stenosis >70% with absence of diffuse disease compromising its distal runoff. A written informed consent was obtained from every patient before surgery.

General exclusion criteria included: patients above the age of 70 years, emergency CABG, recent acute myocardial infarction (<7 days), patients presenting in cardiogenic shock, patients with severe LV dysfunction (EF <35%), patients undergoing combined CABG and valve procedure, LV procedure or another vascular/general surgical procedure and redo operations. **Specific contraindications to the use of RA included:** previous trauma to the forearm, presence of A-V fistula for the purpose of hemodialysis, radial dependent hand circulation as evidenced by positive Allen's test or dynamic Doppler evaluation, Raynaud's disease or scleroderma, known subclavian ar-

tery disease and patients with chronic renal failure (serum creatinine >2 mg%) in whom future A-V fistula may be required. **Specific contraindications to the use of RITA included:** obese patients with body mass index (BMI) > 35, Insulin-dependent diabetics, severe chronic obstructive airway disease and past history of chest wall irradiation.

Preoperative assessment of all of the studied patients included routine clinical evaluation and routine panel of preoperative studies. Emphasis was placed on documentation of preoperative risk factors (e.g. smoking, obesity, hypertension, diabetes, CVD (Cerebrovascular disease), PVD (Peripheral Vascular Disease), COPD (Chronic Obstructive Pulmonary disease) and family history of coronary artery disease. Angiographic patterns, including number and location of diseased coronary arteries along with the severity of stenosis of target coronary arteries were noted. Data regarding previous PCIs (Percutaneous Coronary Interventions) were also recorded.

Adequacy of ulnar collateral circulation was assessed using both Modified Allen's test and duplex ultrasound imaging. patient with positive Allen's test or those with dominant radial artery as evidenced by dynamic Doppler testing were excluded.

All patients underwent operation through a standard median sternotomy, myocardial revascularization was performed on cardiopulmonary bypass, which was instituted in the standard fashion with aortic and right atrial cannulation.

Radial artery Harvesting

The radial artery was always harvested from the non-dominant hand. A pulse oxymeter probe is attached to the index of the side from which radial artery is to be harvested. The numerical value and the magnitude of the pulse oxymetry were noted. Both, the radial and ulnar arteries were occluded via applying external pressure and changes in the trace of the pulse oxymetry is noted. If there was no significant fall in the amplitude and in the value of the pulse wave, radial artery harvesting would be considered safe. Harvesting of the RA was accomplished using a combination of low-energy diathermy and sharp dissection using scissors, which was mostly used in the lower 1/3 of the arm as the RA in this area is superficial. Diathermy was used to divide tissues to the deep fascia. Attention must be paid to avoid injury of the lateral antecubital cutaneous nerve which crosses the RA from lateral to medial near the distal extremity of the incision.

After dissection of the RA is completed, a small plastic bulldog clamp is applied to the middle of the RA and pulsation distal to the clamp denotes adequate ulnar collateral circulation. During dissection, the RA was sprayed from time to time by verapamil-nitroglycerine (VG) solution to avoid graft spasm. The distal end was divided following full systemic heparinization. A bulldog clamp was applied to the cut distal end to allow the RA to dilate under the effect of the arterial blood pressure. Moreover, the conduit is bathed in VG solution.

The VG solution used consists of: 300 ml of Ringer's solution, verapamil hydrochloride 5 mg, nitroglycerine 2.5 mg, heparin 500 U, NaHCO₃ 0.2 ml.

Anti-spasm Protocol

Before skin incision; continuous low-dose verapamil infusion was started to prevent RA spasm (0.5 mg/hr; 5 mg of verapamil in 100 ml 5% dextrose in water, intravenously at a rate of 10 ml/hr). In addition, intravenous nitroglycerine is initiated at a dose of 0.5-4 µg/Kg/min and kept for 24 hours postoperatively. Verapamil infusion was kept until patient is able to take oral medications, where oral verapamil, 120 mg in 3 divided doses is given for at least 6 months. Moreover, patients were discharged on a regimen of aspirin, 75 mg daily along with a lipid-lowering drug, continued indefinitely.

Harvesting of RITA

After harvesting of LITA, attention was directed towards the RITA. The ITAs (Internal Thoracic Arteries) were harvested as either pedicled or skeletonized graft, based on the surgeon's preference. When pedicled harvestin was used we tried to harvest it with a narrow pedicle. Throughout the process of dissection, larger branches are clipped on the ITA side and cauterized or clipped on the chest wall side; cauterizing vessels close to the ITA must be avoided since thermal injury may occur. The proximal dissection is carried to the inferior border of the subclavian vein; special attention was given to avoid injury to the phrenic nerve in this location. Distal dissection is carried to the level of the ITA bifurcation. Following systemic heparinization, the distal end was divided first. After confirming adequate and satisfactory flow through the RITA, Similarly the proximal end was clipped and divided. The conduit was sprayed with papaverine solution and wrapped in a papaverine-soaked sponge.

Patients receiving bilateral ITAs did not receive any special pharmacological management apart from local application of papaverine.

Grafting Strategy

After institution of CPB (Cardiopulmonary Bypass), all distal anastomoses were constructed first with the aorta cross clamped. All proximal anastomosis on the aorta were constructed after application of a side occlusion clamp on the ascending aorta on a beating heart. All radial arteries and RITA grafts were proximally anastomosed to the LIMA in an attempt to make maximal use of the length of the conduit as well as to increase the chances of arterial revascularization. The RA or RITA were anastomosed to LIMA in an end-to-side manner either before the institution of cardiopulmonary bypass or on cross-clamp after construction of distal RA or RITA anastomosis (based on the surgeon's preference) usually at the site of entry of the LIMA in to the pericardial sac, in a T- or Y-configuration. In some cases, sequential grafting was used.

LIMA was uniformly used to bypass the LAD in all patients. If additional grafts were needed, saphenous vein was used to complete the revascularization.

RA or RITA was uniformly grafted to the largest, most important coronary artery apart from the LAD on the left coronary system. All distal RA or RITA anastomoses were constructed on coronary arteries with severe stenosis (>70%) and good distal run-off, in order to minimize the effect of competitive native flow.

Data Collection and Analysis

Demographic and intraoperative data were recorded. Patients were followed throughout their hospital stay and for 3 months after hospital discharge. Post discharge data were collected through office visits, physician reports or telephone encounters.

Categorical variables are presented as frequencies and percentages. Continuous variables are expressed as mean ±SD or medians with ranges. All patients' data were tabulated and processed using SPSS V14.0 (Korean version; SPSS Inc., Chicago, IL, USA).

Results

Patients demographics, preoperative characteristics, operative data and postoperative data are shown in tables (1), (2), (3) and (4).

All patients received LITA graft to bypass the LAD, and one RA graft or RITA graft, with or without additional GSV grafts. RA or RITA grafts were always anastomosed proximal to LITA in a Y- or T-fashion. The LITA was used to sequentially graft a diseased diagonal branch and the LAD artery in 3 patients in the RA group and 4 patients in the RITA. Figure (1) shows the RA and RITA target vessels distribution. The obtuse marginal artery was the main target in the RA group (46.7%) as well as in the RITA group (53.3%).

There was only one in-hospital mortality (3.3%). This complicated an inferior myocardial infarction secondary to occlusion of a venous graft to PDA. We encountered one case of RA spasm that was completely reversed by the re-initiation of IV vasodilator. One patient in the RITA group developed sternal wound dehiscence that required sternal rewiring. He was a 58 year old male, obese, smoker with COPD.

During the 3-month follow up, myocardial ischemia or infarctions were not encountered. Four patients required re hospitalization (6.9%); one patients in the RA group (3.4%) and three (10.3%) in the RITA group. Symptomatic atrial fibrillation was the main culprit. None of these hospital admissions were found related to myocardial ischemia or compromise of the RA or RITA grafts.

	RA	RITA
← No. of patients	30	30
← Clinical characteristics:		
- Age (years)	57.8±6.7 years (40-68 years)	56±7.2 years (38-67 years)
- Female	10 (33.3%)	6 (20%)
← Coronary risk factors:		
- Hypertension	12 (40%)	14 (46.6%)
- Diabetes	14 (46.6%)	6 (20%)
- Hyperlipidemia	18 (60%)	20 (66.6%)
- Smoking	20 (66.6%)	23 (76.6%)
- Obesity(BMI≥30 kg/m ²)	14 (46.6%)	6 (20%)
- Family history	4 (13.3%)	4 (13.3%)
← Co-morbidity:		
- CVD	2 (6.7%)	3 (10%)
- PVD	2 (6.7%)	4 (13.3%)
- COPD	4 (13.3%)	5 (16.6%)
← Cardiac profile:		
- Previous MI	6 (20%)	8 (26.6%)
- EF:		
• ≥50%	25 (83.3%)	24 (80%)
• <50%	5 (16.6%)	6 (20%)
• EF% (mean ± SD)	54.6 ± 6.2	53.5 ± 6.1
- CCS:		
• I	3 (10%)	2 (6.67%)
• II	5 (16.6%)	6 (20%)
• III	18 (60%)	20 (66.6%)
• IV	4 (13.3%)	2 (6.67%)
← Angiographic profile:		
- 2- vessel disease	5 (16.6%)	8 (26.6%)
- 3- vessel disease	25 (83.3%)	22 (73.3%)
- Left main disease	6 (20%)	5 (16.6%)
- Previous angioplasty	7 (23.3%)	10 (33.3%)

BMI= Body Mass Index, CVD= Cerebrovascular Disease, PVD= Peripheral Vascular Disease, COPD = Chronic Obstructive Pulmonary Disease, MI= Myocardial Infarction, EF= Ejection Fraction, CCS= Canadian Cardiovascular Society angina classification

Table 1. Preoperative patients' characteristics

	RA Group	RITA Group
← Total operative time (minutes)	310.0±48.3	353.0±60.2
← Total bypass time (minutes)	118±34.3	124±29.4
← Total aortic cross-clamp time (minutes)	67.8 ± 21.4	72.3±18.2
← RA/RITA Harvest time	31.0±9.3	40.3±12.5

Table 2. Operative data

	RA	RITA
• Total No. of distal anastomosis	105	98
• No. of distal anastomosis per patient	3.5 (2-5)	3.2(2-5)
• Total No. of LIMA anastomoses	33/105 (31.4%)	34/98 (34.7%)
• Total No. of arterial anastomoses	63/105 (60%)	64/98 (65.3%)
• Total No. of GSV graft distal anastomoses	42/105 (40%)	34/98 (34.7%)
• Total arterial revascularization	3 (10%)	4 (13.3%)

Table 3. Grafting patterns in the study group

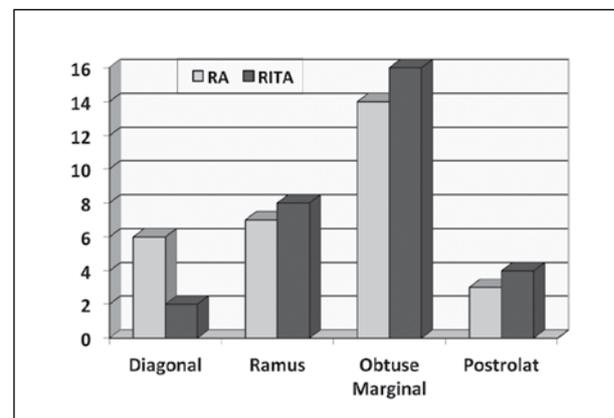


Fig 1. Distribution of RA and RITA target vessels

	RA group	RITA group
• In-hospital mortality	1 (3.3%)	None (0%)
• ICU stay (hours):		
Mean ±S.D	52.6±19.3	51±15.8
Median	46	46
• Hospital stay (days)	6.2 ± 2.0 days	6.1±1.8
• Mechanical ventilation (hours)	10.6 ± 20	11.6±16.2
• Prolonged Mechanical Ventilation (>24hours)	1 (3.3%)	2(6.7%)
• Inotropic support (dose of adrenaline)	0.03 ± 0.045 μg/Kg/min	0.03 ± 0.053 μg/Kg/min
• IABP support	1 (3.3%)	None (0%)
• Postoperative MI	1 (3.3 %)	None (0%)
• Postoperative ischemia	2 (6.7%)	None (0%)
• Postoperative atrial fibrillation	6(20%)	5(16.7%)

	RA group	RITA group
• Mean CK-MB level (IU/L)	12.5±9.5	11.8±9.3
• Re-exploration for bleeding	1 (3.3%)	2 (6.7%)
• Transfusion requirements:	2.2±1.7 units	2 ± 0.75 units
- Packed RBCs (units)	2.5±1 units	2.2 ± 1.3 units
- Fresh frozen plasma (units)	8.0±3.5 units	8.0 ± 3.5 units
- Platelets (units)		
• RA harvest site complications:	-	-
- Hand ischaemia	10 (33.3%)	-
- Paresthesias	1 (3.3%)	-
- Hematoma	-	-
- Forearm wound infection	-	-
- Functional impairment	-	-
• Sternal wound complications	None (0%)	1(3.3%)
• Acute renal failure	1 (3.3%)	-
• Cerebrovascular accident	None (0%)	None (0%)

Table 4. Postoperative morbidity and mortality

Discussion

Multiple strategies have been adopted to improve the outcomes and avoid potential drawbacks of both RA and RITA as conduits for coronary artery bypass grafting. Harvesting the ITA as skeletonized graft and minimizing the use of diathermy has shown to be associated with better preservation of sternal vascularity and perfusion which can potentially reflect on lower incidence of sternal wound complications^{14,15}.

On the other hand, meticulous harvesting techniques (no-touch, delicate manipulation, avoidance of intraluminal instrumentation) and development of different antispasm protocols decreased the incidence of RA vasospasm post-operatively^{13,16}. The routine preoperative use of duplex scanning to assess the quality of RA may have helped to identify diseased RAs and to have them excluded from being used as a bypass conduit, a practice that also protected from inadvertent exploration of the forearm¹⁶.

In summary, our study did not show any significant differences between the RITA and the RA graft as regards to operative mortality, perioperative myocardial ischemia, myocardial infarction, hospital stay or incidence of deep sternal wound infections. It was obvious that both RA and RITA grafts can be safely used to achieve multiple arterial revascularization with the hope of improving long term outcomes as measured by better survival, less cardiac related events and lower rate of repeat revascularization.

When the radial artery is harvested, we recommend harvesting it as a pedicled graft, avoiding mechanical distension, no-touch harvesting technique, starting IV calcium channel blockers preoperatively, throughout the procedure and continuation of oral regimen postoperatively for at least 3-6 months. We believe all of these measures should decrease the incidence of RA graft vasospasm on the short term and increase graft longevity on the long run.

When bilateral ITA grafting is considered, meticulous harvesting technique, skeletonization of the ITA, branch clipping and division by scissors, minimizing the use of electrocautery and preserving ITA bifurcation will allow better preservation of sternal vascularity. Minimizing the usage of bone wax, and electrocautery on sternal edges and sternal closure with at least 8-10 sternal wires will probably decrease the incidence of sternal wound infections.

Unfortunately we were unable to answer the question "which conduit is better". This is potentially because of the small number of patients we recruited, short follow up and relatively low morbidity and mortality in this study.

Sometimes the answer has to be tailored for each patient. We believe that in addition to technical considerations, surgeons should take into account patient's expected survival and characteristics, related co morbidities, target vessel anatomy, surgical and institutional expertise before deciding which conduit to use.

The RAPCO trial; randomized controlled trial illustrates that when patients receive a left in-situ ITA graft to the LAD, the next best target may be grafted equally with a RA or a free RITA to achieve similar clinical outcomes at mean 6-year follow-up (Hayward *et al.*, 2007).

In the light of these results and our results we believe that surgeons have a high degree of flexibility to offer the majority of patients more the one arterial conduit to achieve multiple arterial revascularization (MAR) and even total arterial revascularization (TAR). This has the potential of providing unique advantage to higher risk patient population, with multiple co morbidities that will markedly benefit from multiple arterial revascularization.

Study Limitations

The limitations of our study included the relatively small number of patients that may have obscured small differences between the studied conduits. Longer term follow up was needed to appreciate discrepancies in patency. Our study was observational, which resulted in some selection bias. This was evident with the higher prevalence of diabetes and obesity in patients receiving RA graft. We hope that this study encourage many of our surgeons to increase their utilization of BITA in these high risk patients.

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Chordal Transfer Versus Chordal Replacement in Anterior Mitral Leaflet Prolapse

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Amr Rouchdy³

Objective: The aim of the study is to compare the effectiveness of chordal transfer (transposition) and chordal replacement using artificial PTFE chordae to treat pure mitral valve insufficiency due to anterior mitral leaflet (AML) prolapse.

Patients and Methods: In a prospective, comparative, and non-randomized study, 40 patients diagnosed of having mitral valve regurgitation (MR) due to anterior mitral leaflet prolapse were included. The patients were divided into two groups well-matched for age, sex and preoperative risk factors. Group A: (20 patients) who underwent mitral valve repair, by chordal transfer; and Group B: (20 patients) who underwent mitral valve repair by artificial (PTFE) chordae replacement. Patients were followed for 5 years postoperatively.

Results: There was no statistically significant differences regarding the total cardiopulmonary bypass time, aortic cross clamp time, and the need for inotropes. Neither mortality nor conversion to mitral valve replacement occurred intraoperatively. In both groups, there was a matchable obvious improvement in the patient's symptomatology during postoperative follow-up by clinical examination and echocardiography. Despite no statistical significance between both groups, there was a favorable step-up in the postoperative NYHA's clinical condition. After 2 years of follow up in both groups, there was no recurrence of severe MR, no reoperation, and no mortality. At 5 years of follow up, 2 patients of group A (12.5%) and 1 patient in group B (6.6%) had severe MR necessitating reoperation. There were no morbidity complications, thromboembolic episodes nor anticoagulant related hemorrhage and there appears to be preserved and improving LV function.

Conclusion: Both surgical procedures were performed with no mortality, acceptable low morbidity and reasonable technical ease. We hence considered both techniques to be soundly-safe, easy to perform, under TEE guidance, and are hence reproducible. However, Chordal replacement was found more durable at 5 years of follow up.

KEYWORDS: Mitral valve – repair-insufficiency – anterior leaflet-leaflet prolapse - chordae Tendinae-chordal transfer - artificial chordoplasty

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Mitral valve repair is the treatment of choice in patients with pure mitral valve insufficiency. Even well functioning prosthetic valves, have inferior haemo-dynamics compared to native valves. Prosthetic valves are associated with higher morbidity due to thromboembolism, anticoagulant-related hemorrhage and endocarditis¹.

Anterior mitral leaflet prolapsed (AML) is technically challenging for repair. Some surgeons prefer chordal transfer, claiming that it is technically-easier requiring moderate experience but allowing sound leaflets coaptation with no-need for complex measurements^{1,2}. While others preferred artificial chordae for better durability³.

This prospective study was carried out to compare and evaluate the surgical results of two patient groups having mitral insufficiency (due to AML prolapse) that underwent mitral valve reconstructive procedures. We studied two methods of repair namely chordal transfer versus chordal replacement by artificial chordae as regards their intraoperative efficiency; as well as midterm (five years) postoperative durability.

Patients and Methods

Between April, 2006 and April 2009, 40 patients had mitral repair for AML prolapse, in Cairo University hospitals. Patients were divided into two non-randomized equal groups: **Group (A)**: Including **20** patients who underwent mitral valve repair, by chordal transfer and **Group (B)**: Including **20** patients who underwent mitral valve repair by artificial chordate.

Patients with ejection fraction less than 40 % were excluded from this study. All patients signed an informed consent. All data were collected in an Excel based sheets. Preoperative patient characteristics and detailed Transthoracic echocardiography were noted.

Operative Technique

All patients had intraoperative trans-esophageal echocardiography (TEE). Systematic valve analysis begins with TEE evaluation. Proper identification of the prolapsed segment and the magnitude of jets allowed for proper planning for the type of repair. Standard median sternotomy and cardiopulmonary bypass were used in all patients.

For mitral valve exposure, left atrial approach was used in 13 patients in group A and 15 patients in group B. Transeptal approach was used in 5 patients in group A and 4 patients in group B. Extended trans-septal approach was used in 2 patients

in group A and 1 patient in group B. Once the valve is exposed, iced saline is injected into the LV and the valve competency and motion assessed noticing also the direction of regurgitation.

Valve analysis started by systematic evaluation of the annulus for dilatation and/or deformity. Nerve hooks were used to assess leaflet pliability and to assess leaflet prolapse or restriction. All chordae tendinae were then examined to evaluate length, thickening, fusion, or rupture. Finally, the papillary muscles were assessed, looking for elongation.

In group A patients, a "chordal transfer" was done to the anterior leaflet in order to support its abnormal mobility (prolapse). A solid normal 2ry Chorda was identified adjacent to the prolapsing area of the AML. The chorda was detached 2 mm from the margin of the body of the leaflet. The 2ry Chorda was then reattached to the free margin of the AML using a figure-of-8 6/0 polypropylene suture. Prosthetic ring remodeling annuloplasty was then inserted by multiple interrupted sutures taking more distance in the ring compared to the patient's annulus. Another method of chordal transfer is the chordal transposition, where part of the posterior leaflet (opposing the prolapsed part in the anterior leaflet) is detached with its attached chordae from the posterior leaflet and sutured to the prolapsed area in the anterior leaflet.

In group B patients, "artificial chordoplasty" was done. An artificial pledgeted CV-4 Gore-Tex chorda was placed into the head of the papillary muscle at the initial phase of the repair, before remodeling annuloplasty and is left aside while the leaflet reconstruction is performed. After remodeling annuloplasty, systemic leaflet apposition limits valve incompetence to the prolapsing anterior leaflet segment.

Also, both arms of the Gore-Tex suture are passed through the free edge of the prolapsing leaflet from the ventricular to

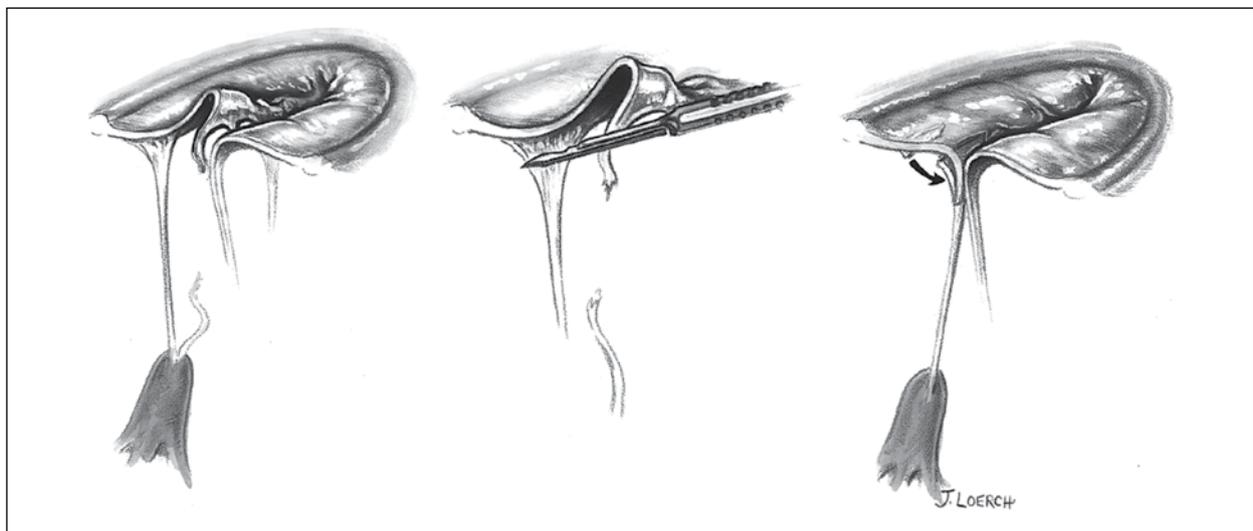


Fig 1. Chordal transfer from anterior leaflet. A normal secondary chord is transferred from the body to the free edge of the anterior leaflet to correct prolapse caused by anterior chordal rupture (Carpentier, 1983).

the atrial side. If the native chorda to the corresponding part of the opposing leaflet are normal, the edges of the anterior and posterior leaflet are temporarily approximated by a simple or figure 8 suture and then the suture is tied against the temporary suture. Three knots are used. The suture is passed again through the edge of the leaflet from the ventricular to the atrial side and tied permanently. Thus the optimal artificial chordal height was determined as described by Sarsam⁴.

In both groups testing for residual MR was done in two ways: 1st. before closure of the left atriotomy consisting of manual injection of saline inside the left ventricular cavity by a pump. The 2nd method of confirmation was by TEE after the left atriotomy was closed and going off bypass.

Follow up

Patients were followed up for 5 years postoperatively. Symptoms, residual or new onset MR detected by transthoracic echocardiography and survival were analyzed.

Statistical Analysis

Management of data was done using SPSS package (Statistical Package for the social science). Descriptive measures included mean and standard deviation. Taking the raw data from the database in MS Excel® for Windows version 2003, these data were transferred to Smith's Statistical Package version 1 (SSP) and then analyzed. Comparison of mean of 2 independent groups was done using student t test. Chi square testing was done to compare (qualitative variables) such as sex and NYHA. *p* value is considered significant when the test value equals to or less than 0.05 .

RESULTS

All patients were matched in both groups regarding age, sex, and echocardiographic criteria. preoperative patient characteristics were shown in table (1). 15 patients (75%) of group A and 17 patients (85%) of group B had rheumatic aetiology versus 5 patients (25%) in group A and 3 patients (15%) in group B had a degenerative aetiology. Associated mitral valve pathology were shown in table (2).

The distribution of AML prolapse was shown in table (3). In group A, **Chordal Transfer** was done in 20 (100%) of patients. Commissural Splitting was done in 3 patients (15%), insertion of fixed Carpentier rigid annuloplasty ring was done to correct annular dilatation in 13 patients (65%) pericardial annuloplasty in 4 (20%) and band annuloplasty in 3 (15%) and dissection of subvalvular involvement (fusion) by papillary muscle splitting or fenestration was done in 6 patients (30%). In group B, **Chordal Replacement** was done in association with Commissural Splitting was done in 4 patients (20%), insertion of fixed Carpentier rigid annuloplasty ring was done to correct annular dilatation in 14 patients (70%), pericardial

patch annuloplasty in 2 patients (10%) and band annuloplasty in 4 patients (20%) and dissection of subvalvular involvement (fusion) by papillary muscle splitting or fenestration was done in 5 patients (25%)

In group A, the range of The aortic cross clamp time was 39-55 minutes with the mean of 40.2 ± 3.14 min; versus 43-62 minutes in group B with the mean of 43.4 ± 6.22 min, with no statistical significance as $p < 0.14$.

Intraoperative postbypass TEE revealed, a competent mitral valve repair in 18 (90%) of group A patients; versus 19 (95%) in group B. Two patients had Trivial Residual MR in group A (10%), versus 1 patient in group B (5%) with no statistical significance.

Echocardiographic data in the immediate postoperative period prior to discharge showed improvement versus preoperative values but with no statistical significance in favor of either groups. There were 3 patients (15%) with residual trivial MR in group A; versus 2 patients (10%) in group B. (Table 4)

After one year, one patient in each group was lost follow up. Echocardiographic data 12 months postoperatively showed improvement from 6 months postoperative results but with no statistical significance in favor of either group. In group (A), there was 1 patient (5.2%) with residual trivial MR; 1 (5.2%) having Mild MR; and 2 (10.5%) having Moderate MR. In group (B), 1 patient (5.2%) had Mild MR, while another 1 (5.2%) had Moderate MR (table 5)

Follow up was 92.5% complete at 2 years as 3 patients were lost during the study course: 2 patients in group A and one patient in group B. there was no recurrence of severe MR, no reoperation, no mortality, no thromboembolic episodes nor anticoagulant related hemorrhage and there appears to be preserved and improving LV function **NYHA Class** ranged between 0-2 (mean 0.8 ± 0.3) in group (A) and 0-2 (mean 0.7 ± 0.2) in group B with no statistical significance (*p* value 0.31). Echocardiographic data showed improvement versus preoperative results but with no statistical significance in favor of either group. There was 1 patient with mild MR in each group (5.5% in group A versus 5.2% in group B). In group A, there were 2 patients (11.1%) with moderate MR versus 1 patient (5.2%) in group B. The MR Jet area ranged from 4.9 cm^2 (mean of $6 \pm 1.7 \text{ cm}^2$) in group A; versus 5-8.5 cm^2 (mean of $6.1 \pm 1.4 \text{ cm}^2$) in group B with no statistical significance (*p*-value 0.35).

At 5 years follow up was 77.5% completed, 4 patients of group A and 5 patients of group B were lost. Severe MR was found in 2/16 patients in group A (12.5%) and 1/15 patient in group B (6.66%). Moderate MR was found in 4/16 patients in group A (25%) versus 3/15 Patients in group B (20%). All other patients had trivial to mild MR (10/16 patients in group A (62.5%) and 11/15 patients in group B (73.33%). Patients with severe MR had a redo mitral valve replacement.

		Group A	Group B	p-value
Age	Range	16-48 yrs	20-50 yrs	0.71 (NS)
	Mean \pm S.D	30.85 \pm 8.55	33.4 \pm 8.13	
Sex	Female	13 (65%)	14 (70%)	0.75 (NS)
	Male	7 (35%)	6 (30%)	
	Asymptomatic	2 (10%)	1 (5%)	
Indications of surgery	Dyspnea	FCII 8 (40%)	10 (50%)	0.79 (NS)
		FCIII 10 (50%)	9 (45%)	
	AF (new onset)	5 (25%)	6 (30%)	
	Pulmonary hypertension	9 (45%)	7 (35%)	
Associated disease	Diabetes	2 (10%)	3 (15%)	0.24(NS)
	hypertension	5 (25%)	3 (15%)	
	COPD	1 (5%)	2 (10%)	
Other lesions	Tricuspid valve disease	11 (55%)	9 (45%)	0.32(NS)
	Aortic valve disease	3 (15%)	4 (20%)	
Echo criteria	LVEDD	Range 6.1-7.9	6.2-7.7	0.72 (NS)
	Mean	6.95 \pm 0.57	6.89 \pm 0.48	
	LVESD	Range 4.5-6.0	4.2-5.9	
	Mean	5.1 \pm 0.4	4.94 \pm 0.45	
	LVEF	Range 40-52	40-54	
	Mean	45.15 \pm 6.85	45.7 \pm 5.92	
Echo criteria	LAD	Range 4.5-7.9	4.8-7.7	0.39(NS)
	Mean	6.3 \pm 0.98	6.4 \pm 0.87	
	MVA	Range 3.6-5.0	3.8-5.3	
	Mean	4.55 \pm 1.3	4.32 \pm 1.1	
	MR	Moderate 6 (30%)	5 (25%)	
	Severe	14 (70%)	15 (75%)	
	Jet area(cm ²)	8.1 \pm 2.15	8.6 \pm 1.13	

NS=non-significant, AF=atrial fibrillation, COPD=chronic obstructive pulmonary disease, LVEDD=left ventricular end diastolic volume, LVESD=left ventricular end systolic volume, LAD= left atrial diameter, MAV=mitral valve area, MR=mitral regurge

Table 1. Preoperative patient characteristics

	Group A			Group B		
	Commissural fusion	Annular dilatation	Subvalvular involvement	Commissural fusion	Annular dilatation	Subvalvular involvement
No.	4	13	6	5	14	5
%	20%	65%	30%	25%	70%	25%

Table 2. Associated mitral valve pathology

	Group A					Group B				
	A1	A2	A3	A1+2	A2+3	A1	A2	A3	A1+2	A2+3
No.	5	4	3	4	4	4	3	5	5	3
%	25%	20%	15%	20%	20%	20%	15%	25%	25%	15%

No= Number of patients A1,2,3 refers to segments of anterior mitral leaflet (AML)

Table 3. Distribution of AML prolapse

Variable	Values	Group A	Group B	P value
Residual Trivial MR	No. and %	3 (15%)	2 (10%)	0.33*
	Range	6.1-7.7	6-7.5	
LVEDD(cm)	Mean	6.9 ± 0.55	6.82 ± 0.45	0.42*
	Range	4.3-5.9	4.9-5.7	
LVESD(cm)	Mean	5 ± 0.41	4.91 ± 0.4	0.12*
	Range	42-50	42-53	
EF%	Mean	49.2 ± 0.4	50.5 ± 0.2	0.37*
	Range	4.2-7.5	4.5-7.5	
LA (cms)	Mean	6 ± 0.95	6.2 ± 0.83	0.23*
	Range	1-3	1-2.9	
MR Jet Area(cm ²)	Mean	1.8 ± 0.2	1.7 ± 0.3	0.37*

EDD: End-Diastolic Dimension ESD: End-Systolic Dimension LA: Left Atrial Diameter FS: Fractional of Shortening EF% : Ejection Fraction%
MR: Mitral Regurge NYHA: New York Heart Association *: Data result is of no statistical significance

Table 4. In-hospital Postoperative Follow-up Data

Variable	Values	Group A	Group B	p-value
Residual MR	Trivial	1 (5.2%)	0(0%)	NS
	Mild	1 (5.2%)	1 (5.2%)	
	Moderate	2 (10.5%)	1 (5.2%)	
NYHA Class	Range	0-2	0-2	0.221*
	Mean	0.8 ± 0.7	0.6 ± 0.8	
LVEDD(cm)	Range	5-5.8	4.9-5.6	0.111*
	Mean	5 ± 0.4	5.1 ± 0.6	
LVESD(cm)	Range	3.3-4.3	3.1-4.2	0.23*
	Mean	3.1 ± 0.6	3.3 ± 0.3	
EF%	Range	50-56	51-57	0.33*
	Mean	52 ± 2.5	53 ± 0.7	
Jet Area of MR(cm ²)	Range	2-6	2.5-6.3	0.34*
	Mean	3.5 ± 0.9	3.7 ± 1.2	

EDD: End-Diastolic Dimension ESD: End-Systolic Dimension LA: Left Atrial Diameter FS: Fractional of Shortening EF% : Ejection Fraction%
PASP: Pulmonary Artery Systolic Pressure MR: Mitral Regurge NYHA: New York Heart Association *: Data result is of no statistical significance

Table 5. 12 Months Postoperative Follow-up Data

Discussion

Rheumatic fever remains the commonest cause of MR in the eastern communities. Pure regurgitant rheumatic valves have diffuse fibrous thickening of leaflets and elongated barely thickened chordae tendinae, and relatively non fused commissures⁵. Compared to degenerative valves, repair of rheumatic valves represents a surgical challenge^{6,7}, yet the advantages of mitral repair make it superior to replacement. Patients with mixed rheumatic stenosis and regurge are least amenable for repair⁸ and where avoided in this study. Bando et al showed a limited durability for repair of such patients and half of them will need a repeat operation within 14 years⁹.

In our study, we tried a simple method of repair that is technically less demanding namely the chordal transfer to test its efficacy compared to the sophisticated and technically demanding repair with artificial chordae. Our sample was homogeneous regarding the demographic data and pathology, However young females in the child bearing period represented about two thirds of our sample. We chose our surgical candidates from the moderately symptomatic population with early NYHA class. Our patient subset had moderate to severe MR with preserved left ventricular function and low percentage of atrial fibrillation (about quarter of cases) as we believed that only in this situation would surgery succeed to provide an optimal chance for a successful MV repair.

Accurate preoperative and intraoperative echocardiography is the corner stone to a successful surgery. Patients with severely distorted leaflets and fused commissures and amalgamated chordae were denied for repair¹⁰. The versatility of reconstructive techniques and the mixed patient population series created a mystery about the proper type of repair. Chordal transfer is limited by the availability of unaffected native chordal tissue¹¹

The most important late complication of mitral valve repair is recurrent MR, which may occur in as many as 30% of patients. The reoperation rate approximates 0.5 to 1.5% of patients per year¹² Failure after repair can be classified as immediate failure, early failure (<2 years) and late failure(>2 years). Immediate and early failures are often related technique whereas late failure is due to progression of the original disease. Late failure is often seen in patients having the rheumatic aetiology in contrast to early failures seen in degenerative valves^{13,14}

Late failures are often related to the progression of the disease with new prolapsing areas in patients with degenerative disease and progression of the fibrotic process in rheumatic patients. Several clinical series have reported a re-repair rate of 15-20%^{15,16}. There is a 7% to 10% reoperation rate at 10 years in patients undergoing mitral valve repair, for severe recurrent MR^{17,18}

In a similar study done by Kumar et al, 898 patients with rheumatic MR had a mitral repair both by chordal transfer and artificial chordae. Early results showed freedom from MR in

69% and 71% respectively. By the end of follow up there were Moderate MR in 18% and 16% of patients respectively and severe MR in 14% and 12% respectively¹⁹.

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Outcome of Australian Technique in Repair of Complete AV Canal Septal Defects

T. Salah, M.D.

Recent advances in understanding the anatomy of CAVC have led to alternative methods of repairing these defects. However, the technique used to close the inter-ventricular communication is still debated. Wilcox and colleagues ⁽¹⁾ introduced the modified single patch technique (Australian technique) of repair for patients of CAVC with small VSDs. The aim of the study was to evaluate the early results of repair of CAVC defects using the modified single patch technique and mid-term results after 1 year follow up.

Patients & Methods: Twenty Patients with CAVC defects undergone total repair using the modified single patch technique between January 2011 and March 2013 at Cairo university hospitals. Follow up was continued for 1 year with a closeout date March 2014. Preoperative, intraoperative, postoperative, and one year follow up data were analyzed and presented in that study.

Results: In that study, the mean±Sd age was 11.5±6.49 month, the mean± SD weight was 7.55±2.12 Kg. 11 patients (55%) were Down's syndrome, and 9 patients (45%) were not in Down's syndrome. As for sex distribution, there were 12 female patients (60%), and there were 8 male patient (40%) s. There were 15 patients (75%) Rastelli type A, 2 patients (10%) Rastelli type B, and 3 patients (15%) Rastelli type C. As for LAVV regurgitation, 9 patients (45%) had moderate Lt AV valve regurgitation, and 11 patients (55%) had severe Lt AV valve regurgitation. The Mean±Sd height of VSD was 6.2±1.73 mm, and the mean±Sd pulmonary artery pressure was 49.2±9.90 mmHg. As for intra operative results, the mean± Sd cross clamp time was 59±8.67 min, while the mean± Sd total bypass time was 74.25±12.48 min ,and the mean ±SD total operative time was 197.25±45.46 min. After weaning from the cardiopulmonary bypass, the patients' rhythms were recorded : sinus rhythm was restored in 16 (80%) patients, while 2 patients (10%) showed nodal rhythm and 1 patient (5%) showed 2nd degree Heart block which was managed by temporary pace maker which was transferred with the patient to the ICU. Postoperative results showed that the median mechanical ventilation time was 16 hrs, the mean± SD ICU stay was 3.57±0.96 days, and the mean±Sd total hospital stay was 7.47±1.17 days. We had one case of intraoperative mortality(5%) and two cases of ICU mortality(10.5%).The total in hospital mortality was 3 cases(15%). Fifteen patients (88.23%) completed there one year follow up echo-cardiography, none of the patients showed residual shunts or LVOT obstruction. we had Fourteen of the followed patients (93.3%) showed trivial to mild Lt AV valve regurgitation and one patient (6.6%) showed moderate Lt Av valve regurgitation which was managed medically by diuretics and ACE inhibitors.

Conclusion: The technique of modified single patch repair of CAVC defects appears to render the valve competent. It also provides a native continuity with the atrial and ventricular components, which might increase the solidity of the whole structure, reducing the risk for late dehiscence between the LAVV tissue and pericardial patch. However, larger series of patients and longer follow-up are required for an appropriate evaluation of this technique.

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Codex : o3/14/1409

There are few congenital anomalies of the heart that have benefited more from thorough anatomic analysis than the complex anomaly known as atrioventricular septal defect in the setting of common atrioventricular junction. Recent advances in understanding the anatomy of this lesion have led to alternative methods of repairing these defects.⁽¹⁾

Various surgical approaches have been developed since the first successful repair of complete atrioventricular septal defect (AVSD) in 1955 by Lillehei et al. However, the technique used to close the interventricular communication is still debated. Wilcox and colleagues⁽¹⁾ introduced the modified single patch technique of repair for patients of CAVC with small VSDs. Nicholson and colleagues⁽²⁾ advocated that the VSD patch could be avoided in most cases of complete AV canal with moderate and large VSD.

The Modified single-patch technique (the so-called Australian technique) is now becoming more and more popular. A primary characteristic of the modified single-patch technique, is the obliteration of interventricular communication by direct attachment of the bridging leaflet to the septal crest, lowering the level of the left AV valve implantation at the crest of the septum, increasing the area of coaptation resulting in better competence. The creation of a competent left atrioventricular valve is the cornerstone in successful AVSD surgical repair, as LAVV regurgitation remains the most important complication following AVSD correction, ranging from 3 to 18%.⁽³⁾

The aim of that study was to evaluate the early results of repair of CAVC defects using the modified single patch technique and the mid-term results after 1 year follow up.

Patients and Methods

Twenty Patients with CAVC defects undergone total repair using the modified single patch technique in the period between January 2011 and March 2013 at Cairo university hospitals. Follow up was continued for 1 year with a closeout date March 2014. Patients of CAVC with Tetralogy of Fallot (TOF), double outlet right ventricle (DORV), ventricular hypoplasia and anatomical variants not compatible with biventricular repair were excluded from the study.

Preoperative Parameters

After approval of local ethical committee and written consent from parents or guardians, all patients were subjected preoperatively to complete history taking & full clinical examination. Routine preoperative investigations were done with special emphasis on Echo cardiography (cardiac dimensions, contractility, Cardiac valves, pulmonary artery pressure and the Rastelli type). Cardiac catheterization & angiography were performed when pulmonary artery pressure was near systemic to determine operability or the possibility of staged repair following pulmonary artery banding.

Intraoperative management

Surgical technique

All operations were performed with cardiopulmonary bypass (CPB), moderate hypothermia, aortic cross-clamp (ACC) application, and the infusion of antegrade blood cardioplegic solution. The operation was done through a right atriotomy parallel to the right AV groove, extending from the right atrial auricle to the level of the entrance of the inferior caval vein. Cold saline solution was used to fill the ventricular chambers and float the AV valve tissue into a closed position to establish the line of coaptation between the superior and inferior components of the valve and to identify the proper line of separation into right and left parts of these components. Direct suture closure of the ventricular component was done by placing 6-0 polypropylene mattress sutures with Teflon pledgets into the right ventricular aspect of the muscular septum. These sutures were placed well below the crest of the septum to avoid damage to the exposed conduction tissue. These sutures were then passed through the superior and inferior bridging leaflets at an appropriate point of separation, demarcating the boundary between right and left components of the superior and inferior bridging leaflets. When appropriate, these sutures were placed toward the right side of the valve tissue, producing a more generous left atrioventricular valve. When possible, 5-0 stay suture was placed in the zone of opposition, or "cleft," between the bridging leaflets before septal suture placement, in anticipation of later repair, usually, to enhance visualization. These septal sutures were then used to anchor the leading edge of a pericardial patch used to close the primum ASD defect. Tying these sutures obliterated the ventricular septal component. After these septal sutures were tied, the left atrioventricular valve was repaired using simple 5-0 polypropylene sutures on the cleft. Testing of the Lt Valve competence was done using the water test. Then a continuous suture was used in the remaining part of the pericardial patch to close the atrial component of the CAVC defect, usually leaving the coronary sinus on the right side. In case of presence of ASD secundum, it was closed either by direct suture or by another pericardial patch. In some cases, the Rt AV valve was also repaired by 5-0 polypropylene suture to reattach the floating leaflets to the pericardial patch. (Picture 1)

After finishing the CAVC repair, closure of right atriotomy was performed by running 6/0 prolene sutures. Weaning from the CPB, decannulation, homeostasis and routine closure of chest were done.

Intra-Operative Parameters:

- Cross-clamp time, total bypass time and total operative time
- Use of inotropes after weaning from cardiopulmonary bypass.
- Patient rhythm on discharge from the operating theatre.



Picture 1. CAVC repair using modified single patch technique.

Postoperative Management

Postoperative management was based on optimizing the cardiac output and avoiding pulmonary hypertensive crisis. Attention was paid to hypoxia, hypercapnea, acidosis, pain, and hypothermia which are the triggers of pulmonary vasospasm.

Postoperative Parameters

1. Postoperative mechanical ventilation time.
2. Incidence of pulmonary hypertensive crisis.
3. Chest tube drainage.
4. Patients rhythm in the ICU.
5. Total intensive care unit stay & total hospital stay.
6. Postoperative morbidities and in-hospital mortality. (Death within 30 days of the operation)
7. Follow up echocardiography before hospital discharge to assess residual shunts and atrioventricular valvular function.

Follow up

The patients were assessed in the follow-up visit after 1 year by echocardiography, to assess residual shunts, atrioventricular valvular function and LVOT obstruction. The LAVVR was graded as trivial (I), mild (II), moderate (III), and severe (IV) depending upon the degree of opacification of the left atrium and observation under a color Doppler signal. Mitral valve (MV) stenosis was considered when the mean transvalvular gradient was more than 5 mm Hg.

Statistical analysis

Data were statistically described in terms of frequencies (number of cases), relative frequencies (percentages), mean, standard deviation values (SD) and median (range) as appropriate. All statistical calculations were done using Microsoft excel 7 computer program (Microsoft cooperation, NY, USA).

Results

Preoperative results

Patients' demographic data were shown in table (1).

	Range	mean±Sd	median
Age (month)	6-30	11.5±6.49	9
Weight (Kg)	5.5-12	7.55±2.12	7

Table 1. Demographic data of the patients

In that study, 11 patients (55%) were Down's syndrome, and 9 patients (45%) were not Down's syndrome (Figure 1). As for sex distribution, there were 12 female patients (60%), and there were 8 male patients (40%).

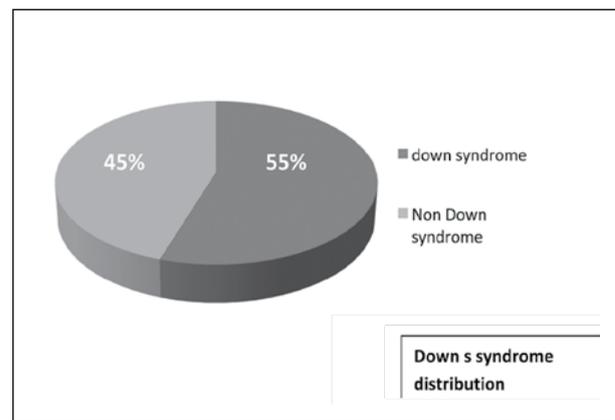


Fig 1. Down's syndrome distribution in our patients

Preoperative Echocardiographic data

As for AVCD classification, there were 15 patients (75%) Rastelli type A, 2 patients (10%) Rastelli type B and 3 patients (15%) Rastelli type C. As for LAVV regurgitation, 9 patients (45%) had moderate Lt AV valve regurgitation, and 11 patients (55%) had severe Lt AV valve regurgitation. These data were shown in Figure (2) (3). Other echocardiographic data were shown in table (2).

	Range	Mean± SD	Median
VSD height (mm)	4-9	6.2±1.73	6
PAP(mm hg)	30-65	49.2±9.90	50

Table 2. Preoperative echocardiographic data of the patients

Cardiovascular

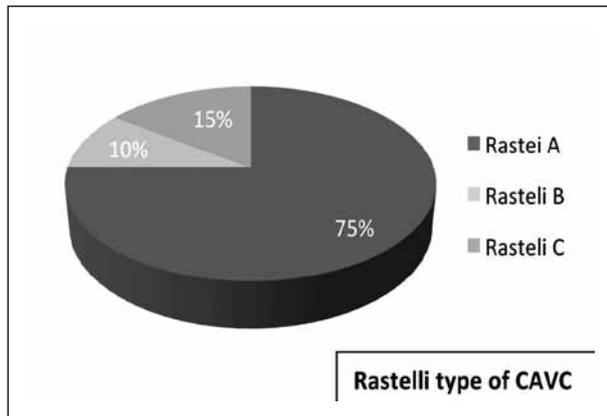


Fig 2. Rastelli distribution of the Patients

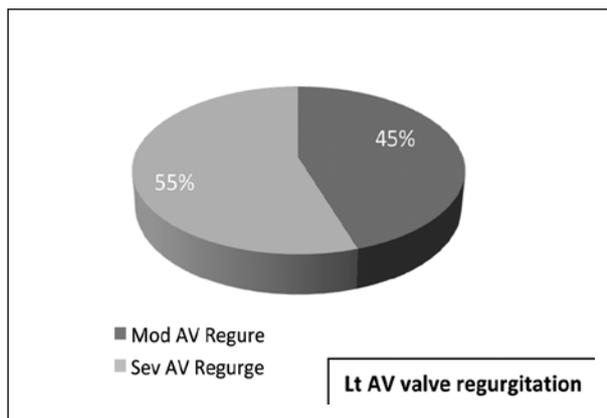


Fig 3. Degree of Lt AV valve regurgitation in the patients

PA banding was performed in 3 patients (15%) in our study before complete repair of CAVC. Associated anomalies in the patients with CAVC were shown in table (4).

	Number of patients	percentage
Previous PA banding	3	15%
PDA	5	25%
PFO	3	15%
ASD secundum	4	20%
LSVC	3	15%
Muscular VSD	2	10%

Table 4. Associated anomalies of the patients

Intraoperative results

The intraoperative surgical data were collected and presented in table (5).

	Range	mean±Sd	median
Cross clamp time (min)	50-75	59±8.67	57.5
Total bypass time (min)	60-100	74.25±12.48	70
Total operative time (min)	165-350	197.25±45.46	180

Table 5. Cross clamp time, Bypass time and total operative time

Gradual weaning from cardiopulmonary bypass was done in all patients. Inotropic support in the form of Adrenaline infusion (100-250 µg/kg/h) was used in 14 patients (70%) of patients. All patients received variable doses of vasodilators, in the form of Nitroglycerine infusion. Milrinone infusion (0.5 µg/kg/min) was used in 12 patients (60%) of that study.

Intraoperative mortality

We had one case of intraoperative mortality (5%) due to failure of weaning from cardiopulmonary bypass inspite of maximum pharmacological support and prolonged support on cardiopulmonary pass. That patient had CAVC with a mid muscular VSD which was closed with the repair of CAVC. After trials of weaning from CPB, the heart was arrested again by Cardioplegia and the intracardiac repair was revised but no abnormality was detected, then trials of weaning from CPB were done with maximum Pharmacological support, but the patient developed severe low cardiac output with failure of weaning from cardiopulmonary bypass.

Patients Rhythm

After weaning from the cardiopulmonary bypass, the patients' rhythms were recorded : sinus rhythm was restored in 16 (80%) patients, while 2 patients (10%) showed nodal rhythm and 1 patient (5%) showed 2nd degree heart block, pacing using temporary pace makers was done at this stage and the pace maker was transferred with the patient to the ICU.

Postoperative results

Postoperative results of the patients were shown in table (6).

	Range	Mean ±SD	Median
Mechanical ventilation time (hrs)	6-130	In appropriate	16
Chest tube drainage during 1 st 24 hrs(ml)	50-250	113.6844.87±	100
Total ICU stay(days)	3-7	3.570.96±	3

Table (6). Postoperative results of the patients.

Recurrent attacks of pulmonary hypertensive crises developed in 6 patients (31.5%) in that study, while no pulmonary hypertensive crises attacks occurred in 13 patients (68.5%) in that study. Those attacks were managed by hyperventilation with higher positive airways pressures, sedatives using IV shots of Fentanyl at a dose of 3 - 5 µcg/kg or Dormicum (Midazolam) at a dose of 0.2 mg/kg and sometimes muscle relaxants using IV boluses of Pancuronium at a dose of 0.1 mg/kg.

The patient's rhythm was recorded in the ICU. We had 18 patients (94.7%) of patients were in sinus rhythm and one patient (5.3%) showed accelerated nodal rhythm which was managed conservatively.

In hospital Mortality

We had 2 cases (10.5%) of in hospital mortality during the ICU stay. The first patient died during the second postoperative day due to severe pulmonary hypertensive crises which was failed to be managed by the protocol of management of pulmonary hypertensive crises described before. The second case died during the 7th postoperative day due to septicemia secondary to severe chest infection after prolonged ventilation. The overall in hospital mortality of the study was shown in table (7).

	Mortality/total number	Percentage
Intraoperative mortality	1/20	5%
ICU mortality	2/19	10.5%
Total in hospital mortality	3/20	15%

Table (7) Total In hospital mortality

All patients were examined during their hospital stay by echocardiography to determine patch leaks, residual VSD, and left AV valve insufficiency. No patients showed residual VSD leak or patch leak from the ASD patch. 16 patients (94.1%) showed trivial to mild Lt AV valve regurgitation while 1 patient (5.9%) showed mild to moderate Lt AV valve regurgitation. figure (4).

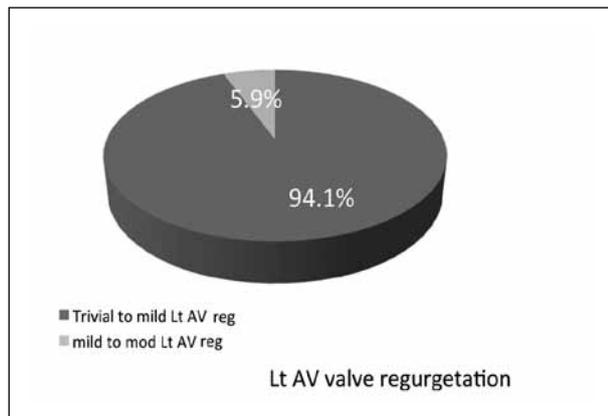


Fig 4. Lt AV valve regurgitation by in hospital echocardiography

Postoperative complications of the patients were recorded during their hospital stay. Those data were shown in table (8).

	Number	Percentage
Chest infection	2	11.76%
Arrhythmia (Nodal)	1	5.8%
No complication	14	82.35%
Total number of patients	17	100%

Table (8) postoperative complications

The total hospital stay of the patients ranged from 6-9 days with mean±Sd 7.47±1.17 and a median of 7 days. All patients were discharged from the hospital on diuretics 2 mg/Kg/day and Captopril 1 mg/Kg /day.

Follow up results

Complete follow up echocardiographic data was available after 1 year for 15 patients (88.23%) out of the 17 patients who were discharged from the hospital, while 2 patients (11.77%) did not show up at their 1 year follow up visit. No haemodynamically significant residual lesions were found in the patients who completed the follow up and none of the patients developed LVOT obstruction. Fourteen of the followed patients (93.3%) showed trivial to mild Lt AV valve regurgitation and one patient (6.6%) showed moderate Lt Av valve regurgitation which was managed medically by diuretics and ACE inhibitors. Figure (5).

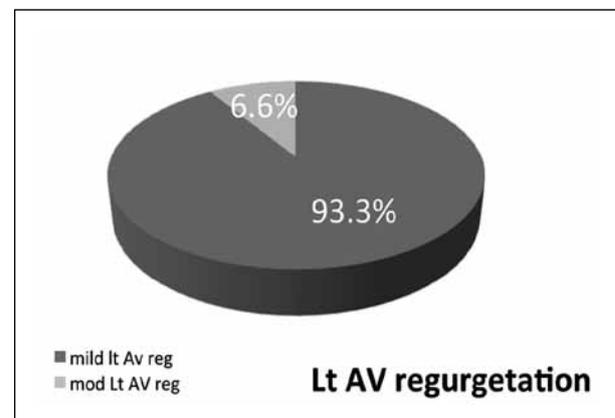


Fig 5. Lt AV valve regurgitation by echocardiography after 1 year follow up.

Discussion

Surgical correction of the AVSD has undergone continuous improvements regarding the employed surgical techniques, myocardial protection, preoperative management, and decreased age at repair.⁽⁴⁾

In the early years of open heart surgery, such defects were often thought of as simply another form of atrial or ventricular septal defects in the setting of common atrioventricular junction. These hearts are now understood to be much more complicated in their deformation. Perhaps most important from a surgical point of view was the realization that the atrioventricular valves in such hearts are unique structures, not merely distortions of the usual mitral or tricuspid valves.⁽⁵⁾

Repair before 6 months of age is common however medical therapy is generally used in neonates and low-weight birth babies primarily because of technical concerns about the fragility of the CAVV tissue. The common scenario of the AVSD is that soon after the fall of pulmonary vascular resistances (first month of life) the QP/QS rises and chronic heart failure develops. Pulmonary vascular disease develops during the first year of life. Intimal fibrosis of the pulmonary vessels can be found already at the age of 6 months. Another argument in favor of repair in early infancy is the possible increase in degenerative changes of the CAVV as the age increases.⁽⁴⁾ In fact, a competent common A-V valve seems to be less frequent with increasing age at operation. As demonstrated by Michielon et al.⁽⁶⁾ repair at an early age is associated with a very good likelihood of preoperative competence of common A-V valves, despite the presence of a 'cleft' in the left A-V component.

Palliation for AVSD with pulmonary artery banding remains an important option particularly in children with low birth weight or major extra cardiac morbidity. Palliative strategy may also be appropriate when a definitive repair may require a valved conduit; particularly in the presence of severe right ventricular outflow tract obstruction/hypoplasia and hypoplastic pulmonary arteries. In patients with AVSD and severe hypoplasia of one ventricle, a strategy leading to a functional single ventricle may be the next best option. The precise timing and nature of staged procedures will inevitably be determined by both anatomical and physiological considerations as well as the experience of the congenital heart disease unit treating the child.⁽⁷⁾

Down syndrome is well known to be associated with congenital heart disease with an incident rate between 33 and 48%. Atrioventricular septal defect is the most common heart defects in Down syndrome. Some authors reported that Down syndrome was a risk factor for rapid progression of obstructive pulmonary vascular disease, and others reported that Down syndrome affected the operative results of complete AVSD, and presumed that early progression of obstructive pulmonary vascular disease in patients with Down syndrome might be one of the most important factors of its high preoperative mortality.⁽⁸⁾

The results of CAVSD repair have improved, as evidenced by a decline of early mortality for primary repair to 2-5%. The estimates of survival 10 years after repair of CAVSD are reported as 78-91%, with a freedom from any reoperation of 83-95%. Reoperation is most often required for left atrioventricular valve regurgitation (LAVVR), followed by left ventricular out-

flow tract obstruction (LVOTO) and residual ventricular septal defects (VSDs). Early and late outcome after first surgical correction of these defects depend mainly on the left AV-valve function. Left atrioventricular valve regurgitation remains the most important complications following AVSD correction, ranging from 3 to 18%. The creation of a competent LAVV is a cornerstone in successful AVSD surgical repair.⁽⁹⁾

The operative repair of the AVCD had undergone significant modification since early techniques were described. The single-patch technique described by Rastelli et al. in 1968 offered a series of advantages such as a better exposure and visualization of the VSD and subvalvular apparatus, less sutures close to the valvular plane, and shorter aortic cross clamping times than the two-patch technique.⁽⁴⁾ However that technique required the division of the common valve leaflets which when sewn back into a single patch, 3-4 mm of leaflet tissue was used up. This situation is important in patients weighing less than 5 kg in which the sacrificed valve tissue comprises a greater proportion of the whole. The deficiency of valvular tissue predisposes a reduction of the mobile valve area due to incorporation of leaflet tissue in the suture line placed under tension. This might induce a higher incidence of suture dehiscence and, as a consequence, important postoperative LAVVR especially in cases when valvular tissue is deficient such as severely dysplastic LAVV, double orifice LAVV.⁽¹⁰⁾

In 1976 Trusler and colleagues introduced the two-patch technique with a prosthetic patch for the ventricular septal defect. Most of the authors agree that sandwiching the valves between the pericardium and Gore-Tex according to the two patch technique allows respect of valve architecture by avoiding the leaflets' division, therefore limiting the secondary tissue sequestration and decreasing the chance of dehiscence. From a practical standpoint, the double patch as opposed to the single patch repair allows more selective adjustment of the height of the VSD, ventricular outflow tract and angle of the AV leaflet to the VSD patch as well without the need to divide the bridging leaflets. Given these advantages, the double patch technique has been the most widely published repair modality for both simple and complex AVSD associated with DORV, TOF and relative ventricular hypoplasia. Studies have reported a reoperation rate between 6.8% and 14.7% in patients with AVCD undergoing two-patch technique correction.⁽¹¹⁾

It is not always necessary to fill this potential deficiency with new material, namely, a ventricular patch. In some instances, one should be able to attach the atrioventricular valve leaflets to the septum in such a way that they close the ventricular communication and yet allow satisfactory function of the reconstructed atrioventricular valves and do not cause arterial valve obstruction. Wilcox et al.⁽¹⁾ reported a modified single-patch technique (Australian technique) consisting of suturing the common atrioventricular valve to the ventricular septum to close the ventricular component. Such technique offers the possibility to save the valvular tissue that is normally sacri-

ficed when the leaflets are reattached to the patch. However this technique cannot be employed in cases with large ventricular septal defect. Intraoperative considerations in making this decision included the tension required to bring the valve to the septum, with the accompanying concern that the sutures might pull through the muscle of the septum. In addition, if too great space existed, then distortion of the atrioventricular valve could lead to an unacceptable level of regurgitation postoperatively. Attempting to pull the bridging leaflets down to such a distant location will cause undue tension and may result in disruption of the septal closure or cause valve malfunction. Selecting which defects will lend them to direct closure remains a difficult judgment call. The preoperative echocardiogram can be useful, but it may exaggerate the size of the defect. At this time, the best predictor of the need for a patch is the presence of an exaggerated "scoop". That is, the central portion of the defect is more toward the apex than is often found in hearts with less "scooping". Thus, depending on these specific anatomic findings at operation, care must be taken not to extend its use beyond the bounds of prudence, particularly in the setting of severe "scooping" of the ventricular septum.⁽¹²⁾

Excellent short- and mid-term results of the modified single-patch technique have been reported. The shorter cross-clamp time does hold promise for better postoperative performance haemodynamically. These considerations of time saved notwithstanding, the greater benefit of the direct closure technique which is the resultant anatomic advantage.⁽¹⁾ Placement of a single or double patch often necessitates extensive surgical manipulation, particularly of the bridging leaflets of the common atrioventricular valve. Exact sizing of the ventricular patch, or attachment of the divided leaflets to a single patch, can be technically challenging. Once one has determined that direct closure is feasible, the technical demands are limited. However, concern exists that any left AV valve deformity, LVOTO, or residual VSD would deteriorate after repair with the modified single-patch technique.⁽¹³⁾

However there remain some theoretical concerns with this approach and long-term results from many centers are awaited. Some studies thought that stresses and strains placed on the lower zone of approximation of the inferior and superior bridging leaflet is at two levels; leaflet to leaflet and leaflet to ventricular crest. This dual strain effect can increase substantially when the VSD component is large and available leaflet tissue is limited somewhat. This will result in injury to the valve leaflets with propensity for worsening AV valve regurgitation. Moreover, plastering the leaflets to the septal crest increases the outlet to inlet axial length ratio creating a potential substrate for subaortic stenosis especially when the leaflets already have attachments to the septal crest. Again, though these are theoretical concerns, objective multicentre data is awaited.⁽⁷⁾

Repair of complete AVSD without any patch material has been successfully reported in three cases (two small and one large VSD component). The authors claim that patchless repair

lowers the level of the left AV valve implantation at the crest of the septum, increasing the coaptation height and reducing both ischemic and total pump times. Pre'tre et al. stated that without the patch there is reduced atrial volume that may help in preventing the occurrence of postoperative arrhythmias. However, with the exception of small residual septal defects authors remain concerned about applying tension on the valve tissues with possible increased risk of valvular disruption. Although it seems that it is possible to directly close atrial defects, long-term outcome and reconfirmation by other surgical units is awaited before patchless repair becomes more widely adopted.⁽¹⁴⁾

Critical appraisal of comparative techniques despite the limitations of era, surgeon and institutional experience has demonstrated that the three techniques are all very feasible to common atrioventricular junction morphologies. The single, double and modified patch have demonstrated equivalent efficacy in short- and intermediate-term outcomes with respect to left AV valve regurgitation and left ventricular outflow tract and residual septal defects. No single technique is proven to be superior to another.⁽⁷⁾

Conclusion

The technique of modified single patch repair of CAVC defects appears to render the valve competent. Once one has determined that direct closure of VSD is feasible, the technical demands are limited. It also provides a native continuity with the atrial and ventricular components, which might increase the solidity of the whole structure, reducing the risk for late dehiscence between the LAVV tissue and pericardial patch. However, larger series of patients and longer follow-up are required for an appropriate evaluation of this technique. Application of this technique to patients with various intracardiac anatomies, such as a huge size VSD, complete AVSD with TOF pathology, and AV valve anomalies, is still a challenging problem.

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Nicorandil is as Effective as Limb Ischemic Preconditioning in Reducing Myocardial Injury During Cardiac Valvular Surgery

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Preventing myocardial injury during cardiac surgery is so important to increase success rate, decrease complications and mortality.

Aim and methodology: To study the effect of remote ischemic and pharmacological preconditioning in reducing myocardial injury in patients undergoing cardiac valvular surgery; 42 patients were randomized into 3 equal homogenous groups: remote ischemic preconditioning (RIPC) group, pharmacological preconditioning (Nicorandil) group and control group. Then pre, intra and post-operative data were collected and statistically analyzed.

Results and conclusions: Both RIPC and nicorandil significantly reduced myocardial injury during cardiac valvular surgery as they decreased postoperative use of inotropes, R-wave amplitude reduction and cardiac enzymes, while they improved postoperative left ventricular ejection fraction (LVEF%) with no significant complications.

Key words (RIPC, preconditioning, nicorandil)

Still there is a need to improve myocardial protection in cardiac surgery as the number of operations on older and higher risk patients increases. (1)

Remote ischemic preconditioning reduces myocardial injury and improves cardiac function in patients undergoing cardiac valvular surgery either heart valve replacement or repair, regardless of the cause of the valve malformation. (2) It also reduces myocardial injury in coronary artery bypass grafting (CABG) surgery patients with or without concomitant aortic valve surgery. (3)

Nicorandil is known as an ATP-sensitive potassium channel opener with a nitrate like action. Clinical evidence has demonstrated that nicorandil protects the heart against ischemic injury which improves the recovery of post-ischemic contractile dysfunction. (4)

So it is always necessary to search for new approaches to improve cardiac function during cardiac surgery in order to increase success rates and decrease complications and mortality. (2)

Aim of the work

The aim of this work is to study the effect of remote ischemic and pharmacological preconditioning in reducing myocardial injury in patients undergoing open heart valve surgery.

Patients and Methods

This prospective controlled randomized study was conducted at cardiothoracic surgery department, Tanta University Hospital during the period from January 2012 to October 2012. The study protocol was approved by research ethics committee of faculty of medicine, Tanta University.

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Codex : o3/15/1409

Patients undergoing open heart valve surgery were included while we excluded those with associated heart abnormalities (ischemic heart disease or congenital anomalies), severe systemic (endocrine, hepatic, renal and pulmonary) disorders and patients taking the oral sulfonylurea as glibenclamide because this agent has been shown in experimental studies to block the cardio-protection induced by ischemic preconditioning, also we excluded redo and emergency surgery.

During the period of study 42 patients fulfilled the inclusion criteria and were randomized into 3 equal groups; Control group included 14 patients who did not receive neither remote ischemic nor pharmacological preconditioning, remote ischemic preconditioning (RIPC group) included 14 patients who underwent upper arm ischemia after induction of anesthesia and before skin incision by cuff-inflator placed on upper arm and inflated to 200 mmHg for 5 minutes then deflated for 5 minutes that was repeated for 3 cycles and pharmacological preconditioning group (Nicorandil group) included 14 patients who received nicorandil since preparation for surgery till the night before surgery from 5 to 15 days ; the maximum daily dose was 20 mg/ day divided on 2 doses.

1. Preoperative work-up:

All demographic, clinical, laboratory, electrocardiographic and echocardiographic data were collected.

2. Operative work –up:

Surgical techniques were applied to all groups using the same procedure; with the patient in supine position full median sternotomy was done. Activated clotting time was maintained above 480 seconds using heparin. All patients underwent moderate hypothermic cardiopulmonary bypass (28°C to 32°C). Myocardial protection was achieved by a cold antegrade or retrograde crystalloid cardioplegia. Arterial pressure was maintained at 50-70mmHg. Valve replacement with a mechanical prosthesis was done. Total bypass time (TBT), ischemic time (IT) and use of inotropes were recorded.

3. Postoperative work-up:

- Use of inotropes.
- Echocardiography evaluation: left ventricular ejection fraction (LVEF %) was assessed 24 hours before and after surgery.
- CKMB evaluation: Venous blood samples approximately 5 ml each were collected at 24 hours before and 4, 12 and 48 hours after removal of aortic cross clamp. Samples were centrifuged and serum was used for test, the assayed for CK-MB mass utilizing a commercially available assay

(kinetic method) serial reading every 1min for 4 readings then the mean of reading was taken. Reference range up to 25 ng/L.

- Plasma level of cardiac troponin I was assayed. The samples were assayed for cardiac troponin I mass utilizing a commercially available assay (ELISA method) and the reading was taken. Reference range up to 1.0 ng%.
- Intensive care unit stay.
- Postoperative hospital stay.

Statistical analysis

The collected data were organized, tabulated and statistically analyzed using SPSS software statistical computer package version 13. For qualitative data, comparison between two or more than two groups; Chi-square test (X²) was used. For quantitative data, the range, mean and standard deviation were calculated. For comparison between means of two groups; student's t-test was used. For comparison between more than two means, the F value of analysis of variance (ANOVA) was calculated. A p-value of less than 0.05 was considered statistically significant.

Results

There was no statistically significant difference between the 3 groups as regard pre-operative and intra-operative variables that may affect myocardial function and preservation; which indicate that these groups were homogenous groups. (Table 1)

Both RIPC and nicorandil significantly reduce myocardial injury during cardiac valve surgery as regard postoperative use and overall number of inotropes, postoperative LVEF%, postoperative R-wave amplitude reduction and cardiac enzymes; CKMB and troponin I, while both methods did not affect operative use of inotropes, postoperative ICU and hospital stay. (Table 2)

In this study remote ischemic and nicorandil preconditioning reduced myocardial injury after valvular cardiac surgery which was detected by serial CKMB and troponin I levels postoperatively. CKMB value increased after surgery in all groups reaching its peak at 4 hours then decreased gradually. CKMB values 4 hours and 12 hours after cross clamp removal were statistically significant lower in RIPC and nicorandil groups than control group, whereas this decrease was insignificant after 48 hours (Figure 1). Troponin I values increased after surgery in all groups reaching its peak at 12 hours then decrease gradually. Troponin I values 4 hours and 12 hours after cross clamp removal were statistically significant lower in RIPC and nicorandil groups than control group, whereas this decrease was insignificant after 48 hours. (Figure 2)

		Control	RIPC	Nicorandil	p. value
Age (y)		45.85±12.51	37.57±13.76	40±14.15	0.290
Sex	Male	5(35.7%)	6(42.9%)	6(42.9%)	0.906
	Female	9(64.3%)	8(57.1%)	8(57.1%)	
DM	Yes	1(7.1%)	2(14.3%)	2(14.3%)	0.797
	No	13(92.9%)	12(85.7%)	12(85.7%)	
Hypertension	Yes	2(14.3%)	2(14.3%)	2(14.3%)	0.999
	No	12(85.7%)	12(85.7%)	12(85.7%)	
Smoking	Yes	2(14.3%)	2(14.3%)	3(21.4%)	0.885
	No	12(85.7%)	12(85.7%)	11(78.6%)	
pre-op NYHA class III	Yes	11(78.6%)	11(78.6%)	10(71.4%)	0.241
	No	3(21.4%)	3(21.4%)	4(28.6%)	
pre-op LVEF%		65±4.54	66.07±4.63	65.42±4.70	0.727
pre-op R-wave amplitude in V5 mm		23±0.54	25±0.37	26±0.77	0.327
pre-op CKMB		6±0.69	5.28±0.82	5.64±0.64	0.495
Pre-op Troponin I		0.21±0.11	0.22±0.13	0.21±0.08	0.611
Type of valve surgery	DVR	2(14.3%)	3(21.4%)	3(21.4%)	0.886
	AVR	2(14.3%)	2(14.3%)	2(14.3%)	
	MVR+TR	1(7.1%)	2(14.3%)	2(14.3%)	
	MVR	9(64.3%)	7(50%)	7(50%)	
TBT		72.21±14.24	85.28±13.32	75.92±13.55	0.335
IT		53.50±15.88	54.85±12.81	57.85±13.08	0.334

Table 1. Pre-operative and intra-operative variables that may affect myocardial function and preservation.

		Control	RIPC	Nicorandil	p. value
Operative use of inotropes	Yes	11(78.6%)	8(57.1%)	8(57.1%)	0.335
	No	3(21.4%)	6(42.9%)	6(42.9%)	
Post-op use of inotropes	Yes	8(57.1%)	4(28.6%)	4(28.6%)	0.019*
	No	6(42.9%)	10(71.4%)	10(71.4%)	
Overall number of inotropes.		1.42±1.01	0.85±0.77	0.64±0.63	0.042*
post-op LVEF%		57.57±3.77	65.71±1.64	63.14±3.33	0.049*
Post-op R-wave amplitude reduction in V5 (4h) mm		4.5±0.95	3.23±0.54	3.52±0.99	0.001*
Post-op R-wave amplitude reduction in V5 (24h) mm		3.69±0.88	2.25±0.33	2.62±0.57	0.0002*
CKMB (4H)		50.85±3.97	33.57±3.25	37.57±3.25	0.001*
CKMB (12H)		42.07±2.26	30.05±3.13	35.85±2.29	0.001*
CKMB (48H)		13.05±2.77	11.71±2.60	12.05±3.44	0.715
Troponin I (4H)		1.35±0.17	1.06±0.24	1.10±0.14	0.019*
Troponin I (12H)		1.44±0.20	1.11±0.29	1.16±0.18	0.004*
Troponin I (48H)		0.51±0.20	0.47±0.21	0.53±0.21	0.731
post-op ICU stay		2.57±0.51	2.64±0.49	2.42±0.64	0.588
post-op hospital stay		10.50±0.85	10.50±2.06	10.35±1.64	0.964

*Significant or $P < 0.05$

Table 2. Intraoperative and postoperative results of different methods of myocardial protection.

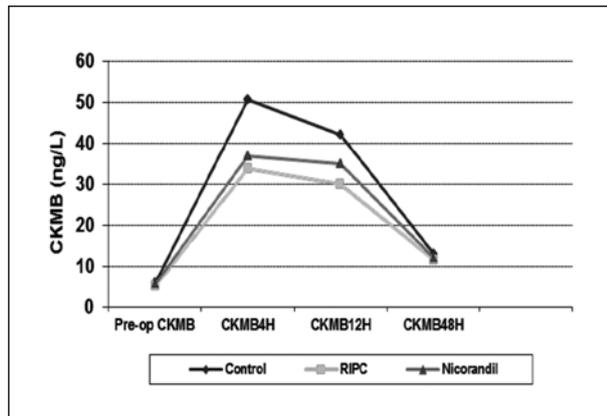


Fig 1. CKMB changes in the three groups.

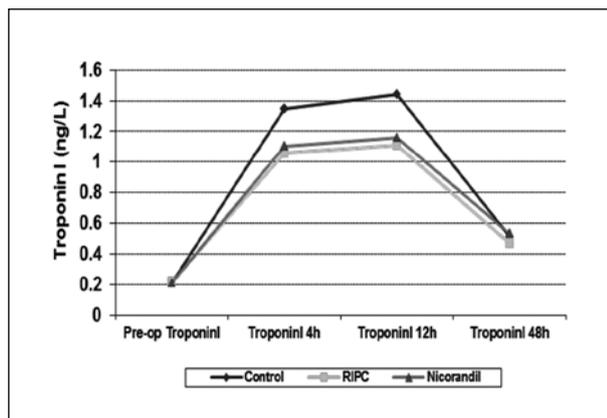


Fig 2. Troponin I changes distribution in the three groups.

We did not encounter complications in our study related to RIPC or nicorandil use.

Discussion

In our study there was statistically significant improvement in post-operative LVEF% in nicorandil and RIPC groups than control group and that means better myocardial protection by this drug and this protocol of ischemic preconditioning. That is consistent with the study of Xie JJ et al. who had studied the effect of remote ischemic preconditioning on myocardial injury in patients undergoing heart valve surgery. In this study; patients were randomized to either the RIPC (n=38) and control (n=35) group. They found that greater improvement in post-surgical cardiac function was noted in the RIPC group than in the control group. (2)

As regard postoperative inotropic support; Michael et al. studied effects of remote ischemic preconditioning on children undergoing cardiac surgery. In this study; Thirty-seven patients were studied: 20 control patients and 17 patients in the RIPC

group. They found that there was significantly greater inotropic requirement in the control group compared with the RIPC group. (5) This is consistent with our study; where there was statistically significant reduction in postoperative use and overall number of inotropes in RIPC and nicorandil groups than in control group.

During cardiac surgery and after weaning from CPB; usually there is a reduction of R-wave amplitude that indicate occurrence of myocardial injury. (6) In our study there was statistically significant increase in R-wave amplitude reduction in V5 in control group than RIPC and nicorandil groups after 4h and 24h.

In our study remote ischemic and nicorandil preconditioning reduced myocardial injury after valvular cardiac surgery which was detected by serial CKMB and troponin I levels postoperatively.

Many studies revealed the cardio-protective effect of remote ischemic pre-conditioning in cardiac surgery detected by cardiac enzymes changes; for example Xie JJ et al. found that troponin I concentration was significantly reduced in the RIPC group compared with the control group after heart valve surgery. (2) Also Nasir et al. found that remote ischemic pre-conditioning had significantly reduced CKMB levels after CABG surgery. (7)

Teoh LK et al. had studied the effect of preconditioning (ischemic and pharmacological) on myocardial necrosis (detected by measuring troponin T) following CABG surgery in 30 patients who were randomized to receive intermittent cross-clamp fibrillation, pharmacological preconditioning with a specific adenosine A1 agonist (GR79236X) or ischemic preconditioning (two 3-min periods of ischemia each followed by 2 min of reperfusion). They found that ischemic preconditioning is superior to the other techniques at limiting myocardial necrosis during CABG and pharmacological preconditioning using (GR79236X) was not significantly beneficial. (8)

While in a study by Li L et al.; there was no statistically significant difference between groups as regard postoperative cardiac troponin I. However, the RIPC protocol used by Li L et al. was different to that we used; In their trial RIPC consisted of three cycles of 4 min ischemia intervened by 4 min reperfusion and limb ischemia was induced by a blood pressure cuff around the right thigh inflated to 600 mm Hg, this different RIPC protocol may lead to different results. (9)

Blanc P et al. administered oral nicorandil 10 mg twice a day (n=22) or placebo (n=23) to patients undergoing CABG surgery. The effects of nicorandil on cardiac enzyme release and hemodynamics were neutral. The authors stated that nicorandil, as an anti-angina agent was safe to use as a premedication but there was a doubt about its cardioprotective effect. (10) Our results are consistent with Blanc P et al. about the safety of

nicorandil and the difference in the results of cardiac enzyme release may be explained as our patients had valve replacement surgery which produces more myocardial injury (that leads to a wide range of variations in cardiac enzyme release) than do CABG surgery.

Both methods of preconditioning (remote ischemic and pharmacological) did not affect postoperative ICU and hospital stay and were easy and used safely with no complications.

Conclusion

Both remote ischemic and pharmacological preconditioning with nicorandil reduce myocardial injury and improve cardiac function in open heart valve replacement surgery and are safe and easy methods with no significant complications. We recommend further study to investigate the possibility of augmenting myocardial protection by using both remote ischemic and pharmacological preconditioning together to reduce myocardial injury after open heart surgery.

Limitations of the study

The optimal duration and dosage of oral nicorandil and the optimal protocol of RIPC could not be assessed in our study.

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Prevention and Management of Air Leaks After Thoracic Surgery

Thoracic

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Nasr Ezzat

Background: Postoperative air leaks after thoracic surgery are common and can influence morbidity and postoperative hospital stay. Decisions regarding management of air leaks depends on individual experiences. In this study we tried to find the best method to prevent and manage postoperative air leaks.

Methods: Patients underwent isolated thoracic surgery at two thoracic surgery centers in the southern region of Saudi Arabia during the period from January 2012 to the end of September 2014 were studied. Clinical presentation, diagnostic evaluation, operative and postoperative methods for prevention and management of air leaks and outcome were reviewed.

Results: A total of three hundred and twelve adult patients underwent thoracic surgery were studied. After surgery 147 (47.1%) patients had an air leak. Most of patients with air leak managed conservatively, pleurodesis done for 6 patients, VATS for 3 and thoracotomy for 2 patients.

Conclusions: Prolonged air leak after thoracic surgery is a preventable and easily treatable complication. Prediction, diagnosis and management of air leak can improve the quality of their lives and their hospital stay duration.

Despite recent progress in surgical technique and improved perioperative care, prolonged air leak remains a frequent complication after thoracic surgical operations involving mobilization or resection of lung parenchyma. Air leak typically manifests as persistent bubbling in a chest tube drainage system, but may also present with increasing subcutaneous emphysema or pneumothorax in a post-operative patient(1,2,3).

Air leak is considered abnormal when still present at postoperative day 7, although a limit of 5 days is utilized in some centers . This is quite frustrating both for the patient and the surgeon(4,5).

Prolonged air leaks are undesirable because they prolong the duration of chest tube drainage with associated pain and risk of infection such as pneumonia and empyema . They also prolong hospitalization and delays adjuvant therapy if that is planned(6,7).

The management of persistent air leaks (PALs) is one of the most common problems in general thoracic surgery, especially after elective pulmonary resections. The statistically most frequent air leak is caused by alveolar-pleural fistula (APF), which is defined as a link between the pulmonary parenchyma distal to a segmental bronchus, and the pleural space. In most instances this air leak resolves spontaneously(8,9).

Numerous methods have been employed to manage persistent air leak including prolonged chest tube drainage, surgical repair, chemical pleurodesis (via the infusion of sclerosing agents such as doxycycline or talc). Recently, several reports have been published which suggest that Autologous blood pleurodesis appears to be efficacious for persistent air leaks associated with pneumothorax and with those occurring after lung resection(10,11,12).

This study aimed to find the best way to control air leak after thoracic surgery and how to minimize its complications.

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Codex : o4/01/1406

Materials and methods

This was a randomized, prospective study carried out at two thoracic surgery centers in the southern region of Saudi Arabia (Asser Central Hospital in Abha and Military Hospital in Khamis Mushait) and designed to study the best management of air leak after thoracic Surgery. Hundred patients underwent isolated thoracic surgery included in this study. All patients were subjected to:

Preoperative evaluation: History, physical examination and radiological evaluation.

Before the entrance of the patients into the operating room, they asked to stop smoking. Infection and diabetes mellitus controlled and steroid dose stopped or reduced trying to raise the general condition and reduced the predisposing factors for prolonged air leak. Patients given an antibiotic during induction of anesthesia that continued after surgery.

Intraoperative prevention of air leaks

The lung tissue was handled as carefully as possible during dissection and manipulation to ensure minimal trauma. Denuding visceral pleural surfaces were avoided by carefully lysing pleural adhesions. Any obvious parenchymal tears that were identified during surgery were repaired meticulously.

A horizontal mattress suture to coapt a visceral pleura defect was helpful. Autologous tissues including the pleura, pericardium, or pericardial fat pad, were used as biologic pledgets. Teflon pledgets also were useful. We usually minimize dissection within the fissure, minimize inspiratory pressures when re-inflating the lung, careful attention to avoid overlapping parenchymal staple lines, and closing the surgical stapler slowly in thick tissues. Standard technique for lobar resection included division of parenchymal fissures using linear stapler gastrointestinal anastomosis (GIA). Bronchial closure was performed by thoraco-abdominal (TA) stapler 30 mm in all the patients. In patients undergoing sleeve lobectomy, bronchial anastomosis was performed by interrupted sutures of 4-0 absorbable monofilament material. Several techniques were used to minimize residual space and attaining pleural apposition. Mobilization of all intrapleural adhesions, decortications of the remaining parts after partial resection and division of the inferior pulmonary ligament were often practiced and likely helpful. Rib resection and limited thoracoplasty were done in some patients. Creation of an apical pleural tent was also routine at the time of upper lobectomy. Transient diaphragmatic paralysis via injection of the phrenic nerve with a local anesthetic was routine in all lower lobe resection. We usually leave a basilar and apical chest drains within the hemithoracic cavity.

Postoperative prevention of Air Leaks

We use adequate analgesia in all the patients. Alternate -20 cm H_2O suction was applied to the chest drain system in all the patients. Intensive postoperative respiratory physiotherapy was associated in all the cases. Fiberoptic bronchoscopy was

performed in all patients to clean the airway and to rule out any bronchial problem. A chest radiography was repeated 24 h after air leaks stopped, to confirm the complete expansion of the residual lung. If a pneumothorax was present suction was installed again with -20 cm H_2O . The chest tubes were removed 24 h after the disappearance of the air leak and complete expansion of the residual lung.

If the air leak persists, it was evaluated daily and divided into 4 status according to Cerfolio RJ and coworkers 1998 (13):

Grade 1: forced expiratory only;

Grade 2: expiratory only;

Grade 3: inspiratory only;

Grade 4: continuous (inspiratory and expiratory).

Postoperative Management of Prolonged Air Leaks :

It is of paramount importance to separate two clinical entities: does the leak originate from the alveoli through a peripheral lesion in the visceral pleura or from bronchial structures, or in other words do we face an alveolar air leak or a bronchopleural fistula. If a significant air loss was encountered and there is suspicion of a problem at the bronchial anastomosis or stump early bronchoscopy was done. In most of our patients the background was an alveolar air leak and were effectively treated by prolonged chest tube drainage, physiotherapy and pleurodesis with talc slurry or bleomycin after the residual lung was fully expanded.

If a significant air leak persisted in a patient despite above mentioned conservative measures or if water seal was not tolerated due to a larger leak, surgical revision was considered. In order to minimize the risk of pleural space infection or partial obstruction this decision was made as early as possible within a few days, when it became evident that bedside pleurodesis was ineffective. VATS used to accomplish pleural symphysis with application of sclerosing agents under vision, pleural abrasion, decortication of surrounding lung or pleurectomy. VATS over stapling of parenchymal lesions also done. In two patients, thoracotomy done for completion lobectomy following sublobar resection in one patient, serratus anterior muscle flap with limited thoracoplasty to obliterate the pleural space in the other patient.

Statistical Analysis

The collected data were organized, tabulated and statistically analyzed using SPSS software statistical computer package version 13. For quantitative data, the range, mean and standard deviation were calculated. For qualitative data, Chi-square test were used. Correlation between variables was evaluated. Significance was adopted at $p < 0.05$ for interpretation of results of tests of significance.

Results

A total of three hundred and twelve adult patients underwent thoracic surgery during the period from January 2012 to the end of September 2014 at two thoracic surgery centers in the

southern region of Saudi Arabia (Asser Central Hospital in Abha and Military Hospital in Khamis Mushait) were studied for prevention and management of air leak after thoracic surgery.

The age of the patients at time of operation ranged from 22 to 88 years with a mean of 52±13.8 years. There were 217 (69.6%)males and 95 (30.4%)female patients (Table1).

After surgery 147 (47.1%) patients had an air leak, 118 patients of them (80.3%) had lung resection and 29 patients (19.7%) had other procedures (table 1,2).

Most of patients with air leak managed conservatively. Duration of chest tube and Hospital stay after operation were affected by the duration of air leak (table 2).

	Parameter	Number	Percentage	P Value
Age	Range	22-88		
	Mean	52±13.8		
Sex	Males	217	69.6%	0.031*
	Females	95	30.4%	
Indication for surgery	Lung mass	112	35.9%	0,787
	Bronchiectasis	23	7.4%	
	Lung abscess	21	6.7%	
	Emphysematous bullae	35	11.2%	
	Neglected hemothorax	33	10.6%	
	Tracheobronchial injury	27	8.7%	
	Empyema	13	4.2%	
	Lung injury	31	9.9%	
Type of surgery	Lung resection	234	75%	0.001*
	Other procedure	78	25%	
Postoperative air leak	Air leak	147	47.1%	0,648
	No air leak	165	52.9%	

*Significant (P<0.05)

Table 1. Patients' Characteristics, Indication for surgery, Type of surgery and Postoperative air leak.

	Parameter	Number(147)	Percentage	P Value
Duration Of air leak (days)	1-3	96	65.3%	0.034*
	4-7	37	25.2%	
	7>	14	9.5%	
Type of surgery	Lung resection	118	80.3%	0.021*
	Other procedure	29	19.7%	
Air leak management	Conservative	136	92.5%	0.013*
	Bedside pleurodesis	6	4.1%	
	VATS	3	2%	
Duration of chest tube (days)	Thoracotomy	2	1.4%	0.029*
	2-4	96	65.3%	
	5-9	28	19%	
	10-14	17	11.6%	
	15-19	6	4.1%	
Hospital stay after operation (days)	3-5	96	65.3%	0.029*
	6-10	28	19%	
	11-15	17	11.6%	
	16-20	6	4.1%	

*Significant (P<0.05)

Table 2. Postoperative results in Patients with air leak.

Thoracic

Discussion

Air leaks are a common problem after pulmonary resection and can be a source of significant morbidity and mortality. Air leaks are associated with prolonged hospital stays, and infectious and cardiopulmonary complications, and they occasionally require reoperation (3,14).

Several methods have been used to control postoperative air leak. The ingenuity and experience of the surgeons greatly affect the approach in the individual patient in whom infection of any accompanying air space is absent (15).

Our work was designed to evaluate the best way to prevent and control air leak after thoracic surgery. The age of our patients ranged from 22 to 88 years with a mean of 52 ± 13.8 years. This was similar to one study who had done research on age group ranged from 17 to 86 years with main age 61.9 ± 0.5 years and different as compared with the results of other series where age ranged from 4 to 65 years with main age 23 ± 1.5 years (5,16).

The predominance of male gender in our study was similar to the results of some authors (17).

Our study revealed 147 (47.1%) patients had an air leak, 118 patients of them (80.3%) had lung resection and 29 patients (19.7%) had other procedures. Several studies show an air leak to be present immediately at the completion of an operation in 28% to 60% of patients who undergo routine pulmonary resections, including both lobectomies and lesser resections (18–22). On the morning of 1st postoperative day, an air leak is present in 26% to 48% of patients (13, 23); on the morning of 2nd postoperative day, an air leak is present in 22% to 24% (13,24); and on the morning of 4th postoperative day, an air leak is present in 8% (14). In our study it was also decreasing with time.

Alternate -20 cm H₂O suction was applied to the chest drain system in all our patients through the 1st 24 hours postoperatively. While in other two studies they did not use negative suction routinely. They reported that only 7% and 12% of their patients needed to add suction to the chest tubes. The 1st one used -20 cm H₂O suction (5 to 30 minutes period of suction intermittent for 24 hours) because these patients were operated for inflammatory causes as lung abscess and bronchiectasis. While the 2nd one used -10 cm H₂O suction for 24 hours because their patients had small pneumothorax developed without any clinical problems (20,24).

Beside pleurodesis were done for 4.1% of patients with postoperative air leak in our study. Pleurodesis with autologous blood needed for 3% of patients in another study (25).

The duration of the air leak in our study was in the range of 1-18 days with mean 4.6 ± 1.3 days. This was slightly shorter than the duration reported by some authors who reported the mean durations 7.2 ± 1.3 and 8 ± 1 days, while it was longer than that reported by others which was 1.7 ± 0.5 days. This because

they used fibrinogen\ thrombin coated patch to control air leak intraoperatively which is not available in our centers (10,26,27).

Prolonged air leak was found in 14 of our patients (9.5%). This was higher than that found by others where Prolonged air leak was found in 8% and 3.6% of their patients this may be due to larger sample size and the indication for surgery was spontaneous pneumothorax (28,29).

The duration of the chest tubes drainage ranged from 2 to 19 days with mean duration 6.4 ± 0.7 days in our patients with air leak and from 1 to 6 days with a mean duration 3 ± 0.5 in patients without air leak. The duration ranged from 1 to 17 days by others. In another studies showed that conversion of the chest tubes to water seal after a brief period of suction results in shorter time to remove the chest tubes (mean 2.7 days) than dose suction only (mean 3.8 days), the duration of the tubes drainage was ranged from 8 to 19 days in the untreated patients and was 10 days in the single fibrin glue cases and that the mean drainage duration was 11.2 days in the group without pleural tenting and 7 days in group with pleural tenting (17,28,30,31)

Hospital stay duration for our patients with air leak ranged from 3 to 20 days with mean 7.3 ± 0.9 days. This was similar to that of other study who reported that hospital stay duration for patients after pulmonary resection with pleural tenting 8.2 days and 11.6 days for patients after pulmonary resection without pleural tenting. Also it ranged from 1 to 29 days with a mean duration 6 ± 1.5 days in other series (30,32).

In our patients without air leak, the hospital stay duration ranged from 2 to 7 days with a mean duration 3.2 ± 0.6 days. This was similar to reported in other study that the duration ranged from 1 to 11 days with a mean 3 ± 0.5 days in patients without air leak (17).

Conclusions

- Prolonged air leak after thoracic surgery is a preventable complication.
- Prediction, diagnosis and management of air leak intraoperatively in patients who are candidate for thoracic surgery can improve the quality of their lives and their hospital stay duration.
- Under-water seals with negative suction are effective in most cases but bedside chemical pleurodesis may be needed in some patients with prolonged air leak.
- Indications of reoperation nowadays, is greatly decreased or considered rare due to advances in the surgical techniques and instrumentations.

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Empyema Incidence in Surgically Treated Patients After Isolated Chest Trauma

Nasr E. Mohamed

Objective: Determining incidence of occurrence of empyema in surgically treated patients after isolated chest trauma. **Patients and methods:** This study includes 320 patients with chest trauma, there is 243 with blunt trauma and 77 patients with penetrating chest trauma, 38 patients managed by conservative treatments, 256 patients are managed by chest tube insertion and 26 patients are in need for exploratory thoracotomy. All patients were followed up by clinical and radiological examination monthly for 3 months for detection of occurrence of posttraumatic empyema.

Results: Occurrence of empyema is reported in 24 patients (7.5%). Incidence of empyema occurs more in cases with incomplete drainage of the pleural space, associated lung contusion, multiple chest tube placements and long duration of chest tube placement.

Conclusion: Most thoracic trauma patients can be treated in emergency room either conservatively or simple procedures as chest tube insertion in 88%. Empyema thoracis occurred in 7.5% of all patients. Empyema thoracis still has significant morbidity and mortality. Complete aseptic technique should be followed in all patients needing surgical intervention with giving broad-spectrum antibiotic for all patients. It should be to remove chest tube as early as possible and chest physiotherapy for all patients with optimum position of chest tube. Decision of exploratory thoracotomy should be taken as fast as possible when indicated.

Chest trauma remains showing a high incidence in the emergency room among trauma patients. Chest trauma is classified into blunt and penetrating chest trauma, but the majority is presented with the blunt one. Chest trauma leads to multiple serious injuries including chest wall (skin, muscles and ribs), pleural injuries (pneumothorax, hemothorax and hemopneumothorax), lung injuries (laceration and contusion), cardiac injuries (contusion, perforation and hemopericardium), diaphragmatic injuries, great vessel injuries and tracheobronchial injuries.

Development of empyema thoracis in trauma victims gains special concern due to highly distressing complications associated with it.

Patients and Methods

This study included 320 patients with isolated chest trauma in Thoracic Surgery Units in King Abdel Aziz Specialist Hospital (KAASH), Taif, Kingdom of Saudi Arabia (KSA) from January 2010 till December 2011.

Inclusion criteria

All patients presented with isolated chest trauma (either blunt or penetrating) which need thoracic surgical care.

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Exclusion criteria

Patients with polytrauma, patients with previous thoracotomy and patients with preexisting lung diseases as tumours or chronic lung disease e.g. TB.

All patients were subjected to:

- Complete history taking.
- General physical examination.
- Local chest examination (inspection, palpation, percussion and auscultation).
- Complete laboratory investigations.
- Radiological examination [chest X-ray (PA and lateral) for all patients and CT chest for selected cases].

Management

General care as IV fluid, blood, broad-spectrum antibiotics, analgesics, physiotherapy, close observation was applied in 38 patients. Insertion of chest tubes was applied in 256 patients.

26 patients with severe injuries underwent posterolateral thoracotomy or anterolateral thoracotomy.

All patients were followed up by close observation in the hospital till discharge hour and in Outpatient Department (OPD) weekly for one month and monthly for the next 3 months to detect any complications.

Patients with posttraumatic empyema were subjected to:

- **Clinical examination:** Complete laboratory investigations.
- **Surgical management:** Chest tube drainage, exploratory thoracotomy with rib resection drainage and/or decortication.

RESULTS

320 patients fulfilled the inclusion criteria and they were subjected in this study, all of them had isolated chest trauma, 76 % had blunt chest trauma, but 24 % had penetrating chest trauma (table 1).

Type of chest trauma	No	%
Blunt trauma	243	76
Penetrating trauma	77	24

Table (1) Types of chest trauma

Regarding sex, male patients account for 76% of all patients, while the percentage of females was 24% of them presented with penetrating chest trauma (table 2).

Type of injury	Sex	
	Male	Female
Blunt	171	72
Penetrating	72	5
Total	243	77
Percentage	76	24

Table (2) The relation between sex and type of trauma

Regarding age, the majority of patients were ranged from 30 to 50 years representing 52% and patients less than 30 years accounting for 29.2% and patients more than 50 years representing 18.8% (table 3).

Age group	Type of injury		Total	Percentage
	Blunt trauma	Penetrating trauma		
< 30 years	58	36	93	29.2
30-50 years	140	26	166	52
> 50 years	46	15	61	18.8

Table (3) The relation between age and type of trauma

Regarding the varieties of injuries, simple fracture ribs account for 10%, pneumothorax accounts for 23%, hemothorax 19%, hemopneumothorax accounts for 14.5%, lung contusion accounts for 19.3% and fracture sternum in 3.2% and 4.6% were presented with flail chest. Obviously, there is more than one lesion in the same patient (table 4).

Type	No	%
Stab wound	67	70.1
Gunshot	10	29.9

Table (4) Types of penetrating trauma

Diaphragmatic injuries occurred in 1.25%, tracheobronchial injury in 0.6%, and cardiac injury represented by 1.25% (table 5).

Regarding management, 38 patients were managed by conservative management, 256 patients were managed by insertion of chest tube, but exploratory thoracotomy was done in 26 patients (table 6).

Chest tube was inserted in emergency room or in intensive care unit (61:39%) .

In most of patients, the chest tube was removed < 10 days (91%), while removed after 10 days in 9% of cases due to incomplete expansion of lung or prolonged air leak (especially patients needing to be on mechanical ventilation). Incidence of empyema among all groups was 5% (16 patients).

The difference between groups managed either conservatively by chest tube insertion or by exploratory thoracotomy is insignificant ($p > 0.005$).

The incidence of empyema increases progressively with longer duration of > 6 days of staying of chest tube.

Also, complete drainage of pleural space decreases incidence of empyema.

Presence of lung contusion, FB and flail chest increases incidence of empyema.

Once empyema diagnosis was established, aggressive management had to be started, 14 patients (87.5%) were managed by chest tube insertion, while one patient (6.25%) required rib resection drainage and in one patient, decortication was performed (table 8).

No mortality was recorded in our study with minor morbidity as prolonged stay of chest tube and prolonged ventilation (> 24 hours), postoperative ileus, atrial fibrillation and deep venous thrombosis (table 9).

Type of injury	No	%
Simple fracture rib	33	10
Multiple fracture ribs	83	26
Flail chest	15	4.6
Fracture sternum	10	3.2
Pneumothorax	73	23
Hemothorax	60	19
Hemopneumothorax	46	14.5
Lung contusion	61	19.3
Diaphragmatic injury	4	1.25
Tracheobronchial injury	2	0.6
Cardiac injury	4	1.25

Table (5) Different types of chest injuries

Type	No	%
Conservative	38	11.88
Chest tube insertion	256	80
Exploratory thoracotomy	26	8.12

Table (6) Types of management in chest trauma

Site	No	%
Emergency Room	156	61
Intensive Care Unit	100	39

Table (7) Sites of ICT insertion in both trauma

Type of management	No	%
Chest tube	14\16	87.5
Rib resection drainage	1\16	6.25
Decortication	1\16	6.25

Table (8) Lines of management of posttraumatic empyema

Complication	No	%
Mortality	0	0
Prolonged ventilation	2	12.5
Prolonged stay of ICT	6	37.5
Atrial fibrillation	3	18.75
Postoperative ileus	1	6.25
Deep venous thrombosis	1	6.25
Chest infection	2	12.5

Table (9) Morality and morbidity (thoracotomy cases)

DISCUSSION

There is increase in the number of chest trauma patients in this study due to the locality of our hospital in coverage of different high ways.

The vast majority of our patients with thoracic trauma require only observation or tube thoracostomy (ICT), and limited percentage of patients require exploratory thoracotomy. It is important to determine incidence of infection following chest trauma. Empyema itself remains as a distressing complication and its cause is multifactorial as host resistance, degree of bacterial contamination, presence of foreign body, type of trauma and type of intrathoracic lesion.

In our study, we aim to determine the incidence of empyema in all patients with isolated chest trauma and need surgical intervention.

The age of our patients ranged from 13 years to 83 years with a mean of 33 ± 10.5 years, the same was reported by **Eddy (1990)** as patients ranged from 14 to 83 years old, with a mean of 34 ± 11.3 years.

In our study, the percentage of male to female was 76% versus 24% respectively. This result was different from obtained by **Aguilar (1997)** as male to female was 51.6% to 44.4%. This can be explained by increased number of female driving care in west countries, this was not allowed in our locality.

Regarding type of chest trauma, blunt trauma was 76% versus 24% in penetrating trauma. This was different from study obtained by **Eddy (1990)** in his study, the percentage of blunt chest trauma was 60% versus 40% in penetrating chest trauma. This can be explained by increased number of

road traffic accidents in our locality versus west countries where penetrating injuries are more especially gunshot injury. However, in both study, the blunt trauma is more prevalent.

Regarding type of injury, pneumothorax represents 23% of cases, hemothorax in 19% and hemopneumothorax in 14.5%. This was different from study of **Saunders-Plassman (1998)** where pneumothorax reported in 44% and 56% of patients had hemothorax or hemopneumothorax. This can be explained by increased number of penetrating injuries in his study. In contrast, our result was the same as obtained by **Aguilar (1997)**.

As regard type of management in our study, conservative treatment was applied in 11.88%, tube thoracostomy applied in 80% of patients and exploratory thoracotomy in 8.12% and these results nearly parallel to that obtained by **Gregory (1997)** who reported 12.2%, 74.8% and 13% respectively. The difference is in percentage of exploratory thoracotomy due to increased number of penetrating injuries in Gregory study.

In our study, the duration of stay chest tube in the patient recorded higher incidence of empyema thoracis. This is the same recorded by **Michael (1996) and Eddy (1996)**.

Also, incomplete pleural evacuation (drainage) of pleural space developed empyema. This is the same reported by **Manrdal (1997) and Eddy (1990) (7)**.

In our study, incidence of empyema increases with associated lung contusion, pleural foreign body and associated flail chest. This was consistent with findings obtained by **Helling et al. (1989); Augilar (1997); Etoch et al. (1995) and Chettipalli (1999)**.

CONCLUSION

Most thoracic trauma patients can be managed in emergency department either conservatively or by insertion of chest tube.

- Incidence of empyema thoracis in chest trauma patients is low but have significant morbidity.
- When surgical intervention is decided, complete aseptic procedure should be applied with coverage by broad-spectrum antibiotic.
- Removal of chest tube should be as early as we can with chest physiotherapy to all patients from first day of admission.
- Exploratory thoracotomy when decided should not be delayed.

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Adding Talc Pleurodesis to VATS in Recurrent Ipsilateral Primary Spontaneous Pneumothorax, Improved Outcome?

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Background: Primary spontaneous pneumothorax (PSP) most commonly occurs due to rupture of emphysematous change or blebs in the apex of the lung. The estimated recurrence rate is 23-50% after the first episode and increases to 60% after the second. The high recurrence rate stimulated the development of many different therapeutic approaches to manage.

The aim of this study is to evaluate the use of talc poudrage as a pleurodetic modality in cases of recurrent PSP undergoing VATS bullectomy in terms of safety of use, early postoperative effects related to its induced inflammatory effect and the beneficial effect in the form of preventing recurrence of pneumothorax.

Methods: Prospective nonrandomized controlled study in which fifty two patients (mean age, 22 years) with recurrent PSP were admitted for VATS bullectomy, 24 of them (46%) underwent additional talc pleurodesis and the others (54%) had bullectomy only, in the period from 2009 to 2012. Patients were evaluated regarding postoperative pain, fever, chest tube drainage, time to tube removal, infections, pulmonary complications, ICU and hospital stay and rate of recurrence for which patients were followed for 2 years.

Results: Demographic characteristics were similar including age, sex and smoking habit. The talc pleurodesis group showed higher rate of pain sensation, tube drainage, prolonged time to tube removal, hospital stay and higher incidence of low grade fever but they showed no recurrence of pneumothorax in the follow up period contrary to 14% recurrence in the non talc group. No documented pulmonary complications were detected in the talc group.

Conclusion: Thoracoscopic talc poudrage using sterile medicated asbestos-free large particle talc to prevent recurrence of PSP can be considered safe, effective and reproducible with negligible morbidity.

A pneumothorax occurs when there is air in the pleural space. Pneumothoraces are classified as spontaneous, which occur without preceding trauma or other obvious cause, or traumatic, which occur as a result of trauma to the chest. Spontaneous pneumothoraces are subclassified as primary or secondary. A primary spontaneous pneumothorax occurs in an otherwise healthy person without underlying lung disease. A secondary spontaneous pneumothorax complicates an underlying lung disease, most commonly chronic obstructive pulmonary disease (1)

Spontaneous pneumothorax is a relatively common occurrence, usually young tall smoker males usually due to the presence of small apical bulla, bleb or microbullous disease, but in some cases this is not the case, usually the visceral pleura is not normal (2)

The management of patients with spontaneous pneumothorax remains controversial. The initial treatment of primary spontaneous pneumothorax is not standardized throughout the world. Although aspiration is less painful and requires less hospitalization than chest tube drainage does, the latter is still frequently used as the initial treatment. After a recurrence or failure of aspiration, chest tube drainage,

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again, is often the procedure of choice although VATS and talc poudrage have been proven to be much more effective (3,4, 5). VATS can be recommended as pneumothorax surgery (6).

Recurrence is the most common complication after an initial episode of primary spontaneous pneumothorax (PSP). However, preventive surgery remains a controversial issue. The presence of air-containing lesions on HRCT scans and bullae on chest X-rays are independent risk factors for ipsilateral recurrence. (7).persistent smoking and Initial pneumothorax size were found to be predictors of recurrence in PSP (8)

Talc is predominantly hydrated magnesium silicate and was first used for pleurodesis in 1935. Formal standards for talc production for pleurodesis are lacking, and there is a wide variation in composition and particle size in the various talc preparations used worldwide (9).

It is the treatment of choice for recurrent pleural effusion in oncological patients or in spontaneous pneumothorax in elderly patients. However, its use in young patients had some considerations due to the immediate post-surgical side effects (severe hypoxaemia, respiratory distress syndrome or pneumonitis) and also long-term effects related to cancerous effects and restriction of respiratory function in addition to an increase in the incidence of pleural or lung cancer. Several studies point out that these effects seem more related to the size of talc particles or the average doses (10)and show that doses <3 g and particles >6 µm minimize the appearance of acute side effects (11). These adverse effects are rare nowadays as the preparations are regulated by international drug agencies and are free of amianthus, asbestos and other impurities (12)

The aim of this study is to evaluate the use of talc poudrage as a pleurodetic modality in cases of recurrent PSP undergoing VATS bullectomy in terms of safety of use, early postoperative effects related to its induced inflammatory effect and the beneficial effect in the form of preventing recurrence of pneumothorax.

Patients and methods

Prospective nonrandomized controlled study of 52 cases with recurrent PSP having VATS as the primary management between Jan (2009) and Dec (2012) were studied at King Fahd University Hospital, Alkhobar and Almousat General Hospital, Dammam, Saudi Arabia.

Patient selection

All cases with recurrent PSP were included. We excluded from the study all cases of secondary spontaneous pneumothorax (COPD- emphysema) as well as all traumatic pneumothorax.

All patients had routine laboratory work, CXR and CT chest prior to going to OR. Figure (1)

Advantages and disadvantages of talc were explained to the patients and informed consent taken.

Patients were randomly divided into two groups

Group A: 24 Patients (46%) who underwent VATS bullectomy and Talc poudrage.

Group B: 28 Patients (54%) who underwent VATS bullectomy only without talc powder. (Control group)

Operative technique: 3 port VATS was used in all cases. Fig (2)

All patients were operated under general anaesthesia using single-lung ventilation. Patients positioned in the dead lateral position with flexion of the waist of the table. Deflation of the lung in concern followed by camera port insertion; usually in the 7th space midaxillary line to have a panoramic view of the entire hemithorax. Identification of the bullae or blebs [fig (3)] is followed by stapler bullectomy.

Asbestos free talc was used in group A patients as an adjunct to the thorascopic bullectomy being insufflated into the pleural cavity at the end of the procedure. Current preparations used are sterile and asbestos-free. In our study we used STERITALC® which is large particle size talc; latex and asbestos free.

The lung is then inflated, confirmed and seen by the camera.

Chest tube inserted in the previously camera port, connected to underwater seal then connected to low suction to assist lung expansion. Morning CXR is done. Fig (4)

Patient's demographics, postoperative variables including: pain, fever, mean total chest tube drainage, mean time of tube removal, infections, pulmonary complications, ICU and hospital stay and rate of recurrence were tabulated and statistically studied.

Pain was assessed subjectively. Several pain scores are available but we used the numeric pain rating scale instructions [fig (5)] in which the patient is asked to make three pain ratings, corresponding to current, best and worst pain experienced over the past 24 hours, the average of the 3 ratings was used to represent the patient's level of pain in the last 24 hours (13). In our study, we calculated the numeric pain scoring in the first 3 days postoperatively and the mean of each patient was taken.

Pain management was aimed to be standardized; all patients received patient controlled analgesia (PCA) in 1st 24 hours then NSAIDs and paracetamol afterwards.

Statistical analysis

Both groups were statistically compared using the Student *t* test for continuous variables and chi-square test for categorical variables.

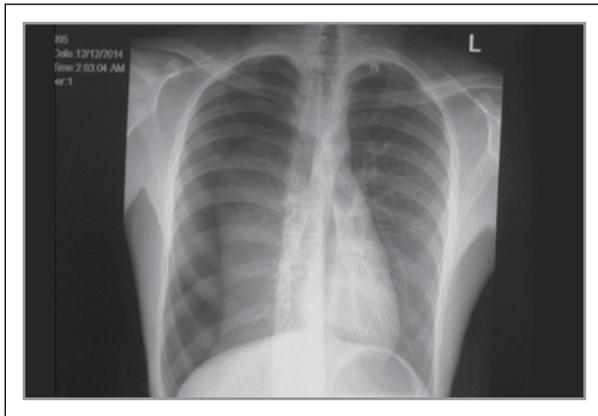


Fig 1. Preoperative CXR of right sided pneumothorax

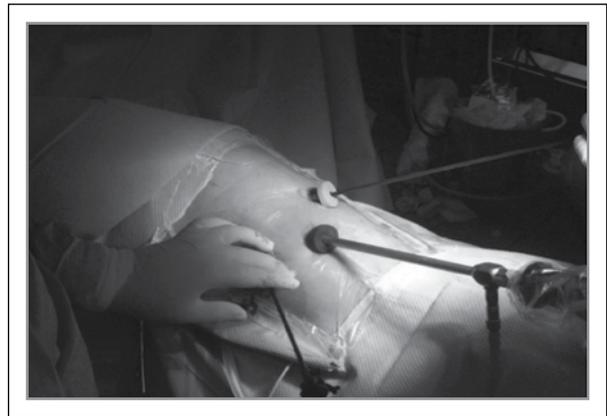


Fig 2. 3 port VATS



Fig 3. Apical bulla

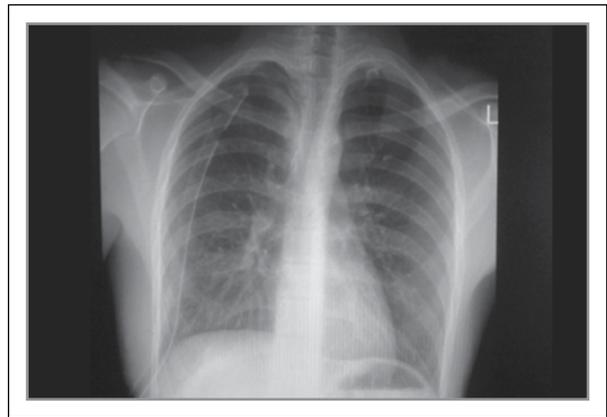


Fig 4. postoperative CXR

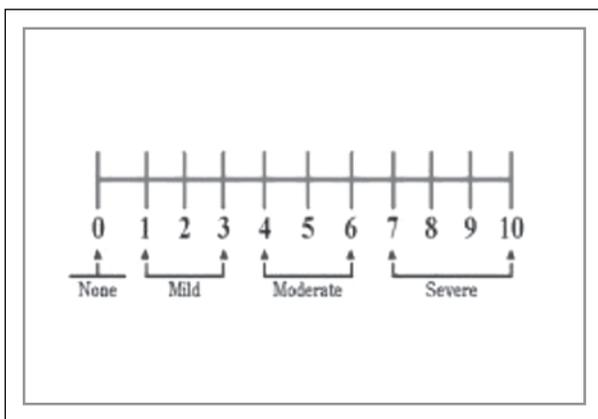


Fig 5. Numeric pain scale

Results

Fifty two cases diagnosed with recurrent primary spontaneous pneumothorax presented in the period between 2009 and 2012; all were primarily managed with thoracostomy

tube insertion in the 1st pneumothorax event; they underwent VATS stapler bullectomy upon establishing the diagnosis of recurrent pneumothorax and were followed up till December 2012 with a mean follow up period of 27± 4 months (range 1.2-3.5 years).

The patient>s demographics are shown in table (1). Age ranged between 15 to 37 years in talc group and 16 to 41 in the control group. (p value 0.18)

In talc group (A) , only one case is a female (4.2%) while in control group (B) two are females (5.6%) , (p value 0.12)

Most of the patients are cigarette smokers with a history of more than 5 years smoking (71% in group A, 72% in group B) (p value 0.35). Female patients were not smokers. Non smoker males tended to be of younger age than smokers.

The study entailed following the postoperative variables entitled in table (2):

Postoperative pain assessment targeted the painful effect of talc inflammatory response; pain was more intense in the

Thoracic

	Talc group(A) (24 cases)	Control group(B) (28 cases)	P value
Age (mean in years)	21.9 ± 4 y	22.5 ± 3 y	(0.18) NS
Sex	M à 23 (95.8%) F à 1 (4.2%)	M à 26 (94.6%) F à 2 (5.6%)	(0.12) NS
smoking	17 (71%)	20 (72%)	(0.35) NS

Table (1) Demographic characteristics

	Talc group	Control group	P value
Pain score (according to the numeric pain rating scale instructions)	4.6±1.2	2.5±0.8	<(0.05)
Temperature(low grade fever)	8 (33%)	1 (3.6%)	<0.001
Total tube drainage (mean)	470 ml	210 ml	<0.001
Time to tube removal	81 hs ±5	39 hs ± 4	<0.001
infection	2(8.3%)	1(3.6%)	Ns
Pulmonary complications	0	0	Ns
ICU stay	0	0	ns
Hospital stay	5 days ± 11 hs	3 days ± 10 hs	<0.05
Rate of recurrence	0(0%)	4(14%)	<0.05

Table (2) Post operative variables

talc group, which required increasing analgesics; in form of extending duration, frequency or dose of PCA, parenteral or oral analgesia.

In the talc group: pain score was 4.6±1.2 on this scale, compared to 2.5±0.8 in the control group, which was significant (p value <0.05).

Low grade fever (37.5-38 °C) was observed in 8 patients of talc group (33%) compared to 1 only of group B (3.6%) which was self limiting and subsided in all patients by use of antipyretics. (P value < 0.001)

Mean total tube drainage (470 ml in group A versus 210 ml in group B) & mean time to tube removal (81 ±5 hours versus 39±4 hours) were significantly higher in the talc group. These observations can be attributed to the inflammatory response of talc particles causing more pleural fluid secretion which explains the need for longer tube drainage duration. (p value <0.001)

Pleural space infection manifested by +ve pleural fluid culture complicated two (8.3%) cases of talc users and one

case of control group (3.6%). That infection was limited by the use of specific antibiotics and didn't need further intervention. Statistically non significant (NS)

Pulmonary complications in form of ARDS, pulmonary fibrosis and/or respiratory failure were not detected in both groups in the follow up period. (NS)

All patients had adequate oxygen saturation so no ICU transfer was needed in both groups. (NS)

The mean hospital stay was 5 days ± 11 hours in the talc group compared to 3 days ± 10 hours in the control group. (p value <0.05)

In the follow up period, 4 patients of the non talc patients (14%) were readmitted with recurrence of pneumothorax in the ipsilateral side (all smokers, mean latent period of 7 months) with no recurrence in the talc pleurodesis group. (p value < 0.05)

No mortality in both groups during the follow up period.

Discussion

Primary spontaneous pneumothorax is a benign disease occurring mostly in young males. There is no general consensus on the treatment. Most of authors prefer simple drainage in case of first episode of PSP and reserve surgery for recurrent PSP (14).

In the last 20 years, video assisted thoracoscopic surgery (VATS), bullectomy with associated procedures (pleurectomy, talc poudrage, pleural abrasion or a combination) has been accepted as the management option of choice in surgical treatment of recurrent pneumothoraces (15)

As the number of patients treated by thoracoscopic stapler blebectomy increased, the postoperative recurrence rate had risen unexpectedly. **Muramatsu** and colleagues retrospectively investigated the cause and management of primary spontaneous pneumothorax recurrence after that procedure. They found that the most common cause of recurrence was new bulla formation (57% of which were apparently related to the staple line and 43% of which were not related to the staple line). They recommended the necessity to establish additional procedures involving either the visceral pleura or the parietal pleura to reduce the recurrence rate (16)

Clinical guidelines do not specify the type of pleurodesis that should be conducted, but as shown in human and animal studies, talc powder is the most inexpensive, efficient, widely available and easy to use agent for pleurodesis (11). However, the success of this brilliant agent has been shadowed by the potential risks for respiratory insufficiency, ARDS, and death (17)

In an animal model, a study on 100 rabbits receiving intrapleural talc; half of them with small sized particles, the other half with mixed size, in order to analyze the pulmonary and systemic changes secondary to intrapleural administration of different talc particle sizes; talc particles have been found in samples from bronchoalveolar lavage and pulmonary parenchyma, (migrating through the stomas of the parietal pleura), more in smaller particle group, recommending the use of larger particles for more safe pleurodesis.(18)

In a study by **Hunt and colleagues** (12), they addressed the issue of the safety of talc use for pleurodesis in young patients with spontaneous pneumothorax: does it have any long-term adverse effects? One hundred and eighty-one papers were identified. They focused on the long term sequelae of talc use as carcinogenic effect and pulmonary fibrosis. They found that talc pleurodesis in young patients with primary pneumothorax appears to have minimal long term adverse effects with mild restrictive impairment of lung function (mean total lung capacity 89% of predicted in talc patients versus 96% in those who had simple chest drainage)

In another study by **Cardillo and colleagues** (14), videothoracoscopic talc poudrage showed a good short term result in terms of very high success rate with a low morbidity

rate, a short in-hospital stay, a fast recovery and an excellent cosmetic result. For the long term effects, they evaluated lung function (FEV1-FVC-TLC-RV) and DLCO at 5 years in a series of 100 patients of recurrent PSP; 50 of them were surgically treated for PSP by means of videothoracoscopic bullectomy and talc poudrage, the other 50 had only chest drain because of refusing surgery from September 1995 to January 2006. They found no statistically significant differences in long-term lung function between patients treated with pleural drainage only versus patients treated with videothoracoscopic talc poudrage for PSP.

Bridevaux and colleagues (19) studied 418 cases with recurrent PSP between 2002 and 2008 in nine centers in Europe and South Africa, during the 30-day observation period following talc poudrage, no ARDS, intensive care unit admission or death were recorded. Seven patients presented with minor complications (1.7%) after pleurodesis, mean body temperature increased by 0.41°C at day 1 and returned to baseline value at day 5. Pleural drains were removed after day 4 in 80% of patients.

Serious adverse events, including ARDS or death, did not occur in this large, multicentre cohort. They concluded that thoracoscopic talc poudrage using larger particle talc to prevent recurrence of PSP can be considered safe.

In our study, we enrolled the patients in the study in the period between January 2009 to December 2012; followed up during and after this period on outpatient clinic basis till June 2014 (mean follow up period of 27±4 months).

Patients were followed up clinically and radiologically for the safety of talc intrapleural instillation, pneumothorax recurrence rate and the occurrence of any radiologic abnormality in form of pulmonary fibrosis, pleural or lung opacities.

Although in-hospital parameters were not in favor of talc use (in terms of pain, mean total tube drainage, mean time to tube removal and longer hospital stay), the long term effect in term of rate of recurrence was significantly in favor of talc use, with no detected complications in the follow up period.

Our results go with the previously mentioned studies and others in the confirmed benefit of talc as a pleurodetic substance to prevent recurrence with documented induced inflammatory reaction. However those bothersome early disadvantages were tolerable and self limiting.

Study limitations: the relatively small number of patients and the short period of follow up. The inability to perform pulmonary function tests to all patients.

Conclusion

VATS is becoming the gold standard in management of recurrent ipsilateral PSP with good outcome regarding postoperative pain, hospital stay and rate of recurrence.

Thoracoscopic talc poudrage using sterile medicated asbestos-free large particle talc to prevent recurrence of PSP can be considered safe, effective and reproducible with negligible morbidity.

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Evaluation of VATS Sympathetic Cauterization in Treatment of Hyperhidrosis, Experience with 125 Cases

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Background: Primary Hyperhidrosis is idiopathic excessive sweating can cause significant professional and social handicaps. Although treatments such as oral medications, Botox, and iontophoresis are available, surgical sympathectomy is being increasingly utilized.

Methods: Between December 2009 and January 2012, 125 patients with palmar, axillary, facial, or plantar hyperhidrosis underwent a thoracoscopic sympathectomy in Alhada military hospital. Surgical technique was performed for them included cauterization of the sympathetic ganglia at T2, T3, and/or T4 depending on the location of the sweating, using monopolar cautery. A retrospective study was done to evaluate the results of the VATS sympathectomy for those patients.

Results : All patients were males, data were collected after approval of the ethical committee, mortality was 0%, recurrence was 1.6%, dry facial skin was 10.4%, compensatory sweating was 88.8%, sensory loss was 17.6%, breast parathesia was 8%, intercostal neuralgia was 9.6%, hemothorax was 2% and pneumothorax was 2.4%, patients' satisfaction showed significant difference between the pre and postoperative symptoms on the sweating satisfaction scale.

Conclusion: VATS sympathectomy is a very safe maneuver for treatment of primary hyperhidrosis, it gives satisfactory results and accepted controllable complications.

KAY WARDS: Hyperhidrosis, VATS, Sympethectomy

P rimary hyperhidrosis is an idiopathic excessive localized sweating not related to physiologic requirements of the body with a reported incidence of approximately 1% of the population. Palms, feet, axilla, scalp and face are the most commonly affected areas. It is also associated with severe noncontiguous flushing of the head and neck. Sometimes it is associated with abnormal respiration. (1)

Secondary hyperhidrosis usually manifested by increase total body sweating as a part of the manifestations of systemic disease such as hyperthyroidism, lymphoma, pheochromocytoma or central nervous system abnormalities. Hyperhidrosis usually begin in childhood or adolescence often representing an incapacitating and embarrassing disorder that can interfere with social and professional activities. (2)

Non-surgical treatment for hyperhidrosis, includes topical antiprspirants, orally administered anticholinergic medication which may partially block the transmission of nerve impulses to sweat glands, or iontophoresis, which uses water and a very mild electrical current to microscopically thicken the outer layer of the skin. (3)

Surgical management for hyperhidrosis started with an operation required an open thoracotomy. This was accompanied by a prolonged recovery period and significant morbidity. With recent advances in video assisted thoracoscopy upper thoracic dorsal sympathectomy has emerged as one of the preferable lines for management of primary hyperhidrosis. (4)

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Codex : o4/04/1408

Experience over time decreased the incidence and severity of complications following treatment with video assisted thoracoscopy. (5)

This study is a retrospective descriptive review of 125 patients underwent thoracoscopic dorsal sympathectomy in Alhada military hospital to analyze the results and experience with this modality of treatment for primary hyperhidrosis.

Patients and Methods

All operations were performed in Alhada military hospital, after taking written consents from all patients. The operations were performed under general anesthesia with double lumen endotracheal intubation so that the lung on the operative side can be deflated, patients were put in supine position with extended arms

The sequences of operations that had been done for all patients were as follow; three separate 5mm incisions made along the inframammary fold. We usually started by operating the right side first. Three sealed thoracoscopic ports were placed; carbon dioxide (CO₂) insufflation to less than 8mmHg of pressure was used routinely to improve exposure of the dorsal sympathetic trunk. The pleural space was then inspected using a 0 degree 5mm endoscope. The intercostal spaces and corresponding segments of the sympathetic chain then visualized and the overlying parietal pleura incised using monopolar cautery. The sympathetic ganglia at T2, T3 and/or T4 were isolated and individually cauterized except in fourteen patients in whom only T3 was cauterized as they complained from isolated palmar hyperhidrosis. In general T2 usually cauterized for patients with facial and scalp symptoms, T3 ganglion for palmar hyperhidrosis and the T4 ganglion for patients with axillary hyperhidrosis.

Hemostasis is then obtained and air was evacuated from the pleural space through a small bore catheter as the ports were removed so, usually chest tube insertion was unnecessary. After securing the right side, the procedure is then repeated on the left side.

At the end of the procedure a chest roentgenogram was then obtained. The patients were observed in the recovery area routinely and then discharged to regular beds within one to two hours.

Data Collection

Clinical data were reviewed and collected for all patients from data base of the hospital after approval of the ethical comity off ALHADA MILITARY HOSPITAL, including demographic data, family, history; duration and severity of symptoms which based on a scale from 0 to 10 considering ten as very severe symptoms. Post-operative results and complications were picked up from follow up sheets and progress notes, patient followed-up throughout the outpatient clinic files over the following 6 months post discharge from the hospital to assess early and late operative outcome.

Results

125 patients were operated between December 2009 and January 2012 in ALHADA Military Hospital for hyperhidrosis, all patients were males. table (1) Fourteen patients (11.2%) were complaining from isolated palmar hyperhidrosis, 58.4% were complaining from palm & axilla while 8.8% were axillary hyperhidrosis. 1.6% were scalp and palms, 4% were face and scalp, 0.8% were scalp and axilla, while 15.2% were complaining from hyperhidrosis of all the above. Table (2)

Female	0/125
Male	125/125
<u>Length of problem</u>	
Life long	90
Not of life long	35
<u>Received previous treatment</u>	
Topical agent	13
Botox	30
Beta Blockers	4
Anticholinergic	1

Table (1) Patients' demographic characteristics

Body Area	Patients
Palms (isolated)	14(11.2%)
Palms + Axilla	73(58.4%)
Axilla	11(8.8%)
Scalp + Palms	2(1.6%)
Face Scalp	5(4%)
Scalp + Axilla	1(0.8%)
All body	19(15.2%)

Table (2): Body area affected

72% of patient their complains started early in life, while 28% their symptom started under the age of twenty, 68% of patient suffered from extreme sweating episodes during daily activity, 72% only during emotional situations, 100% of them during exercise and only 24% during sleep. Table (3)

Daily Activity	85
Emotional Situations	90
Exercise	125
Sleep	30

Table (3) Episodes Extreme Sweating

24% of the patients treated by Botox before surgery but the results were unsatisfactory for them, 3% treated by Beta-blockers, 10% by topical agents and only one of them tried anticholinergics to relief the symptoms. All patients were prepared and scheduled for surgery on elective base from outpatient clinic. There were no deaths or major intraoperative complications.

In ninety patients there was no need for insertion of intercostal tube postoperatively. In 35 patients insertion of intercostal drainage tube was needed because of bleeding from the intercostal veins. The tubes were removed in the 2nd postoperative day, only in one patient the intercostal tube remained for 3 days as the lung was not fully inflated after surgery.

In three patients reinsertion of intercostal tube was needed for pneumothorax that discovered after removal of the chest drain. Two patients developed hemothorax and intercostal tube reinserted for 3 to 5 days until drainage was stopped and chest x-ray showed free costophrenic angles and inflated lungs.

Twelve patients complained from intercostal neuralgia, in three of them pain disappeared on the 7th postoperative day, two were in need of strong analgesic and intercostal nerve block twice before disappearance of pain, and in 7 of them pain was insignificant and disappeared on the 3rd postoperative day. Ten patients complained from breast paresthesia which disappeared within 6 to 8 weeks without medications except for one of them who needed reassurance and medical treatment in the form of vitamin B complex plus carbamazepine tablets.

Twenty two patients developed sensory loss along the intercostal nerve distribution of the 5th and 6th intercostal spaces; they were not in need for any medication or intervention. One hundred and eleven patients complained from compensatory sweating while 14 patients did not, those patients underwent cauterization for T3 only. Thirteen patients complained from dry facial skin, three of them complained from dandruff which treated by local skin moisture cream, and two had recurrence of symptoms on the left side, one of them underwent reoperation and the other refused and he used Botox. Table (4)

Complication	No (%)
Pneumothorax	3(2.4%)
Hemothorax	2(1.6%)
Intercostal Neuralgia	12(9.6%)
Breast parathesia	10(8%)
Sensory loss	22(17.6%)
Compensatory sweating	111(88.8%)
Dry Facial skin	13(10.4%)
Recurrence	2(1.6%)

Table (4) Complications

Patients were asked to evaluate their satisfaction with the procedure on a scale from 0 to 10, with 10 being the highest degree of satisfaction.

This was then converted to a satisfaction rating based on patient's response as following; scores 0-2 classified as very unsatisfied, 3-7 as satisfied and 8-10 as very satisfied. Preoperative assessments of the sweating severity in their affected areas were compared with the postoperative satisfaction on the same scale of 0 to 10 and showed significant improvement. Table (5)

Presenting Symptoms	Pre-OP Severity Score (0-10 scale)	Severity Score Post OP (0-10 scale)	Change in Score P- Value
Palms	9	1	8 <0.001
Axilla	8,7	2,1	6,6 < 0.001
Face/Scalp	7,5	3,1	4,4 < 0.001

Table (5) Patients' satisfaction

Discussion

The sympathetic trunk can be easily identified through the parietal pleura thoracoscopically and surgical division of the trunk can be safely performed with minimal associated morbidity.

88.8% of our patient experienced compensatory hyperhidrosis which usually affecting the upper abdomen, lower back, inner thigh and behind the knee. Similar studies reported variable range of occurrence of compensatory hyperhidrosis; **de-Campos et al.**,⁽⁶⁾ reported 94% in his study, **Wolosker**,⁽⁷⁾ **Lin et al.**,⁽⁸⁾ **Licht**,⁽⁹⁾ and **Licht et al.**,⁽¹⁰⁾ reported 100% while **Cameron**,⁽¹¹⁾ study showed zero percent .

Some theories explained that compensatory sweating is a thermoregulatory mechanism by which the sweat gland attempt to compensate for the decreased amount of secretory tissue. Many authors felt that compensatory symptoms could be reduced or eliminated by limiting the extent of sympathetic nerve excision, while others claimed that these symptoms can be correlated to both the level and the extent of resection.⁽¹²⁾

It is noticed that there is a relation between the number of levels excised and the degree of compensatory hyperhidrosis as we did only T3 resection for fourteen patients (11.2%) those were complaining from isolated palmer hyperhidrosis and they did not complain from compensatory hyperhidrosis while in the other patients we did resection for T2, T3 and T4. For the same reason **Lin et al.**,⁽¹³⁾ recommend limitation for the extent of resections for hyperhidrosis to a single level if possible in order to reduce the incidence of severe compensatory hyperhidrosis.

In this study; all patients were young age males in their productive period of life. 96% of them had social embarrassment due to hyperhidrosis. Other researchers as **Wolosker et al.**,⁽¹⁴⁾

and Milanez et al.,⁽¹⁵⁾ showed female predominance. Our study was conducted in a military hospital with most of the medically insured patients are males working in the army. Also, because of social attitude of the male predominant community where males are more and freely presented than females, this study included 100% male patients.

Most of cases had long history before seeking surgical attention and 38% of them received other modality of treatment but they were unsatisfied. We did not report Horner's syndrome in any case in this study, while it was reported in most of other studies with low incidence rate ranged from one to two cases like Gossot et al.,⁽¹⁶⁾ who reported two cases and Dewey et al.,⁽¹⁷⁾ who reported one case out of two hundred and twenty two cases. In this study, cauterization was not used much near T1 level to avoid such complication.

Intercostal neuralgia, breast paresthesia and transient sensory loss were time limited complications that disappeared within 3 to 6 months. Zacherl et al.,⁽¹⁸⁾ and Gossot et al.,⁽¹⁹⁾ reported similar percentages for these complications like this study.

In this study, 13 patients complained of dry facial skin which treated by local moisture cream and this complain disappeared after 2 months of treatment.

Two cases complained of recurrence, and this was because of over precaution not to burn T1 ganglia in order to avoid Horner syndrome. One underwent redo surgery on the left side and he developed satisfaction after that, the other patient refused to redo surgery and he tried another line of medical treatment (Botox).

Conclusion

VAT sympathectomy is a very safe maneuver for treatment of primary hyperhidrosis and it gives satisfactory results with accepted controllable complications which are not life threatening.

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Effectiveness of Surgical BioGlue in Controlling Alveolar Air Leak After Bullectomy

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Background: Despite advancing thoracic techniques and technical advances in sutures, the occurrence of postoperative air leak is not eliminated. Although air leaks are accepted morbidity following thoracic surgery, patients and surgeons are discouraged by the need for prolonged periods of chest tube drainage and extended hospital stays. BioGlue surgical adhesive (CryoLife, Kennesaw, GA, USA), received CE mark approval for use in pulmonary surgery and its use has been an area of concern for surgeons, especially thoracic surgeons.

The aim of this study is to evaluate the effectiveness of BioGlue Surgical Adhesive in controlling alveolar air leak (AAL) in patients who undergo bullectomy.

Methods: A prospective randomized controlled study was performed between January 2102 and December 2013. It was done on patients with recurrent or persistent primary spontaneous pneumothorax (PSP) who underwent Video-Assisted Thoracoscopic Surgery (VATS) for bullectomy. BioGlue was applied on the staple line in 18 patients (study group, 45%) and they were matched for age and sex with 22 patients (control group, 55% of patients) who underwent VATS bullectomy without the use of BioGlue. Follow up was done: (1) In-hospital for presence of air leak, duration of chest tube drainage, early postoperative complications and hospital stay and (2) within six months (range 1-12 months) of discharge in the OPD, for recurrence of pneumothorax or pulmonary complications.

Results: The mean duration of air leak (in days) was significantly shorter in the BioGlue group (0.8 with a range of 0-4 days) versus (2.3 with a range of 0-8 days) in the control group, the mean time for chest tube removal was significantly shorter in the BioGlue group (2.8 with a range of 2-6 days versus 4.3 with a range of 2-9 days). The mean time of hospital stay was shorter in the BioGlue group and this was statistically significant. There was no significant difference in morbidity between both groups. There was no mortality in both groups.

Conclusion: The use of BioGlue has offered an advantage in decreasing the time of air leak and chest tube drainage as well as hospital stay in patients with primary spontaneous pneumothorax undergoing bullectomy. BioGlue proved to be safe, effective and reproducible.

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Postoperative alveolar air leakage (AAL) following pulmonary resection is a common complication. Prolonged postoperative AAL is generally defined as an air leak that lasts more than 7 days.¹ AAL prevalence is reported to be greater than 15%, and incidence increasing to as high as 55% in patients with emphysematous lungs.² It may result in serious complications including longer duration of intercostal drainage and increased immobility with associated risks of infection, empyema, and thromboemboli.³ Although air leaks are accepted morbidity following thoracic surgery, patients and surgeons are discouraged by the need for prolonged periods of chest tube drainage and extended hospital stays. In addition, the cost of the operation and the risk of further complications are increased when postoperative air leak occurs.⁴

Various attempts have been made to prevent or reduce the incidence of post-thoracotomy AAL including additional surgical techniques, postoperative water-seal drainage with application of low suction, and surgically applied sealants.⁵⁻⁷

The use of adhesives or sealants in cardiothoracic surgery is well documented in the cardiothoracic surgery literature.^{8,9} The earliest publication in the English language literature came in the early 1980s from Harevich and colleges,¹⁰⁻¹¹ Walterbusch¹² and associates, and Borst and coworkers¹³, who reported success in sealing porous prosthetic vascular grafts with fibrin glue.

BioGlue (CryoLife, Kennesaw, GA, USA) surgical adhesive is a topically applied mixture of bovine serum albumin and glutaraldehyde. In North America, it is approved for use as an adjunct to standard methods of hemostasis in open surgical repair of large vessels.^{9,10,13,14} It also has European approval for use in a wide range of soft tissue repairs.¹¹ In March 1999 BioGlue (Cryolife, Kennesaw, GA, USA) received CE mark approval for use in pulmonary surgery.

The **aim of this study** is to evaluate the effectiveness of BioGlue Surgical Adhesive in controlling AAL in patients who undergo bullectomy.

Patients and Methods

This study included 40 patients who underwent video-assisted thoracoscopic bullectomy for persistent or recurrent Primary spontaneous pneumothorax (PSP), in the period between January 2013 and May 2014. Exclusion criteria included extremes of age and patients with secondary pneumothorax. Bullectomy was done using Endo GIA stapler (60 or 45mm). BioGlue was then applied over the staple line in 18 patients (study group, 45%) where an air leak was observed, and in the rest 22 patients (control group, 55%) nothing was applied.

The study was conducted in two centers: King Fahd university hospital, Khobar and Almowasat general hospital, Dammam, KSA.

BioGlue is composed of purified bovine albumin and glutaraldehyde. It is supplied in a prefilled cartridge. Its components are mixed within a double-helix syringe outlet and appear as a sticky yellow fluid at the tip of its applicator. It was applied topically over the suture staple line and any other area of air leak in the BioGlue group. The amount used ranged from 5-10 ml according to the site of leak. Air leak was graded as minor or minimal air leak, or moderate which is not detected by the anesthetist, or major leak which is observed by the anesthetist as loss of ventilatory pressure. No cases with major air leak were detected in our cohort. A period of 30 to 60 seconds was waited until the glue forms an amber yellow colored thin film over the suture line. One 28F chest tube was inserted at one port site, usually the camera port, and connected to underwater seal system. Low grad suction (- 20 cm water) was applied to the underwater seal system for the next 24 hours. Chest tubes were

assessed daily and removed when both air leak stopped for 24 hours and drainage was less than 100 ml in the last 24 hours.

Patients were monitored postoperatively for presence of air leak, which was defined as the presence of at least one bubble in the underwater seal unit with cough or deep inspiration, duration of chest tube drainage, postoperative complications, and hospital stay. Follow up was extended to a mean of 6 months (range 1-12 months) postoperatively for the recurrence of pneumothorax and occurrence of pulmonary complications.

The two groups were statistically compared using the Student *t* test for continuous variables and chi-square test for categorical variables.

Results

Two groups of patients were studied; BioGlue group included 18 patients who underwent bullectomy and consumed BioGlue at the staple line and, control group included 22 patients in whom BioGlue use was not added to bullectomy.

The mean age of the BioGlue group was 22± 4 years (ranging from 16 to 26 y), of them 17 were males and one female. The mean age of the control group was 25±5 years (ranging from 16 to 31 y), included 20 males and 2 females. Both demographic variables showed no statistical significance in distribution between both groups.

All patients were observed in the recovery room for the presence of air leak. Immediate postoperative leak was not present in 9 patients in the BioGlue group (50%) and in 6 patients in the control group (27.3%); this difference was statistically significant. (**P value** 0.042).

As regards duration of air leak, we found 15 patient of the BioGlue group to be free of air leak 83.3% (i.e. 3 patients with air leak, 16.7%) in the first postoperative day compared to 10 patients from the control group 45.5% (i.e. 12 patients with air leak, 54.5%). This freedom from air leak in the BioGlue group was statistically significant (**p value** 0.023).

The mean duration of air leak in the BioGlue group was 0.8 day (ranging from 0 to 4 d) their distribution was : 9 (50%) patients had no air leak postoperatively, 6(33.3%) had air leak for one day, 2(11.1%) patients for 2 days and last one(5.6%) had air leak for 4 days. In the control group, the mean duration of air leak was 2.3 days (ranged from 0-8 days). Their distribution was; 6 (27.3%) patients had no air leak immediately postoperative, 4 (18.2%) patients had air leak for one day, 4(18.2%) patients for 2 days, 3 (13.6%) patients for 3 days, 3 (13.6%) patients for 5 days, one patient (4.5%) for 7 days, and the last patient (4.5%) had air leak for 8 days. The difference of mean duration of air leak between both groups is statistically significant, (**p value** 0.03)

Time to tube removal in the BioGlue group had a mean duration of 2.8 days (range 2 - 6 d). In the control group the

mean duration of chest tube was 4.3 days (range 2 - 9 d). This difference was statistically significant in favor of the BioGlue group. (**P value** 0.015)

As regards hospital stay, the mean hospital stay duration was 4.1 days (range 3-7 d) in the BioGlue group versus 5.8 days (range 3-10 d) in the control group. This was statistically significant. (**P value** 0.048)

Postoperative complications in the BioGlue group was in the form of development of mild insignificant ipsilateral pneumothorax after removal of chest tube which occurred in 2 patients and was treated conservatively (both in the same hospital stay), and one patient developed chest infection. In control group, 3 patients developed mild ipsilateral pneumothorax (one before discharge and two in the first week after discharge) and were treated conservatively, 2 patients developed chest infection, one patient developed basal pleural thickening which was treated conservatively. The recurrence rate after discharge was found to be statistically significant. **P value** 0.046.

No mortality occurred in both groups. There was no significant statistical difference between both groups as regard morbidity and mortality.

After discharge, follow up was done at least for one month (ranging from one to 12 months) with chest radiography. All patients were seen in the outpatient clinic or contacted by phone for development of any other incidents.

Variable	BioGlue n= 18(45%)	Control n= 22(55%)	p-value
Age (years)	22±4 y	25±5 y	0.36 (NS)
Female sex	1 (5.55%)	2 (9.1%)	0.41(NS)
Male sex	17 (94.45%)	20 (90.9%)	0.27(NS)
Freedom from air leak in recovery room	9 (50.0%)	6 (27.3%)	0.042
Freedom of air leak in 1 st postoperative day	15(83.3%)	10(45.5%)	0.023
Mean duration of air leak (In days)	0.8 d(0-4 d)	2.3 d(0-8 d)	0.03
Mean duration of intercostal tube drainage (In days)	2.8 (2-6 d)	4.3 (2-9 d)	0.015
Mean hospital stay (In days)	4.1(3-7 d)	5.8(3-10 d)	0.048
Recurrence within the same hospital stay	2 (11.1%)	1 (4.5%)	0.184
Recurrence within the follow up period	0 (0%)	2 (9.1%)	0.046

Discussion

BioGlue surgical sealant (CryoLife, Kennesaw, GA, U.S.A.) is a topically applied mixture of bovine serum albumin and glutaraldehyde. It is approved for use as an adjunct to standard methods of hemostasis and for use in a wide range of soft tissue repairs. BioGlue has also been shown to reduce air leaks, length of chest drains and hospital stay in thoracic surgical practice.¹ However BioGlue is not an alternative to meticulous surgery and there have been many investigations into its value as adjunctive therapy for patients with difficult air leak at surgery that doesn't respond to conventional surgical techniques.

The aim of this work is to evaluate the role of BioGlue, in a prospective randomized controlled study, in management of alveolar air leak (AAL) and the potential benefits behind its use.

We observed an advantage in the BioGlue group as regard the period of air leak and duration of chest tube drainage which was significantly shorter, and this was reflected significantly on the period of hospital stay. Also, the beneficial effects of BioGlue started from the time of application as there was a higher number of patients free from air leak in the BioGlue group in the recovery room. Numerous studies and reports in the literature tried to prove the efficacy of tissue glues and the majority of them have advocated the use of these glues but have either been nonrandomised or involved a heterogeneous group of patients (there have been many anecdotal cases demonstrating the use of fibrin glue in reinforcing bronchial stumps, tracheal suture lines, and closing post-pneumonectomy bronchopleural fistula¹⁵. Wong and Goldstraw⁴ reported that the use of fibrin sealants does not add to the benefits of conventional techniques in reducing moderate-to-severe air leak in thoracic operations.

In a multicenter trial, a group of 172 patients undergoing thoracotomy were intraoperatively randomized to receive the only sealants currently approved by FDA or to have the standard lung closure. Application of the sealant resulted in control of air leak in 92% of the treated patients. Moreover, in the treatment group, trends were observed towards earlier chest tube removal and earlier discharge. No significant difference was observed between the two groups with regard to postoperative morbidity and mortality.⁷

In our study, the percentage of patients free from air leak in BioGlue group in the recovery room was significantly higher than the control group (50% versus 27.3%). Also the mean period of air leak in the BioGlue group was significantly lower than in the control group (0.8 versus 2.3).

Nine out of total twelve examined trials about the effectiveness of tissue sealants, showed a statistically significant difference between treatment and control groups in reducing postoperative air leak.¹⁶ However in only 2 trials this lead to a significant reduction in duration of chest tube drainage¹⁷ or hospital stay.¹⁸ We found a significant reduction in both air leak

and chest tube drainage duration. Wain et al.⁷ found no significant difference in the duration of pleural drainage in their series. However, they found a significantly shorter time of air leak in the group treated with lung sealant. Similar results were reported by Porte et al.⁶ Jurgen et al.¹⁹ retrospectively reviewed the benefits of using BioGlue in 40 patients, 36 of them were having intraoperative air leak. In 35 out of 36 patients alveolar air leak was controlled at the site of application of BioGlue.

As with all medical supplies, the improper use of BioGlue may be associated with negative outcomes, especially when it is applied unnecessarily. Some generic concerns remain regarding tissue glues, including the potential risk of blood borne disease transmission.⁶ Although we are not aware of any specific incidences with BioGlue, yet its bovine product formulation must be considered. In this respect, efficacious autologous fibrin preparations might confer advantage. Other concerns include foreign body implantation, exacerbated by slow resorption, that may predispose to empyema formation.^{20,21}

Our study suggests that the use of BioGlue tissue adhesive after VATS bullectomy is warranted due to its beneficial effects on reducing postoperative alveolar air leak and plural drainage duration and consequently hospital stay, also its use should be studied over larger population who are undergoing thoracotomy for other different pathologies with suspected major air leak.

Conclusion

The use of BioGlue in our study has offered an advantage to patients with PSP undergoing VATS bullectomy in terms of decreasing time of air leak and chest tube drainage with shorter hospital stay. BioGlue proved to be safe, effective and reproducible.

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Schwannomas are neurogenic tumours arising from Schwann cells of neural sheath. The peak incidence of these tumours is in 30s to 50s of life, with men and women being equally affected. Schwannoma is an encapsulated tumour which distinguishes it from neurofibroma without encapsulation. With both Schwannoma and neurofibroma, surgical excision results in cure. Our patient, fifty year male, presented with mild, dull aching pain over right antero-lateral chest and non-productive cough associated with breathlessness on physical exertion. Computed tomography of the chest was suggestive of neurogenic tumour (differential diagnoses: ganglioneuroma/ganglioneuroblastoma). The mass was excised via open right posterolateral thoracotomy and was sent for histopathological examination after which he was diagnosed as having Mediastinal Schwannoma. Mediastinal schwannomas, although generally benign and asymptomatic, should be excised upon discovery to prevent the development of life-threatening complications.

KEY WORDS: Benign, Neurogenic tumours, Schwannoma, Surgical excision

Schwannomas are neurogenic tumours arising from Schwann cells of neural sheath. Mediastinal schwannomas most frequently arise in a paravertebral location from sympathetic trunks or intercostal nerves¹. Forty per cent of schwannomas occur in the head and neck, with nine per cent occurring in the mediastinum². They are benign, slow growing neoplasms that frequently arise from a spinal nerve root, but can involve any thoracic nerve. They arise from the nerve sheath and extrinsically compress the nerve fibres. The peak incidence of these tumours is in 30s to 50s of life, with men and women being equally affected³. Schwannoma is well encapsulated and generally benign tumour which distinguishes it from Neurofibroma without encapsulation. Two characteristic histologic components of benign Schwannoma exist and are referred as Antoni type A and Antoni type B regions. Antoni type A regions contain compact spindle cells with twisted nuclei and nuclear palisading. Antoni type B regions contain loose and myxoid connective tissue with haphazard cellular arrangement. These characteristics allow them to be distinguished from malignant, fibrosarcomatous tumours that have no Antoni feature.

Our patient presented with mild, dull aching, right antero-lateral chest pain and non-productive cough associated with shortness of breath on physical exertion with no any other features of complication.

He was diagnosed to have postero-inferior mediastinal mass by contrast enhanced computerized tomography (CECT) scan chest and found to be Mediastinal Schwannoma on histopathological examination. He underwent open right posterolateral thoracotomy, accessed via incision over right sixth intercostal space under general anaesthesia.

CASE REPORT

A sixty year male from Cairo presented with mild, dull aching pain over right antero-lateral chest and non-productive cough associated with breathlessness on physical exertion. At presentation his general condition was normal and his vital parameters were stable. Systemic examination revealed no abnormalities. There was no localized swelling, deformity, tenderness, local rise in temperature and skin over

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Codex : 05/01/1407

the right chest wall was normal. Routine blood investigation showed Haemoglobin: 12 gm/dL, Total count: 6000/mm³, Platelet count: 166,000/mm³, Differential count with neutrophil 70%, lymphocyte 28% and Eosinophil 1%, Random blood sugar: 89 mg/dL, Blood Urea: 17 mg/dL, Serum creatinine: 0.9 mg/dL, Sodium: 144 mEq/L and Potassium: 3.3 mEq/L. Chest X-ray showed round hyperdense shadow over the right inferior region in postero-anterior view and over the posterior region in lateral view (Figure 1).

He had already undergone Contrast enhanced Computerised tomography (CECT) scan (Figure 2) chest which showed 13×14×9 cm³ mildly enhancing sharply margined mediastinal mass along the right costal, paravertebral region with inferior extension showing extrinsic mass effect and apparent extrathoracic extension suggestive of neurogenic tumour (differential diagnoses: ganglioneuroma/ganglioneuroblastoma). Pulmonary Function test (PFT) revealed Pxed upper airway obstruction with the ratio of Forced expiratory volume in one second (FEV1) to Forced vital capacity (FVC) 65.3% (less than 70%), reduced FEV1 55.5% (less than 80%), normal FVC 96% (more than 80%), normal Vital capacity (VC) and Bow volume loop showing

adequate volume but severe reduction in flow on exhalation with characteristic flattening with well-preserved inspiratory limb. Patient was diagnosed to have mass over right postero-inferior mediastinum and was planned for excision of the mass. He underwent open right posterolateral thoracotomy, via incision over right sixth intercostal space under general anaesthesia. Grossly round, smooth, rubbery mass (Figure 3) of about 14×15×16 cm³ was seen over the postero-inferior aspect of the right lung with avulsion of the lung around the mass and depression of the mass over the right lung. Surrounding structures like Aorta, Inferior vena cava and oesophagus were not involved. Histologically, mass was consistent with Schwannoma characterised by encapsulated variegated appearance exhibiting cellular spindle cells with fascicular and storiform patterns interrupted by hypocellular oedematous and hyalinised areas with focal degenerative nuclear atypia (figure 4). During the procedure and following procedure patient status was normal. Patient was stable and shifted to Intensive Care Unit for monitoring as resection of huge thoracic tumours may result in arrhythmia and post-operative bleeding. He was discharged on ninth post-operative day and had a steady recovery.

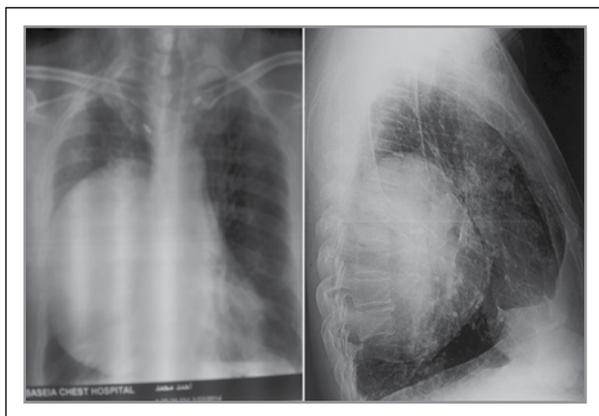


Fig 1. Round hyperdense shadow in right inferior region in Postero-anterior view and in posterior region in Lateral chest X-ray

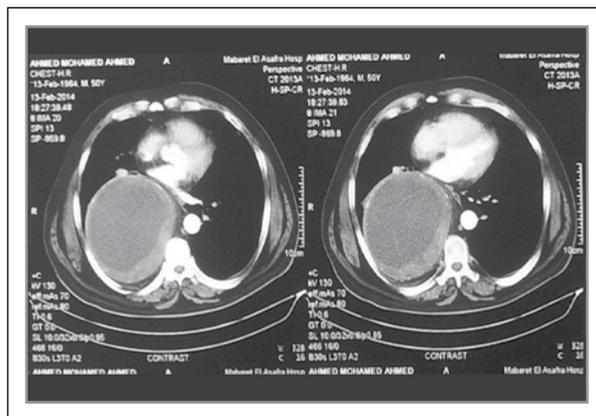


Fig 2. CECT chest showing mildly enhancing sharply margined mediastinal mass

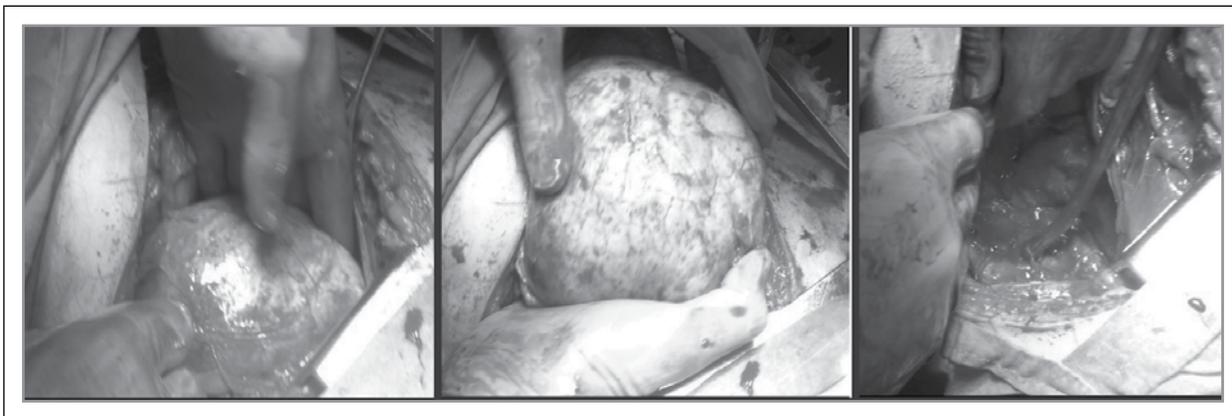


Fig 3. Round, smooth and rubbery mediastinal mass,

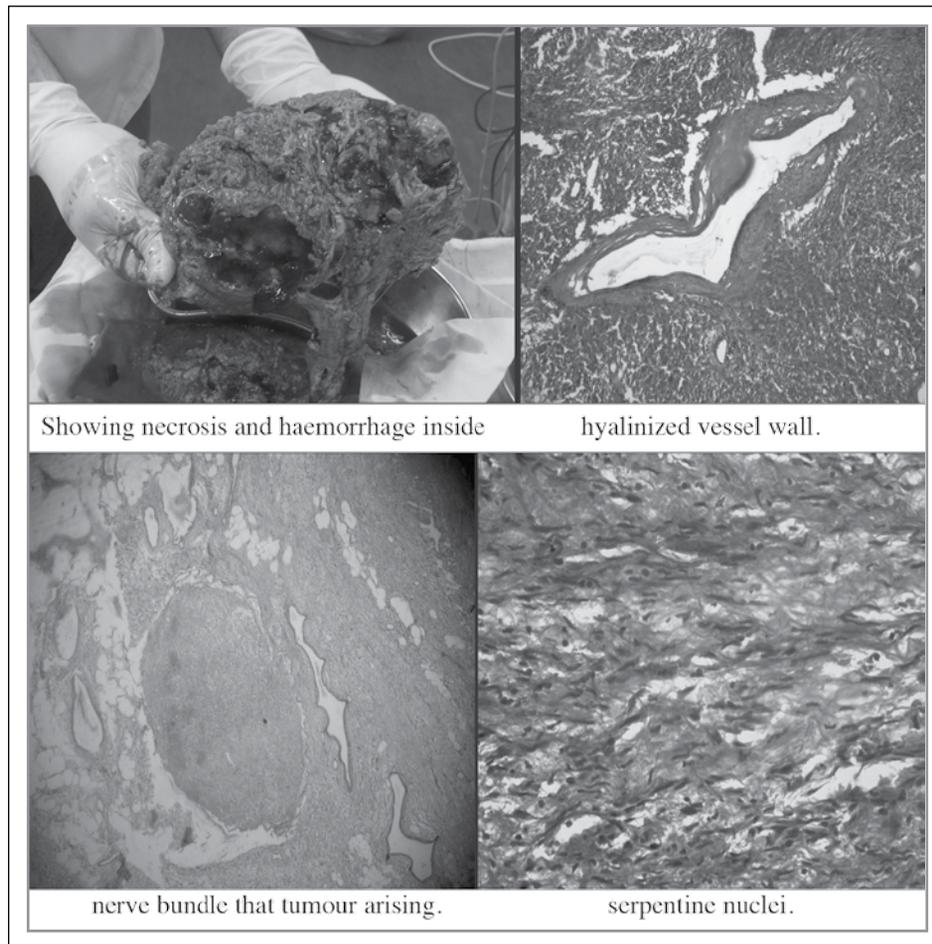


Fig 3. degenerated and necrotized cystified and cellular spindle cell tumor with feature of cellular Schwannoma

DISCUSSION

Benign neurogenic tumours are mostly located in the posterior mediastinum. These include nerve root tumours (Schwannomas or neurofibromas), sympathetic ganglion tumours (neuroblastomas, ganglioneuroblastomas, ganglioneuromas) and paragangliomas (chemodectomas and pheochromocytomas). Among these tumours benign Schwannomas are the most frequently encountered type in clinical practice.

The peak incidence of these tumours is in 30s to 50s of life, with men and women being equally affected. In children and infants, neurogenic tumours are the most commonly occurring tumour. Approximately two thirds of mediastinal masses are symptomatic in the paediatric population, while only approximately one third produce symptoms in adults. When considering all age groups, nearly 55% of patients with benign mediastinal masses are asymptomatic at presentation, compared to only approximately 15% of those in whom masses are found to be malignant⁴. Rarely patient with left posterior

Mediastinal Schwannoma may present with cardiac tamponade, a life threatening condition⁵.

Radiological tools like CT and magnetic resonance imaging of the chest and spine are useful in determining the exact anatomic location of the mass, as well as exclude any vascular origin, local and intraspinal invasion of the mass. These modalities are also very useful in excluding other differential diagnoses of posterior mediastinal mass.

Mediastinal Schwannomas most frequently arise in a paravertebral location from sympathetic trunk or intercostal nerves⁶. Radical surgical excision of the mass by thoracoscopy or thoracotomy is the treatment of choice⁷. However, there is no way to determine the malignancy of the lesion; even benign tumours can grow to large dimensions and cause compression symptoms⁸. The tumour will continue to increase in size if left untreated; hence, prompt management would affect the prognosis. Thoracotomy via the posterolateral approach has been in practice for long as a conventional surgical technique for resection of these posterior mediastinal masses⁹.

Now days, video-assisted thoracoscopic surgery is the preferred technique for the diagnosis and management of benign posterior mediastinal masses, as it is less invasive and results in fewer lung complications and a shorter hospital stay. However, malignant lesions are best approached via open thoracotomy¹⁰. Patients with benign neurogenic tumours have excellent survival prospects following complete resection, whereas those with malignant tumours have a poorer prognosis¹¹.

CONCLUSION

Schwannoma is a benign and slowly growing neurogenic tumour of mediastinum. Though mostly diagnosed incidentally but sometimes patient present with chest pain, cough and shortness of breath and rarely with cardiac tamponade, a life threatening complication of mediastinal masses like Schwannoma; timely intervention by open thoracotomy or thoracoscopy can lead to cure of these benign mediastinal pathology.

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