Jul-Sep. 2015

Number (3)



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# Journal of The Egyptian Society of Cardio-Thoracic Surgery

Volume 23

Jul-Sep. 2015

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**ISSN 1110-578X** 

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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.

# MANAGEMENT OF SEVERE ORGANIC TRICUSPID VALVE DISEASE: TO REPAIR OR TO REPLACE?

Yasser Ahmad Boriek, MD Alaa Eldin Farouk, MD <u>Background:</u> Organic tricuspid valve (TV) disease is uncommon. Few studies have compared TV repair with replacement in these patients. The purpose of this study was to compare operative, one year mortality and early outcomes of patients with severe organic tricuspid disease undergoing tricuspid valve repair versus replacement.

<u>Materials and Methods</u>: The present retrospective study was performed from March 2011 to April 2014 at Cairo University hospitals using the medical records of 80 cases of patients with severe organic tricuspid disease performing surgery including: 48 repairs and 32 replacements. Clinical and echocardiographic followup were obtained. There were 28 women (58%) in repair group and 20 women (62%) in replacement group in the study with a mean age of 34.5±10 years in repair patients and 34.6±9 years in replacement patients. In addition, tricuspid valve repair was associated with mitral valve surgery, aortic valve surgery, and both in 58%, 8%, and 10% of repair patients, and 56%, 9%, and 12.5% of replacement patients respectively.

<u>Results</u>: Both cardiopulmonary bypass and cross clamp times were statistically significant shorter in repair group (111±25 and  $83\pm20$  in repair Vs  $133\pm26$  and  $98\pm19$  in replacement respectively). According to the results, early mortality was higher in the replacement group, 25% versus 6.3% in the repair group (*p* value of 0.023). Follow-up echocardiography revealed recurrence of moderate to severe tricuspid regurgitation in (17%) of repair patients.

<u>Conclusions</u>: Tricuspid valve repair is associated with better early and one year survival than TV replacement in patients with organic tricuspid disease. Tricuspid valve repair is associated with recurrence of moderate to severe regurge during follow-up period. In patients with severe organic tricuspid disease, tricuspid valve repair is superior to replacement and should be considered whenever possible.

<u>KEYWORDS</u>: Tricuspid valve repair, Tricuspid valve replacement, Organic tricuspid disease.



urgical management and replacement of the tricuspid valve is a comparatively rare operation and is reserved for those few cases where repair of the tricuspid valve is not feasible or attempts at repair have failed<sup>[1]</sup>.

Tricuspid valve (TV) dysfunction can occur either with valves that are structurally normal or with organic valvular disease. Functional or secondary Tricuspid regurgitation in patients with normal leaflets is usually secondary to left heart pathology. It is the most common cause of TV disease, and its management is usually by simple TV repair techniques<sup>[2]</sup>. In contrast, organic TV disease is uncommon and comprises less than 1% of all valve operations<sup>[3]</sup>. The etiologies of organic TV disease include rheumatic valvulopathies, endocarditis, myxomatous disease, carcinoid syndrome, rheumatoid arthritis, radiation therapy, Marfan disease, congenital anomalies (e.g., Ebstein's anomaly, atrioventricular septal defect), systemic lupus, antiphospholipid syndrome, and other rarer causes<sup>[4]</sup>. Surgical management of organic

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Codex : o3/01/1507

TV disease is a challenge and its outcomes are significantly worse than after repair of secondary  $TR^{[\underline{S}]}$ .

Few studies have compared TV repair with replacement in these patients, so the optimum procedure is not well established. Several factors affect the decision of whether to repair or replace the tricuspid valve. These factors include patient age and comorbidities, surgical expertise, other concomitant procedures (repair or replacement), extent of the disease process, and amount of salvageable leaflet tissue. Regarding the perioperative mortality, there are several studies that revealed a high perioperative mortality rate (around 20%) in TV replacement<sup>[3,5]</sup>. However, it is unclear whether the increased mortality is a consequence of associated patient comorbidities or related to the surgical procedure. Although TV repair is associated with better perioperative survival, it has relatively high recurrent rates of late TR<sup>[3]</sup>. Residual TR can lead to biventricular heart failure, death, or reoperation<sup>[3,4]</sup>.

There is a lack of contemporary study in the literature to guide the choice of surgical management for organic TV disease. The aim of the current study was, therefore, to compare early, one year mortality and clinical outcomes of patients with severe organic tricuspid disease undergoing tricuspid valve repair versus replacement<sup>[6]</sup>.

# **PATIENTS AND METHODS**

This retrospective review includes 80 patients with severe organic tricuspid disease who underwent tricuspid valve surgery between March 2011 and April 2014 at Cairo University hospitals. There were 28 women (58%) in repair group and 20 women (62%) in replacement group in the study with a mean age of  $34.5\pm10$  years in repair patients and  $34.6\pm 9$  years in replacement patients with no statistically significant difference. Of these patients, 48 underwent tricuspid valve repair and 32 underwent tricuspid valve replacement.

## **Patient Characteristics**

**Table 1** shows the preoperative characteristics of the 80 patients who underwent either repair (n = 48) or replacement (n = 32) surgery for documented organic TV disease. The two groups were similar in most aspects. Thirty-one patients (65%) in repair group and twenty patients (62.5%) in replacement group were in New York Heart Association functional class III or IV. Twenty-seven (56%) had prior atrial fibrillation in repair and nineteen (59.5%) in replacement. There was a trend toward more regurgitant lesions in the repair group (p<0.05). Seven patients (21.9%) in replacement and three (6.3%) in repair group were presented by active endocarditis.

Tał	ole	1.	Preop	erative	charact	eristics	of	patients
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	Variable	Repair (n=48)	Replacement (n=32)	<i>p</i> -value
Age (years)		$34.5 \pm 9.9$	$34.6 \pm 9.1$	0.879
Sex (female)		28 (58.3%)	20 (62.5%)	0.709
LV ejection fraction (	<40%)	4 (8.3%)	3 (9.4%)	1.000
Diabetes		10 (20.8%)	5 (15.6%)	0.559
Renal insufficiency		2 (4.2%)	3 (9.4%)	0.384
Coronary artery disea	se	1 (2.1%)	1 (3.1%)	1.000
Preoperative stroke		7 (14.6%)	6 (18.8%)	0.621
Preoperative shock		0 (0.0%)	2 (6.3%)	0.157
NYHA Class III/IV		31 (64.6%)	20 (62.5%)	0.849
Endocarditis (Active)		3 (6.3%)	7 (21.9%)	0.080
Endocarditis (Healed)	•	13 (27.1%)	5 (15.6%)	0.229
	Rheumatic	28 (58.3%)	20 (62.5%)	
TV pathology	Infective endocarditis	16 (33.3%)	12 (37.5%)	0.224
	Myxomatous	4 (8.3%)	0 (0.0%)	
	Regurgitation	44 (91.7%)	12 (37.5%)	
TV disease	Stenosis	2 (4.2%)	17(53.1%)	<0.0001
	Mixed	2 (4.2%)	3 (9.4%)	
D	Sinus	20 (41.7%)	12 (37.5%)	
Preoperative	AF	27 (56.3%)	19 (59.4%)	0.905
rhythm	Complete heart block	1 (2.1%)	1 (3.1%)	
EF = ejection fraction	n; NYHA = New York Heart Association;	PA = pulmonary artery pressure	е.	

# **Surgical Technique**

A midline sternotomy was the surgical approach. Cardiopulmonary bypass was instituted with venous cannulation of the superior and inferior vena cava. In the reoperative setting, peripheral cannulation prior to sternotomy was performed in patients with severe right atrial or right ventricular dilatation. Tricuspid valve surgery was performed after concomitant cardiac procedures were completed, usually with the aortic cross-clamp in place. Myocardial protection was achieved with antegrade cold blood high potassium cardioplegia. The TV repair techniques varied according to the specific valve pathology and included ring annuloplasty, suture annuloplasty, band annuloplasty, and other techniques as required. Tricuspid valve replacement was performed by bioprosthetic valves. For bioprosthetic valves the decision to anticoagulate was made on an individual basis and depended on factors such as atrial fibrillation, presence of other prosthetic valves, and atrial size or thrombus.

## Follow-up

Patients were followed up clinically for 12 months postoperatively and received echocardiography before discharge from hospital and after a period of three, six and twelve months.

#### **Statistical Analysis**

The collected data was organized, tabulated and statistically analyzed using SPSS software statistical computer package version 18 (SPSS Inc, USA). For quantitative data, the mean and standard deviation were calculated. Independent t-test was used to compare between study groups regarding different parameters. For qualitative data the number and percent distribution was calculated, chi square ( $\chi^2$ ) or Fisher's exact test was used where appropriate as a test of significance. For interpretation of results of tests of significance, significance was adopted at P < 0.05.

# RESULTS

Operative details are summarized in **Table 2.** In the repair group, 15% had previously undergone cardiac surgery, compared with 28% in the replacement group with no statistical significance. In the repair group, tricuspid valve repair alone was performed in 10 patients (21%), whereas 38 (79%) underwent concomitant procedures, most commonly, intervention on another valve. In the replacement group, tricuspid valve replacement alone was performed in six patients (19%), and 26 (81%) underwent concomitant procedures, again most commonly, intervention on another valve. The operative procedure was urgent in six patients in replacement group (18.8%) versus two patients in repair group (4.2%) with no statistical significance.

Cross-clamp and cardiopulmonary bypass times were significantly different between the two groups. Both cardiopulmonary bypass and cross clamp times were statistically significant shorter in repair group ( $111\pm 25$  and  $83\pm 20$  in repair Vs 133 $\pm 26$  and 98 $\pm 19$  in replacement respectively).

#### **In-Hospital Outcomes**

In-hospital mortality was higher in the replacement group (**Table 3**). There was mortality in eight patients (25%) compared to three patients (6%) in repair group, which was statistically significant. Postoperative duration of ventilatory support and lengths of intensive care unit were significantly longer in the TV replacement group. There was a trend toward increased low cardiac output syndrome in the replacement group, but there was no differences found for hospital stay, inotropic support, postoperative renal failure and chest reopening.

Variable Urgent operation		Repair (n=48)	Replacement (n=32)	<i>p</i> -value	
		2(4.2%)	6(18.8%)	0.054	
Redo cardiac surger	у	7(14.6%)	9(28.1%)	0.138	
	TVR	10(20.8%)	6(18.8%)		
0	TVR+MVR	28(58.3%)	18(56.3%)		
Concomitant	TVR+MVR+AVR	5(10.4%)	4(12.5%)	0.993	
procedures	TVR+AVR	4(8.3%)	3(9.4%)		
	TVR+CABG	1(2.1%)	1(3.1%)		
Bypass time (minute	es)	$111.4 \pm 25.1$	$133.0 \pm 26.3$	<0.0001	
Cross clamp time (minutes)		$83.9 \pm 19.9$	$98.4 \pm 18.7$	0.001	

#### Table 2. Operative characteristics of patients

## Table 3. In-hospital adverse events

Variable	Repair (n =48)	Replacement (n=32)	<i>p</i> -value
Mechanical ventilation (hours)	15.6 ± 9.5	22.2 ± 12.7	0.001
ICU stay (days)	$2.9 \pm 0.9$	$4.6 \pm 2.5$	<0.0001
Hospital stay (days)	$12.1 \pm 2.8$	$11.9 \pm 4.2$	0.610
Inotropic support	34(70.8%)	25(78.1%)	0.468
In-hospital mortality	3(6.3%)	8(25.0%)	0.023
Postoperative low COP syndrome	3(6.3%)	6(18.8%)	0.146
Postoperative renal failure	2(4.2%)	3(9.4%)	0.384
Perioperative chest reopening	4(8.3%)	4(12.5%)	0.707
Permanent pace maker	1(2.1%)	5(15.6%)	0.035

# **Follow-up**

Recurrence in repair group was assessed by echocardiography to evaluate recurrence at the end of twelve months as shown in **Fig. (1)**.

Follow-up demonstrated recurrent moderate-to-severe regurgitation in eight (17%) of repair patients. Four patients presented by moderate tricuspid regurge 4/48 (8.3%) and another four patients presented by severe tricuspid regurge 4/48 (8.3%). Two of the four patients with severe tricuspid regurge were followed up medically (received medical treatment), while the other two patients were managed surgically by tricuspid valve replacement by bioprosthetic valve.

Follow-up during one year demonstrated one mortality in the replacement group to be totally nine mortalities by the end of 12 months, **9/32 (28%)** versus another two mortalities in the repair group to be totally five mortalities by the end of 12 months, **5/48 (10%)** as shown in **Table 4**.

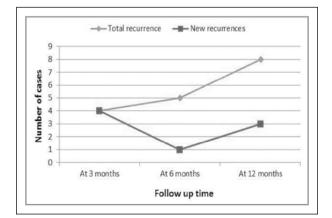


Fig. 1. Recurrence in repair group

Table 4. Mortality in both groups at 12 months of follow up

Variable		Repair (n =48)	Replacement (n =32)	<i>p</i> -value
Mortality	Died Survived	5 (10.4%) 43 (89.6%)	9 (28.1%) 23 (71.9%)	0.04

# DISCUSSION

Clinically significant tricuspid valve disease that may require surgical management in the form of repair or replacement is uncommon. This significant disease is usually presenting in patients with medically refractory congestive heart failure, endocarditis, or severe, irreversible pulmonary hypertension with secondary tricuspid regurgitation<sup>[1]</sup>. Because of these preoperative serious co-morbidities and concomitant cardiac procedures required for these often critically ill patients, the optimal surgical approach whether tricuspid valve repair or replacement, remains controversial<sup>[5,2,8]</sup>. In the current study, the goal was to compare operative mortality and early outcomes of patients with severe organic tricuspid disease undergoing tricuspid valve repair versus replacement.

Organic TV disease is very different from functional tricuspid regurge. It is due to a primary structural pathology of the tricuspid valve, and not secondary to other valvular or cardiac disease. It is an uncommon clinical entity and therefore there is limited experience from any one<sup>[6]</sup>.

There are different techniques of tricuspid valve repair that can be divided into those that are suture-based and those that utilize an annuloplasty ring. They are well described in the literature in case of secondary (functional) TR. These techniques of repair are simple and usually do not add significantly to the operative time and have low rates of morbidity and mortality. Tricuspid valve repair is associated with improved long-term survival but their long-term durability is associated with relatively high-published recurrence rates for  $TR^{[2,L0]}$ . Regarding Tricuspid valve replacement, in contrast, is associated with longer operative time and higher in-hospital mortality rates<sup>[2]</sup>.

In our study, both cardiopulmonary bypass and cross clamp times were statistically significant shorter in repair group (111 $\pm$ 25 and 83 $\pm$ 20 in repair Vs 133 $\pm$ 26 and 98 $\pm$ 19 in replacement respectively). These results are similar to that reported by Singh et al.<sup>[6]</sup>. regarding cardiopulmonary bypass time (122 $\pm$ 54 in repair vs 155 $\pm$ 79 in replacement), but cross clamp times were similar in both groups.

Tricuspid valve replacement remains associated with significant operative mortality and suboptimal long-term survival. In our study, early mortality rate of 25% in patients with tricuspid valve replacement compares well with most series published in the literature. Ratnatunga and colleagues<sup>[3]</sup>, reported the largest series in the literature, a multicenter registry study from the United Kingdom that included 425 patients with an operative mortality of 17.3%. A meta-analysis of studies published between 1994 and 2003 found a mortality of 19.2% in 1258 patients from 11 series<sup>[1]]</sup>. In addition, Tamer Farouk reported in his study an early mortality rate of 15% (three patients out of 20 in the study of early and mid term results of tricuspid valve replacement with bioprosthetic valve in organic tricuspid valve disease)<sup>[12]</sup>.

In our study, one-year survival in patients with tricuspid valve replacement was 71.9%. These results are consistent with the largest series of tricuspid valve replacements from the United Kingdom Heart Valve Registry, comprising 425 patients operated on between 1986 and 1997, that reported survival rates at 1, 5, and 10 years of 72%, 60%, and 43%, respectively<sup>[3]</sup>.

In an attempt to decrease the morbidity and mortality associated with tricuspid valve surgery, most surgical centers prefer to do tricuspid valve repair when technically feasible. In the current report, operative mortality for all 48 patients undergoing tricuspid valve repair was 6%, which is statistically significant lower than mortality in the replacement group (25%) with p value <0.05. Furthermore, one-year survival in the repair group was (89.6%).

Several studies have reported similar results with tricuspid valve repair, including Singh et al.<sup>[6]</sup> who in 2006 reported the results of their study comparing the results of tricuspid valve repair with tricuspid valve replacement. In that series consisting of 178 repairs and 72 replacements, the Toronto group demonstrated improved perioperative, midterm, and event-free

survival with repair over replacement. Singh et al reported 4% mortality in repair patients versus 22% mortality in replacement patients, which was statistically significant and similar to results in our study (6% in repair Vs 25% in replacement).

Improved survival in TV repair in our study is explained because of a higher early (perioperative) mortality rate in the TV replacement group. The worsened mortality is possibly due to that there were increased number of patients in replacement group presented urgently, (six patients in replacement group 18.8% versus two patients in repair group 4.2%) and Seven patients (21.9%) in replacement versus three (6.3%) in repair group were presented by active endocarditis. In addition, the worsened mortality is possibly due to progressive RV dysfunction in the TV replacement group. Our results support this theory by the findings of increased perioperative low output syndrome (19% in replacement patients). The association of acute RV failure post-cardiac surgery with increased mortality is well supported in the literature<sup>[5]</sup>.

Follow-up echocardiography over one year demonstrated recurrent moderate-to-severe regurgitation in 17% of repair patients. In 2004, McCarthy and colleagues<sup>[10]</sup>, reported a retrospective series of 790 patients who underwent tricuspid valve annuloplasty and documented a recurrence rate for 3+ to 4+ regurgitation of 10% at one month and nearly 20% at 8 years. Other investigators have reported rates of recurrent tricuspid regurgitation after repair approaching 40%, especially for repairs without ring annuloplasty<sup>[9,13]</sup>. The recurrence rate varies according to the type of repair performed, with higher recurrences for suture annuloplasty, particularly the De Vega repair<sup>[10]</sup>.

# **Study Limitations**

Our study results are limited by its retrospective nature with all of the limitations of such investigations. The statistical power of the study is low due to the relatively small patient population, and the follow-up might be short to estimate survival and complications over longer time. Further prospective randomized trials with longer duration of follow up and larger patient's population may give results that are more conclusive.

# CONCLUSION

Tricuspid valve repair is associated with better early survival than TV replacement in patients with organic tricuspid disease. Tricuspid valve repair is associated with recurrence of moderate to severe regurge during follow-up period. In patients with severe organic tricuspid disease, tricuspid valve repair is superior to replacement and should be considered whenever possible.

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# Comparative Study of the Effect of Normothermic versus Hypothermic Cardiopulmonary Bypass during Coronary Revascularization in Postoperative Bleeding and Transfusion Requirements

Nasr E. Mohamed, MD.

**Background:** Hypothermic cardiopulmonary bypass (CPB) was introduced in cardiac surgery in order to protect organs against hypo perfusion. Hypothermia is associated with many adverse effects on the vital organs and inhibits coagulation, which is an enzymatic procedure that depends on temperature. Normothermia on the other hand is more in agreement with the physiology of human organs.

<u>Objectives</u>: Evaluating the effect of body temperature during *CPB* on postoperative blood loss, transfusion requirements and platelet functions in coronary surgery compared to moderate hypothermia.

<u>Methods</u>: Sixty four patients were randomized between June 2012 to January 2014 into normothermic (Group A...35-37 °C, N=32) and moderate hypothermic (Group B...30-32° C, N= 32) and compared with respect to blood loss, transfusion requirements and need for re-exploration in primary coronary artery bypass grafting. Platelet aggregation was done pre-operation and at two hours post-operative (PO) to ascertain the impact of body temperature during CPB on platelets.

<u>Results</u>: There were no significant differences in preoperative characteristics including patient age, sex, hemoglobin, hematocrit level, and platelet aggregation. Normothermic patients tended to "bleed less at 24 hours p.o (warm, 388.1 $\pm$  126.5 ml vs. cold, 639.87  $\pm$  219.6 ml). Platelet function was preserved better in normothermic patients than in hypothermic patients. The warm group had less transfusion requirements compared to hypothermically- perfused group. There was no statistically significant difference between both groups regarding the need for re-exploration for bleeding.

<u>Conclusions:</u> These data suggest that normothermic systemic perfusion reduces postoperative blood loss, transfusion requirements, and it preserves platelet function.

**KEY WORDS:** Hypothermia, Normothermia, Cardiopulmonary bypass Platelet dysfunction.

xcessive bleeding after cardiac operations remains a major source of morbidity and mortality. (8) Changes in coagulation are the most frequent complications seen of CPB. The patients mostly require treatment by blood products and in approximately 3% surgical re-exploration is necessary. Moderate hypothermic CPB is commonly used to protect tissues from ischemia due to inadequate perfusion during open cardiac surgery. (7, 11).

Hypothermia is known to induce platelet dysfunction and inhibit coagulation, which may exacerbate the bleeding when hypothermia is used in conjunction with CBP (5, 6).

Clinical studies reporting various measures of outcome, but little information has been published as regards to differences in blood loss and transfusion requirements between hypothermic and normothermic techniques . (10).

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# Aim of the Work

Comparing the impact of using hypothermic versus normothermic CPB on post-operative blood loss and transfusion requirements in coronary surgery.

# **Patients and Methods**

# **Patients & Groups**

The study was approved by our ethical committee .It include sixty four patients undergoing elective on-pump coronary artery bypass grafting (CABG) with conventional cardiopulmonary bypass in Armed Forces Hospitals Southern Region between June 2012 to January 2014. These patients were divided equally into two groups:

Group A. Patients undergoing the operation on normothermic bypass (normothermic)

Group B. Patients undergoing the operation on hypothermic bypass (hypothermic group).

Patients were matched in each group for all variables except for the temperature of the bypass.

## Inclusion criteria

Patients with ischemic heart disease who are undergoing first-time, elective and isolated on-pump coronary artery bypass grafting.

## **Exclusion criteria:**

- 1. Pre-existing coagulopathy or other haemostatic disorders.
- 2. Antiplatelet intake in the last 10 days prior to surgery.
- 3. Emergency coronary artery bypass grafting
- 4. Redo coronary artery bypass grafting.
- 5. Patients who have other associated cardiac pathology.
- 6. Hepatic or renal impairment.
- 7. Anemic patients.
- 8. Polythycemic patients.

# Patients were subjected for the following:

## A. Preoperative:

- History and clinical examination.
- Full blood count.
- INR, PTT and ACT. (Coagulation profile)

#### **B. Operative:**

- Operative procedure done and number of vessels grafted.
- Total bypass time and aortic cross-clamp.
- ACT and Hgb before closure of the sternum.
- Need for blood transfusion or other blood products intra-operatively.

## **C.** Postoperative:

- Full blood count 2, 12,24hours postoperatively.
- INR, aPTT 2, 12, 24 hours postoperatively.
- Postoperative blood loss identified as total chest tube drainage starting immediately after closure of the chest in the operating theater.
- Transfusion requirement, Number of units and type of blood products used whether RBC units or FFP or platelets.
- Re-exploration for bleeding.
- Platelet aggregation using ADP was done immediately before operation and at two hours postoperative

## Normothermic technique

Myocardial protection was achieved by using intermittent warm blood cardioplegia with Blood was taken directly from the oxygenator.

# Hypothermic technique

Myocardial protection was achieved by using Cold blood cardioplegia (3 blood : 1 crystalloid) 10-15 ml/kg for induction with 30 mEq/L of potassium, Sodium bicarbonate 13mEq/L, magnesium Img/L & xylocaine 60 mg will be injected into the aortic root after aortic cross clamping. This will be followed by 10 mL/kg every 30 minutes during aortic cross-clamping, and throughout this period, topical myocardial cooling will be used keeping Systemic temperature between 30°C to 32°C during the cross-clamp time.

## **Statistical Analysis**

The collected data was analyzed using SPSS version 12.0 (Statistical Package for Social Sciences). All continuous variables are expressed as mean  $\pm$  standard deviation. Student's paired *t* test was used to determine the significance of difference between pre and post-operative measurements, and independent student's *t* test was used to determine the significance of difference between the mean values of both groups. Both *t* tests were used for quantitative variables. Chi square test and Yates correction was used to ascertain the association between two or more categorical variables. Statistically significant difference was considered to exist when *p* <0.05 in all study phases.

# RESULTS

# **Demographic data**

Analysis of demographic data revealed no difference between the two groups of patients undergoing either normothermic or hypothermic bypass.

The mean age for normothermic group was  $54.36\pm13.1$ and hypothermic was  $53.78\pm11.4$  years. The difference was statistically insignificant (p >0.05). Regarding sex distribution no statistical significant difference could be elicited between both groups. The normothermic group included 36 patients among which 12 patients were females while the hypothermic group included 36 patients among which 11 were females.

## **Clinical Characteristics**

The two groups of patients were homogenous for clinical characteristics

At baseline. Approximately, 72.2% of the normothermic group was in

New York Heat Association (NYHA) function class II compared to 69.4 % of the hypothermic group.

The angina status was nearly similar in both groups. The mean ejection fraction in the normothermic group was  $50.8\pm8.8$ , while the mean ejection fraction in the hypothermic group was  $49.4\pm9.1$  the differences in these previously mentioned three variables were statistically insignificant.

#### **Preoperative Hematological parameters**

The preoperative hematological values investigated were nearly similar in both groups.

No statistically significant difference could be elicited between both groups (table 1).

	Normothermic Group	Hypothermic Group	P value
Hemoglobin (g/dl)	13.9±1.4	13.7 ±1.1	1.00
ACT(sec)	102.68 ±22.9	$103.17 \pm 19.7$	0.637
INR.	1.12 ±0.069	$1.14 \pm 0.076$	0.337
aPTT (second)	39.1 ±2.88	38.44 ±2.81	0.7
Platelet count	258.9 ±35.92	284.94±38.64	0.78

Table 1. Preoperative hematological parameters among studied groups.

# **Operative Data**

Concerning the total time of surgery between the two modalities of surgery, the mean operative time in the normothermic group was  $198.98 \pm 43.8$  minutes compared to  $179.11\pm39.6$  minutes in the hypothermic group. The difference was statistically insignificant. The mean of CPB time was  $78.0\pm21.8$  minutes among the patients who underwent normothermic bypass compared to  $69\pm22.7$  minutes in the hypothermic group and the mean aortic cross-clamp time (ACC) was  $49.6\pm16$  minutes among the patients who underwent normothermic bypass compared to  $42.9\pm14$  minutes in the hypothermic group. The mean number of distal anastomoses per patient was  $2.6\pm1.0$  in the normothermic group compared to  $2.7\pm1.0$  in the hypothermic group. The differences were not statistically significant (Table 2).

	Normothermic group	Hypothermic group	P value
Operative time (min)	198.98 ±43.8	179.11±39.6	0.06
CPB time (min)	78±21.8	69±22.7	0.41
ACC time (min)	49.6±16	42.9±14	0.73
Number of distal anastomoses	2.6±1.0	2.7±1.0	0.38

Table 2. Operative parameters of studied groups

	Normothermic group	Hypothermic group	P value
INR	1.33±.078	1.59±0.17	0.001*
PTT (Sec)	43.88±2.69	49.88±3.98	0.001*
Platelet count (x10 <sup>9</sup> /L)	181.9 ±28.1	173.88 ±38.2	0.81

# Table 3. Hematological values among studied groups at two hours post-operatively

At two hours post-operatively, there were statistically significant differences between INR and PTT values between both groups with a mean INR of  $1.33\pm0.078$  in the normothermic group compared to  $1.59\pm0.17$  in the hypothermic group. Mean PTT  $43.88\pm2.69$  sec in the normothermic group compared to  $49.88\pm3.98$  sec in the hypothermic group. The platelet count decreased in both groups post-operation with no statistically significant difference.

	Normothermic group	Hypothermic group	Р
Pre-operative ADP induced PIT aggregation (%)	69.88± 13.91	64.80±17.90	.320
Post-operative ADP induced PIT aggregation (%)	59.1±12.66	33.1±14.2	.0001*

# Table 4. Changes in platelet aggregation in response to ADP at two hours post-operatively among study groups.

The preoperative platelet studies were similar in both groups. The mean ADP induced platelet aggregation among normothermic patients was  $69.8\pm 13.92$  (%) compared to  $66.1 \pm 19.15$  (%) in the hypothermic group. The differences were statistically insignificant. In the hypothermic group, there was a statistically significant change from pre-operative levels in ADP induced platelet aggregation as the postoperative mean platelet aggregation among\_hypothermic patients was  $33.1\pm14.1$  (%) compared to  $57.66\pm 12.9$  (%) in the normothermic patients .

The difference between the mean post-operatives bleeding in both groups was statistically significant, as the mean blood loss volume was  $388.1 \pm 126.5$  ml in the normothermic group compared to  $639.87 \pm 219.6$  ml in the hypothermic group. But only three patients in the normothermic group and four patients in the hypothermic group were re-explored for bleeding, the difference between re-opening in both groups was not statistically significant (Table 1.8). Two patients originally belonging to the normothermic group and 3 patients originally belonging to the hypothermic group were excluded from the study, as re-exploration for bleeding revealed a definite surgical bleeder and one patient was transferred to the ICU on IABP and heparin infusion.

	Transfus		
Items	Normothermic group	Hypothermia group	- Р
PRBC (mean units)	0.20±0.6	1.19±1.4	0.005*
FFP (mean units)	0.55±1.7	2.1±1.6	0.002*
PLTC (mean units)	1.40±2.90	3.9±4.9	0.004*
Total (total units)	42	86	0.001*

Table 5. Total blood constituents units transfused for both studied groups.

When comparing the total number of units used by each group in the whole post-operative period; the results were in favor of the normothermic group, whose patients needed less allogenic transfusions. There was a highly significant statistical difference between both groups as regards the number of units of all blood constituents transfused (**Table 5**).

# Discussion

Although coronary artery bypass graft (CABG) surgery can be performed without cardiopulmonary bypass, cardiopulmonary bypass remains essential for many cardiac surgical procedures. Cardiac surgery and cardiopulmonary bypass are, however, associated with significant morbidities including arrhythmias, bleeding, stroke, and neuropsychiatric complications (1, 14).

For more than 50 years, hypothermia has been used in cardiac surgery to protect the brain, heart, and other organs during CPB. Impaired platelet function increases postoperative blood loss. (2, 12)

Patients re-explored and found to have bleeding of definite surgical origin. Using this criterion, four patients were excluded and another patient was excluded because of insertion of IABP and starting of heparin infusion postoperatively.

Our results show that patients bleed more when they are hypothermic and are exposed to higher risk of allogeneic blood transfusion, which was observed by

Ho KM' et al, 2011 reviewed the benefits and risks, of maintaining normothermia during cardiopulmonary bypass in adult cardiac surgery, This review concluded that maintaining normothermia during cardiopulmonary bypass surgery in adults was as safe as hypothermic surgery and associated with a reduced risk of allogeneic blood transfusion (3,4,13).

Saeed et al, attributed a reduction of 30% in the volume of bloodshed during the first 24 hours post-operation to warm group (13). Bora et al, 2013 studied the inflammatory response and outcomes after cardiopulmonary bypass; they reported that hypothermic bypass increases blood loss and transfusion requirements after operation (2).

Rajagopalan et al, found that hypothermia significantly increases blood loss by approximately 18% and increases the relative risk for transfusion by approximately 22%. He studied the hypothermic group at  $34^{\circ}$ C while in our study; the hypothermic group studied at 30 -  $34^{\circ}$ C (13).

Joachim et al, found that when there was no difference in duration of CPB, normothermic and hypothermic CPB groups demonstrated similar blood loss and transfusion requirements. We suggest that this difference might be due to the great development in the technology of the CPB pump and the oxygenators (2, 4).

A definite platelet dysfunction was evidenced in the hypothermic group, by the decrease of ADP induced platelet aggregation more significantly than in the normothermic group.

In addition to a definite coagulation defect was evidenced by the prolongation of INR, PTT, and ACT in the hypothermic group more than in the normothermic group.

Similarly, several studies have demonstrated a platelet functional abnormality when using hypothermic perfusion (5, 7, and 9).

# Conclusion

This study shows that normothermic perfusion in the randomized patients was associated with a significant reduction in blood loss and transfusion of blood products post-operatively. Hypothermic CPB results in a more pronounced alteration of platelet aggregation than normothermic CPB.

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# Impact of Preservation of Pleural Integrity Versus Pleurotomy During Internal Mammary Artery Harvesting In Coronary Artery Bypass Grafting Surgeries On Postoperative Outcome

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<u>Background and objective</u>: During internal mammary artery (IMA) harvesting in coronary artery bypass grafting surgeries (CABG) the pleura may be kept closed or opened. The purpose of this study was to compare the effects of keeping the pleura intact versus pleurotomy during IMA harvesting in patients undergoing CABG on short term postoperative (PO) clinical outcome especially postoperative respiratory functional status, blood loss and cardiac tamponade.

<u>Patients and Methods</u>: This prospective study was carried out at Cardiothoracic Surgery Department, Kasr El-Aini Hospital, Cairo University, in the period between December2013 and July 2014. Forty patients with IHD for CABG were randomized and divided into 2 groups. Group (A): included twenty patients underwent IMA harvesting with intact pleura, while group (B): included twenty patients underwent IMA harvesting with pleurotomy. The patients were compared regarding their demographic data, surgical data, and postoperative events at 1 week and 3 months duration.

Results: The overall incidence of postoperative complications was more in group (B) patients. Compared to group (B) patients, the mean values of PaO, and SO, were higher, while the mean value of PaCO, was lower in group (A) patients (P value < 0.05), as found in ABGs measurements intra-operatively, immediately before extubation, after extubation and after one week postoperatively. The mean time needed for mechanical ventilation was significantly higher in group (B) patients (22.4 ± 6.3 hours) versus (18.1 ± 6.2 hours) in group (A) patients (P value = 0.03). There was significant difference regarding the duration of ICU stay between both groups in the form of  $(44.6 \pm 8.7 \text{ hours})$  in group (A) versus  $(57.9 \pm 11.2 \text{ hours})$  in group (B) (P value = 0.0002). Pulmonary function tests showed more improvement over a short period in group (A) patients versus group (B) patients. Ten patients had postoperative pleural effusion (50%) in group (B) versus three patients (15%) in group (A) (P value =0.01). Four patients had postoperative cardiac tamponade (20%) in group (A) versus none in group (B) (P value = 0.03). The mean duration of hospital stay was (7.2±1.8 days) in group (A) versus (11.6±5.3 days) in group (B) (P value=0.0012)

<u>Conclusion</u>: According to our results, preserving the pleural integrity had beneficial effect on the respiratory functional status after coronary revascularization as reflected by the shorter ICU stay duration, mechanical ventilation time and the need for blood transfusion. A careful IMA harvesting approach with intact pleura significantly reduces the postoperative morbidity especially that affecting the pulmonary functional status leading to a less prolonged ICU and hospital stay times and consequently reduces the total costs of the surgery.

<u>Background</u>: The left internal mammary artery (LIMA) is mostly used as the conduit of choice for myocardial revascularization. The LIMA has superior graft patency, better long-term survival, and fewer cardiac events. Due to these advantages this artery is widely used in coronary artery bypass grafting (CABG) (1).

ifferent techniques have been employed for IMA harvesting,. Some surgeons prefer to open the pleural cavity during the IMA harvesting for better exposure of this arterial conduit (2).

Respiratory dysfunction is considered one of the most frequent complications of CABG surgery (3). Its pathophysiology is complex and reflects the combined effects of general anaesthesia, surgical technique used, median sternotomy, CPB, finally producing hypoxia, atelectasis, pleural effusion, and diaphragmatic dysfunction (3). In some series, it was noted that the employment of the IMAs versus only vein grafts increased the pulmonary complication incidence and postoperative pain after CABG surgery, inducing a worse postoperative outcome(4). In other studies, in-situ IMAs, as an arterial conduit, was proved to have the favorable influence of a long postoperative outcome (5).

The purpose of this study was to compare and evaluate the effects of keeping the pleura intact versus pleurotomy during IMA harvesting in patients undergoing coronary revascularization surgery on postoperative morbidity especially that affecting the respiratory functional status, blood loss, the need for blood transfusion and cardiac tamponade.

# Patients and Methods

Forty patients with IHD confirmed by coronary angiographic studies for CABG were included in this study. All patients had been evaluated thoroughly preoperatively, intraoperatively, and postoperatively. The study included the assessment of pulmonary function parameters, intraoperative ABGs, postoperative ICU events especially the duration of mechanical ventilation, ICU stay duration, pulmonary complications, cardiac tamponade and hospital stay duration. The study was done after ethical committee approval at Cardiothoracic Surgery Department, Kasr El-Aini Hospital, Cairo University, in the period between December2013 and July 2014.

The patients were divided into two groups group (A): 20 patients underwent IMA harvesting with intact pleura and group (B) 20 patients underwent IMA harvesting with pleurotomy. Particular attention was paid to clinical findings of pulmonary functions parameters forced vital capacity (FVC),forced expiratory volume in first second (FEV<sub>1</sub>),ratio between FEV<sub>1</sub> and FVC (FEV<sub>1</sub> / FVC). These 3 functions were done for all patients using spirometry (**Spirosift 3000, Fukuda Denshi, Japan).** 

## **Statistical Analysis**

Clinical Data were statistically described in terms of mean, standard deviation ( $\pm$  SD), frequencies (number of cases) and relative frequencies (percentages) when appropriate. Differences between groups were investigated by the indepen-

dent samples *t* test and the Chi square ( $\chi^2$ ) test. The effects of variables were investigated by calculating odds ratios in univariate analyses for all patients. A probability value (*P* value) less than 0.05 was considered statistically significant. All statistical calculations were done using computer programs Microsoft Excel version 7 (Microsoft Corporation, NY, USA) and SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) statistical program

# Results

Regarding *the sex*, age, co-morbidities and the cardiac ejection fraction (EF%) ,co morbidities ( DM,HTN,dyslipedimia ,smoking,obesity,stroke or myocardial infarction) and NYHA classification in both groups showed no statistical significance

In group (A), the mean PaO<sub>2</sub> was 156.2  $\pm$  3.69 mmHg with a range of 150-160 mmHg, while in group (B), the mean PaO<sub>2</sub> was 146.5 $\pm$ 3.39 mmHg with a range of 140-150 mmHg. In group (A), the mean PaCO<sub>2</sub> was 33.4  $\pm$  1.18mmHg with a range of 32-35 mmHg, while in group (B), the mean PaCO<sub>2</sub> was 37.9 $\pm$ 1.07 mmHg with a range of 37-40 mmHg.In group (A), the mean SO<sub>2</sub> was 97  $\pm$  1.07% with a range of 96-99%, while in group (B), the mean SO<sub>2</sub> was 96.55  $\pm$  1.23% with a range of 95-98%. There was statistically significant difference between the two groups (P value < 0.05) regarding the PaO<sub>2</sub> and PaCO<sub>2</sub>, while there was no statistically difference regarding the SO<sub>2</sub>.

The total operation time, number of grafts, bypass time, ischemic time,usage inotropic agents showed no statistical significance between the two group

No attempt was done for extubation of the patients in the operating theater. All patients in both groups required mechanical ventilation. The post operative mechanical ventilation time ranged from 2-27 hours with a mean of  $18.1\pm6.2$  hours in group (A), while in group (B), the ventilation time was significantly higher and ranged from 8 - 29 hours with a mean of  $22.4 \pm 6.3$  hours (P value <0.05) as shown in table (1)

In group (A), the mean PaO<sub>2</sub> was 98.7  $\pm$  2.92 mmHg with a range of 96-106 mmHg, while in group (B), the mean PaO<sub>2</sub> was95.9  $\pm$  3.17 mmHg with a range of 92-100 mmHg.In group (A), the mean PaCO<sub>2</sub> was 32.95  $\pm$  0.82 mmHg with a range of 32-34 mmHg, while in group (B), the mean PaCO<sub>2</sub> was 37.1  $\pm$  1.44 mmHg with a range of 35-39 mmHg. In group (A), the mean SO<sub>2</sub> was 98.85  $\pm$  0.74% with a range of 98-100%, while in group (B), the mean SO<sub>2</sub> was 96.75  $\pm$  0.78% with a range of 96-98%.

There was statistically significant difference between the two groups (P value < 0.05) regarding the PaO<sub>2</sub>, PaCO<sub>2</sub> and SO<sub>2</sub>.

The postoperative blood loss (in ml), blood transfusion, need for reintubation showed no statistical significance between the two group

		Group A (n=20)	Group B (n=20)	P value	Significance
Mechanical ventilation	Range	2-27	8 - 29	0.0359	Significant
time (hours)	Mean ± SD	18.1±6.2	$22.4\pm6.3$	0.0359	Significant

Table 1. The mechanical ventilation time in the ICU

The mean duration of ICU stay in group (A) was  $44.6 \pm 8.7$  hours with a range of 24–60 hours, while in group (B), the mean stay was  $57.9 \pm 11.2$  hours with a range of 32-85 hours. The duration of ICU stay in group (A) was less with a statistically significant difference compared to group

In group (A), one patient (5%) had an elevated ST segment, while in group (B), 2 patients (10%) had an elevated ST segment after one week. There was no statistically significant difference between the two groups

The patients in group (A) had LVEF ranging from 39-60% with a mean of  $49.05 \pm 6.54$ , LVEDD ranging from 4.8-6.9 cm with a mean of  $5.81 \pm 0.67$  and LVESD ranging from 3.5 - 5.3 cm with a mean of  $4.42 \pm 0.64$ , while patients of group (B) had LVEF ranging from 43- 58 % with a mean of  $50.55 \pm 4.68$ , LVEDD ranging from 4.6-6.7 cm with a mean of  $5.41 \pm 0.69$  and LVESD ranging from 3.3-5.1 cm with a mean of  $4.37 \pm 0.65$ . There was no statistically significant difference between the two groups.

In group (A), the mean  $PaO_2$  was  $92.5 \pm 3.42$  mmHg with a range of 89-98mmHg, while in group (B), the mean  $PaO_2$  was

 $87.15 \pm 1.46$  mmHg with a range of 85-89 mmHg.

In group (A), the mean  $PaCO_2$  was  $34.95 \pm 1.09$  mmHg with a range of 34-37 mmHg, while in group (B), the mean  $PaCO_2$  was  $36.4 \pm 1.56$  mmHg with a range of 34-39 mmHg.

In group (A), the mean SO<sub>2</sub> was  $98.35 \pm 1.18\%$  with a range of 97-100%, while in group (B), the mean SO<sub>2</sub> was  $96.35 \pm 1.26\%$  with a range of 95-98%

There was statistically significant difference between the two groups (P value < 0.05) regarding the PaO<sub>2</sub>, PaCO<sub>2</sub> and SO<sub>2</sub>

Pulmonary function tests for the patients in group (A) showed that the mean FVC was  $3.04\pm0.53$ , the mean FVC % was  $81.47\pm10.35$ , the mean FEV<sub>1</sub> was  $2.47\pm0.22$ , the mean FEV<sub>1</sub>% was  $79.85\pm7.7$  and the mean FEV<sub>1</sub> / FVC was  $82.08\pm11.72$ , while in group (B), the mean FVC was  $2.57\pm0.66$ , the mean FVC % was  $73.99\pm12.3$ , the mean FEV<sub>1</sub> was  $1.77\pm0.60$ , the mean FEV<sub>1</sub>% was  $56.81\pm17.76$  and the mean FEV<sub>1</sub> / FVC was  $72.02\pm12.17$ . There was statistically significant difference (P value<0.05) in the pulmonary function tests between the two groups as shown in table (3),

		Group A (n=20)	Group B (n=20)	P value	Significance
ICU stay (hours)	Range	24-60	32-85	0.0002	<u>0::6</u>
	Mean ± SD	$44.6\pm8.7$	57.9±11.2	0.0002	Significant

Table 2. The duration of ICU stay in the study groups

		Group A (n=20)	Group B (n=20)	P value	Significance
FVC	Mean ± SD	3.04±0.53	2.57±0.66	0.0176	Significant
FVC %	Mean ± SD	81.47±10.35	73.99±12.3	0.0442	Significant
$\text{FEV}_1$	Mean ± SD	2.47±0.22	1.77±0.60	<0.0001	Significant
$\operatorname{FEV}_1$ %	Mean ± SD	79.85±7.7	56.81±17.76	<0.0001	Significant
FEV <sub>1</sub> / FVC	Mean ± SD	82.08±11.72	72.02±12.17	0.0113	Significant

Table 3. Pulmonary function tests after one week in the study groups

In group (A), 3 patients had atelectasis (15%), while in group (B), 11 patients had atelectasis (55%). There was statistically significant (P value < 0.05) difference regarding the incidence of atelectasis between the two groups as shown in table (21), figure (22).

In group (A), 3 patients had unilateral pleural effusion (15%), while in group (B), 10 patients had unilateral pleural effusion (50%). There was statistically significant difference (P value < 0.05) regarding the incidence of pleural effusion between the two groups as shown in table (21), figure (22).

In group (A), 4 patients had cardiac tamponade which required re-opening (20%), while in group (B), there was no patients had significant pericardial effusion. There was statistically significant difference (P value < 0.05) regarding the incidence of pericardial collection and cardiac tamponade between the two groups.

In group (A), 1 patient had sepsis and mediastinitis (5%), while in group (B), 3 patients had sepsis and mediastinitis (15%). There was no statistically significant difference in the incidence of sepsis and mediastinitis between the two groups.

In our study, we encountered two mortalities (10%) in group (B) and no mortalities in group (A). One patient died after 82 hours and the other one after 85 hours postoperatively from prolonged ventilation (> 24 hours), sepsis, low urine output and finally from multi-organ failure. The difference is statistically insignificant with a (P value >0.05) as shown in table (4),

The mean duration of hospital stay was  $7.2 \pm 1.8$  days with a range of 6-11 days in group (A) and was  $11.6 \pm 5.3$  days in group (B) with a range of 9 – 30 days. This difference is statistically significant with a (P value <0.05)

Three months follow up by echo showed that the patients in group (A) had LVEF ranging from 41-62 % with a mean of 50.1  $\pm$  7.03, LVEDD ranging from 3.9-6 cm with a mean of 5.29  $\pm$  0.74 and LVESD ranging from 2.9-4.5 cm with a mean of 3.85  $\pm$  0.62, while patients of group (B) had LVEF ranging from 44-60 % with a mean of 51.165  $\pm$ 5.53, LVEDD ranging from 4.1-5.9cm with a mean of 5.11  $\pm$  0.61 and LVESD ranging from 2.8-4.4 cm with a mean of 3.53  $\pm$  0.65. There was no statistically significant difference between the two groups

Three months follow up of pulmonary function tests for the patients in group (A) showed that the mean FVC was  $3.52\pm0.97$ , the mean FVC % was  $94.11\pm6.25$ , the mean FEV<sub>1</sub> was  $2.78\pm0.31$ , the mean FEV<sub>1</sub> % was  $94.54\pm16.46$  and the mean FEV<sub>1</sub> / FVC was  $81.25\pm13.92$ , while in group (B), the mean FVC was  $2.62\pm0.68$ , the mean FVC % was  $86.79\pm10.38$ , the mean FEV<sub>1</sub> was  $2.70\pm0.63$ , the mean FEV<sub>1</sub> % was  $84.32\pm17.26$  and the mean FEV<sub>1</sub> / FVC was  $85.03\pm9$ . There was statistically significant difference (P value <0.05) in FVC and FEV<sub>1</sub> / between the two groups, while in FEV<sub>1</sub>, FEV<sub>1</sub> % and FEV<sub>1</sub>/FVC there was no difference statistically between the two groups (P value >0.05) as shown in table (5).

	Group A (n=20)	Group B (n=20)	P value	Significance
Atelectasis	3 (15%)	11 (55%)	0.008	significant
Pleural effusion	3 (15%)	10 (50%)	0.018	significant
Pericardial tamponade	4 (20%)	0 (0%)	0.035	significant
Sepsis & mediastinitis	1(5%)	3(15%)	0.291	NS
Mortality	0 (0%)	2(10%)	0.146	NS
NS: Not significant				

Table 4.

		Group A (n=20)	Group B (n=20)	P value	Significance
FVC	Mean ± SD	3.52±0.97	2.62±0.68	0.0016	Significance
FVC %	Mean ± SD	94.11±6.25	86.79±10.38	0.0102	Significance
$\text{FEV}_1$	Mean ± SD	2.78±0.31	2.70±0.63	0.6133	NS
$\operatorname{FEV}_1$ %	Mean ± SD	94.54±16.46	84.32±17.26	0.1629	NS
FEV <sub>1</sub> / FVC	Mean ± SD	81.25±13.92	85.03±9	0.3143	NS

Table 5. Pulmonary function tests after 3 months in the study groups

# Discussion

Despite the evidence supporting LITA graft use, its harvesting has been associated with greater impairment of pulmonary function and changes in pulmonary mechanics leading to increased risk of respiratory complications ( $\mathbf{6}$ )

Concerning the pulmonary shunt fraction, previous studies demonstrated increased pulmonary shunt during early postoperative period following CABG independent of the surgical technique used (7)

In our study, the intra-operative ABGs withdrawn for the patients in group (A) showed that the mean  $PaO_2$  was  $156.2 \pm 3.69$  mmHg with a range of 150-160 mmHg, the mean  $PaCO_2$  was  $33.4 \pm 1.18$ mmHg with a range of 32-35 mmHg and the mean SO<sub>2</sub> was  $97 \pm 1.07\%$  with a range of 96-99%, while in group (B), the mean  $PaO_2$  was  $146.5 \pm 3.39$  mmHg with a range of 140-150 mmHg, the mean  $PaCO_2$  was  $37.9 \pm 1.07$  mmHg with a range of 37-40 mmHg and the mean SO<sub>2</sub> was  $96.55 \pm 1.23\%$  with a range of 95-98%. There was statistically significant difference between the two groups (P value < 0.05) regarding the ABGs.

Arterial hypoxemia normally occurs after CABG and persists for some weeks and compared to off-pump CABG dysfunction in gas exchange is found more accentuated in on-pump CABG (8).

The mechanism of hypoxemia can be attributed several factors, such as a change in the ventilation/perfusion ratio, hypoventilation, reduction in the diffusion capacity and shunts (9). The contact of the blood with the oxygenator triggers a cascade effect of enzymatic changes, with the release of inflammatory cytokines, increases in the permeability of the alveolar-capillary membrane, reducing the production of alveolar surfactant and diffusion by the blood-gas membrane, which harms the pulmonary compliance and consequently, the pulmonary volume and the gas exchange (10).

## **Postoperative Evaluation**

No attempt was done for extubation of the patient in the operating theater. All patients in both groups required mechanical ventilation. The post operative mechanical ventilation ranged from 2-27 hours with a mean of  $18.1\pm6.2$  hours in group (A), while in group (B), the ventilation time was significantly higher and ranged from 8 - 29 hours with a mean of  $22.4 \pm 6.3$  hours (P value <0.05)

In our study, the postoperative ABGs withdrawn in ICU *just before extubation* for the patients in group (A) showed that the mean PaO<sub>2</sub> was  $98.7 \pm 2.92$  mmHg with a range of 96-106 mmHg, the mean PaCO<sub>2</sub> was  $32.95 \pm 0.82$  mmHg with a range of 32-34 mmHg and the mean SO<sub>2</sub> was  $98.85 \pm 0.74\%$  with a range of 98-100%, while in group (B), the mean PaO<sub>2</sub> was  $95.9 \pm 3.17$  mmHg with a range of 92-100 mmHg, the mean PaCO<sub>2</sub>

was  $37.1 \pm 1.44$  mmHg with a range of 35-39 mmHg and the mean SO, was  $96.75 \pm 0.78\%$  with a range of 96-98%.

The ABGs withdrawn in ICU *after extubation* for the patients in group (A) showed that the mean PaO<sub>2</sub> was  $90.95 \pm 2.74$  mmHg with a range of 89-100mmHg, the mean PaCO<sub>2</sub> was  $35 \pm 1.12$  mmHg with a range of 34-38 mmHg and the mean SO<sub>2</sub> was  $98.07 \pm 1.07$  % with a range of 97-100%, while in group (B), the mean PaO<sub>2</sub> was  $86.55 \pm 2.54$  mmHg with a range of 84-90 mmHg, the mean PaCO<sub>2</sub> was  $37.2 \pm 1.36$  mmHg with a range of 35-39 mmHg and the mean SO<sub>2</sub> was  $95.95 \pm 1.09$  % with a range of 95-98%.

The ABGS withdrawn after **One week** for the patients in group (A) showed that the mean PaO<sub>2</sub> was  $92.5 \pm 3.42 \text{ mmHg}$  with a range of 89-98mmHg, the mean PaCO<sub>2</sub> was  $34.95 \pm 1.09$  mmHg with a range of 34-37 mmHg and the mean SO<sub>2</sub> was  $98.35 \pm 1.18\%$  with a range of 97-100%, while in group (B), the mean PaO<sub>2</sub> was  $87.15 \pm 1.46$  mmHg with a range of 85-89 mmHg, the mean PaCO<sub>2</sub> was  $36.4 \pm 1.56$  mmHg with a range of 34-39 mmHg and the mean SO<sub>2</sub> was  $96.35 \pm 1.26\%$  with a range of 95-98%.

There were statistically significant differences between the two groups (P value < 0.05) regarding the  $PaO_2$ ,  $PaCO_2$  and  $SO_2$  before and after extubation and after one week.

(2) reported that the opened pleurae negatively influenced blood arterial gas concentrations, resulting in a lower  $PaO_2$  and higher  $PaCO_2$  and  $FiO_2$  during the mechanical ventilation and in the first hours after extubation, returning to similar levels only during the fifth postoperative day.

(6)demonstrated that the decrease in  $PO_2$  occurred in both groups in their study; however, the decline in the open pleura group (23.4%) was significantly higher than that in the intact pleura group (14.7%). (11) noted a positive effect on postoperative pulmonary function when the pleurae remained intact during IMA harvesting for CABG surgery.

(2), (5) and (12) reported that the higher morbidity in the pool of patients with opened pleurae, for which the ICU and the total hospital times became prolonged, is probably due to the extensive dissection of the surrounding tissues during to the surgical procedure of IMA harvesting. Another explaining factor of finding such a result may be the incomplete visualization of the IMAs and unclipped mammary vein collaterals in patients in whom pleurae were opened due to the "relatively-wider" surface area that needs to be secured as compared to patients in group (A). 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.

In our study, after **one week** pulmonary function tests for the patients in group (A) showed that the mean FVC was  $3.04\pm0.53$ , the mean FVC % was  $81.47\pm10.35$ , the mean FEV<sub>1</sub> was  $2.47\pm0.22$ , the mean FEV<sub>1</sub> % was  $79.85\pm7.7$  and the mean FEV<sub>1</sub> / FVC was  $82.08\pm11.72$ , while in group (B), the mean

FVC was  $2.57\pm0.66$ , the mean FVC % was  $73.99\pm12.3$ , the mean FEV<sub>1</sub> was  $1.77\pm0.60$ , the mean FEV<sub>1</sub>% was  $56.81\pm17.76$  and the mean FEV<sub>1</sub> / FVC was  $72.02\pm12.17$ .

After **3** months follow up of pulmonary function tests for the patients in group (A), they showed that the mean FVC was  $3.52\pm0.97$ , the mean FVC % was  $94.11\pm6.25$ , the mean FEV<sub>1</sub> was  $2.78\pm0.31$ , the mean FEV<sub>1</sub> % was  $94.54\pm16.46$ and the mean FEV<sub>1</sub> / FVC was $81.25\pm13.92$ , while in group (B), the mean FVC was  $2.62\pm0.68$ , the mean FVC % was  $86.79\pm10.38$ , the mean FEV<sub>1</sub> was  $2.70\pm0.63$ , the mean FEV<sub>1</sub> % was  $84.32\pm17.26$  and the mean FEV<sub>1</sub> / FVC was $85.03\pm9$ . There was statistically significant difference in the pulmonary function tests between the two groups after one week and after 3 months.

The decline of  $\text{FEV}_1$ ,  $\text{FEV}_1$ % and  $\text{FEV}_1$ / FVC after one week was significantly different between the patients of two groups. That decline improved after 3 months so we can say that there were no statistically significant differences between the two groups in  $\text{FEV}_1$ ,  $\text{FEV}_1$ % and  $\text{FEV}_1$  / FVC after 3 months. On the other hand, the decline of FVC after one week was not significantly different between both groups, but there was significant difference after 3 months in FVC between both study groups.

(11) and (13) reported almost the same results concerning the pulmonary function tests differences one week and 3 months postoperative between the two studied groups.

CPB can increase the degree of diaphragmatic dysfunction. Currently, one of the most accepted explanations to justify the reduction in the FVC after the surgery is diaphragmatic dysfunction. This dysfunction starts in the manipulation of the viscera during the surgical procedure, causing reflex inhibition of the phrenic nerve and diaphragmatic paresis (14). Some studies have shown that the cardioplegic solution may cause thermal injury to the phrenic nerve. The cold solution can result in functional and structural abnormalities, damaging the conduction velocity, increasing the degree of diaphragmatic paresis, which may contribute with a greater drop in the pulmonary volumes and capacities (9).

In our study, 15% of patients had atelectasis and 15% had unilateral pleural effusion in group (A), while 55% of patients had atelectasis and 50% had unilateral pleural effusion in group (B). There was statistically significant difference (P value < 0.05) regarding the incidence of atelectasis and pleural effusion between the two groups.

(1), (15) and (16) achieved results that the incidence of atelectasis and pleural effusion were significantly higher in patients with open pleura than in the patients with intact pleura as IMA preparation by opening the pleurae induces the mediastinal blood loss to be shifted towards the pleural cavity, and hence by virtue of its hygroscopic nature, blood causes an increase in the quantity of the finally collected pleural effusion. (17) reported that atelectasis is one of the most important problems after CPB especially in the first 48 hours postoperatively.

The mean hospital stay was  $7.2 \pm 1.8$  days with a range of 6-11 days in group (A), and  $11.6 \pm 5.3$  days in group (B) with a range of 9 - 30 days, this difference is statistically significant with a P value < 0.05.

The study of (16) revealed that the duration of hospital stay was markedly higher in the open pleura group than those in the closed pleura group, which is similar to the findings in our study. (18)and (19) reported almost the same results regarding the duration of total hospital stay.

This shows that CABG patients with open pleura may contribute significantly in increasing the hospital costs and increase the use up of resources when compared to CABG patients with intact pleura.

# Conclusion

According to our results, we may say that preserving the pleural integrity during IMA harvesting in CABG has beneficial effects on the respiratory functional status. A careful IMA harvesting approach with intact pleura significantly reduces the postoperative morbidity especially that affecting the pulmonary functional status leading to a less prolonged ICU and hospital stay times and consequently reduces the total costs of the surgery. We conclude that preservation of pleural integrity, when possible, may decrease the discussed postoperative complications of CABG.

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# Concomitant Use of Bipolar Radiofrequency Left Atrial Ablation for Chronic Atrial Fibrillation During Mitral Valve Surgery: Impact on Clinical and Echocardiographic Outcomes

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Codex : o3/04/1508

<u>Background</u>: Atrial fibrillation is the most common of the serious cardiac rhythm disturbances and commonly complicates the course of heart diseases. Management ranges from medical treatment to complex surgery. As it was documented that in most cases of AF, the trigger of the abnormal impulse comes from the territory of pulmonary veins, the idea of pulmonary vein isolation came in mind. A bipolar probe which transmits radiofrequency waves to that territory can be used to ablate the macro reentrant conduits allowing the left atrium (LA) to function properly.

<u>Methods</u>: The population of this prospective observational study was 17 cases with mitral valve pathology requiring surgery complicated by chronic AF (onset > 1 year). They underwent mitral valve surgery and bipolar radiofrequency ablation in the period of October 2012 to October 2014 in King Fahd University hospital. They were followed for at least one year following surgery; mean follow up period was  $17 \pm 2.4$  months. Primary end point was reversion to stable sinus rhythm (SR) at one year follow up.

<u>Results:</u> Mean AF duration was 5.14  $\pm$ 3.14 years. 9 patients had mitral valve replacement, 5 bioprostheses and 3 had repair concomitantly with bipolar radiofrequency ablation. 4 patients had associated tricuspid valve repair. Mean bypass and cross clamp times were 92.35  $\pm$  16.7, 66  $\pm$  10.28 minutes, respectively. No mortalities, postoperative complications were few: one patient required reexploration for bleeding, one with severe bradycardia who had permanent pacing, one stroke which was tolerated (right upper monoparesis). At one year follow up 12/17 (70.5%) patients were in stable sinus rhythm, subjective clinical improvement in terms of marked reduction of NYHA class (3.18  $\pm$  0.6 to 1.57 $\pm$ 0.72). Echocardiographic parameters (EF, LA dimensions and LA function) had also significantly improved.

<u>Conclusion</u>: We conclude from our study that bipolar radiofrequency ablation is a safe and effective method of controlling atrial fibrillation and it can be easily added to conventional mitral valve surgery without considerable risk added to the patient.

KEY WORDS: Atrial fibrillation- radio frequency- ablation.



trial fibrillation (AF) is a supraventricular tachyarrhythmia characterized by uncoordinated atrial activation with consequent deterioration of atrial mechanical function <sup>(1)</sup>.

Atrial fibrillation is the most common of the serious cardiac rhythm disturbances and commonly complicates the course of heart diseases. Its prevalence increases with age <sup>(2)</sup>, almost doubles with each advancing decade of age, from 0.5% at age 50-59 years to almost 9% at age 80-89 years. <sup>(3)</sup>

AF is associated with significant morbidity and mortality: Patient discomfort from palpitation, loss of atrioventricular synchrony with resultant ventricular dysfunction and thromboembolic complications <sup>(4)</sup>.

The prevalence of AF in patients scheduled for a mitral valve procedure is still between 30 and  $84\%^{(5)}$ . In the presence of permanent AF the likelihood of SR recovery after a conventional heart operation alone ranges from 4.5 to  $36\%^{(5)}$ ,  $25\%^{(6)}$  and is even more unlikely in patients with left atriomegaly.

Even after otherwise successful cardiac surgery, patients with persisting AF often remain symptomatic, experience little improvement in exercise capacity and require life-long anticoagulation. Postoperative maintenance of sinus rhythm (SR) is associated with improved survival as compared to postoperative AF <sup>(6)</sup>, so it is justified to add AF surgery to the principal operation <sup>(7)</sup>

Management of AF ranges from medical therapy, catheter based intervention and surgery which passed through history from left atrial isolation procedure, corridor procedure, Cox-Maze procedures and pulmonary vein isolation. <sup>(8)</sup>.

Hassaiguerre and colleagues documented the triggers of AF from territory of pulmonary veins in the majority of cases so the idea of pulmonary vein isolation using bipolar radiofrequency (RF) ablation had a great appreciation <sup>(9)</sup>. It can be done without cardiopulmonary bypass (CPB), through a minimally invasive approach; also can be added easily to cardiac surgery procedures.

# Aim of work

As atrial fibrillation can be a serious concomitant problem in patients undergoing mitral valve surgery, this prospective trial aimed at studying the safety and early results of bipolar radiofrequency ablation of left atrium in those patients and follow up the rate of conversion to stable sinus rhythm and restoration of atrial function among other variables.

# **Patients and Methods**

- The population of this prospective study consisted of 17 patients having AF diagnosed for more than 12 months undergoing mitral valve surgery combined with radio-frequency ablation between October 2012 and October 2014 in King Fahd University hospital using bipolar probe (Medtronic atricure).
- All patients had written informed consent about the procedure and possible failure rate and complications.
- The primary end point of the study was stable SR, and success was defined as stable SR at 1-year follow-up.
- Patients' characteristics are shown in table (1)
- Exclusion criteria were: emergency operation, redo operation, low ejection fraction (EF<30%), big LA thrombus, endocarditis, AF duration < 12 months, recent MI (<10 days), heart rates less than 60/min, LA diameter of > 65 mm, old age > 65 years, pregnancy and nursing.

ECG, Holter monitoring and Transthoracic echocardiogram (TTE) were routinely performed on admission, TTE was performed to measure the ejection fraction (EF) using biplane method, LA anteroposterior diameter according to the American society of echocardiography <sup>(10)</sup>. LA volumes were determined at mitral valve opening (maximal volume) and at mitral valve closure (minimal volume). LA volumes were measured from the apical 4- and 2-chamber views by means of the biplane area-length method <sup>(11)</sup> From the LA volumes the left atrial function was calculated as (maximal volume –minimal volume /maximal volume %)<sup>(12)</sup>.

- Coronary angiography was done for those > 45 years of age.
- Daily ECG monitoring during postoperative period. Standard 12-lead ECG, TTE and Holter monitoring were performed on discharge, 3, and 12 months after operation.
- During ICU stay, all patients were given IV amiodarone infusion for 2 days then were changed after that to oral administration of 200 mg once daily for 3 months.
- AF recurrence was detected by Holter in the follow up period.
- The mean follow up period was 17±2.4 months ranged from 12 to 21months.

Surgical technique: (left atrial isolation procedure) figure (1)

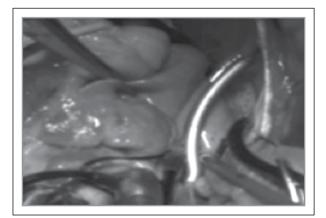


Fig 1.

After induction of anaesthesia, transesophageal echocardiography (TEE) probe was inserted to check for the presence of left atrial thrombus.

After initiation of cardiopulmonary bypass, the standard device (Medtronic atricure) is used to encircle the atrial tissue around the right then left pulmonary veins, impacting the atrial tissue in between the jaws of the device, applying automated handheld thermal ablation with temperature of  $55^{\circ}$ C

The generator continuously monitors voltage, current, temperature, time and conductance till the sensing unit indicates very low tissue conductance signifying full thickness coagulation then it stops automatically. Cross clamp is then applied, cardioplegia given, left atriotomy done as standard, the probe is then applied from orifice of right pulmonary veins till posterior mitral annulus. Left atrial appendage is then excised, from the opened base the probe is passed towards the mitral annulus then the base is sutured then mitral surgery done.

The principle of RF energy ablation is to produce a transmural line of cellular death by raising tissue temperature to greater than 55°C thereby, similar to a surgical incision, creates lines of conduction block preventing electrical conduction.

## Results

### Statistical analysis

Data are expressed as mean  $\pm$  standard deviation (SD). Student's t-test for paired data was used to assess the statistical significance of differences between pre and postoperative variables. A P-value of < 0.05 was considered significant. Preoperative variables considered for comparison to evaluate the modality of our study are: NYHA class, LA dimension, left atrial function and ejection fraction. -patient enrollment and demographics: starting since October 2012, 17 patients with mitral valve pathology necessitating valve surgery with chronic AF were enrolled in the study. Their characteristics are shown in table (1)

Age (years)	Mean 41.8 years ± 15.5 SD Range 19.9- 65.5 years
Sex	Males 7 (41%) Females 10 (59%)
AF duration(years)	Mean 5.14 ±3.14 years Range 1.2- 12.5 years
LA diameter (cm)	Mean 5.76 ±0.4 cm Range 5-6.4 cm
LA function (%)	38.76± 4.78% Range 29-45%
EF (%)	Mean 53.5±5.15 % Range 45- 62 %
NYHA class	Mean 3.18±0.64 (2-4)
Logistic euro score	Mean 2.024± 0.447 Range 1.5- 2.9
AF complications	Stroke 2 patients Acute LL ischemia 1 patient

Table 1. Preoperative data

Perioperative variables are shown in table (2). The operative data revealed mean bypass time of  $92.35 \pm 16.7$  minutes, mean cross clamp time of  $66\pm10.28$  minutes. Cardioversion needed in 47% of cases and patient reverted to sinus rhythm were 13 out of the 17 (76.5%)

All had mitral valve surgery done: mitral valve replacement (MVR) by mechanical prostheses in 9 patients (53%), bioprostheses in 5 patients (30%), MV repair in 3 patients (17%) with associated tricuspid valve repair in 4 patients (23.5%). Temporary pace maker was needed for bradycardia in 3 patients (17%). Mean hospital stay was 11.65  $\pm$  4.39 days (range 8-25 days).

Bypass time (min)	Mean 92.35 ± 16.7 min Range 67-122 min.
Cross clamp time (min)	Mean 66 ± 10.28 min Range 49- 80 min.
Cardioversion needed	8/17 (47%)
SR	13/17 (76.5%)
Principal operation	-MV replacement Mechanical: 9 (53%) Bioproshesis : 5 (30%) -MV repair: 3 ( 17 %)
Associated surgery	TV repair 4/17 (23.5%)
Temporary pace maker needed	3/17 (17.6%)
Hospital stay (days)	Mean 11.65 ± 4.39 days Range 8-25 days. Median 10 days

#### Table 2. Perioperative data

Postoperative data: No mortalities encountered in our study, only one patient had stroke in the follow up period (one of the residual AF patients), it was in the form of right upper monoparesis; blood loss was not significant with one reexploration for postoperative bleeding.

NYHA class improved (most of patients improved at least one class) from mean of  $3.18\pm0.6$  to  $1.53\pm0.72$  at one year follow up which was of significant improvement, stable sinus rhythm was encountered in 70.5% at one year of follow up. Five out of 8 patients who underwent repair or replacement with bioprostheses were in sinus rhythm at 3 months follow up and so anticoagulation was discontinued. Pace maker was needed in 3 patients intraoperatively, of which 1 required permanent pace maker insertion for severe conduction defect.

Echocardiographic data (mean EF, LA dimensions and left atrial functions) showed insignificant improvement at 3 months follow up which became of high significance at one year follow up which denoted the good long term effect of our modality of concern.

		In hospital	At discharge	3 m	12 m
Mortality		None	None	None	None
Morbidity	stroke	0	0	1	1
Blood loss (ml)	Mean Range	413± 192 ml 950-150	-	-	-
Reexploration		One	-	-	-
Stable SR		17/13 (%76.4)	17/13 (%76.4)	17/13 (%76.4)	17/12 (%70.5)
NYHA class		3.18± 0.6	-	1.71±0.67 P value <0.0001	0.72±1.53 P value<0.0001
Warfarin use		17 (%100)	17 (%100)	17 (%100)	17/12 (%70.5)
Pace maker required		17/3	17/1	17/1	17/1
Echo cardiography	-LA(cm) dimension (mean)	0.4±5.76 cm	-	0.57±5.51 P value (0.17) (NS)*	0.67±5.21 P value (0.0081)
	-EF % (mean)	%5.15±53.5	-	%3.98±56.35 P value (0.0773) (NS)*	%5.21±58.65 P value (0.0056
	LA function (mean)	38.76± %4.78	-	%42.18±5.03 P value (0.0509) (NS)*	%45.65±6.34 P value (0.0011)

#### Table 3. Postoperative follow up

Despite the limited number of patients in this study, We tried to detect variables associated with failure to restore to sinus rhythm, in this regard we compared in a descriptive way failed cases versus the whole study group regarding preoperative variables: age, LA dimension, NYHA class, AF duration and EF and also operative variables: CPB and cross clamp times as shown in table (4):

	Failed cases	Study group
Age (mean)	48	41.8
LA dimension (cm) mean	6.1	5.76
NYHA class (mean)	3.6	3.18
AF duration (years) mean	7.3	5.14
EF (%) mean	55.5	54.5
CPB time (min) mean	107.2	92.35
Cross clamp time (min) mean	68.0	66.0

Table 4. Comparison between failed and study groups

From that table we can detect that older age, larger LA diameter, prolonged AF duration, higher preoperative NYHA class and CPB time were variables associated with less favorable sinus rhythm restoration while EF and cross clamp time were not.

No RF ablation device-related adverse events were reported. All significant adverse events were classified as 'related to cardiac surgery' or to 'pre-existing condition'.

## Discussion

The BRFA (bipolar radiofrequency ablation) modality is designed based on the stable and good penetration properties of radiofrequency current. The local hyperthermia effect induced by the radiofrequency current can produce tissue coagulation necrosis and thus AF re-entrant loop is blocked.<sup>(13)</sup>

SR recovery allows withdrawal of anticoagulant medications when mitral valve repair or valve replacement with a bioprosthesis is carried out. Moreover even in patients on anticoagulant medications after mitral valve replacement with a mechanical prosthesis, intracavitary thrombosis and prethrombotic phenomena are favored by AF.<sup>(14)</sup>

The combination of a modified Maze operation, characterized by an extensive use of right and left atrial incisions, has proven effective in restoring SR. Drawbacks are: technical challenge and complexity, rendering it a non standard procedure, requires a considerable prolongation of cardiopulmonary bypass (CPB) and aortic cross clamp (ACC) times when performed in combination with other standard open heart procedures. Moreover even when SR is restored after combined valve surgery and maze procedure, recovery of atrial function is below 80%<sup>(15-16)</sup>

A systematic review of the surgical treatment of atrial fibrillation by Khargi et al did not show any significant difference in the success rate between the classical cut-and-sew and alternative ablation devices techniques <sup>(17)</sup>. They found also that despite unsure complete transmurality of the ablation lines, the rate of conversion to stable sinus rhythm was comparable to classic cut and sew technique.

The problem of transmurality was addressed through animal studies which showed that when conduction reached a stable minimum, lesions were always transmural .Also transmural ablations needed seconds to be performed contrary to the minutes required for unipolar probes. The lesions were discrete (1 to 2 mm in width) and there was little lateral spread of thermal energy, thus eliminating the risk of collateral damage to vital structures<sup>(18)</sup>.

In addition to mitral valve cases, the use of BRFA was studied in permanent AF patients undergoing CABG and/or aortic valve surgery, with a good overall sinus rhythm conversion rate (80% at 3 year follow up). Predictors of residual AF were big LA dimensions and longer AF duration.<sup>(19)</sup>

In the study done by Benussi et al, 76.9% success rate about 1 year after operation, whereas spontaneous SR restoration following conventional heart surgery occurs in 4.5 to 36% of patients in chronic AF <sup>(5)</sup>. Gillinov and colleagues reported freedom from atrial fibrillation at one year follow up of 260 patients with chronic AF undergoing mitral valve surgery divided into 2 groups ( ablation vs. control) to be (63.2% vs 29.45) respectively which was of statistical significance<sup>(8)</sup>.

Our study was designed to evaluate the method of BRFA in patients with mitral valve surgery with chronic AF and the results were satisfactory regarding acceptably long bypass and cross clamp times, sound rate of conversion to stable SR (70.5%) at one year of follow up, absence of mortalities, insignificant postoperative complications (bleeding, pacemaker need, pulmonary complications from possible pulmonary vein stenoses and thromboembolic complications). Five out of 8 patients (62.5%) who underwent repair or bioprosthetic valve could stop anticoagulation safely due to stable sinus rhythm. Improved clinical and echocardiographic parameters were appreciable at one year follow up. NYHA class improved markedly (at least one class down); Ejection fraction, LA dimension and LA function showed significant improvement.

The previously mentioned clinical and echocardiographic improvements can be attributed at least in part to the correction of valve pathology and stabilized hemodynamics. So further studies are recommended to evaluate the effects of our modality in question in cases with lone AF to overcome the bias of valvular correction on the clinical and echocardiographic outcomes.

Variables associated with higher incidence of residual AF were older age, big LA diameter, longer preoperative AF duration, higher NYHA class preoperatively and prolonged bypass time.

Limitations of the study: the limited number of study group. Inability to perform cardiac MRI to study possible pulmonary venous stenoses attributable to the ablation technique. Patients' satisfaction survey can be included in coming studies to evaluate improvement of lifestyle and exercise tolerance.

Conclusion: We conclude from our study that BRFA is a safe and effective method of controlling atrial fibrillation associated with mitral valve pathology and it can be easily added to conventional mitral valve surgery without considerable risk added to the patient but with a favorable outcome including good rate of conversion to sinus rhythm, subjective clinical improvement and significantly improved echocardiographic parameters: increased EF, reduction of LA dimensions and improved LA function.

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# Tricuspid Septal Leaflet Detachment as an Access For VSD closure ; Safety and Convenience Assured by TEE

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<u>Background:</u> Successful transatrial closure of a VSD requires excellent visualization and examination, both by the naked eye and TEE, of the margins of the defect in order to avoid any residual VSDs.

<u>Aim of work:</u> To evaluate our experience in this approach compared to the routine trans atrial approach without detachment of the tricuspid valve septal leaflet, by the aid of TEE for assessment, and how beneficial it is to our patients.

<u>Patients and methods</u>: From March 2008 till September 2010, transatrial closure of isolated ventricular septal defects was performed in 48 patients, between Kasr El Ainy Medical School, Cairo University and Prince Sultan Cardiac Center at Ryiadh, Saudi Arabia. Tricuspid valve detachment (TVD) was used in 24 cases, the patients of whom represented group A; vs. another 24 patients, group B, where closure of VSDs was done through the tricuspid valve orifice without detachment of any of its leaflets.

<u>Results:</u> Two in hospital mortalities occurred in this study, one hospital mortality was in group B (4%) and another one in group A (4%). Both were due to non cardiac related issues.

Otherwise, there were no complications as regarding heart block, significant tricuspid regurgitation, or long standing residual septal defects. No high-degree atrioventricular block was encountered.

<u>Conclusion</u>: Use of TVD followed by TEE assessment to optimize and assess visualization of the defect may result in decrease in cross clamp and total pump times, with preservation of tricuspid valve function with no added risk of heart block or significant tricuspid regurge.

<u>Key words:</u> TVD - TR - VSD TVD: Tricuspid valve septal leaflet detachment TR: Tricuspid regurge VSD: Ventricular septal defect

losure of a VSD through the transatrial approach requires adequate visualization of the margins of the defect in order to avoid any residual VSDs, distortion of the tricuspid valve as well as causing heart block. In some patients, the margins of the defects may be obscured by chordal attachments which increase the difficulty of both visualization and closure of the defect. Postoperative TR may occur due to distortion of the tricuspid valve apparatus with tethering of the septal leaflet or the chordae by sutures. Also, when it is difficult to visualize the defect, the risk of a residual VSD or surgically created heart block is increased. Detachment of the septal leaflet of the tricuspid valve from the annulus has been advocated by some investigators as a simple and a reliable technique for better visualization of the margins of conoventricular VSDs <sup>(1-2)</sup>. On the other hand, others have expressed their concern about the potential risk of heart block and postoperative TR when adopting this technique. Detachment of the papillary muscle or chordae from the septum allowing leaflet retraction is an alternative technique for better

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Codex : o3/05/1508

visualization and exposure, the chordae are reattached to the septum or the VSD patch after VSD closure<sup>(3)</sup>.

TVD requires the know how and the surgical skills needed for incision and repair of the valve apparatus, as well as carrying the potential risk of iatrogenic complications such as heart blocks and tricuspid dysfunction<sup>(4)</sup>. Heart block was attributed to the mechanical traction on the septal leaflet by sutures during the repair process <sup>(5)</sup>.

Post bypass use of TEE in pediatric patients have been shown to aid in altering the surgical management including giving the chance to return to CPB for repair of significant residual lesions when indicated, preoperative TEE can affect the decision of medical management as the need of additional inotropes or vasodilators and the need of pacemakers <sup>(6,7)</sup>

## Aim of Work

Evaluate our experience using tricuspid valve septal leaflet detachment, compared to the routine trans atrial approach without detachment, by the help of TEE for assessment, and how beneficial it is to our patients.

### **Patients and Methods**

This prospective study was carried out in the Unit of Pediatric Cardiac Surgery, a division of the Department of Cardiothoracic Surgery, Faculty of medicine, Cairo university hospitals as well as Prince Sultan Cardiac Center at Ryiadh, Saudi Arabia. From March 2008 till September 2010, transatrial closure of isolated ventricular septal defects was performed for 48 patients. Patients with other types of VSDs who underwent VSD closure via either a ventriculotomy or through the pulmonary artery were excluded. Review of each patient's medical record was performed. Follow-up data as well as echocardiography reports were obtained from medical records and via correspondences with the patient's cardiologists.

Tricuspid valve detachment (TVD) was used in 24 cases, the patients of whom represented group A; vs. the other 24 patients where closure of VSDs was done through the tricuspid valve orifice without detachment of any of its leaflets (group B).

#### Anesthetic technique

Patients were premedicated with ketamine (5 mg/kg), midazolam (0.1 mg/kg), and atropine (0.02 mg/kg) intramuscularly 20 min before induction. ECG, pulse oximeter, and a noninvasive blood pressure monitor were connected to the patients. Fentanyl (2  $\mu$ g/kg) and midazolam (0.1 mg/kg) intravenously were used for induction, pancuronium (0.15 mg/kg) was used to facilitate endotracheal intubation, and 0.08 mg/kg was repeated intraoperatively to maintain muscle relaxation; they received isoflurane 1–1.5, with the bispectral

index maintained between 40 and 60%. Fentanyl (15–20  $\mu$ g/kg) which was administered at divided doses to maintain analgesia during the procedure (3–5  $\mu$ g/kg before skin incision, 3–5  $\mu$ g/kg before sternotomy, 5  $\mu$ g/kg during bypass, and 3–5  $\mu$ g/kg in the postbypass period).

A three-channel central venous line (internal jugular or femoral vein) for inotrope and vasodilator infusion and central venous pressure monitoring were performed.

An arterial line (radial or femoral) was inserted for invasive blood pressure monitoring. A urinary catheter was inserted to monitor urine output. The body temperature was monitored using two probes, one in the nasopharynx for core body temperature monitoring and the other on the big toe for peripheral temperature monitoring. Arterial blood gases were assessed after induction and repeated as required. A 7.5-MHz multiplane TEE probe and system(NC,USA) was used for echocardiographic monitoring.

In all patients, median sternotomy was performed. Heparin (300–400 IU/kg) was administered for anticoagulation and confirmed at an Activated clotting time level not less than three times the baseline level or greater than 450 s. CPB was initiated after a standard aorto-bicaval cannulation, and a membrane oxygenator and a non-pulsatile roller pump were used.

### **TEE role**

Views used :

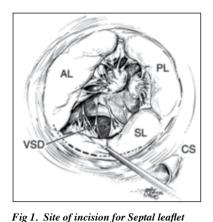
- a. Mid-oesphageal 4 chamber view for muscular VSD & TV.
- b. Short axis view (between 0 to 30), longitudinal view (between 90 to 120) to evaluate the presence or absence of aortic valve insufficiency.
- c. Mid-oesphageal right ventricular inflow, to evaluate the tricuspid valve
- d. Transgastric view (short axis view, RV inflow view "100 to 120") to evaluate RV also to detect papillary muscles of TV.
- e. Doppler eshocardiography (colour flow Doppler).

#### **Preoperative use of TEE**

The use of TEE to assess, evaluate the site, size of VSD and the way of closure. Assessment of right ventriclular size and function as well as the right atrial size and the tricuspid valve <sup>(6.8)</sup>.

#### Procedure

Aorto bicaval cardiopulmonary bypass was established with crystalloid cold cardioplegic solution. An oblique right



detachment

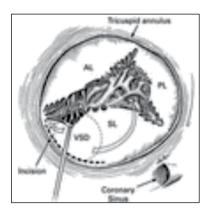


Fig 2. Relation of AV node and bundle to the incision

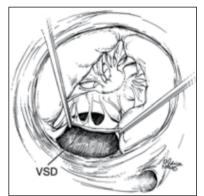


Fig 3. The good exposure for all VSD boundaries

atrial incision was made parallel to the atrioventricular groove. A left atrial vent was inserted through the interatrial septum. The VSD was examined by retracting the septal leaflet toward the right atrium. The technique for VSD closure (patch or primary closure) and the use of TVD was at the surgeon's own discretion. When TVD was used to improve visualization, a circumferential incision was made in the septal leaflet 1–2 mm from the annulus. If necessary, the incision can be extended onto the anterior leaflet to improve visualization of the superior margin of the defect. The VSD was closed with a patch using a continuous suture (an interrupted technique can also be used) and the patch was attached to the annulus, the incision in the leaflet was closed with a second continuous suture. (Fig. 1, 2&3) <sup>(9)</sup>

The patient demographics and preoperative data are expressed in Table (1).

Variable	Group A (TVD)	Group B	P Value
Number of patients	24 (50 %)	24 (50 %)	
Age: Mean (months)	24.5	21.7	0.23
Range (months)	4.2–122	2.8–151	0.4
Weight: Mean (Kg)	9.3	7.7	0.4
Range (Kg)	(4.5-48)	(3.8–51.3)	0.35
Gender Male	14 (58.3 %)	9 (37.5 %)	0.12
Female	10 (41.7%)	15 (62.5%)	0.8

Table 1. The patient demographics and preoperative data

### Post bypass use of TEE

Primary objective was detecting the presence of any residual defects, as well as evaluating the tricuspid valve in regards to its function and competence  $^{(6.8)}$ .

#### **Follow-up of patients**

Patients were followed-up for 6 months postoperatively by clinical examination and with the aid of special investigations. Follow-up information, regarding current activity level, medications, and presence of complications, was obtained from the follow up physicians and or parents of the patient. Postoperative follow up echocardiography with color flow mapping was performed for all patients 3 weeks to 6 months after the operation.

#### **Statistical Analysis**

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 ( $\chi^2$ ) 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

Two in hospital mortalities occurred in this study, one hospital mortality was in group B (4%), it occurred in a 4 months old patient who had severe chest infection and failure to wean off mechanical ventilation, another non cardiac related mortality occurred in group A (4%) in a 6 months old patient, due to major reaction and renal failure after matched blood transfusion. One Patient of group A, had a small residual VSD with spontaneous resolution within 6 months, as well as one patient in group B who was subjected to conservative management where spontaneous resolution also occurred within the 6 months follow up period. One significant morbidity occurred in group A, in the form of right phrenic palsy requiring phrenic plication after 2 weeks from primary surgery, otherwise there were no complications as regarding heart block or tricuspid regurgitation. No highdegree atrioventricular block was discovered. At postoperative follow-up echocardiography, tricuspid valve dysfunction was not present in any patient. Tricuspid regurgitation was trivial in 14 of group A patients (58%), and mild in another 2 patients (8%), as opposed to 3 patients from group B (12%), who also showed mild TR. None of those patients needed reoperation to correct the tricuspid regurgitation.

Patients of group A, had shorter cardiopulmonary bypass time than the other group B with mean of  $46 \pm 17$  minutes; vs 55  $\pm$  12 minutes (p= 0.041). The aortic cross-clamp time was also significantly longer for group B patients (35 ± 18); vs. group A patients  $(30 \pm 9)$  (p = 0.008). No patient in either group needed late reoperation to correct any residual VSDs. One small residual VSD less than 3mm was found in a patient of group A, as well as another small VSD less than 4mm in a patient of group B. Both patients were followed up conservatively, and showed complete resolution within the 6 months follow up period. No patient in group A had greater than mild TR, as vena contracta was less than 3<sub>mm</sub> but three in group B had greater than mild TR vena contracta between 3 to 7 mm shown by colour Doppler, pulsed wave Doppler for hepatic and caval veins assessment didn't reveal any abnormalities. No child in either group has needed reoperation for TR. Freedom from greater than mild TR, heart block, or residual VSDs at 6 months was found as shown in table (2)

Variable	A Group (TVD)	B Group	Value P
(minutes) time CPB	$17 \pm 46$	12 ± 55	0.041
Time Clamp-Cross Aortic	$9 \pm 30$	18 ± 35	0.008
TR residual Mild	(% 8) 2	(12%) 3	0.57
VSD Residual	(% 4) 1	(% 4) 1	
Block Heart	0	0	
Rate Mortality	(4%) 1	(% 4) 1	
data up Follow			
TR Mild	2	0	0.15
VSD Residual	0	0	
block Heart	0	0	

Table 2. Post operative and follow up data

## Discussion

In this study, we found that the incidence of both mortality and morbidity was significantly low when closing the VSDs through the trans atrial approach, whether using TVD or not, even in children with significant associated non cardiac anomalies. The use of TVD did not result in an increased incidence of residual VSDs, TR or surgically induced heart block, which was approved by the use of TEE and follow up echocardiography. Actually, there was a trend toward a lower incidence of TR in patients whom TVD was used. This observation suggests that better visualization and proper examination by TEE before and after bypass, resulted in better suture placement after detachment of the septal leaflet with less distortion of the tricuspid valve apparatus <sup>(8,10)</sup>.

It is well known that, in some patients, good visualization of the defect is difficult, therefore detachment of the tricuspid valve septal leaflet is required to properly seal the defect. In this study the percentage of the VSDs that required TVD as part of the repair, was similar to the percentages reported by Pridjian and associates <sup>(11)</sup>.

So it is of great importance to stress that non use of TVD in some types of VSDs could result in incomplete visualization and closure of these VSDs. Difficult visualization of the margins of the defect may also require excessive traction of the tricuspid valve apparatus in order to better visualize the margins of the defect, leading to unfavorable tricuspid regurge or heart block. In a single patient of the non TVD group, we found enough echocardiographic evidence of a small residual VSD lesion, this finding was similar to the findings reported by *Gaynor and associates*<sup>(4)</sup>.

Septal leaflet detachment of the tricuspid valve can be used in any situation in which exposure of the VSD is extremely difficult. This technique is not as challenging as chordal detachment of the tricuspid valve as demonstrated by Mullen and associates <sup>(2)</sup>.

In this study, it was found that the use of a continuous suture to repair the detached tricuspid valve septal leaflet did not lead to any late tricuspid valve regurge or stenosis as shown both by TEE and follow up echocardiography, as opposed to the findings reported by Tatebe and associates <sup>(12)</sup>, who did not recommend the use of a continuous suture to repair the incised septal leaflet.

Our results show that it is appropriate to use a continuous suture to repair the incised septal leaflet.

This study has several limitations.

#### **Study Limitations**

This study has many limitations, in this study, the follow-up is limited. Use of TVD was at the surgeon's own discretion, not according to a certain protocol. It is likely that all of the VSDs

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could have been closed without TVD, although it may have been more difficult to close these VSDs. Follow-up data were obtained from echocardiograms performed by the referring cardiologists, and thus interpretation and quantification of the residual VSDs and TR may have been dependent on the echocardiographers.

## Conclusion

TVD results are comparable to the conventional approach with potential benefits in terms of better visualization and less cross clamp and cardio pulmonary bypass times.

The concerns about resultant TR seem negligible. This procedure may thus be applicable in VSDs that are difficult to visualize.

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# Early Results of Tricuspid Valve Repair for Moderate Functional Tricuspid Regurge in Concomitant Mitral Valve Surgery

**Bassem Ali Hafez** 

<u>Backgroud</u>: Tricuspid regurgitation (TR) secondary to left heart disease is the most common aetiology of tricuspid valve (TV) insufficiency. Treatment of functional TR with left-sided valvular disease still remains controversial. Many surgeons favoring a conservative approach to functional moderate TR claiming that appropriate correction of the left-sided valve disease would most probably result in a decrease in the TR. On the other hand, many investigators have recommended surgical treatment of moderate to severe TR to obtain a better prognosis.

The objective of the present study is to analyze the outcome of patients, who underwent TV repair for functional moderate tricuspid regurgitation concomitant with mitral valve replacement focusing on early postoperative results.

<u>Methods</u>: This study included fourty patients underwent tricuspid valve repair using De Vega annuloplasty technique for functional moderate tricuspid regurgitation in association with mitral valve replacement. All patients were followed up during the post-operative hospital stay and after discharge at one week, two weeks, and one month and six month intervals.

<u>Results</u>: There was a significant improvement in NYHA functional class as 32 patients (80%) became class I postoperatively on follow-up (p<0.05) with subsequent improvement in the activity and lifestyle. There was a highly significant improvement in TR, 85% of patients had no residual TR and 15% had grade I TR six months postoperatively (p= 0.001), with subsequent improvement in systolic pulmonary artery pressure and cardiac dimensions postoperatively.

<u>Conclusion</u>: Moderate functional TR secondary to left-sided valve diseases should be surgically treated to improve patient outcomes and to prevent regurgitation progression and RV dysfunction.

KEYWORDS: Tricuspid valve repair. Tricuspid regurge. Mitral valve replacement.



ricuspid valve (TV) surgery is usually performed as a concomitant reconstruction procedure in addition to the correction of other cardiac pathologies. Isolated tricuspid procedures are exceptionally rare <sup>(1)</sup>.

Although early mortality and late results for aortic and mitral valve repair or replacement have improved considerably over the past years, tricuspid valve (TV) surgery, remains more complex and the prognosis is not as favorable <sup>(2)</sup>.

Tricuspid regurgitation (TR) secondary to left heart disease is the most common aetiology of tricuspid valve (TV) insufficiency <sup>(3)</sup>.

The presence of significant TR has been reported to be an important prognostic indicator of outcomes following mitral valve surgery <sup>(4)</sup>.

Surgical treatment of functional tricuspid valve regurgitation (TR) with left-sided valvular disease still remains a challenge for the cardiac surgeon. Uncorrected functional TR after repair of left-sided valvular lesion has been reported to have an adverse effect on early and late results <sup>(5)</sup>.

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Moderate tricuspid regurge 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 <sup>(6)</sup>. Thus, surgical management of moderate to severe functional TR is now widely recommended to achieve better early and late clinical outcome <sup>(5)</sup>.

There is abundant literature reporting operative results of tricuspid valve surgery. However larger series with a long follow-up period are limited <sup>(7)</sup>.

The objective of the present study was to analyze the outcome of patients, who underwent TV repair for functional moderate tricuspid regurgitation concomitant with mitral valve replacement focusing on early postoperative results, and to analyze independent predictors of adverse results.

## **Patients and Methods**

This was a multicenter study conducted in Menoufia university hospital and in Sharque ElMadena hospital from Jun 2012 to Feb 2015 where fourty patients underwent tricuspid valve repair for functional moderate tricuspid regurgitation in association with mitral valve replacement. Patients with tricuspid valve disease associated with congenital heart disease and patients with organic tricuspid valve disease were excluded from this study.

Each patient was subjected to full history taking, thorough clinical examination, preoperative laboratory and radiological investigations, and full transthoracic echocardiographic assessment including mitral valve pathology and morphology, degree of tricuspid regurgitation and measurement of: Systolic pulmonary artery pressure (sPAP), Left Ventricular End Diastolic Diameter (LVEDD), Left Ventricular End Systolic Diameter (LVESD), Ejection Fraction (EF), left atrial dimension, and right ventricular dimension.

All operations were done through median sternotomy with the use of cardiopulmonary bypass with moderate systemic hypothemia (28–32°C). Intraoperative myocardial protection was provided by topical cooling of the heart and antegrade infusion of cold (4 °C) crystalloid cardioplegia into the aortic root.

In this study, left atriotomy was the approach performed in all patients for mitral valve replacement and all valves used were mechanical low profile bileaflet valves. After closure of the left atriotomy, de-airing and removal of the cross-clamp and on a beating heart during the period of reperfusion De Vega tricuspid annuloplasty was performed through right atriotmy.

All operative data including cross clamp time, total bypass time and intraoperative complications were obtained and recorded.

All patients were followed up during the post-operative hospital stay and after discharge at one week, two weeks, and one month and six month intervals recording postoperative morbidity, mortality and hospital stay. Echocardiographic examination was the corner stone in patient's evaluation either preoperatively or postoperatively at one month and six month intervals (Hewlett-Packard Sonos 1000; with a 2.7- or 3.5-MHz transducer).

#### Statistical analysis

The data are expressed as proportions or as the mean  $\pm$  standard deviation. Mann–Whitney test (for continuous variables) were used to determine statistical significance. All data were analyzed with SPSS software. Results were considered significant if p values were less than 0.05.

### Results

#### Preoperative patients' characteristics (table 1)

The study population consisted of 40 patients who underwent De Vega tricuspid annuloplasty for functional moderate tricuspid regurgitation in association with mitral valve replacement. The leading cause of mitral valve lesion necessitating operation was pure or predominant mitral stenosis in 26 patients (65%), pure or predominant mitral regurgitation in 6 patients (15%) and combined stenosis and incompetence in 8 patients (20%) due to rheumatic etiology.

Average age at operation was  $43.9 \pm 10$  years (range 24–58 years). Thirteen patients (32.5%) were men and 27 (67.5%) women. The preoperative NYHA functional class was assessed in all patients. Twenty seven patients (67.5%) demonstrated class II and thirteen patients (32.5%) class III.

Fourteen patients (40%) presented in sinus rhythm and 26 (60%) with atrial fibrillation.

	TV Repair (no.=40)
Variable	<b>No.</b> (%)
Age (mean $\pm$ SD) (years)	$43.9 \pm 10$
Gender	
Male	13 (32.5%)
Female	27 (67.5%)
NYHA class	
Class II	27 (67.5%)
Class III	13 (32.5%)
Cardiac rhythm	
Sinus	14 (40%)
AF	26 (60%)
Mitral Valve Pathology	
MS	26 (65%)
MR	6 (15%)
Combined	8 (20%)

AF = Atrial Fibrillation; MS = mitral stenosis; MR = mitral regurge.

Table 1. Preoperative clinical and hemodynamic data

#### Perioperative data (table 2)

Mean aortic cross-clamp time was  $48.9\pm6.3$  min. while the mean total bypass time was  $84.3 \pm 4.5$  min. Intensive care unit stay was  $34.5\pm2.8$  hours. Eight patients (20%) required inotropic support.

	TV Repair (no.=40)
Cross- clamp time (min.)	$48.9 \pm 6.3$
CPB time (min.)	$84.3 \pm 4.5$
Inotropic support (no. %)	8 (20%)
ICU stay (hours)	34.5 ± 2.8
Hospital stay (days)	$9.5 \pm 1.3$
CPB= cardiopulmonary bypass;	ICU= Intensive care unit.

#### Table 2. Perioperative data

#### Follow- up data (table3)

There was a significant improvement in NYHA functional class, where 32 patients (80%) demonstrated class I, 6 (15%) class II and 2 patients (5%) class III and the difference was statistically significant (p < 0.05).

Postoperatively, there was a clinical improvement in cardiac rhythm where 20 patients (50%) were in sinus rhythm but the difference did not reach a statistical significance.

	TV Repair (no.=40)		
-	Preoperative	Postoperative	P- value
NYHA class			
Class I	0 (0%)	32 (80%)	
Class II	27 (67.5%)	6 (15%)	< 0.05
Class III	13 (32.5%)	2 (5%)	
Cardiac rhythm			
Sinus	14 (40%)	20 (50%)	0.07
AF	26 (60%)	20 (50%)	

NYHA= New York heart association; AF= atrial fibrillation.

Table 3. Follow- up data

## **Preoperative vs postoperative Echocardiography** (table 4- 5)

Echocardiography was performed at one month and repeated at six month interval postoperatively. Table 4 shows comCardiovascular

parison between echocardiographic data preoperatively and at one month postoperatively. Residual TR early after De Vega tricuspid repair is a major concern. There was no residual TR in 28 patients (70%), grade I TR in 11 patients (27.5%) and one case (2.5%) with residual mild to moderate (grade II) TR and the difference was found to be statistically significant (p= 0.019). There was no statistically significant difference in all other variables as p > 0.05

Table 5 shows comparison between echocardiographic data preoperatively and at 6 months postoperatively. We had only six patients (15%) with grade I TR and the difference was found to be highly significant (p=0.001).

Left atrial dimension, systolic pulmonary artery pressure and right ventricular diameter were significantly reduced. Also, there was a significant reduction in both left ventricular end diastolic dimension (LVEDD) and left ventricular end systolic dimension (LVESD).

Despite the fact that there was improvement in the mean left ventricular ejection fraction (LVEF %) ( $65.2\pm2.6$ ) vs ( $62.9\pm14.2$ ), yet it does not reach statistical significance.

	TV Repa	ir (no.=40)	
	Preoperative	Postoperative	P- value
Tricuspid regurge: no. (%)			
None	0	28 (70%)	0.019
Grade I	0	11 (27.5%)	0.019
Grade II	6 (15%)	1 (2.5%)	
Grade III	34 (85%)	0	
LVEF %	$62.9 \pm 14.2$	63.5±3.2	0.43
Systolic PAP (mmHg)	$46.7\pm5.8$	$43.5\pm7.1$	0.08
LVESD	3.8+0.68	3.5+0.08	0.065
LVEDD	5.8+0.75	5.6+0.6	0.73
LA dimension (cm)	$6 \pm 0.3$	$5.7 \pm 0.4$	0.07
RVD	$2.7 \pm 0.4$	$2.5 \pm 0.7$	0.059

LVEF= left ventricular ejection fraction; PAP= pulmonary artery pressure; LVESD= left ventricular end-systolic dimension; LVEDD= left ventricular end-diastolic dimension; LA= left atrium; RVD= right ventricular diameter.

Table 4. Preoperative vs 1 month postoperativeEchocardiography

	TV Repai	TV Repair (no.=40)		
	Preoperative	Postoperative	P- value	
Tricuspid regur- ge: no. (%)				
None Grade I Grade II Grade III	0 0 6 (15%) 34 (85%)	34 (85%) 6 (15%) 0 0	0.001	
LVEF %	$62.9 \pm 14.2$	$65.2 \pm 2.6$	0.06	
Systolic PAP (mmHg)	$46.7 \pm 5.8$	39.5 ± 7.1	0.002	
LVESD	3.8+0.68	3.3+0.68	0.001	
LVEDD	5.8+0.75	5.2+0.96	0.003	
LA dimension (cm)	$6 \pm 0.3$	$5.1 \pm 0.9$	0.007	
RVD	$2.7 \pm 0.4$	$2.2 \pm 0.1$	0.039	

LVEF= left ventricular ejection fraction; PAP= pulmonary artery pressure; LVESD= left ventricular end-systolic dimension; LVEDD= left ventricular end-diastolic dimension; LA= left atrium; RVD= right ventricular diameter.

Table 5. Preoperative vs 6 month postoperative Echocardiography

## Discussion

Treatment of functional TR with left-sided valvular disease still remains an important issue in cardiac surgery because there are several uncertainties regarding its accurate diagnosis, surgical indication, appropriate surgical procedure, and late results of surgical treatment <sup>(5)</sup>.

Mild degree of functional TR could be expected to diminish after surgical relief of left-side valve pathology. Also, it is well accepted that severe tricuspid regurge should be treated at the time of surgical correction of left-sided valve pathology. However, surgical indication for the correction of moderate TR remains controversial <sup>(8)</sup>.

Many surgeons favoring a conservative approach to functional moderate TR claiming that appropriate correction of the left-sided valve disease would most probably result in a decrease in the TR <sup>(9)</sup>. However, an increasing number of studies have shown that such a conservative TR management may lead to a progressive worsening of tricuspid insufficiency <sup>(10)</sup>.

Many investigators have recommended surgical treatment of moderate to severe TR to obtain a better prognosis <sup>(5)</sup>. This study was performed to evaluate the early outcome of tricuspid valve repair for patients with functional moderate TR to justify its advantage over conservative management.

In our study, patients who required TV repair were more likely to be female (67.5% vs 32.5%). The same was recorded by Dokhan et al.<sup>(8)</sup> and by Thomas et al.<sup>(1)</sup>.

Clinical assessment of the patients was classified according to the NYHA classification. Thirteen patients (32.5%) were in class III and Twenty seven patients (67.5%) demonstrated class II. Postoperatively, there was a significant improvement in NYHA class as 32 patients (80%) became class I with no dyspnea and all patients showed improvement in the activity and lifestyle.

Dokhan et al. <sup>(8)</sup> also reported postoperative improvement in patients' activity and lifestyle with significant improvement in NYHA functional class. Same results were demonstrated by Musharaf et al. <sup>(11)</sup> and Koelling et al. <sup>(12)</sup>.

In our study, the aortic cross-clamp time was 48.9 + 6.3 min and total bypass time was 84.3 + 4.5 min. it should be mentioned that De Vega repair of the tricuspid valve was performed during reperfusion after removal of the aortic cross-clamp and on beating heart without additive risk of myocardial ischemia. Dokhan et al. <sup>(8)</sup> compared patients with moderate TR who underwent conservative management and those who underwent surgical repair during mitral valve surgery and found no statistical significant difference in aortic cross-clamp time and total bypass time between the two groups.

Postoperative echocardiography demonstrated a highly significant improvement in tricuspid regurgitation with no residual regurge in 34 patients (85%) and grade I regurge in 6 patients (15%). In the study of Matsunaga et al. <sup>(13)</sup> about 50% of the patients who are treated conservatively showed significant TR despite of successful mitral repair. Also, Cohn L.H. <sup>(7)</sup> stated that tricuspid valve repair is the treatment of choice for the majority of patients with functional tricuspid valve disease. Unlikely, Dokhan et al. <sup>(8)</sup> found no statistical significant difference between conservative vs surgical repair of tricuspid valve during mitral valve replacement.

Our study recorded a significant improvement in Systolic pulmonary artery pressure postoperatively; also left atrial dimension, right ventricular diameter, left ventricular end-systolic dimension LVESD and left ventricular end-diastolic dimension LVEDD were significantly improved on follow-up denoting a favorable remodeling of the heart.

Many studies have also demonstrated that dimensions and function of the heart are improved with TV repair in patients with moderate to severe TR in association with correction of left sided valve disease <sup>(14-15)</sup>.

## Conclusion

Tricuspid valve repair at time of correction of left sided valve disease is a safe procedure and does not add risk to myocardial ischemia or prolonged cardiopulmonary bypass when performed on a beating heart after removal of the aortic crossclamp. Moreover, it is associated with good perioperative outcomes and improved activity and lifestyle.

Moderate functional TR secondary to left-sided valve diseases should be surgically treated to improve patient outcomes and to prevent regurgitation progression and RV dysfunction.

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# **Impact of Hypothermia on Postoperative Bleeding Following Bypass Grafting Operations**

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<u>Background</u>: Hypothermia adversely affects the coagulation that could be of clinical significance in patients undergoing elective coronary artery bypass grafting .

<u>Objective</u>: This study investigated the influence of hypothermia on the incidence of postoperative complications as amount of blood loss, amount of blood transfused, length of hospital stay, and sternal wound infection in patients undergoing elective coronary artery bypass grafting.

<u>Patients and Methods</u>: A prospective randomized parallel group study was conducted over 80 patients scheduled for elective on pump elective coronary artery bypass grafting at Ain Shams university hospital.

After institutional review board approval and obtaining written consents, the patients were randomly divided into hypothermiac<36°C (n=40) group and normothermic  $\geq$ 36,( n=40) group. Perioperative blood loss, number of blood units given, coagulation profile, length of hospital stay, and incidence of sternal wound infection was recorded.

<u>*Results*</u>: The amount of blood loss was significantly larger in hypothermic group compared with normothermic group (p<0.001).

The number of blood units transfused was significantly higher in hypothermic group compared with normothermic group.

The PT and PTT were prolonged significantly in hypothermic group compared with normothermic group.

There was a trend towards increased length of hospital stay in hypothermic group compared with normothermic group.

There was no significant difference regarding the incidence of sternal wound infection among study groups.

<u>Conclusion</u>: This study suggested that hypothermia was associated with increased amount of blood loss and the number of blood units transfused in patients undergoing on pump elective coronary artery bypass grafting.

KEY WORDS: Hypothermia, Bypass, Bleeding, Transfusion

ypothermia is defined as a core body temperature less than 35 <sup>(1)</sup>. Although hypothermia is known to decrease the metabolic demand of the body and promotes impairement in various systems causing decrease oxygen release to tissues.

Hypothermia results in impairement of the coagulation cascade and the white cell count also decreases <sup>(2)</sup>, hypothermia impairs immune function so nosocomial pneumonia will occur in over half of patients who are hypothermic for more than 7 days. <sup>(3)</sup> Hypothermia-induced increase in catecholamines leads to an increase in cardiac output and oxygen demand <sup>(4)</sup>. Indeed previous studies depicted the predictive

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role of hypothermia at the time of ICU admission on adverse outcomes after major surgeries.<sup>(5,6)</sup>

During prolonged induced hypothermia, bleeding time will be lengthened as a result of a reduction in the number and function of platelets. Platelets may be sequestered by the spleen and liver, <sup>(7,8,9)</sup> and thus leads to increased transfusion requirements.

As most of postoperative bleeding and transfusion usually occur within a few hours after surgery so we monitor the core temperature of a post surgical patient at the time of ICU admission and during the first 6 hours postoperatively.

The aim of this prospective study was to evaluate the influence of core temperature on postoperative amount of blood loss, transfusion requirements, coagulation profile and the length of hospital stay in patients undergoing on pump coronary artery bypass grafting operations.

Incidence of sternal wound infection was also recorded.

## **Patients and Methods**

After institutional review board approval of Ain Shams university and written informed consent, eighty subjects ASA II-III Physical status presenting between 2012-2013, for elective on pump coronary artery bypass surgery, aged from 45-77 years old of either sex, were enrolled in this prospective randomised parallel group study.

Using allocation concealment, the patients were assigned into 2 groups. In normothermic group (n=40) patients were warmed using fluid warmer and a warm mattress. In hypothermic group (n=40), patients were allowed to develop hypothermic. Exclusion criteria included patients were with preexisting hypothermia (<36°C) or hyperthermia (>38°C), a postoperative temperature >38°C.

Preanaesthetic check and investigations as CBC, coagulation profile, ehocardiography and coronary angiography and on night of surgery preperative evaluation was performed. In the induction room, the aneshesiologist secured a 18 gauge cannula and gave midazolam 0.05 mg/kg i.v, and an infusion of Ringer acetate was started. Standard monitoring was used in the form of 5 lead electrocardiogram with ST segment monitoring, pulse oximetry, end tidal CO2, invasive arterial blood pressure.

Prior to induction of anaesthesia, a baseline laboratory evaluation was done including prothrombin time, hemoglobin, hematocrit and renal function tests and liver function tests. Induction of anaesthesia was done using thiopental (3-5 mg/kg), fentanyl (5 mic/kg), Atracurium (0.5 mg/kg) for patient intubation.

Anaesthesia was maintained with isoflurane 1.2%, fentanyl (3-5mic/kg), and Atracurium 0.1mg/kg and patients were ventilated by volume controlled mechanical ventillation, to maintain the end expiratory carbon dioxide from 34-36 mmHg.

After sternotomy, Cardiopulmonary bypass was instituted with 1500 ml crystalloid priming volume and mild hypothermia (32 C) with a Trillium affinity oxygenator and a sarns CPB machine at a flow rate of 2.6 l.min -1.m-2.

Myocardial protection was achieved by cold blood cardioplegia at 20 C. During CPB, homologous donor packed RBCs were transfused if HB is below 6 g.dl -1.

On bypass anticoagulation for extracorpeal circulation was accomplished using heparin 300 U/Kg administered into the right atrium. An elite activated clotting time (ACT) more than 400 was considered adequate for commencing CPB.

CPB was conducted with non occlusive roller pumps, membrane oxygenators, arterial line filtration and cold blood enriched hyperkalemic arrest. Hemofiltartion was used to maintain a minimum HCT of 22% during CPB as long as the blood reservoir volume is adequate. Systemic hypothermia to an oesophageal temperature of 30 c was maintained during aortic cross clamping.

After completion of CPB and removal of the arterial cannula, heparin was neutralised by 1 mg of protamine sulphate for every 100 U of heparin administrated, the anesthesiologist administrated the protamine into the central line by continous infusion over a period of 15 minutes. Then a second dose of protamine 50 mg was administered if ACT remained above baseline ACT.

Core body temperature, urine output, arterial blood gases, total amount of blood loss and transfusion requirements were monitored .

Surgery were performed to all patients by the same surgical team.

After surgery all patients were transferred to the ICU during the perioperative period.

#### **Measured parameters**

Assessed postoperative variables included amount of blood loss, length of stay in the ICU, PT and PTT (prothrombin time and partial thromboplastin time)<sup>(5)</sup>.

The time points at which temperature was measured, were 1, 2, 4, 6 and 10 hours postoperatively.

The primary outcome measure was to compare the amount of postoperative blood loss between patients of normothermia group (temp >36°C) and hypothermia group (temp <36).

The secondary outcome measure was to compare transfusion requirements, the length of stay in the hospital, prothrombin time and partial thromboplastin, and incidence of surgical site infection among the study groups. In order to measure PT and PTT, blood samples were collected via arterial catheter <sup>(10)</sup>.

The initial 5ml of each blood sample was discarded, blood sample (5ml) were collected in 0.109 M trisodium citrate tubes and centrifuged immediately for 10 min at 3000/min. The plasma was used to measure PT and APTT using reagents from Dade Behring Inc. (west wood, Mossochusetts, USA) and an automated blood coagulation analyzer (sysmex CA-1500, Kobe, Japan).

#### Statistical analysis

#### Sample size justification

EpiInfo® version 6.0 program was used for calculations of sample size, statistical calculator based on 95% confidence interval and power of the study 80% with  $\alpha$  error 5%, According to a previous study by **Mircea I**, et al.<sup>(11)</sup> who showed that

postoperative bleeding and transfusion requirements were significantly greater in hypothermia group( P= 0.02, P= 0.03 respectively) thus a sample size of 40 patients is per group enough to find such a difference. 5% will be added for possible drop out.

#### **Statistical analysis**

The collected data was coded, tabulated, and statistically analyzed using SPSS program (Statistical Package for Social Sciences) software version 17.0.

Descriptive statistics were done for numerical parametric data as mean±SD (standard deviation), while they were done for categorical data as number and percentage.

Inferential analyses were done for quantitative variables using independent t-test in cases of two independent groups with parametric data.

P value <0.05 was considered significant.

## Results

Table 1. Demographic characteristics and surgical factors:

		Groups		Test	
	-	Group I (N=40)	Group II (N=40)	t/X2	P-value
Age (Years)	Range	40.000-77.000	46.000-74.000	-1.129	0.263
	Mean±SD	57.800±8.032	60.000±7.022		
Weight (Kg)	Range	58.000-116.000	69.000-119.000	0.431	0.668
	Mean±SD	90.800±15.755	89.233±12.136		
Height (Cm)	Range	167.000-191.000	164.000-192.000	-0.252	0.802
	Mean±SD	179.233±6.224	179.633±6.094		
Sex	Female	19 (47.5%)	17 (42.5%)	0.132	0.473
	Male	21 (52.5%)	23 (57.5%)		
No of grafts	1	10 (25%)	11 (27.5%)	0.271	0.621
	2	15 (37.5%)	16 (40%)		
	3	15 (37.5%)	13 (32.5%)		

Regarding demographic characteristics and operative data, there was no significant difference between the study groups (table 1).

			Grouj	ps			TT 1	<b>F</b> = =4	
Temp	No	Normothermic			Hypothermic			- T-Test	
_	Mean	±	SD	Mean	±	SD	t	P-value	
T 0	35.320	±	0.353	35.447	±	0.377	-1.344	0.184	
T 1	37.007	±	0.455	35.503	±	0.350	14.350	< 0.001*	
Т2	36.793	±	0.406	35.610	±	0.532	9.686	< 0.001*	
T 4	36.713	±	0.319	36.823	±	0.267	-1.447	0.153	
Т б	36.920	±	0.303	36.840	±	0.340	0.962	0.340	
* _ Cianifoant									

\* = Significant

#### Table 2. Core body temperature measured on arrival at ICU and in the first 6 hours postoperative.

Forty patients were classified as having hypothermia with a mean of 35.3±0.353 based on their core body temp. measured postoperative and during the first 6 hours. Another 40 patients were classified as having normothermia (36.7±0.319) (table 2).

		Gro	oups	Te	est
	-	Group I	Group II	t/X2	P-value
Blood loss	Range	90.000-266.000	421.000-586.000	-30.878	<0.001*
	Mean±SD	185.667±41.340	516.033±41.536		
РТ	Range	11.000-13.000	16.000-19.000	-25.876	<0.001*
	Mean±SD	11.967±0.669	17.167±0.874		
PTT	Range	31.000-38.000	29.000-49.000	-6.037	<0.001*
	Mean±SD	35.433±1.612	40.500±4.305		
Hospital stay	Range	6.000-8.000	7.000-9.000	-1.789	0.076
	Mean±SD	7.099±0.905	7.467±0.935		
Amount of blood needed (unit)	0	15 (37.5%)	0 (0%)	35.005	<0.001*
	1	17 (42.5%)	10 (25%)		
	2	8 (20%)	13 (32.5%)		
	3	0 (0%)	15 (37.5%)		
	4	0 (0%)	2 (5%)		
Abbreviations: PT= prothron	nbin time, PTT= part	tial thromboplastin time	* = Significant		

#### Table 3. Postoperative outcomes:

The normothermic group had significantly lower PT from 30 min. to 4 hours after surgery and lower APTT levels during the same period compared to hypothermia group (p<0.001) (table 3)

The trend towards a longer length of hospital stay in the hypothermia group was observed when compared with the

normothermia group, but without statistical significance (p=0.076) (table 3).

The amount of postoperative blood loss was significantly higher in hypothermic group compared with normothermic group. (table 3)

	Normathannia Crown	Usmothoumic Cucun		<b>Chi-Square</b>		
	Normothermia Group	Hypothermia Group –	<b>x</b> <sup>2</sup>	p-value	Sig.	
Sternal wound infection	5 (12.5%)	7 (17.5%)	0.098	0.756	NS	

Non significant difference regarding sternal wound infection among study groups

#### Table 4. Incidence of sternal wound infection among study groups

The number of blood units transfused were significantly higher in hypothermic group compared with normothermic group. (table 3)

There was no significant difference regarding incidence of surgical site infection among study groups.(table 4)

## Discussion

The current prospective study, showed that hypothermia was associated with an increased postoperative blood loss and transfusion requirement in patients undergoing elective on pump coronary artery bypass surgery.

In previous study, in a case of on pump CABG, 46.7% of the patients were reported to be hypothermic after leaving the operating room. A part from its beneficial influence of providing organ protection against ischemia - reperfusion injury, hypothermia is associated with multiple adverse physiologic alterations in terms of coagulation, hypothermia has been shown to be associated with platelet dysfunction as well as a mild decrease in platelet count<sup>(12)</sup>. Proposed mechanisms include impaired thromboxone A<sub>2</sub> release and inhibited exposure of P selectin on platelet surface<sup>(13)</sup>. Moreover, hypothermia has been shown to inhibit coagulation enzyme activities delaying the onset of thrombin generation<sup>(14)</sup>. Hypothermia is also accompanied by acidosis which in turn results in profound inhibition of thrombin generation in the propogation phase in a previous study <sup>(15)</sup>. Even mild hypothermia (<0.5°C) has been shown to be associated with increased blood loss and transfusion requirements in patients undergoing hip arthroplasty of paticular interest, a follow up study reported that aggressive warming reduced blood loss during the some surgical procedure implicating that hypothermia may be a modifiable risk factor of perioperative bleeding and transfusion requirement.

Another study by Mircea, et al. showed that that postoperative bleeding and transfusion requirements were significantly greater in hypothermia group( P=0.02, P=0.03 respectively, this agreed with our results.<sup>(11)</sup>

A meta analysis based on literature indicates that mild hypothermia significantly increases blood loss by on estimated 16%(CI 4-26%) <sup>(16)</sup>.

Another study by **Muhammad**, et al. showed that systemic warming of the surgical patient is also associated with less

perioperative blood loss through preventing hypothermiainduced coagulopathy.<sup>(17)</sup>

**Nathan H, et al** showed that there was no significant difference in blood product utilization, intubation time, hospital stay, myocardial infarction, or mortality. The mean time in the intensive care unit was 8.4 hours less in the hypothermic group<sup>(18)</sup>, The results of this study were inconsistent with our study.

Multivariate analysis determined that a single intraoperative temperature measurement less than 35°C independently increased the site infection risk 221% per degree below 35°C, but this did not agree with our study<sup>(19)</sup>.

In our study the amount of postoperative blood loss were significantly greater in the hypothermic group and that aggreed with the other studies mentioned before.

Our Data showed that the whole body mild hypothermia prolonged APTT and PT consistent with a previous studies<sup>(11, 15-17)</sup> that demonstrated that mild hypothermia resulted in platelet dysfunction and decreased platelet count.

## Conclusion

This study suggested that postoperative hypothermia assessed by core body temp. was associated with increased blood loss and transfusion requirements and prolonged PT and PTT in patients undergoing elective on pump coronary artery bypass surgery.

Considering the high prevalence of hypothermia and the possibility of hyothermia being a modifiable risk factor of transfusion requirement more aggressive measures should be taken to maintain normothermia in patients undergoing cardiac surgery for better outcomes.

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# Impact of Intrapleural Streptokinase Instillation On Management Of Empyema Thoracis: A prospective Randomized Study

Ahmed Labib Dokhan, Montaser Elsawy Abd elaziz\* **Background:** To evaluate the effect of intrapleural streptokinase in the management of empyema.

<u>Methods</u>: one hundred nineteen patients with empyema were prospectively enrolled in this study from 2011 to 2015, classified into two groups, group A (n=60) treated by chest tube only, group B (n=59) treated by chest tube plus intrapleural streptokinase instillation on the fourth day of tube insertion. In group B streptokinase was injected via the chest tube, the tube was clamped for 4 hours after instillation then opened. This was done once daily for 3 successive days, repeated radiological imaging was done and amount of drainage was calculated daily.

<u>Results:</u> This study revealed increase in the amount of drainage in the streptokinase group in comparison to control group, as the mean amount of total fluid drained in groups A (control) & B (streptokinase) in the first 3 days was ( $676.66\pm286.35$ ) ml and ( $334.44\pm243.044$ ) ml respectively with a statistically significant difference, and from the fourth to sixth days of treatment and after three days of streptokinase application to group B, the mean amount of total fluid drained in groups A &B was ( $168.88\pm143.9$ ) ml, ( $348.88\pm192.09$ ) ml respectively with a great statistical difference between two groups. Radiologically, the improvement in more than 2/3of the hemithorax was in 28 patients of group A, and 40 patients in group B. After 3-months follow up 48 (80%) patients had totally inflated lung in group A, and 56 (94.9%) patients in group B. Minimal complications were observed. From control group, 12 patients referred to surgery(decortication), and 4 patients in streptokinase group. The mean duration of hospital stay differs significantly from group A ( $27.67\pm67$ ) days to group B ( $20.27\pm7.32$ ) days.

<u>Conclusion</u>: Streptokinase use has a safe and effective influence on the course of treatment of Empyema.

KEYWORDS: Intrapleural streptokinase; Empyema; Chest tube

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Codex : o4/01/1507

he goals of empyema treatment are directed to save the life of the patient, eliminate the empyema, re-expand the lung, restore mobility of the chest wall/diaphragm, return normal respiratory function, eliminate complications or recurrence and reduce length of hospital stay [1]. The appropriate management of empyema remains controversial. Most

cases are treated initially using antibiotics with or without repeated thoracentesis, closed thoracostomy with or without fibrinolytics. Surgical approaches as open thoracotomy, decortication, and thoracoplasty are generally reserved for patients with deteriorated clinical conditions after conservative treatment. Video-assisted thoracoscopic surgery (VATS), which plays a bridging role between medical and aggressive surgical management has assumed greater importance in the treatment of complicated empyema[2]. Although these surgical procedures have been a major step forward in search of lesser invasive approach for management of empyema thoracis, they still carry the risk of significant morbidity, lack free availability and costs involved

remain prohibitive [3]. With the introduction of pure forms of streptokinase (SK) there has been renewed interest generated in the use of intrapleural thrombolytics with documented successful drainage of difficult to drain chronic empyemas [4] The use of intrapleural fibrinolytic agents to chemically disrupt the fibrinous pleural septations of empyema has been used to aid the drainage of infected pleural fluids for over 50 years. It was first described in 1949 by Tillet and Sherry, who used partially purified streptococcal fibrinolysin that contained both streptokinase and strepdornase (a DNAse) to drain infected postoperative haemothoraces [5]. Studies of whether fibrinolytic drugs given into the pleural space induce systemic activation of fibrinolytic mechanisms are also reassuring. Systemic fibrinolytic activation is best quantified from the thrombin time, fibrinogen levels and the presence of fibrinogen degradation products. Two studies have assessed whether these change after the administration of intrapleural streptokinase. Neither of these studies revealed any detectable changes in the coagulation indices when compared with baseline [6]. The objective of the study was to evaluate the safety, and effectiveness of streptokinase use in management of empyema.

## **Patients and Methods**

## 1. Study design

This study was carried out in Cardiothoracic Surgery Department, Faculty of Medicine, Menoufia University from June 2011 to may 2015. 119 patients who had thoracic empyema were randomly enrolled in the study. Menoufia Ethics Committee approved this study, written informed consent for procedures was obtained from all patients prospectively. The diagnosis of empyema was established by pleural fluid analysis revealing one or more of the following criteria: Grossly purulent pleural fluid aspirate [5], Positive gram stain or culture, Pleural fluid glucose level less than 40 mg/dl [7]. Pleural fluid PH<7.20[5], Pleural fluid lactic dehydrogenase (LDH) >1000 IU/l [8], Whereas the inclusion criteria were: all patients with thoracic empyema of different etiological types, Patients with stage-II (fibropurulent stage) and early stage-III, and exclusion criteria were: Bleeding tendency, evidence of hypersensitivity to streptokinase, presence of associated broncho-pleural fistula. Patients were randomly allocated sequentially to each group for certain duration of time according to the computerized random number generator. And compared at the end of the study regarding radiological improvement, duration of hospital stay, the need for further intervention, and complications.

Only the surgeon and his team were aware of the assignment of patients. Patients, data collectors, and the statistician were blinded to group assignment. group A, managed by chest tube drainage and proper antibiotics (control group), group B was managed by chest tube and intrapleural streptokinase instillation (sedonase, Sedeco, Egypt) and proper antibiotics according to culture and sensitivity (streptokinase group). Intrapleural streptokinase injection was confined to group B, and as early as possible after 3 days when drainage decreased or stopped and was applied on the 4th day (Streptokinase vial containing 1.5 million IU). The dose was 10.000 IU/kg with a maximum dose of 250.000 IU/dose, the calculated dose was diluted in 50 ml normal saline and injected via the chest tube. The tube was clamped for 4 hours after instillation then opened to allow drainage. This was repeated once daily for three successive days (provided no complications occurred) then chest x-ray was done. Follow up of the patients for three months by expert radiologist who was blinded to the study through serial chest X-rays to detect improvement of the radiological findings, which was described as: [9]

- No improvement
- Improvement in less than 1/3 of the hemothorax.
- Improvement between 1/3 and 2/3 of the hemithorax
- Improvement in more than 2/3 of the hemothorax.

Successful outcome (clinically, rate of drainage & radiologically), development of any side effects as fever, allergic reactions and bleeding, patients requiring further management (decortication), and duration of hospital stay all were calculated.

#### 2. Statistical Analysis

Based on the total number of patients received intrapleural Streptokinase installation and the prevalence rates of drainage, complications, radiological outcome and hospital stay reported in the previous studies [11,16], sample size was calculated by Epi Info<sup>TM</sup> 7 Program to be 48 patients in each group with 95% confidence interval. The data collected were tabulated and analyzed by SPSS (Statistical Package for Social Science) version 17.0 on IBM compatible computer. Two types of statistics were done: descriptive statistics: e.g. percentage (%), mean (x) and standard deviation (SD), and analytic statistics: e.g. Chi-square test ( $\chi$ 2): was used to study association between two qualitative variables. Mann-Whitney test (nonparametric test): is a test of significance used for comparison between 2 groups not normally distributed having quantitative variables. P-value of <0.05 was considered statistically significant.

## Results

Patients randomly allocated in this study were 140 patients. We finally excluded all patients who did not met the inclusion criteria or refused to participate and the remaining patients were statistically analyzed, 60 patients in control group and 59 patients in Streptokinase group. There were no significant differences in the demographic data between the two groups as regard age, sex, and occupation (Table 1).

The amount of drainage in the first three days after chest tube insertion (table 2), showed a statistical significant difference between both groups. In group A, the mean drainage

	Dama markin data	Group	A (n=60)	Group	B (n=59)	V2	
	Demographic data	No	%	No	%	— X <sup>2</sup>	P-value
Sex	Male	40	66.7	35	59.3	0.14	0.71
Se	Female	20	33.3	24	40.7	0.14	0.71
	Age in Years (X±SD)	29.3	±25.24	15.5	±18.84	1 25*	0.10
	Range		3-65	2.	5-64	1.35*	0.18
	Carpenter	4	6.7	4	6.7		
	Driver	8	13.3	0	0	8.22	
_	Manual worker	4	6.7	8	13.5		
atior	Mechanic	4	6.7	0	0		
Occupation	Perfume seller	4	6.7	0	0		0.31
0	Worker	8	13.3	0	0		
	No employment	28	46.7	44	74.6		
	Ceramic factory work	0	0	4	6.7		
Aann Wh	nitney test X2: Chi-square test						

Table 1. Comparison between the demographic data in group A & group B.

on the 3rd day was  $(533.33\pm205.87)$ ml, while in group B, it was  $(193.33\pm132.11)$ . The mean value of drainage in group A on the 6th day after chest tube insertion (table 2) was  $(86.67\pm63.99)$ , while in group B, it was  $(236.67\pm127.43)$  ml. Regarding group B before streptokinase use, mean drainage was  $(193.33\pm132.11)$ ml and on the 1st day after streptokinase (SK) injection increased significantly to  $(436.67\pm223.18)$ ml. (table 3).

The complications related to streptokinase injection among group B (table 4) were fever in 16 cases (27.1%), minimal bleeding through chest tube was in 4 cases (6.77%), no allergy recorded. Comparing the radiological changes between the two groups table 5, there was no significant improvement in more than 2/3 of the pleural opacity, After the 6th day of treatment, it was 67.8% in Streptokinase group and 46.7% in control group.

The effect of streptokinase instillation on radiological changes in streptokinase group before & after streptokinase injection was statistically significant as in table 6, and figure 1.

There was no significant difference between patients in Streptokinase group requiring further surgery and in control group, but it was lower in the Streptokinase group (table 7). Follow up after 3 months revealed 94.9% of patients in the streptokinase group have totally inflated lung, while 20% had residual opacities and 80% had totally inflated lung in group A (table 7). The mean duration of hospital stay was significantly lower among SK group than that of control group, (p<0.05).

Drainage	Group A (n=60)	Group B (n=59)	U-test	P-value	
Einst dass	796.67±323.74ª	490±266.73	2 40	0.01	
First day	350-1400 b	150-500	2.49	0.01	
Second day	700±269.26	320±222.65	3.39	< 0.001	
Second day	350-1200	50-500	5.59	< 0.001	
Third days	533.33±205.87	193.33±123.11	3.96	< 0.001	
Third day	150-800	50-500	3.90	< 0.001	
Total	676.66±286.35	334.44±243.044	5.33	< 0.001	
drainage	150-1400	50-1000	5.55	< 0.001	
	234.33±179.15	436.67±223.18	2.00	0.004	
Fourth day	100-700	150-100	2.86	0.004	
Eifth day	176.67±125.17	373.33±165.69	3.08	0.002	
Fifth day	50-400	100-800	5.08	0.002	
Sinth dow	86.67±63.99	236.67±127.43	3 14	0.002	
Sixth day	50-300	50-450	5.14	0.002	
Total	168.88±143.9	$348.88{\pm}192.09$	5.3	<0.001	
drainage	50-700	50-100	5.5	< 0.001	
U-test =	Mann Whitney test,	a-data described	l as mean	&SD,	
b- range	of drainage in ml.				

 Table 2. Comparison between group A & group B regarding the

 amount of drainage before intrapleural injection of streptokinase.

Duration	Drainage [Mean±SD]	Test used	P-value
1- Third Day before Streptokinase Use n=59	193.33±132.11 ml	W-test ( 3.24 )	0.001
2- First Day after Streptokinase Use n=59	436.67±223.18 ml		
1- Total drainage before Streptokinase Use n=59	334.44±243.044 ml	T-test ( 0.487 )	0.6
2- Total drainage after Streptokinase Use n=59	348.88±192.08 ml	1 (0.107)	0.0
W-test : Wilcox on signed ranks test	T-test : paired t-test		

CL Com	1	Group B		
SK Comp		No	%	
E	Present	16	27.1	
Fever	Absent	43	72.9	
Dlasting	Present	4	6.77	
Bleeding	Absent	55	93.22	
A 11	Present	0	0	
Allergy	Absent	59	100	

## Table 4. Streptokinase(SK) complications among group B.

X-ray	After 6 days of ICT Group A (n=60)		After SK Group B (n=59)		X2	P-value
	No	%	No	%		
Improvement in less than 1/3 of the lung	20	33.3	4	6.8	3.33	0.06
No improvement	12	20	0	0	3.33	0.06
Improvement in more than 2/3 of the lung	28	46.7	40	67.8	1.22	0.27
Improvement between 1/3 and 2/3 of the lung	0	0	16	27.11	4.62	0.03

 Table 5. Comparison between radiological findings after 6 days from ICTs insertion in both groups.

	Before SK (N=59)		After SK (n=59)		<b>X</b> <sup>2</sup>	P-value
X-ray						
	No	%	No	%		
Improvement in less than 1/3 of the lung	40	67.8	4	6.8	11.63	< 0.001
No improvement	20	33.9	0	0	60	0.01
Improvement in more than 2/3 of the lung	0	0	40	67.8	15.0	< 0.001
Improvement between 1/3 and 2/3 of the lung	0	0	16	27.1	4.62	0.03
X2: chi-square test, SK:Streptokinase						

Table 6. Comparison between radiological findings before & after SK injection in group B

	Group A (n=60)	Group B (n=59)	Test used	P-value
Duration of hospital stay in days (mean±SD)	27.67±7.84	20.27±7.32	U-test (2.46)	0.01
Required Surgery (number& percent) ■yes ■No	12 (20%) 48 (80%)	4 (6.8%) 55 (93.2%)	X <sup>2</sup> (1.15 )	0.28
Radiological 3-months follow up (number & percent) ■residual opacity ■totally inflated lung	12(20%) 48(80%)	3 (5.1%) 56 (94.9%)	X <sup>2</sup> (3.4)	< 0.05
U-test : Mann Whitney test X <sup>2</sup> : Chi-	square test			

Table 7. Outcome of patients regarding duration of hospital stay, need for further surgery, and radiological 3- months follow up .

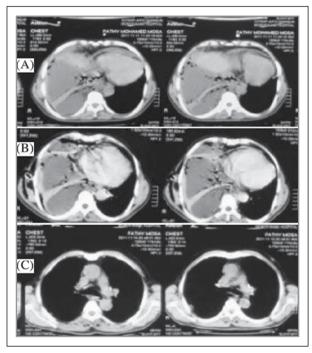


Fig 1. CT chest (Mediastinal window) showing: A: (on admission) right sided empyema.

A. (on aumission) right stated empyema.

B: (After ICTs insertion by 3 days): show failure of drainage and persistence of loculi

C: (After 3 days of streptokinase instillation): show totally inflated lung field

## Discussion

Use of fibrinolytic agents for intrapleural instillation has provided an option for managing patients with empyema of different eitiologies without subjecting them to surgical procedures. This therapeutic modality helps to break the loculations by virtue of its fibrinolytic property [10].

In our study the mean age in the control group was 29.3 years and in the streptokinase group was 15.5 years. There was no significant difference between both groups regarding distribution of age (p>0.05). This was different from the study done by Misthos et al.[11] where the mean age in control group was 46 years and 45 years in streptokinase group. About drainage of pus before streptokinase use, we noted in control group, the mean drainage was 796.67  $\pm$  32 3.74 ml, 700  $\pm$ 269.26 ml, and 533.33  $\pm$  205.87 ml in the first, second, and third days respectively, while in streptokinase group, it was  $490 \pm 266.73$  ml,  $320 \pm 222.65$  ml, and  $193.33 \pm 132.11$  ml during the first three days respectively. These results were different from that in the study done by Amit Banga et al.[12] in which the mean drainage in group treated with ICTs only on the 1st, 2nd and 3rd day after ICTs was 215, 166, 104 ml respectively and in streptokinase group was 188, 96, 76 ml respectively, the difference in values of drainage between before and after streptokinase was significant. In our study after the first 3 days, the mean value of total amount of drainage was  $(676.67 \pm 286.35 \text{ ml})$  in group A, while in streptokinase group was  $(334.44 \pm 243.044 \text{ ml})$ , these results were near to that of Diacon et al.[13], where they observed that the drainage of pus in the control group was significantly higher than that of the streptokinase group.

Comparing the drainage of pus in streptokinase group versus that in the control group for the same period (4th, 5th and 6th day), In the control group the mean values of drainage were ( $243.33 \pm 17.15$ ml), ( $176.67 \pm 125.17$  ml), ( $86.67 \pm 63.99$  ml) respectively, while in streptokinase group, were ( $436.67 \pm 223.18$ ml), ( $364.29 \pm 168.05$  ml), ( $235.71 \pm 132.18$ ml) respectively. The mean value of drainage in streptokinase group after streptokinase injection was significantly higher than that of control group on the 4th, 5th and 6th day after ICTs insertion which corresponds to days after streptokinase injection, these results were in agreement with Diacon et al.[13] Also, Amit Banga et al.[12] reported that increase in drainage following instillation of streptokinase could be quantitated and

radiologically documented. The mean value of total drainage in the three days after streptokinase injection was  $348.88 \pm 192.02$  ml, The mean value of total drainage in the three days after SK injection was significantly higher than the mean value of total drainage in the same period in group A (p<0.001). Results in our study came in agreement with Davies et al.[14] The mean value of drainage on the 1st day after SK use ( $436.67\pm223.18$ ) is significantly higher than that on 3rd day before SK injection ( $193.33\pm132.11$ ) as (p<0.001). These results were in agreement with Bouros et al.[15].

Complications related to streptokinase injection, among the streptokinase group, fever was found in 16 cases (27.1%), bleeding through chest tube was found in 4 cases (6.77%), allergy not found in any case (0%), these result are in agreement with Misthos et al.[11] where no systematic adverse effects of streptokinase were recorded. But our study is dissimilar to that done by Talib et al.[4] in which fever occurred in all cases used streptokinase, but no allergy and hemorrhage occurred and also in disagreement with Maskel et al.[16] in which hemorrhage occured in 7 cases (3%) from 208 cases, fever in 5 cases (2%) and allergy occurred in 5 cases (2%).

Regarding effect of streptokinase instillation on changes in radiological imaging before and after streptokinase injection, we found that among group B, after ICTs insertion by three days we observed that 40 cases (67.8%) had improvement in less than 1/3 of the lung field and 20 cases (33.9%) had no improvement, while after streptokinase injection there were 40 cases (67.8%) had improvement in more than 2/3 of the lung, 16 cases had improvement between 1/3 and 2/3 of the lung and only 4 cases (6.8%) had improvement in less than 1/3 of the lung, our study was in agreement with Talib et al.[4].

By comparing radiological findings between the two groups, it was found that in group A, after the 6th day 20 cases (33.33%) had improvement in less than 1/3 of the lung, 12 cases (20%) had no improvement and 28 cases (46.7%) had improvement in more than 2/3 of the lung, while in group B, after three days of streptokinase injection that only 4 cases (6.8%) had improvement in less than 1/3 of the lung, 40 cases (67.8%) had improvement in more than 2/3 of the lung, 16 cases (27.1%) had improvement between 1/3 and 2/3 of the lung field and no case reported to have no improvement. These results were in agreement with Talib et al.[4] regarding his streptokinase group, in which 8 cases (66.66%) from 12 cases (33.33%) had improvement between 1/3 and 2/3 of the lung. Also our results were in agreement with Bouros et al.[15].

We recorded 12 cases (20%) referred to surgery (decortication) in group A, while in group B, only 4 cases (6.8%) needed surgery. There is no significant difference between group A & B regarding referral to surgery as (p>0.05). This was slightly in agreement with Davies et al.[14] in which the control group 3 (25%) from 12 cases were referred to surgery, while in the streptokinase group no patients required

Surgery, but in Mithos et al.[11] was found that ICTs were successful in 47 (67.1%) from 70 cases in control group and 23 (23.9%) cases referred to surgery, while in streptokinase group it was found favorable outcome in 50 (87.7%) from 57 cases and 7 cases referred to surgery (12.3%), in which the difference between the two groups was statistically significant (P<0.05).

During follow up after 3 months, in the streptokinase group, we had 56 cases (94.9%) totally inflated lung, while in control group 12 cases (20%) still have residual opacities and 48 cases (80%) had totally inflated lung, these results were in disagreement with Maskell et al;[16] where after 3 months, 7 cases (75%) from 102 showed totally inflated lung and 25 cases still had residual opacity, while in control group 85 cases (64%) from 133 showed totally inflated lung, while 48 cases (36%) still have residual opacity, but the difference was insignificant. In well-organized study by Maskell et al. [16], the intrapleural instillation of streptokinase did not improve mortality, the rate of surgical interventions or the length of hospitalization. The fact that our results are completely different should be attributed to the entirely diverse characteristics of the two studied populations.

Our succes rate (totally inflated lung) was higher than that reported by A.Omar et al in 2015, [17] where in their study for assesment of the response to intrapleural streptokinase, success (complete adhesiolysis) was recorded in 60% of cases and partial success in 24% while the procedure failed in 16% of cases.

With fibrinolytic therapy, success rates of 70-90% have been reported. Streptokinase has been used in a dose of 250,000 IU in 100 mL of normal saline once or twice a day. Urokinase was also effective and in a randomized trial of patients with multiloculated pleural effusions. Subjects in the urokinase group drained significantly more pleural fluid, required less surgical intervention, and required fewer days in the hospital [18].

Combination of intrapleural tPA/DNase was significantly superior to the other combinations in improving pleural fluid drainage.Pulmozyme is a recombinant DNAse that digests DNA in the mucous secretions in lungs. Alteplase and Reteplase are the second generation recombinant tPAs. Pulmozyme cleaves extracellular DNA in mucus of cystic fibrosis patients, reducing the adhesiveness and viscoelasticity of the mucus [19].

## Conclusion

Intrapleural streptokinase instillation is generally safe, useful Fibrinolytic agent in management of empyema. Early use of streptokinase is an efficient and excellent non-invasive procedure. It decreases the rate of surgical interventions and the length of hospital stay with minor associated morbidity.

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# Small Versus Large Bore Chest Drains for Management of Spontaneous Pneumothorax Running Heading: Small Vs Large Drains

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<u>Background</u>: There is an increasing trend nowadays for using small bore catheters for drainage of nontraumatic pneumothorax.

<u>The aim</u> of this retrospective non randomized study was to compare efficacy and complications of small and large bore chest drain in management of non traumatic pneumothorax.

<u>Methods</u>: From Jan 2012 to Jun 2014, 100 patients with pneumothorax were treated by different sized chest tubes. We inserted small bore catheters ( $\leq$ 14 F) in 59 patients (Group A)and large bore (24-28 Fr) in 41 patients (Group B).

<u>Results</u>: A total of 57 patients had primary spontaneous pneumothorax and 43 had secondary spontaneous pneumothorax. There was no significant difference between the two groups regarding baseline patient characteristics that included age, sex and size of pneumothorax. Regarding type of pneumothorax, primary pneumothorax was more frequent in group A (40 versus 17. P value=0.023) and secondary type was more frequent in group B (24 versus 19, p value=0.006). Our primary end point was to assess complications and success rate (defined as complete lung expansion without additional tube or need for surgery). We achieved success rate of 86.44% and 85.27% for small bore and large bore drains respectively (p value=1). Complication rate was more among large bore drain (17.07% versus 8.47% for small bore). However, this was statistically significant (p=0.19). Duration of drainage was nearly similar (9.15 and 8.4 days for group A and group B respectively, p=0.311).

<u>Conclusion</u>: We found small bore chest tube safe, less traumatic, as effective as large bore tubes in draining non traumatic pneumothorax.

KEY WORDS: Pneumothorax, Spontaneous, Small Bore Catheters.

pontaneous pneumothorax is a common cause of hospital admission. The trend nowadays is for drainage by small bore pleural catheters ( $\leq$ 14 F) (1). They have the advantages of less pain, easier insertion and less complications (2). Increasing evidence shows comparable efficacy of small bore catheters in pleural drainage needed for pneumothorax, malignant pleural effusion and pleural infection (3). We conducted our study to compare small and large bore catheters regarding complications and efficacy of drainage in patients with spontaneous pneumothorax.

## **Patients and Methods**

From Jan 2012 to Jun 2014, 100 patients were diagnosed as pneumothorax either primary or secondary. They were treated by different sized catheters . Small bore catheters ( $\leq$ 14 Fr) were inserted for patients in group A and large bore (24-28 Fr) in group B. Patients with traumatic pneumothorax were excluded because associated lesions and accompanying hemothorax might affect the results. We retrospectively collected and reviewed data including age, sex, type of pneumothorax, and duration of drainage. Our primary endpoint was the success rate defined as complete lung expansion following

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insertion and the rate of complications. Failure was defined as ineffective drainage and the need to change the catheter or to perform surgery. Regarding indications, chest tube was inserted for symptomatic or large pneumothorax (more than 2 cm from the lung margin to chest wall at the level of the hilum). Diagnosis was based on clinical examination and plain chest x ray. CT chest was ordered if there was doubt about the size of pneumothorax or if underlying lung lesions were suspected. All catheters were inserted by thoracic surgeons and the size was chosen according to surgeon preference. No attempt for initial needle aspiration was done.

#### **Placement of chest drains**

Consent was taken and the procedure was explained to the patient. Adequate analgesia was achieved using local anesthesia (1% lidocaine HCL up to 3mg/kg). Our preferred approach was the 4<sup>th</sup> or 5<sup>th</sup> interspace just anterior to anterior axillary line. Large sized chest tubes were inserted by blunt dissection into the pleural space without trocar. Small bore catheters were inserted inserted with the aid of a

guidewire by a Seldinger technique. All catheters were positioned anteriorly for better drainage of air. Chest x ray was obtained immediately after insertion to evaluate tube position and lung expansion. We did not use negative suction routinely. Prophylactic antibiotics (3<sup>rd</sup> generation cephalosporins) were given.

Patients were encouraged for ambulation and chest physiotherapy. Daily chest x ray was done for follow up. Chest drains were removed after achieving full lung expansion and cessation of air leak more than 24 hrs. Chest x ray was repeated next day to check recurrence if any.

#### **Statistical Analysis**

The data were entered and analyzed using the statistical package for social sciences (SPSS Inc, Chicago, IL, USA), version 16.00. The quantitative data were presented in the form of mean, standard deviation and range, and were compared using independent t-test. Chi-square and Fisher tests were used to compare qualitative data. We considered statistical significance when P value < 0.05 and confidential interval of 95 percent.

## Results

We enrolled 100 patients including 62 males and 38 females with spontaneous pneumothorax in our study. The causes of pneumothorax was primary spontaneous in 57 and secondary spontaneous in 43. The causes of secondary spontaneous pneumothorax were COPD in 27 patients, TB in 12 patients and postpneumonic in 4 patients. The baseline characteristics of patients are shown in table (1).

No significant difference was noticed regarding duration of

drainage among the 2 groups (9.15 and 8.4 days for group A and B respectively, p value=0.311). Success rate was similar in the 2 groups (86.44% in group A and 85.27% in group B) Failure of lung expansion was detected in 8 patients in group A and 6 in group B with no statistically significant difference (p value=1). In addition, the etiology of pneumothorax did not affect failure rate.

	Group A (small bore chest drain)	Group B (large bore chest drain)	P value
Age	17-59 (23±13)	27-59 (27±11)	0.074
Sex (M/F)	37/22	25/16	0.913
Pathology			
PSP	40	17	0.023
SSP	19	24	0.006
Total no. of patients	59	41	
Duration of drainage	9.15	8.4	0.311
Failed lung expansion	8	6	0.684
Complications			
Bleeding	0	2	
empyema	1	1	
Residual pneumothorax	2	3	
Surgical intervention	2	1	
Total complications	5	7	0.19

#### Table 1. Data of the patients

The causes of failure to achieve complete lung expansion was improper position of chest drains in 6 patients, tube blockage in 5and excessive air leak in 3 patients. Reposition of drains improved lung expansion while surgery was necessary in those 3 patients (2in group A and 1 in group B) with excessive air leak. Their postoperative course was uneventful. We did not have any mortality. Complications included bleeding, empyema, residual pneumothorax and surgical conversion. They are presented in table (1) and no significant difference was noticed.

## Discussion

Spontaneous pneumothorax is a common health problem. Different modalities for drainage were developed. Nowadays there is an increasing trend for small bore catheters with the advantages of easier insertion, less complications, better cosmetic when compared to large bore catheters. Several studies showed no significant difference in terms of success rate, length of hospital stay, extubation time, recurrence rate, and complication. A study on 41 patients with PSP showed success rate 50.0% and 65.2% in the small-bore pigtail and

large-bore catheter groups, respectively (4). Tsai et al in a retrospective study compared pig tail and large bore chest tubes for management of first episode of SSP .Fifty patients(72.5%) undergoing the pigtail drainage and 16 (72.7%) undergoing large-bore chest tube treatment of SSP were successfully treated. No significant difference regarding hospital stay, extubation time, recurrence and complications (p value=088) (5). Similar results were shown by Chen et al in 168 patients of SSP treated by pig tail. Success rate was 70% and it was higher in patients with COPD than infection related pneumothoraces (6). Small bore catheters are efficient for iatrogenic pneumothorax. Noh and Ryu treated 105 of such patients using 7 F (French) central venous catheter, 10 F trocar catheter, 12 F pigtail catheter. Total success rate of thoracostomy was 78.1%. The success rate was not significantly difference by tube type (7). In a study including 212 patients with pneumothoraces of different causes, the failure rate was similar between the 112 patients treated using central venous catheters (CVC) and the 100 patients treated using chest tube (18% vs 21%, P = .60). However, the durations of drainage and of hospital stay were significantly shorter in CVC group.(8) Cho and Lee used 7F catheter for 200 patients with pneumothorax (primary, secondary, iatrogenic). Overall failure was 24%, more in secondary group (9). Our overall success rate was 84.42% for small bore catheters and 86% for large bore catheters, with no significant difference regarding tube size or etiology of pneumothorax. Our success rate was comparable to other studies (9,10). The average duration of drainage in our study were 9.15 and 8.4 days for small and large bore catheters respectively. It was not statistically significant (p=0.311) however it was relatively long. Our policy is to intervene surgically when air leak persists beyond 14 days. We agree with Chee et al about this period although some authors consider 5 to 7 days sufficient indication for surgery (11,12). Few studies was conducted about the efficacy of small bore chest tube in traumatic pneumothorax. In a prospective randomized clinical trial comparing pigtail and chest tube in patients with traumatic pneumothorax, tube- site pain was less in pig tail group. Lesser tissue trauma and flexible nature of pig tail catheters account for that (13). Although we excluded patients with traumatic pneumothorax in our study, the success rate of small bore chest tube will encourage us to include those patients in a future study. Our results appear to reflect BTS guidelines for management of spontaneous pneumothorax recommended small bore catheters 8-14 Fr when chest tube is indicated for drainage (11). Complications encountered with large bore catheters include pain, infection, direct injury to the lung or other organs while small catheters are more linked with blockage and dislodgement (9,14 ). In our study we did not find significant difference in complication rate between both groups. Placement of small bore catheters is more optimal when guided by US, with less complication rate (15). We did not use US routinely. With expertise of surgeons preferring insertion without trocar, we had few complication rate. Nevertheless, small bore catheters have limitations regarding flow rate. An invitro study compared functions of pleural drains concluded

that small bore catheters have a significantly lower flow rate compared with large catheters . Caution should be taken for patients with expected large air leak or on MV (16). Large bore 24-28Fr is recommended in such situations (17). This was our policy for managing such patients. Lin et al used small bore (pigtail sized 12 to 16 Fr.) for management of pneumothorax in mechanically ventilated patients. The overall success rate was 68.8% with more promising results in iatrogenic than barotrauma pneumothoraces (18).

In conclusion, small bore catheters are safe, well tolerated and have comparable efficiency to large bore catheters for drainage of nontraumatic pneumothorax.

#### List of abbreviations

COPD: chronic obstructive pulmonary disease CVC: central venous catheters PSP: primary spontaneous pneumothorax SSP: secondary spontaneous pneumothorax US: ultrasonography

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# **Subject Search**

#### By:

**Prof. Khaled Karara.** Prof of Cardiothracic Surgery, Alexandria University. IT Editor of the ESCTS. Co-Editor of the Journal of the ESCTS. n this appendix of the journal, all the papers published in the journal till January 2015 are listed. The first effort to list published papers appeared in the appendix of the journal 2004; 12 (3,4): 107–58, including the first ten years of journal publications. In this appendix the following ten years' publications are listed. All are now available for free on the society websit <u>www.escts.net</u>, both as abstracts and as full texts.

## INDEX

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- (19) Miscellaneous

# **1. Valvular Heart Diseases**

- Early post-Operative Results in Cases of Moderate Ischemic Mitral Regurgitation in Patients undergoing revascularization Alone Versus those undergoing revascularization plus Mitral Valve Repair. Mahmoud M. El-Zayadi, Yasser Ahmed Boriek, Mohamed Abul-Dahab M. and Ahmed M. N. Aboul-Azm. J Egypt Soc Cardiothorac Surg 2015; 23 (1):113-20.
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