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Oct - Dec 2013

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**ISSN 1110-578X** 

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# **Guidelines for Reviewers**

### **Purpose of Peer Review**

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

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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.

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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.

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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.
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- '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.
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- · How well the technology is described and illustrated.
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- All studies used in the evaluation.
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- 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.

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*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.

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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.

# Beating Heart CABG with help of the Resting heart system in High Risk Patients

# Cardiovascular

Farouk Oueida; MD\* Mohamed Ahmed Elawady; MD\*\* Ahmed M. Allam MD\*\*\* <u>Objectives:</u> CABG in high risk patients is associated with high postoperative morbidity and mortality. Miniaturized extracorporeal circulation (MECC) was developed to reduce the side effects of the conventional extracorporeal circulation (CECC) machine.

<u>Methods:</u> A retrospective study from January 2010 to June 2012 to evaluate the outcome of isolated elective beating CABG in high risk patients using the Resting heart system.

Results: 116 patients were enrolled in the study, 59 in Resting heart (Groups I) and 57 in CECC (Group II). EF was 28.26±4.23 in I versus 27.00±4.81in II, P value 0.13. EURO SCORE was 14.08±2.25 in I versus 14.61±2.37in II, P value 0.22. No significant difference between both Groups regarding the operative data. Ventilation time was 12.20±3.16hours in I versus 14.01±3.07 hours in II, P value 0.002). 24 hours chest tube drainage was 452.37±269.82 in I versus 673.68±392.81 in II, P value 0.001. PRBCS transfusion was 0. 35±.1.14 in I versus 1.00±1.39 in II. P value 0.04. FFP transfusion 1.00±2.20 in I versus 1.50±2.20 in II, P value 0.04). Platelets transfusion was 0.45±1.43 in I versus 1.50±3.27 in II, P value 0.02).Two patients in I were re-opened for bleeding (3.38%) versus three patients (5.26%) in Group II, P value 0.29. I4 patients (6.77%) in I had POAF versus 5 patients (8.77%) in II, P value 0.47. One patient needed CRRT in I (1.69%) versus two patients in II (3.50%), P value 0.54. Maximum Troponin level was 2.58±1.05 ng/ mL in I versus 2.81±0.78 ng/mL in II, P value 0.68. mean ICU stay was 52.15±21.97 hours in I versus 73.47±59.47 in II hours, P value 0.01. Two patients (3.38%) in I had postoperative wound infection versus 3 patients (5.26%) in II, P value 0.38. Hospital stay was 7.76±0.93 days in I versus 8.36±1.26 days in II. P value 0.004. Two patients died in I (3.38%) versus two patients (3.50%) in II, P value 0.68.

<u>Conclusion</u>: Beating CABG with mini bypass system is better tolerated in high risk patients than conventional CPB with less postoperative morbidity and mortality.

### KEYWORDS: CABG, High risk, MECC.



atients with coronary artery disease (LVEF) < 35%, have a poor longterm prognosis, with survival less than 25% at 3 years on medical therapy alone.1

Coronary artery bypass grafting (CABG) has shown to be superior to medical therapy alone for low ejection fraction (EF) patients with significant clinical improvement and better long-term survival .2

Surgical intervention nowadays is delayed due to widespread of thrombolytic therapy and PCI, which makes coronary arteriosclerosis, is more extensive and left ventricular dysfunction more severe, also it is associated with other co morbidity like old age, peripheral vascular disease, carotid stenosis and other risk factors which place the patients at much higher surgical risk due to increase in the perioperative morbidity and mortality3, 4.

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Codex : o3/01/1310

Due to the systemic inflammatory response syndrome (SIRS), which associated with the use of extracorporeal circulation (ECC), myocardial, renal, pulmonary and neurologic complications can occur. Usually those effects are subclinical but in high risk patients it can be responsible of worse outcome in the early post-operative period. Using the cross-clamp in poor left ventricular function patients usually induces myocardial ischemia and aggravates the adverse systemic effects of CPB leading to increase in the morbidity and mortality. 5

Beating heart operations without using the cross-clamping avoids global ischemia in patients with left ventricular dysfunction who have minimal cardiac reserve leading to better left ventricular segmental wall motion. 6

In the early 1990s, many surgeons started to perform coronary revascularization using the off pump technique (OPCABG) to avoid the side effects of using CPB machine, but the recently published studies debate about the significance of benefit of off-pump when compared to on-pump CABG specially in high risk patient regarding early postoperative mortality, incidence of stroke, myocardial infarction, percentage of complete revascularization and the long term grafts patency rates. 7-10

Over the past 15 years, concepts of miniaturized extracorporeal circulation (MECC) were developed aiming to reduce the side effects of the standard ECC and strengthening its advantages aiming to reduce the subclinical and clinical effects associated with conventional CPB machine. 11

There is a positive association between the lowest haematocrit during bypass and organ dysfunction which occurs during the use of CPB machine leading to decrease the oxygen carrying capacity which is not compensated due to loss of auto regulatory mechanisms leading to more end organ hypoxia and damage. 12-15

As the length of the tubing system in the Resting Heart System is much reduced so the usual priming in MECC is nearly half of ECCC, so Haemodilution is reduced in and a higher intra-operative haematocrit is expected. Also shorter tubing length leads to more reduction in clotting factor consumption and complement activation which triggers the systemic inflammatory response due to exposure to bypass. 16

The Resting heart system (RHS) has an option of retrograde arterial priming (RAP). The RAP allows for further 500 ml removal from the system, ending up with a total of 990 ml of priming volume, with the potential for further reduction of haemodilution.

Using the heparin-coated tubing systems reduces systemic heparin requirements from 300IU/kg to 150IU/kg as well as providing more biocompatibility for blood components.17

Resting Heart System has no venous reservoir so reduces the size and volume of the circuit and removes the blood-air interface, reducing the activation of clotting factors and inflammatory mediators. Without a reservoir or pericardiotomy suction, there is no blood 'reserve' that can be given if needed in case of major bleeding which is considered one of its side effects but the Resting Heart System has a vent circuit giving the chance for the venting blood to be re injected into the pump inflow. Also blood from the cell saver machine can be added to the system through the soft-shell reservoir bag attached to the system.18-19.

A centrifugal pump in the Resting heart system reduces zones of stagnant blood flow and believed to be less cellular damage than a roller pump leading to less haemolysis and platelets aggregation. Also it has one of the largest membrane surface area for gas exchange nearly 2.5 m<sup>2</sup>.

The Resting Heart System has integrated bubble detectors and arterial line filters to reduce the potential complications of air bubbles. The Resting Heart System uses the same venous cannulation pipe, arterial cannula and tubing lumen diameter to maintain CPB flow rates. Operation time should, therefore, not be increased and minimal further training is required by the surgical team.

Postoperative liver and renal function had been proved to be better in patients who use MECC due to better end organ protection.20, 21.

So the use of miniaturized extracorporeal circulation in high risk patients has the advantage of reducing the systemic inflammatory response and better haematocrit value during CPB, consequently better bleeding profile and less blood products transfusion leading to better end organ protection including the lungs, brain, myocardium, kidney and the liver.22, 23.

# **Patients and Methods**

A retrospective study from January 2010 to June 2012 evaluating the outcome of isolated beating CABG in high risk patients with the help of Resting Heart System ® machine (miniaturized extra corporal circulation, MECC) in SAUD AL BABTAIN CARDIAC CENTER (SBCC), Damman, KSA.

### **Inclusion criteria:**

- 1- Elective CABG.
- 2- EF ≤35%.
- 3- Euro score (Logistic)  $\geq 10$ .

### **Exclusion criteria:**

- 1- EF ≥35%.
- 2- Euro score (Logistic)  $\leq 10$ .
- 3-CABG plus other surgeries
- 4- Redo CABG.
- 5- Associated valvular lesion.

Cardiovascular

### Surgical technique

All Patients were anaesthetized with Propofol and Fentanyl using a target-controlled intravenous anesthesia protocol. Each patient had a central venous catheter and Swan-Ganz catheter with invasive monitoring of blood pressure. All patients had median sternotomy. Left internal mammary artery (LIMA) and the right internal mammary artery (RIMA), when indicated are harvested in skeletonized technique. Y graft is used in selected patients. The great saphenous vein is harvested in o pen technique method in all patients.

Single stage venous cannula (size 32-34 F) (Medtronic Inc., Minneapolis, MN, USA) were used to drain the venous blood from the right atrium with special precaution in MECC group to make tight atrial 3/0 Prolene purse around the venous cannula to avoid air from entering circuit. Aortic purse done by 4/0 Prolene along with a 20-22 F DLP<sup>®</sup> Straight Tip Arterial cannula (Medtronic Inc., Minneapolis, MN, USA).

# Miniaturized extracorporeal circulation (MECC): Group I

Particular care must be taken to avoid air intake into the circuit, especially at the site of the right atrial purse-string suture and during connection of the venous cannula to the venous line. We used The Resting Heart System<sup>™</sup> (RHS; Medtronic, Inc., Minneapolis, MN, USA) with **CARMEDA®** AFFINITY®NT oxygenator and a heparin coated closed-loop (Carmeda<sup>®</sup> Bio-Active Surface, Medtronic Inc., Minneapolis, MN, USA) in our patients.

The final priming volume of the circuit is 800 ml (excluding the tubing set and a filter, which is removed when the tubing set is connected to the arterial and venous cannulas). The system is equipped with an active venous air detector and removal device that detects and automatically removes venous air. After weaning, the shed blood during the operation was collected and washed in a cell saver together with the remaining blood from the RHS circuit and re-transfused to the patient. In our center in all MECC cases we used the cell saver system (XTRA Auto <sup>®</sup> Transfusion System, Sorin Group, Mirandola, Italy).

# Conventional extracorporeal circulation (CECC): Group II

A non-pulsatile roller pump (Stöckert S3<sup>®</sup>) consisted of an open system with a non-heparin-coated tube system is used. The system was primed with Ringer's Lactate, and mannitol 20%. Heparin (4000 units) was added to the prime volume. Blood was saved and collected in an open cardiotomy reservoir and transfused back to the patient. In this group PrimO2x <sup>®</sup> oxygenator (Sorin Group USA, Inc) is used.

After induction and stabilization of the CBP (either conventional or mini bypass), surgery was carried out without aortic cross clamp and cardiac arrest. Myocardial stabilization was performed with the help of the Octopus<sup>®</sup> Evolution AS Tissue Stabilizer (Medtronic Inc., Minneapolis, MN, USA)

Distal anastmosis construction of the grafts on the anterior surface of the heart is done in all cases without initiation of CPB system unless the patient had hemodynamic instability. After complete weaning of the CPB, Protamine sulphate dose is given to neutralize the heparin.

### Data collection and statistical analysis

There were 116 enrolled in the study, 59 patients in beating miniaturized extracorporeal circulation (MECC Group I) and 57 patients in beating conventional (CECC Group II).

Al preoperative and demographic variables including age, sex, body mass index, diabetes mellitus, hypertension, chronic obstructive pulmonary disease, renal failure on dialysis, hepatic failure, previous myocardial infarction, smoking history, carotid disease, peripheral vascular disease and the preoperative use of intra-aortic balloon pump (IABP) are collected and analyzed.

All operative data including CPB time mean number of the graft per patients; difficult weaning of CPB, intra operative use of intra-aortic balloon pump (IABP) and any intra-operative event are collected and analyzed.

Postoperative complications were classified as follow:

<u>*Myocardial:*</u> Arrhythmia, peri-operative myocardial infarction and low cardiac output syndrome.

<u>Pulmonary</u>: pneumonia, ventilator dependence greater than 48 hours, excessive pleural effusion requiring an additional drainage.

Infectious: superficial and deep sternal wound infection.

**Bleeding:** re-exploration due to excessive mediastinal bleeding or cardiac tamponade.

**<u>Renal</u>**: increase in serum creatinine greater than 1.5mg/dl, oliguria (<0.5 ml/kg/min) for more than 6 hours postoperatively or any other indication for Continuous Renal Replacement Therapy (CRRT).

Mortality is defined as death during a hospitalization for surgery, regardless of length of stay, or within 30 days of hospital discharge.

Values of continuous variables were expressed as mean standard deviation. Nonparametric tests (Mann-Whitney test and Fisher's exact test) were used for comparison between both groups of patients. Values of *P* less than 0.05 were considered significant. Statistical analyses were performed with computerized statistical packages (SPSS 18.0 software, SPSS, Chicago, IL, USA).

There was no statistically significant difference between both group regarding preoperative and demographic data. No significant difference between both Groups in mean EF 28.26 $\pm$ 4.23 in Group I versus 27.00 $\pm$ 4.81in Group II, *P* value 0.13). No significant difference in Logistic EURO SCORE (14.08 $\pm$ 2.25 in Group I versus 14.61 $\pm$ 2.37in Group II, *P* value 0.22). Table (1) summarizes all preoperative demographic data, of the two groups.

No significant difference between both groups regarding CPB time (83.94 $\pm$ 22.28min in Group I versus 87.21 $\pm$ 18.80min in Group II, *P* value 0.39). No significant difference regarding difficult weaning from CPB and need intra operative IABP insertion (5 patients (8.47%) in Group I versus 4 patients (7.01%) in Group II, *P* value 0.79. Table (2) summarizes operative data of the 2 groups.

Postoperatively there was significant difference regarding the ventilation time  $(12.20\pm3.16$  hours in Group I versus  $14.01\pm3.07$  hours in Group II, *P* value 0.002). There in first 24 hours postoperative chest tube drainage  $(452.37\pm269.82$  in Group I versus  $673.68\pm392.81$  in Group II, *P* value 0.001.

There was significant difference in packed RBCS transfusion 0.  $35\pm.1.14$  in Group I versus  $1.00\pm1.39$  in Group II, *P* value 0.04.There was significant regarding the FFP transfusion ( $1.00\pm2.20$  in Group I versus  $1.50\pm2.20$  in Group II, *P* value 0.04).There was significant regarding the platelets transfusion  $(0.45\pm1.43$  in Group I versus  $1.50\pm3.27$  in Group II, *P* value 0.02).

Two patients in Group I were re-opened for bleeding (3.38%) versus three patients (5.26%) in Group II with no significant difference between both Groups, *P* value 0.29. I 4 patients (6.77%) in Group I had postoperative atrial fibrillation (POAF) versus 5 patients (8.77%) in Group II with no significant difference between both groups, *P* value 0.47.

One patient needed continues renal replacement therapy (CRRT) for renal impairment in Group I (1.69%) versus two patients in Group II (3.50%) with no significant difference, P value 0.54.

Maximum serum Troponin level was higher in Group I but there was no significant difference  $(2.58\pm1.05 \text{ ng/mL} \text{ in} Group I versus 2.81\pm0.78 \text{ ng/mL} in Group II,$ *P* $value 0.68). There was significant difference Groups regarding ICU stay <math>(52.15\pm21.97\text{hours in Group I versus 73.47\pm59.47}$  in Group II hours, *P* value 0.01. Two patients (3.38%) in Group I had post-operative wound infection versus 3 patients (5.26%) in Group II with no significant difference between both groups, *P* value 0. 38. There was significant difference between both groups regarding the hospital stay  $(7.76\pm0.93 \text{ days in Group I versus 8.36\pm1.26days in Group II.$ *P*value 0.004).

Two patients died in Group I (3.38%) and two patients (3.50%) in Group II with no significant difference in 30- day mortality, P value 0.68. Table 3 summarizes post-operative data of the two Groups.

VARIABLE	Group I (n=59)	Group II (n=57)	P value
Age, mean ±SD	60.1±5.08	61.10±5.03	0.28
Male, n (%)	51(86.44%)	50(87.71%)	0.37
Female, n (%)	8(13.66%)	7(13.31%)	0.48
Hypertensive, n (%)	23(38.98%)	20(35.08%)	0.78
Diabetics, n (%)	23(38.98%)	22(38.95 %)	0.29
BMI	23.63±3.31	23.05±2.54	0.29
CREATININE	$1.24 \pm .28$	1.33±.32	0.29
Smokers, n (%)	20(33.89%)	17(29.82%)	0.26
Old MI, n (%)	37(62.71%)	38(66.66%)	0.27
LEFT MAIN LESION	9 (15.25 %)	11 (19.29 %)	0.86
IAPB	7(11.86%)	8(14.03%)	0.88
EF	28.26±4.23	27.00±4.81	0.13
PVD	5(8.47%)	3 (5.26%)	0.52
CAROTID STENOSIS>50%	4(6.77%)	3 (5.26%)	0.53
EUROSCORE (Logistic)	14.08±2.25	14.61±2.37	0.22

*BMI: body mass index, MI: myocardial infarction, IABP: intra-aortic ballon pump, EF: ejection Fraction, PVD: peripheral vascular disease. Values of P less than 0.05 were considered significant.* 

Table 1. Preoperative Demographic Data of the two Groups.

VARIABLE	Group I (n=59)	Group II (n=57)	P value
CPB, mean± SD (min)	83.94±22.28	87.21±18.80	0.39
Number of Grafts, No. of grafts/patient	3.03±0.61	2.89±0.58	0.21
Y- GRAFT	5(8.47%)	4 (7.01%)	0.77
DIFFICULT WEANING	5(8.47%)	4(7.01%)	0.79
Intra operative IAPB insertion	5 patients (8.47%)	4 patients (7.01%)	0.79.

Table 2. Operative data of the Two Groups

VARIABLE	GROUP I (n=59)	GROUP II (n=57)	P value
Ventilation TIME, HOURS	12.20±3.16	14.01±3.07	0.002
CHEST DRAINAGE, ML	452.37±269.82	673.68±392.81	0.001
PRBCS	0.35±.1.14	1.00±1.39	0.04
FFP	1.00±2.20	1.50±2.20	0.04
PLATLETS	0.45±1.43	1.50±3.27	0.02
Reoperation for Homeostasis, n (%)	2(3.38%)	3(5.26%)	0.29
Max Troponin ng/mL	2.58±1.05	2.81±0.78	0.19
POAF	4(6.77%)	5(8.77%)	0.47
CRRT	1(1.69%)	2(3.50%)	0.54
Intensive Care Unit Stay, Days	52.15±21.97	73.47±59.47	0.01
INFECTION INCIDENCE	2(3.38%)	3(5.26%)	0.38
Hospital STAY, Days	7.76±0.93	8.36±1.26	0.004
Hospital MORTALITY, n (%)	2(3.38%)	2(3.50%)	0.68

PRBCS: packed red blood cells, FFP: fresh frozen plasma, CRRT: continuous renal replacement therapy, POAF: postoperative atrial fibrillation.

Table 3. Postoperative Data of the Two Groups.

# Discussion

Coronary artery bypass surgery still gold standard treatment for patients with multi-vessel disease with high risk score. Many surgical techniques had been used to decrease the incidence of postoperative complications.

One of these techniques used in high risk patients is the concept of on pump beating-heart surgery (OPBH). This method means that CABG is performed using systemic extracorporeal circulatory support and avoids aortic cross-clamping avoiding myocardial damage. OPBH was described as an acceptable technique between off-pump CABG (OPCAB) and conventional extracorporeal cardiopulmonary bypass (CECC).24

Although the conventional extracorporeal circulation (CECC) still safe method with a low related mortality rate in coronary artery bypass surgery.

But due to due to stimulation of a systemic inflammatory response, neurological disorder, coagulopathy and multi-organ dysfunction, CECC may be responsible relatively high morbidity rate specially in high risk patients.

The systemic inflammatory response syndrome (SIRS) is high in CECC due to blood contact with the artificial surface of the bypass circuit and with air as well as with blood aspirated from the pericardial and pleural cavities, ischemia–reperfusion injury, endotoxemia and operative trauma. Using the MECC system reduces the complications related to the systemic inflammatory response and provides greater organic protection during the surgical procedure as it reduces the need for blood product transfusion which increases the risk of serious complications and death in patients undergoing cardiac surgery.25-29.

This encourages the concept of using Miniaturized extra corporal circulation (MECC) is in high risk patients to avoid

all these side effects of conventional CPB which is reflected on the peri operative morbidity and mortality in this critical group of patients.

Some studies found that the using the MECC with beating heart technique in patients with high risk patients is effective with safe perform of complete revascularization. Due to less end organ damage it decease the early postoperative morbidity and mortality rates.30, 31

Due to relatively high intraoperative haematocrit value, less haemolysis and platelets aggregation, the postoperative blood loss and consequently need for blood transfusion is less in MECC patients. This is of great importance in high risk patients which are more liable to blood transfusion related complication like postoperative pulmonary complications and high incidence of infection.32-34.

In our study the Resting Heart patients had significant less blooding and less need for blood and blood products transfusion which was reflected on less ventilation hours and incidence of post operative wound infection.

Same results confirmed in many studies which could be explained by better oxygenation due to relatively high haematocrit value and decease the need for blood transfusion which recent studies correlate it to postoperative pulmonary complication.35

Some studies found a significant difference in the incidence of postoperative atrial fibrillation and less Troponin level at a sign of better myocardial protection when using MECC which is of great importance in poor LV function patients 36, but in our study there was no significant difference in both although the maximum Troponin level and the incidence of POAF in higher in conventional CPB group.

In our study there was no significant difference in postoperative renal impairment but other studied studies confirmed the better postoperative liver function, less incidence of acute kidney injury and better renal function in MECC patients which is reflected on the postoperative morbidity incidence of especially in high risk patients. 20.21.

The neurological complications secondary to the cerebral hypo perfusion and microembolization are well known associated with CPB use especially in high risk group of patients. MECC systems can preserve brain tissue oxygenation and reduce cerebral microembolization due to low systemic inflammatory response and relatively high haematocrit value when compared to conventional CPB. 37-38. in our study although there was no major neurological insult in both groups, but better recovery and less agitation was noticed in MECC group.

# Conclusion

Beating CABG with the help of mini bypass system is better tolerated in high risk patients than conventional CPB as it is safe, effective for complete revascularization with less postoperative morbidity.

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# Outcome of surgical treatment of atrial septal defects in adult age groups

A Nosier; MD T Salah; MD O Abouel-Kasem; MD M Zekrey; MD <u>Introduction</u>: Surgical closure of an atrial septal defect (ASD) before the age of 30 years has been demonstrated to reduce complications during adulthood. However, the outcome of patients operated after the age of 30 is still debated.

<u>Methods</u>: In a prospective study we examined the outcome of surgical repair of ASD in adults (above 18 years). The patients were classified as (group I) 20 patients underwent surgery after the age of 30 years; (group II) 20 patients underwent surgery before the age of 30 years. The main variables analyzed were left and right ventricular systolic function, right sided dimensions, systolic pulmonary pressure, the degree of tricuspid regurgitation, the prevalence of atrial fibrillation and NYHA functional status.

<u>Results</u>: We found that ASD cases undergone surgical closure of the defect below 30 years as compared with cases done at or above 30 years showed significant improvement of symptoms (NYHA grades) (P =0.02), significant PASP reduction postoperatively (P =0.003) and significant improvement of left sided contractility (EF) (P =0.010) with less ICU stay period (P =0.044). With no statistically significant difference between groups regarding the other variables

<u>Conclusions</u>: Surgical repair of an atrial septal defect in patients before 30 years of age improve patient symptoms and the hemodynamic parameter more than older age patient and is strongly recommended.

here are several reasons why adult patients may present with uncorrected congenital heart lesions. late diagnosis is always a possibility, particularly in cases of atrial septal defects . Atrial septal defect accounts for about one third of cases of congenital heart disease detected in adults. (1)

Survival to adult life is the rule although life expectancy is not completely normal. 75% of adult patients with atrial septal defect will show signs or symptoms of the disease in the third or fourth decade of life as a consequence of pulmonary hypertension, atrial arrhythmia, or heart failure. (2)

The increased pulmonary pressure may contribute to the dilatation of the right ventricle,( right ventricular diastolic dimensions as high as  $4 \text{ cm/m}^2$ .) but probably the effect of the remodeled ventricle as a consequence of a long-standing volumetric overload plays a much more important role. Persistent right ventricle dilatation tends to be progressive and can affect the competence of the tricuspid valve and interact with the function of the left ventricle (3). Mechanisms that account for left ventricular dysfunction include septal displacement secondary to right ventricular dilatation, and systolic anterior movement of the mitral valve.(4)

The age at which symptoms appear is highly variable and is not exclusively related to the size of the shunt. Exercise intolerance in the form of exertional dyspnea or fatigue is the most common initial presenting symptom. Atrial fibrillation or flutter is an age-related reflection of atrial dilation and stretch that occurs at 40 years of age. Its arrival usually causes substantial symptoms because of both the tachycardia and the underlying hemodynamics (governed by impaired left ventricular filling and reduced systemic cardiac output). (5)

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Codex : o3/02/1310

Less commonly, decompensated right heart failure may occur, almost always in the older patient, often in the context of substantial tricuspid regurgitation and often with coexistent pulmonary arterial hypertension of variable severity. Occasionally, a paradoxical embolus or transient ischemic attack may be the first clue to the presence of an ASD. Even less commonly, the discovery of cyanosis may lead to the diagnosis of an intraatrial communication. (5)

Closure of most atrial septal defects is still the treatment of choice in children and young adults, because of the low surgical risk and good long-term outcome. However, the beneficial result of closure in adults over 40 years of age remains controversial. In a study of patients with atrial septal defect aged 40 years, it showed that overall mortality was not different between operated and not operated patients, although there was a tendency in favor of operated patients. Morbidity, however, was clearly higher in not operated patients. (2).Other Studies showed that the hemodynamic and electrophysiological results of the surgical repair of ASD after the age of 25 years were significantly inferior to those obtained when surgery was performed before this age. The reduction of pulmonary pressure and the size of the right ventricle and the degree of tricuspid insufficiency were significantly less in those patients who underwent surgery after the age of 25 years, as well as the size of the left ventricle and the prevalence of chronic atrial fibrillation.(6)

### Aim of work

The aim of that study was to evaluate the outcome of surgical repair of atrial septal defects in adult age group and to highlight preoperative, operative and postoperative factors that affect the early mortality and morbidities.

# Patients & methods

Forty adult patients (above 18 years old) with ASD were operated upon at Cairo University Hospitals in the period between December 2011 and August 2013, with short term follow up (6 months). Patients who had ASD associated with VSD or PDA, or significant valve disease other than the tricuspid or mitral valve, or ischemic heart disease and Eisenmenger syndrome were excluded from the study.

The patients were divided into two groups:

**Group I**: (risk group) 20 patients aged 30 years old or more having atrial septal defect.

**Group II**: 20 patients aged less than 30 years old having atrial septal defect.

### **Preoperative parameters**

Preoperative preparation included standard steps which started by careful and thorough history taking (putting in consideration the patient's age, sex, NYHA class), full clinical examination, Routine preoperative laboratory studies, plain chest Xray, 12 lead ECG, Transthoracic Echocardiographic examination (TTE) (to assess: type and size of the ASD, PAP, Cardiac chambers dimention and function, degree of tricuspid regurge,....), Transesophageal Echocardiographic examination (TEE) was needed in some cases, Coronary angiography. (in males >40 years - females >45 years), and Cardiac catheterization was done in some patients. (to measure PVR, QP/QS, response to VD drugs in cases with severe PHT and bidirectional shunt)

### **Operative parameters**

### Surgical approach

All patients underwent cardiac surgery for ASD closure through median sternotomy, except 5 cases were approached through RT antrolateral thoracotomy (8-10 cm incision under the RT mammary crease and the RT forth intercostal space was entered)

Full operative details were recorded specially The following data:

- Type of approach (median sternotomy or Rt anterior thoracotomy)
- Method of ASD closure. (patch or direct)
- · Other surgical procedures with ASD closure.
- Route of cardioplegia adminstration.
- Ischemic time & bypass time.
- Need for pulmonary vasodilator/Inotropic drugs and types.

### **Postoperative parameters**

Postoperative data were recorded as follows

- ICU stay duration .
- Mechanical ventilator support time .
- Mean hospital stay.
- Hospital mortality (within 30 days of the procedure)
- Operative morbidity or complications.
- Degree of clinical improvement (NYHA function class)
- ECG (For detection of arrhythmias and success of surgical ablation of AF if done )
- Echocardiography was done for all patients before hospital discharge and Follow up echocardiography was also done 3-6 months later .

### **Statistical methods**

Data were statistically described in terms of mean  $\pm$  standard deviation ( $\pm$  SD), median and range, or frequencies (num-

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ber 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

## **Preoperative results**

### Demographic data of the patients

In group I, the age range from 31 to 59 years with the mean age was  $41.9 \pm 9.575$  years. While in group II, the age range from 18 to 29 years with the mean age was  $22.55 \pm 3.649$  years. There was significant statistical difference between the two group (p value <0.05)

As regards sex distribution, in group I, there were 13 female patients (65%) and 7 male patients (35%). The same distribution was found in group II. There were 13 female patients (65%) and 7 male patients (35%). There was no significant sta-

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bution (p =1.00). There was significant statistical difference between the two groups as regards preoperative NYHA CLASS (p =0.043).

tistical difference between the two groups as regards sex distri-

In group I, 8 patients (40% of cases) were in AF, one of them was in paroxysmal AF, and 12 patients (60% of cases) were in sinus rhythm. In group II, 1 patient (5% of cases) were in AF, 19 patients (95% of cases) were in sinus rhythm. 3 patients from group I needed to do holter study as they showed a history of palpitation to rule out associated arrhythmia with –ve result in two cases and +ve in one case with evidence of paroxysmal AF and concomitant maze procedure done for him. There was significant statistical difference between the two groups (p = 0.02).

Preoperative Echocardiographic data:

## **ASD type**

Table 1.

The most commonly presenting ASD type in both groups was ostium secondum followed by primum ASD then sinus Venuses ASD. There was no significant statistical difference between the two groups. (p = 0.833) Table 2.

			Group Group I Group II		Total
					Total
	т	Count	3	8	11
	1	%	15.0%	40.0%	27.5%
	II	Count	7	9	16
NYHA class		%	35.0%	45.0%	40.0%
		Count	10	3	13
	III	%	50.0%	15.0%	32.5%
		Count	20	20	40
Total		%	100.0%	100.0%	100.0%

Table 1. NYHA class distribution in both groups.

			Group		T-4-1
			Group I	Group II	Total
	D '	Count	3	3	6
	Primum	%	15.0%	15.0%	15.0%
ASD type	Secondum	Count	15	16	31
		%	75.0%	80.0%	77.5%
	0.	Count	2	1	3
	Sinus venosus	%	10.0%	5.0%	7.5%
7	P ( 1	Count	20	20	40
1	Fotal	%	100.0%	100.0%	100.0%

Table 2. ASD type distribution in both groups.

### **Preoperative PASP**

In group I, the mean PAP was  $51.95\pm12.386$ , with 18 (90%) cases with PASP  $\geq$  40 mmHg. 3 patients from group I had PASP > 70 mmHg needed to do preoperative cardiac catheter that showed reversible and reactive PVD. while in group II the mean PAP 41±12.603, with only 9 (45%) cases with PASP  $\geq$  40 mmHg. There was significant statistical difference between the two groups as regards the mean preoperative PAP (P =0.009).

### Preoperative tricuspid valve regurge

In group I, 9 (45%) cases had moderate to severe TR while in group II, 6 (30%) cases to moderate and severe TR but with no significant statistical difference between the two groups (p =0.16).

### **Rt side dilatation**

Regarding Rt atrial dilatation there was no significant statistical difference between the two groups (P =0.632). Preoperative RV dilatation measured by RV diastolic diameter in group I, range from 2.8 to 4.5 mm with mean of  $3.59 \pm 0.575$  while in group II, range from 2.7 to 5 mm with mean of  $3.605 \pm 0.6168$ . There was no significant statistical difference between the two groups (P =0.937)

### **Cardiac contractility**

Lt sided contractility as measured by EF showed significant statistical difference between the two groups (P =0.008). RT sided contractility as measured by tricuspid annular plan systolic excursion (TAPSI) showed no significant statistical difference between the two groups (P =0.206). Table 3.

### **Cardiac catheterization**

In group I, preoperative cardiac catheterization was done for 6 cases (30%) for coronary angiography and showed no coronary lesions and was done for 3 cases (15%) for assessment of pulmonary pressure & resistance and found to be operable, while in group II, cardiac catheterization wasn't needed.

### **Operative results**

The surgical approaches used as well as the method of ASD closure done in the patients were shown in table 4. There was no significant statistical difference between the two groups as regards method of ASD closure. (P = 0.342).

The type of Cardioplegia used and the method of administration were shown in table 5. There was significant statistical difference between the two groups. (P = 0.003)

		Mean	St. deviation	Min.	Max.
Group I	EF	65.95	4.084	59	73
	TAPSI	1.74	0.1536	1.5	2
Group II	EF	70.25	5.600	60	80
	TAPSI	1.8	0.1414	1.6	2

Table 3. preoperative Cardiac contractility in both groups.

			Gr	oup	T 4 1
			Group I	Group II	Total
Median sternoton	ny approach	Count/%	19(95%)	16(80%)	35(87.5%)
Rt antrolateral Thoracotomy approach		Count/%	1(5%)	4(20%)	5(12.5%)
Method of clo-	direct suture	Count	1	0	1
0		%	5.0%	0.0%	2.5%
	glutaraldehyde fixed	Count	5	3	8
	pericardial patch	%	25.0%	15.0%	20.0%
	Pericardial patch	Count	14	17	31
		%	70.0%	85.0%	77.5%
Total		Count	20	20	40
		%	100.0%	100.0%	100.0%

Table 4. Approach and methods of ASD closure

In group I, mean ischemic time was  $35.4\pm 16.984$  minutes and mean bypass time was  $53.25\pm 25.406$  minutes while in group II mean ischemic time was  $32.5\pm 16.263$  minutes and mean bypass time was  $45\pm 20.810$ . There was no significant statistical difference between the two groups. (P =0.585, P =0.268 respectively) drugs (3 cases needed Dobutamine, 2 cases needed Milrinone, 4 cases needed nitroglycerin, 1 case needed Dobutamine with nitroglycerin and 10 cases needed no drugs) while in group II, 20% of patient needed inotropic or vasodilator drugs (2 cases needed Dobutamine, no cases needed Milrinone, no cases needed nitroglycerin, 2 cases needed Dobutamine with nitroglycerin and 16 cases needed no drugs.) Figure 1.

Other intra operative procedures other than ASD closure done in the patients were shown in table 6.

There was no significant statistical difference between the two groups regarding needs and types of inotropic or vasodilator drugs (p = 0.96 and 0.95 respectively).

			Gr	oup	Total
			Group I	Group II	Total
		Count	3	0	3
	Ante grade and retrograde cold blood	%	15.0%	0.0%	7.5%
	A . 1 1111 1	Count	17	12	29
Cardioplegia used		%	85.0%	60.0%	72.5%
		Count	0	8	8
	Ante grade warm blood	%	0.0%	40.0%	20.0%

### Table 5. Cardioplegia used in both groups.

			Gr	oup	Total
			Group I	Group II	
	NT.	Count	9	15	24
	No	%	45.0%	75.0%	60.0%
	Claft mitral rangin Triousnid rangin	Count	3	3	6
	Cleft mitral repair, Tricuspid repair	%	15.0%	15.0%	15.0%
	Maze and Tricuspid repair	Count	3	0	3
Other intraopera-		%	15.0%	0.0%	7.5.0%
	Mitral repair (rigid ring No.30)	Count	1	0	1
		%	5.0%	0.0%	2.5%
tive procedures	Tricuspid repair (modified devega), and Mitral repair (PML augmentation and band annuloplasty)	Count	0	1	1
L		%	0.0%	5.0%	2.5%
	Pericardial intracardiac baffle of RSPV	Count	2	1	3
to LA pulmonary valvotomy	to LA	%	10.0%	5.0%	7.5%
		Count	1	0	1
	pulmonary valvolomy	%	5.0%	0.0%	2.5%
		Count	1	0	1
	tricuspid repair only	%	5.0%	0.0%	2.5%

Table 6. Associated Iintraoperative procedures done in both groups.



Figure 1. Inotropic/vasodilator drugs needed in both groups.

# **Postoperative results**

## Early postoperative results

Postoperative results as regards the mechanical ventilation duration, Total ICU stay, and Total Hospital stay were shown in table 7. There was significant statistical difference between both groups as regards total ICU stay, but there was no Statistical significant difference between both groups as regards mechanical ventilation time and total Hospital stay.

### Mortality&Morbidity

There was no mortality in both groups whether Intraoperative or in hospital mortality. As regards morbidity, There was no significant statistical difference between the two groups regarding postoperative morbidity (P =0.401).Table 8.

	Group I	Group II	P value
Mechanical ventilation duration (hrs) mean± SD	7.5±2.68	6.08±3.11	NS (P=0.17)
Total ICU stay (days) mean± SD	2.25±1.37	1.55±0.605	Significant (p=0.044)
Total hospital stay(days) mean± SD	7.05±2.27	5.95±1.73	NS (p =0.137)

### Table: Postoperative mechanical ventilation duration, ICU stay, and Total Hospital stay

			Grou	ıp	T-4-1
			Group I	Group II	Total
		Count	1	1	2
Bleeding needs exploration	%	5.0%	5.0%	5%	
	CHBpermanent pacemaker	Count	1	0	1
		%	5.0%	0.0%	2.5%
		Count	1	0	1
A 1 1 1	Delayed tamponade needs evacuation	%	5.0%	0.0%	2.5%
Morbidities		Count	1	0	1
	Femoral hematoma	%	5.0%	0.0%	2.5%
	N	Count	15	18	33
	No	%	75.0%	90.0%	82.5%
	Patch dehiscence needed exploration	Count	0	1	1
	and repair	%	0.0%	5.0%	2.5%

Table 8: Mmorbidities in both groups

### Follow up data after 6 months:

There is marked reduction in the dyspnea grades after 6 months in both groups which is more evident in group II than in group I. There was significant statistical difference between the two groups as regards the grade of NYHA classification 6 months postoperatively. (P = 0.02).Table 9

	Group I		Group II		
	Pre	Post	Pre	post	
No dyspnea	No	4 (20%)	No	11 (55%)	
Class 1	3 (15%)	9 (45%)	8 (40%)	8 (40%)	
Class 11	7 (35%)	7 (35%)	9 (45%)	1 (5%)	
Class 111	10 (50%)	No	3 (15%)	No	

### Table 9: Degree of NYHA grades improvement

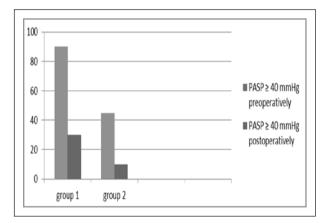


Figure 2. PASP improvement as compared with the preoperative values

# PASP follow up

There was significant statistical difference between the two groups as regards the mean PAP 6 months postoperative. (P =0.003). There is marked reduction in the PASP after 6 months in both groups which is evident in group II more than group I. In group I, 90% of patient had PASP  $\ge$  40 mmHg preoperatively, after 6 months regressed and reached 30% of cases; (33% still have PASP  $\ge$  40). In group II, 45% of patient had PASP  $\ge$  40 mmHg preoperatively, after 6 months regressed and reached 10% of cases only; (22% still have PASP  $\ge$  40). So the improvement is more evident in group II. Figure 2.

### **Cardiac contractility**

Lt sided contractility as measured by EF showed improvement in both groups, more marked in group II. In group I, mean EF preoperatively was 65.95, after 6 months improved and reached 66.55. In group II, the mean EF preoperatively was 70.25, after 6 months improved and reached 73.7, There was significant statistical difference between the two groups (P =0.010). As regarding RT sided contractility measured by the tricuspid annular plan systolic excursion (TAPSI), In group I the TAPSI reached 1.85±0.256, while in group II, the TAPSI reached1.93±0.215. There was no significant statistical difference between the two groups (p =0.292).

**Rt side dilatation:** There was regression in right atrial dilatation after 6 months with normalization in 35% in group I and 60% in group II. But with no significant statistical difference between the two groups (P =0.18). RV normalized in 40% of cases in group I and 65% in group II. There was no significant statistical difference between the two groups (P =0.135).

**Tricuspid valve regurge:** There is marked regression in the degree of tricuspid regurge in both groups but there was no significant statistical difference between the two groups. (P =0.153). Table 10.

			Group		Total	
			Group I Group II		Total	
	Count	5	11	16		
	No	%	25.0%	55.0%	40.0%	
FR degree after 6	m · · · 1	Count	7	4	11	
months	Trivial	%	35.0%	20.0%	27.5%	
		Count	8	5	13	
	Mild	%	40.0%	25.0%	32.5%	
Total		Count	20	20	40	
		%	100.0%	100.0%	100.0%	

Table 10: TR degree after 6 months in both groups.

### **Rhythm distribution follow up:**

In group I, 5 (25%) cases were in AF, 14 (70%) cases were in sinus rhythm. In group II, 1 (5%) case was in AF, 19 (95%) cases were in sinus rhythm. one patient from group 1 developed complete heart block which needed permanent pacemaker insertion after primum defect (PAVC) closure and failed conservative management for 2 weeks. There was no significant statistical difference between the two groups (P = 0.248).

### Discussion

As treatment for congenital heart disease (CHD) has steadily improved over the last 50 years, the number of adult patients with CHD has grown substantially. Atrial septal defects represent approximately one third of congenital heart defects diagnosed in adults. Ostium secondum defects make up about 75%, ostium primum defects make up 15%, sinus venosus defects (SVD) 5-10% and coronary sinus septal defects 1%. (7)

Two large studies have examined mortality and morbidity in surgically versus medically managed patients with ASDs over age 40 years, The first retrospective study held by Konstantinides et al 1995 showed a survival benefit that favored the surgical patients, but this was after the exclusion of patients with coronary artery and mitral valve disease. The second study, a prospective, randomized trial conducted at the National Institute of Cardiology in Mexico City by Attie et al 2001 showed, perhaps surprisingly, no clear survival benefit to surgical closure. However, over the study period (of 15 years), surgery was superior to medical therapy for a composite clinical end point that included recurrent pneumonias, the latter being a major contributor toward the differences observed between the 2 subgroups. These 2 studies also highlight the challenge of conducting clinical trials in congenital heart disease, in which patient's heterogeneity, even within the same diagnostic groups, and low mortality rates are often present. (5)

In our study, we found that ASD cases undergone surgical closure of the defect below 30 years old have better outcome than cases done at or above 30 years regarding improvement of symptoms (NYHA grades), PASP, reduction and improvement of lt sided contractility (EF) with less ICU stay period.

The clinical improvements seen in patients after ASD closure can be explained by the augmentation in LV filling and, consequently, the stroke volume. Improvements in LV function are likely to be a major determinant of the early improvement in NYHA functional class seen after ASD closure. It is of interest that the improvement in LV size and function appears to occur earlier than in the RV. This may suggest that LV remodeling is independent of RV remodeling as supported by multiple studies. (8)

We followed up our patients for 6 months and found that reduction in PASP is less evident in group I than in group II, with PASP still high ( $\geq$ 40 mmHg) in 6 cases (30%) of group I while 2 cases (10%) only in group II. It appears that nearly normalization of PAP within 6 months occurred in the younger age group.

Some authors shows that relative increase in pulmonary pressure in patients who undergo surgery after 25 years of age implicates the presence of an increase in arteriolar pulmonary resistance that persists after surgery, whether it be an increase in passive resistance due to elevation of pressure in the left atrium and pulmonary capillary or a decrease in the elastic properties of the pulmonary arteries caused by chronic dilatation. All mechanisms may co-exist to a greater or lesser degree in different patients, contributing to the maintenance of an increase in the right ventricular afterload following the intervention in contrast to the younger ages that shows nearly normalization of PAP within 6 months. (6)

In our study we tried to use the Advanced therapies for PAH to decrease PAP pre and postoperative period till the pulmonary vascular bed changes take place in order to decrease mortalities and morbidities which is strongly correlated to PAH. We used oral sildenafil on 3 cases with sever pulmonary HTN after doing preoperative cardiac catheterization that showed reversible and reactive PVD before and after using hyper oxygenation test. We used a dose ranged from 25-50 mg t.d.s for 3 months preoperatively and 6 months postoperatively that was successful in decreasing PAP. (9)

When severe pulmonary hypertension persists after operation, it may worsen with passage of time and may cause premature late death. About 25% of patients with preoperative pulmonary hypertension and high Rp at least 10 units/ m<sup>2</sup> die with pulmonary hypertension within 5 years of operation. However, some patients with pulmonary hypertension and elevated Rp late postoperatively have neither progression nor regression of their disease for as long as 20 years, although they have some limitation in exercise tolerance. In general, the younger at time of repair, and the lower the Rp at repair the better are the chances of surviving and having an essentially normal PAP 5 years and more later postoperatively. Generally outcome is good in patients of all ages when preoperative Rp is only mildly or moderately elevated (less than 8 units/m<sup>2</sup>). (10)

Partial closure of a defect with a one-way flap that permits right-to-left shunting could be a way of allowing decompression of the right ventricle during periods of raised pulmonary vascular resistance, especially in the postoperative period, while limiting flow and pressure stress to the pulmonary circulation. Subsequent complete closure of the defect could be performed when pulmonary vascular resistance falls in response to longer term advanced therapy .Another staged approach could be the application of a pulmonary arterial band. Once pulmonary vascular resistance starts to decrease in response to chronic advanced therapy then closure of the defect with debanding could follow. (11) According to ACC/AHA 2008 Guidelines for treatment of Adults With CHD:

# CLASS I

- Closure of an ASD either percutaneous or surgically is indicated for right atrial and RV enlargement with or without symptoms. (Level of Evidence: B)
- A sinus venosus, coronary sinus, or primum ASD should be repaired surgically rather than by percutaneous closure. (Level of Evidence: B)
- Surgeons with training and expertise in CHD should perform operations for various ASD closures. (Level of Evidence: C)

# **CLASS IIa**

- Surgical closure of secondum ASD is reasonable when concomitant surgical repair/replacement of a tricuspid valve is considered or when the anatomy of the defect precludes the use of a percutaneous device. (Level of Evidence: C)
- Closure of an ASD, either percutaneous or surgically, is reasonable in the presence of: a. Paradoxical embolism. (Level of Evidence: C) documented orthodeoxia-platypnea. (Level of Evidence: B)

# CLASS IIb

- Closure of an ASD, either percutaneous or surgically, may be considered in the presence of net left-to-right shunting, pulmonary artery pressure less than two thirds systemic levels, PVR less than two thirds systemic vascular resistance or when responsive to either pulmonary vasodilator therapy or test occlusion of the defect (patients should be treated in conjunction with providers who have expertise in the management of pulmonary hypertensive syndromes). (Level of Evidence: C)
- Concomitant Maze procedure may be considered for intermittent or chronic atrial tachyarrhythmias in adults with ASDs. (Level of Evidence: C)

### CLASS III

Patients with severe irreversible PAH and no evidence of a left-to-right shunt should not undergo ASD closure. (Level of Evidence: B) (12)

Irreversible pulmonary hypertension is the only frank contraindication to ASD closure. It is important to consider that, in a high flow state, with a large Qp: Qs, high pulmonary artery pressure may not represent fixed pulmonary hypertension. Generally, irreversible pulmonary hypertension is characterized by a pulmonary vascular resistance (PVR) 8–12 wood units/m<sup>2</sup>, with Qp: Qs <1.2:1, despite a vasodilator challenge test at cardiac catheterization to determine the reversible component of pulmonary hypertension using short-acting pulmonary vasodilators. (4) .Currently the agents used in acute testing is intravenous prostacyclin (epoprostenol, iloprost) or adenosine, inhaled nitric oxide hyperoxia and tolazoline. A positive acute vasoactive response is defined as a reduction of mean PAP >10 mmHg to reach an absolute value of mean PAP <40 mmHg with an increase or unchanged cardiac output. Positive acute responders are most likely to show a sustained response to long-term treatment with high doses of calcium channel blockers (CCB) and are the only patients that can safely be treated with this type of therapy. (9)

However, there is no evidence regarding the vasodilator challenge usefulness in predicting the response of PH to defect closure after the test, so a hemodynamic study during temporary balloon test occlusion in elderly patients with severe PH (RVSP  $\geq$ 70 mmHg) can be a good indicator of the subsequent evolution of PH and to assess pulmonary arterial hypertension is reversible or not in order to establish whether the defect is operable. The technique depends on recording of basal levels of pulmonary, systemic, and ventricular end-diastolic pressures. Pulmonary flow and systemic flow were determined based on the Fick principle. (13)

Adult patients with an ASD and atrial tachyarrhythmia benefit from defect closure. Closure of the defect may lead to regression of atrial flutter, whereas in older patients (>25 years) with AF, restoration of normal hemodynamics alone may not be sufficient. Most surgical groups are inclined to perform a right-sided Maze concomitant to ASD closure in patients with atrial flutter. Others recommend a left-sided Cox-Maze III for patients with AF, although this has yet to be validated with randomized studies. (14).

Other reports suggest that it might be beneficial to add the Cox-maze procedure to routine surgical closure of an ASD in adult patients with atrial fibrillation or flutter. In fact, since more than 50% of adult patients (aged >40 years) who undergo ASD closure will eventually develop atrial fibrillation; some investigators have suggested that these patients should probably undergo a concomitant Cox-maze procedure even if they do not have preoperative atrial fibrillation. This will expand the applications of this procedure from a therapeutic to a prophylactic modality. (15)

In our study we found that, addition of concomitant Maze procedure (both right and left sided) to ASD closure in 3 cases with AF, one of them was paroxysmal AF resulting in successful restoration of sinus rhythm in all cases, with no mortality and NYHA class improvement noticed from III to I in 2 cases and from III to II in 1 case. Mean ICU stay was 2.5 days and mean hospital stay was 10.33 days. Improvement of EF, TAPSI and Rt sided dilatation occurred after 6 months.

# Recommendations

Our results for adult ASD cases shows that surgical closure of the defect below 30 years old offer better clinical outcome, contractility and PAP improvement so, strongly recommended.

It is mandatory to assess ASD cases preoperatively with cardiac catheterization in cases with sever PHT, bidirectional shunt, for measurements of pulmonary and systemic blood flow and resistance and to do vasodilator challenge test to acertain PHT reversibility. Temporary balloon test occlusion is better than vasodilator challenge test in detection of the response of PH to defect closure.

The most important factors in mortality and morbidity prediction are advancing age, pulmonary hypertension and concomitant arrhythmia.

Irreversible pulmonary hypertension is the only frank contraindication to ASD closure even in old age.

Full Cox-Maze procedure is recommended to be added to ASD closure in adult cases associated with AF for better life quality. We believe that application of Maze procedure in patients as a prophylactic surgery before AF developments need to be supported by further studies on its feasebility against the prolongation of operative time opposite simple ASD defect closure.

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# Effect of Body Mass Index on The Early Clinical Outcomes After Cardiac Surgery

Amr Mohammad Allama\*, Islam Ibrahim\* Ayat Abdallah\*\* <u>Background and aim of the study:</u> Several reports have studied the outcomes of cardiac surgery in relation to the body mass index. Some studies concluded that obesity did not increase morbidity or mortality after cardiac surgery and others demonstrated that obesity was a predictor of both morbidity and mortality. The aim of this study is to evaluate the effect of body mass index on early clinical outcome after cardiac surgery.

<u>Methods</u>: This was a retrospective study of 3370 adult patients undergoing cardiac surgery. Patients were divided into 4 groups according to their body mass index. The 4 groups were compared regarding their preoperative, operative, and postoperative characteristics.

<u>Results</u>: Obese patients had a statistically significant younger age. Diabetes, hypertension, and hyperlipidemia were significantly more common in obese patients. CABG only operations were done more significantly in the overweight and obese groups, but valve only operations were done significantly more in the underweight group. The cross clamp time was significantly longer in the underweight group. Reoperation for bleeding, pulmonary, gastrointestinal, and renal complications were significantly more common in the underweight group. Wound complications were significantly higher in the obese group. Mortality was inversely proportional to the BMI. The adjusted Odds ratio of the early clinical outcomes demonstrated a higher risk of wound complications among overweight and obese patients

<u>Conclusion</u>: Body mass index has no effect on the early clinical outcomes after cardiac surgery except for the higher risk of wound complications among overweight and obese patients.

### KEYWORDS: Body mass index, Obesity, Outcomes, Surgery

besity is a risk factor for the development of cardiovascular diseases and their related complications [1]. It is associated with many cardiac risk factors, including coronary artery disease, heart failure, systemic hypertension, pulmonary hypertension, and cardiac arrhythmias [2]. As the problem of obesity is continuing to progress, it is expected that an increasing number of obese patients will require cardiac

Several reports have studied the outcomes following cardiac surgery in relation to the body mass index (BMI), but the findings were quite variable. Some studies concluded that obesity did not increase morbidity or mortality after cardiac surgery[4-7], while

Underweight is also a conflicting problem, as some reports found that underweight patients may have an increased short-term morbidity and mortality after cardiac surgery[10-13], while others found that they had more favorable outcomes [14].

others demonstrated that obesity was a predictor of both morbidity and mortality [8-9].

The aim of this study is to evaluate the effect of BMI on early clinical outcome in patients undergoing cardiac surgery.

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Codex : o3/03/1310

# **MATERIALS AND METHODS**

This was a retrospective study collected from the systematic database of Morriston Hospital in Swansea in Wales in the United Kingdom. The institutional review board permission was obtained to perform this study. Data of patients operated from January 2005 to January 2012 were analyzed. Patients underwent coronary artery bypass grafting (CABG), valve operations, or combined CABG and valve operations were included in the study. Children (less than 18 years) were excluded from the study. All operations were performed using cardiopulmonary bypass by different surgical teams. The level of blood glucose was maintained in both diabetic and nondiabetic patients at the level of 72-126 mg/dl using insulin infusions, intraoperatively and for 48 hours postoperatively (or until the patient return to his or her normal diet). The BMI was calculated by dividing the weight in kilograms by the square of height in meters. A total number of 3370 patients were included in the study. They were divided into 4 groups according to the World Health Organization (WHO) classification of BMI [15]. Patients with BMI less than 18.5 kg/m<sup>2</sup> were included in the underweight group, patients with BMI from 18.5 kg/m<sup>2</sup> to 24.99 kg/m<sup>2</sup> were considered in the normal weight group, patients with BMI from 25 kg/m<sup>2</sup> to 29.99 kg/m<sup>2</sup> were included in the overweight group, and patients with BMI 30 kg/m<sup>2</sup> or more were classified in the obese group. The 4 groups were compared regarding their preoperative, operative, and early postoperative characteristics. The early clinical outcomes were defined as any morbidity or mortality occurred in the first 30 postoperative days or during hospitalization if the patient stayed in hospital more than 30 days postoperatively.

### Statistical analysis

Data was collected and entered to the computer using SPSS (Statistical Package for Social Science) program for statistical analysis, (version 17; Inc., Chicago. IL). Quantitative data was shown as mean, and SD, while qualitative data was expressed as frequency and percent. Chi- square test was used to measure association between qualitative variables, One Way Analysis of Variance (ANOVA) test was used for comparison between three or more groups having quantitative normally distributed data, while Kruskal-Wallis test was used when this data was not normally distributed. Stepwise logistic regression model was used to give adjusted odds ratio and 95% confidence interval of the effect of the different risk factors on early clinical outcomes in the studied patients. Entry p-value of 0.05 and retention P-value of 0.10 have been considered in forward stepwise logistic regression analysis. The model has included all variables that have been hypothesized on theoretical background to be possible confounders. P-value was considered statistically significant when it was less than 0.05.

# RESULTS

There were 3370 patients included in this study (2427 males and 943 females). The underweight group included 194 (5.8%) patients, the normal group included 944 (28%) patients, the overweight group included 1261 (37.4%) patients, and the obese group included 971 (28.8%) patients.

### **Preoperative data (Table I)**

Obese patients had a statistically significant younger age than the other groups (mean age was 66.1 years). Females constituted the highest percentage of patients in the underweight group (53.6%). Diabetes, hypertension, and hyperlipidemia were significantly more common in obese patients (36.7%, 83%, and 70.3%, respectively), but the calculated Euro-score was significantly lower in this group. Although current smoking was significantly more common in the underweight group (12.4%), chronic obstructive pulmonary disease was significantly less common in this group (7.2%). The preoperative Canadian Cardiovascular Society (CCS) class showed a statistically significant difference between all groups. Class 1 was more common in the underweight group, classes 2 and 3 were more common in the obese group, and class 4 was more common in the normal group. Preoperative ejection fraction, NYHA class, and preoperative myocardial infarction showed no statistically significant difference between all groups. Patients in the underweight group had a statistically significant higher proportion of preoperative percutaneous coronary interventions (PCI) (30.9%) and a lower proportion of preoperative cerebrovascular accidents (1%). No statistically significant difference was found between the 4 groups regarding preoperative peripheral vascular diseases or the history of previous cardiac surgery.

### **Operative data (Table II)**

Elective operations were significantly more common in the underweight group, urgent operations were significantly more common in the normal and overweight groups, and emergent operations were significantly more common in the normal group. CABG only operations were done significantly more in the overweight and obese groups, but valve only operations were done significantly more in the underweight group. No statistically significant difference was found between all groups regarding the total bypass time, but the cross clamp time was significantly longer in the underweight group.

### **Postoperative data (Table III)**

Total blood loss, extubation time, ICU stay, and total hospital stay showed no statistically significant difference between all groups. Underweight patients had a statistically significant higher proportion of reoperation for bleeding (5.7%) followed by the normal, the obese, and the overweight group (4.3%, 2.9%, and 2.7%, respectively). Postoperative arrhythmias, cardiac arrest, and neurological complications did not show any statistically significant difference between all groups. Pulmonary, gastrointestinal, and renal complications were significantly more common in the underweight group followed by the normal group, then the obese group, and lastly the overweight group. Wound complications were significantly higher in the obese group, then the overweight, the underweight, and lastly the normal groups (16.7%, 6.7%, 2.1%, and 1.6%, respectively). Mortality was inversely proportional to the BMI as it was significantly higher in the underweight patients and lower in the normal, overweight, and obese patients (4.1%, 3.5%, 1.7%, and 1.2%, respectively).

Variable	;	Underweight (n=194)	Normal (n=944)	Overweight (n=1261)	Obese (n=971)	P-value
Age (years)		69.7±9.2	68.9±10.5	68.4±9.7	66.1±9.4	< 0.001
Female sex		104(53.6%)	261(27.6%)	288(22.8%)	290(29.9%)	<0.001
Diabetes		23(11.9%)	220(23.3%)	314(24.9%)	356(36.7%)	< 0.001
Hypertension		110(56.7%)	665(70.4%)	976(77.4%)	806(83.0%)	<0.001
Hyperlipidemia		118(60.8%)	590(62.5%)	870(69.0%)	683(70.3%)	<0.001
Current smokers		24(12.4%)	105(11.1%)	103(8.2%)	82(8.4%)	0.035
COPD		14(7.2%)	127(13.5%)	185(14.7%)	143(14.7%)	0.036
	>49	92(47.4%)	454(48.1%)	637(50.5%)	513(52.8%)	
Ejection fraction	30-49	84(43.3%)	367(38.9%)	490(38.9%)	368(37.9%)	0.102
	<30	18(9.3%)	123(13.0%)	134(10.6%)	90(9.3%)	
	1	64(32.9%)	233(24.7%)	303(24%)	206(21.2%)	0.019
	2	65(33.5%)	343(36.3%)	499(39.6%)	399(41.1%)	
CCS class	3	52(26.8%)	286(30.3%)	369(29.3%)	302(31.1%)	
	4	13(6.7%)	82(8.7%)	90(7.1%)	64(6.6%)	
	1	29(14.9%)	131(13.9%)	186(14.8%)	109(11.2%)	
NIX/II A 1	2	82(42.3%)	432(45.8%)	599(47.5%)	459(47.3%)	0.237
NYHA class	3	74(38.1%)	329(34.9%)	426(33.8%)	358(36.9%)	
	4	9(4.6%)	52(5.5%)	50(4.0%)	45(4.6%)	
	No	124(63.9%)	601(63.7%)	818(64.9%)	635(65.4%)	0.212
Preoperative MI	1	65(33.5%)	297(31.5%)	374(29.7%)	273(28.1%)	
	≥2	5(2.6%)	46(4.9%)	69(5.5%)	63(6.5%)	
Preoperative PCI		60(30.9%)	152(16.1%)	120(9.5%)	102(10.5%)	< 0.001
Cerebrovascular accidents		2(1%)	15(1.6)	38(3%)	33(3.4%)	0.030
Peripheral vascular disease		22(11.3%)	148(15.7%)	160(12.7%)	134(13.8%)	0.164
Previous cardiac sur	rgery	7(3.6%)	36(3.8%)	36(2.9%)	21(2.2%)	0.182
Euro-score		6.3±3.3	6.4±3.7	5.6±3.4	5.1±3.3	< 0.001

*BMI* = body mass index; CCS = Canadian cardiovascular society; COPD = chronic obstructive pulmonary disease; MI = myocardial infarction; NYHA = New York heart association; PCI = percutaneous coronary intervention.

 $\label{eq:alpha} All variables are expressed as number (percent) except age and Euro-score which are expressed as mean \pm standard deviation$ 

Table I. Preoperative characteristics of the studied patients according to the BMI

V	<i>V</i> ariable	Underweight (n=194)	Normal (n=944)	Overweight (n=1261)	Obese (n=971)	P-value
	Elective	119(61.3%)	461(48.8%)	649(51.5%)	551(56.7%)	
Timing of	Urgent	72(37.1%)	443(46.9%)	581(46.1%)	397(40.9%)	< 0.001
operation	Emergent	3(1.5%)	40(4.2%)	31(2.5%)	23(2.4%)	
	CABG	91(46.9%)	555(58.8%)	799(63.4%)	618(63.6%)	
Procedure	CABG+Valve	40(20.6%)	203(21.5%)	259(20.5%)	184(18.9%)	< 0.001
	Valve	63(32.5%)	186(19.7%)	203(16.1%)	169(17.4%)	
Bypass time (	(minutes)	111±38	118.7±44.3	119.5±47.6	118.2±46.8	0.117
Clamp time (	minutes)	97.7±35.9	90±39.3	83.7±38.5	82±37.4	<0.001

BMI = body mass index; CABG = coronary artery bypass grafting.

All variables are expressed as number (percent) except bypass time and clamp time which are expressed as mean ± standard deviation

### Table II: Operative data of the studied patients according to the BMI

Variab	le	Underweight (n=194)	Normal (n=944)	Overweight (n=1261)	Obese (n=971)	P-value
Total blood loss (ml)		717.6±517.5	692.6±428.1	710.3±445.9	739.3±484.2	0.162
	<3	2(1.0%)	20(2.1%)	31(2.5%)	23(2.4%)	
	3-6	42(21.6%)	233(24.7%)	342(27.1%)	268(27.6%)	
Ventilation time	6-12	103(53.1%)	480(50.8%)	638(50.6%)	452(46.5%)	0.224
(hours)	12-24	37(19.1%)	143(15.1%)	177(14.0%)	167(17.2%)	
	>24	10(5.2%)	68(7.2%)	73(5.8%)	61(6.3%)	
ICU stay (hours)	<6	4(2.1%)	21(2.2%)	26(2.1%)	21(2.2%0	
	6-12	30(15.5%)	190(20.1%)	281(22.3%)	216(22.2%)	
	12-24	114(58.8%)	485(51.4%)	659(52.3%)	489(50.4%)	0.544
	24-48	30(15.5%)	160(16.9%)	204(16.2%)	169(17.4%)	
	>48	16(8.2%)	88(9.3%)	91(7.2%)	76(7.8%)	
Total stay (days)		18.8±20.7	19.4±27	18.3±24.5	17.1±22.2	0.236
Reoperation for ble	eeding	11(5.7%)	41(4.3%)	34(2.7%)	28(2.9%)	0.04
Arrhythmia		62(32.0%)	272(28.8%)	343(27.2%)	264(27.2%)	0.47
Cardiac arrest		7(3.6%)	19(2.0%)	17(1.3%)	22(2.3%)	0.124
Neurological complications		0(0.0%)	9(1.0%)	13(1.0%)	5(0.5%)	0.298
Pulmonary complications		32(16.5%)	116(12.3%)	123(9.8%)	107(11.0%)	0.026
GIT complications		5(2.6%)	10(1.1%)	4(0.3%)	9(0.9%)	0.008
Renal complications		15(7.7%)	49(5.2%)	44(3.5%)	46(4.7%)	0.033
Wound complication	ons	4(2.1%)	15(1.6%)	85(6.7%)	162(16.7%)	<0.001
Mortality		8(4.1%)	33(3.5%)	22(1.7%)	12(1.2%)	0.001

*GIT* = gastrointestinal tract; *ICU* = intensive care unit.

 $All \ variables \ are \ expressed \ as \ number \ (percent) \ except \ total \ blood \ loss \ and \ total \ stay \ which \ are \ expressed \ as \ mean \ \pm \ standard \ deviation.$ 

Table III. Postoperative data of the studied patients according to the BMI

	Underweight	Normal	Overweight	Obese
Outcome	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Postoperative arrhythmia <sup>I</sup>	1.18(0.83-1.67)	1 (-)	0.99(0.82-1.21)	1.02(0.83-1.27)
Cardiac arrest	1.99(0.79-4.99)	1 (-)	0.81(0.41-1.59)	1.55(0.82-2.96)
Neurological complications <sup>II</sup>	0 (0)	1 (-)	1.15(0.48-2.73)	0.75(0.25-2.31)
Pulmonary complications <sup>III</sup>	1.35(0.86-2.10)	1 (-)	0.82(0.62-1.10)	0.96(0.71-1.28)
GIT complications	2.76(0.91-8.41)	1 (-)	0.33(0.1-1.07)	1.07(0.42-2.72)
Renal complications	1.73(0.91-3.26)	1 (-)	0.75(0.48-1.15)	1.14(0.74-1.76)
Wound complications <sup>III</sup>	1.3(0.43-3.99)	1 (-)	4.5(2.58-7.86)*	12.8(7.44-21.99)*
Mortality <sup>IV</sup>	1.73(0.7-4.23)	1 (-)	0.61(0.33-1.11)	0.49(0.23-1.03)

 $^{\rm I} Adjusted also for preoperative MI and the procedure done.$ 

<sup>III</sup> Adjusted also for COPD.

<sup>11</sup> Adjusted also for preoperative cerebrovascular accidents.

<sup>IV</sup> Adjusted also for peripheral vascular disease and previous cardiac surgery. CI = confidence interval; OR = odds ratio.

\* Denotes p<0.05 compared with normal BMI patients. Normal weight was the reference group in all analysis.

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Table IV. Adjusted Odds ratios for early clinical outcomes in the studied patients according to the BMI

The adjusted Odds ratio of the early clinical outcomes demonstrated a higher risk of wound complications among overweight patients (OR=4.5, 95% CI=2.58-7.86) and obese patients (OR=12.8, 95% CI=7.44-21.99) in reference to the normal BMI patients (Table IV).

## DISCUSSION

The prevalence of obesity and its associated medical problems have been increased in an epidemic fashion and are considered a major health problem especially in the developed countries [16]. Hawn et al [17] found that obesity was not associated with increased risk of complications in most commonly performed general surgical procedures.

Our results revealed that obese patients had a significantly younger age than the other groups. This coincides with Moulton et al [5], Stamou et al [18], Wigfield et al [19], and Thourani et al [20] who recorded a significantly younger age in obese patients compared to the non-obese patients. This could be explained by the documented increased risk of cardiovascular diseases in obese people and subsequently their need for cardiac operations at younger age. In our study diabetes, hypertension, and hyperlipidemia were significantly higher in the obese patients. This also coincides with Moulton et al [5], Stamou et al [18], Wigfield et al [19], Engelman et al [11], and Thourani et al [20]. Our results recorded a significantly higher proportion of current smoking in the underweight group with a significantly lower incidence of COPD in the same group. Engelman et al [11] reported different results, as they found a higher proportion of smoking in patients with BMI more than 30 and a higher proportion of COPD in patients with BMI less than 20. Thourani et al [20] reported a significantly higher proportion of COPD in obese patients and the lowest occurrence was in normal weight patients. On the other hand, Moulton et al [5] and Stamou et al [18] did not record a statistically significant difference between obese and non-obese patients regarding the proportion of COPD.

Our results denoted a significantly higher proportion of patient in the underweight group who needed elective operations, and a significantly higher proportion of patients in the normal weight group who needed urgent and emergent operations. Stamou et al [18] did not record any significant difference between patients regarding urgency of the operation. On the contrary, Reeves et al [21] recorded a significantly higher proportion of elective operations in the overweight patients (47.2%), and a significantly higher proportion of urgent and emergent operation in the underweight patients (47.4% and 18.1%, respectively). Regarding the operative procedures in our study, CABG-only operations were significantly more common in the obese patients (63.6%), and valve-only operations were significantly more common in the underweight patients (32.5%). This coincides with Engelman et al [11] who reported a significantly higher incidence of CABG-only operations in patients with BMI more than 30 (77%), and a significantly higher incidence of valve-only operations in patients with BMI less than 20 (37%). Stamou et al [18] also recorded a significantly higher incidence of CABG operations and lower incidence of valve operations in obese compared to normal patients. Our results revealed that obese patients had the shortest clamp time while underweight patients had the longest time. This coincides with Wigfield et al [19] who reported a significantly longer clamp time in non-obese patients compared to obese and extreme obese patients (110, 102.9, 98.9 minutes, respectively). Engelman et al [11] also recorded a significantly higher number of patients with BMI less than 20 who needed median clamp time more than 90 minutes. Stamou et al [18] also found that the number of patients who needed a prolonged clamp time were significantly less in obese compared to normal BMI patients. On the contrary, Thourani et al [20] recorded a significantly longer clamp time in obese patients. Moulton et al [5] did not find a significant difference between obese and non-obese patients regarding the clamp time. Contrary to the clamp time, the total bypass time in our study did not show a significant difference between groups. This may be due to the significantly large number of overweight and obese patients who had urgent or emergent operations and CABG operations compared to the underweight patients. This may have a smaller number of grafts lowering the clamp time, while waiting for a longer time for complete weaning from bypass.

In our study, no statistically significant difference was found between groups regarding the mechanical ventilation time despite the statistically significant higher proportion of COPD in obese patients. This may be due to the statistically lower proportion of current smoking patients in overweight and obese patients. Stamou et al [18], Moulton et al [5] and Wigfield et al [19] recorded similar results, but Engelman et al [11] found that underweight patients were significantly more liable for prolonged ventilator support. Thourani et al [20] recorded that obese patients had a significantly longer ventilation time.

We did not record a significant difference between groups regarding the ICU stay or the total hospital stay. Stamou et al [18] also did not find a significant difference between obese and normal weight patient regarding these two parameters. Thourani et al recorded a significantly longer ICU and total hospital stay in obese patients. Wigfield et al [19] reported a significantly longer total hospital stay in obese patients, but no significant difference was found regarding the ICU stay. On the other hand, Engelman et al [11] reported a significantly more underweight patient who needed ICU stay more than 3 days or stayed in hospital more than 10 days.

Our results revealed that underweight patients had a significantly higher incidence of reoperation for bleeding. The same results were obtained by Engelman et al [11] and Thourani et al [20]. Stamou et al [18] also reported that obese patients had a significantly lower chance for reexploration compared to the normal weight patients. But Moulton et al [5] and Wigfield et al [19] did not find a significant difference between obese and non-obese patients regarding reexploration. The increased chance of underweight patients with postoperative bleeding could be explained by the increased risk of hemodilution by

a fixed bypass circuit during cardiopulmonary bypass, as confirmed by Ranucci et al [22]. This may cause dilution of the coagulation factors. The increased fat in the mediastinum and around the pericardium may have a tamponading effect on minor bleeding points in the mediastinum in obese patients. In our study, the underweight patients had a significantly higher incidence of elective operations and lower incidence of urgent and emergent operations. They also had a significantly lower incidence of CABG operations. Consequently, less patient in the underweight group were expected to be on antiplatelet agents at the time of operation, so, this factor could not explain the increased incidence of reoperation for bleeding in these patients.

In our study, no statistically significant difference was recorded between groups regarding the occurrence of arrhythmia or cardiac arrest. The same results were recorded by Stamou et al [18] and Wigfield et al [19]. Engelman et al [11] and Thourani et al [20] also recorded no significant difference between BMI groups regarding the occurrence of new atrial fibrillation. Moulton et al [5] found a significantly higher proportion of atrial arrhythmias in obese patients, but they reported no significant difference between obese and non-obese patients regarding the occurrence ventricular arrhythmias.

In this study, no significant difference between patients was found regarding the occurrence of neurological complications. Several studies recorded the same results [5, 18, 19, and 20], but Engelman et al [11] reported a significantly higher incidence of neurological complications in underweight patients.

In our study, the proportion of postoperative pulmonary complications was significantly more common in underweight patients. This may be due to the significantly higher proportion of current smokers in the underweight patients. This coincides with the results obtained by Engelman et al [11] who recorded a higher incidence of postoperative pneumonia in the underweight patients. Other studies did not record any significant difference between patients with different BMI regarding the occurrence of postoperative pulmonary complications [5, 18, 19, and 20].

In our study, postoperative gastrointestinal (GIT) complications were significantly more common in the underweight patients. This is in contrast to both Wigfield et al [18] and Thourani et al [19], who recorded no significant difference between patients with different BMI regarding postoperative GIT complications.

Regarding postoperative renal complications, we found a significantly higher proportion in the underweight patients. This is the same result obtained by Engelman et al [11] and Reeves et al [21], who recorded a higher occurrence of renal failure in patient with BMI less than 20. This may be due to more hemodilution in these patients. On the contrary, Thourani et al [20] found a significantly higher occurrence of new renal failure in patients with BMI more than 36. Stamou et al [18] and Moulton et al [5] did not record any significant difference between patients with different BMI regarding postoperative renal complications.

We found a significantly higher incidence of wound complications in obese patients. These results agree with Engelman et al [11], who also recorded a significantly higher incidence of deep sternal wound infection and leg infection in obese patients. Moulton et al [5] also recorded a significantly higher incidence of superficial sternal wound infection and leg infection in obese patients, but no significant difference was recorded regarding the incidence of mediastinitis. Thourani et al [20] reported a significantly higher incidence of mediastinitis in obese patients, but Stamou et al [18] and Wigfield et al [19] did not. The higher proportion of wound complications in obese patients in our study did not affect the total hospital stay as it was equalized by the higher proportion of pulmonary, GIT, and renal complications in underweight patients.

Regarding mortality, underweight patient had a significantly higher proportion in our study. Underweight patients had a significantly higher proportion of elective operations and subsequently mortality was expected to be lower in this group. But this may be explained by the higher calculated Euro-score in the underweight patients, and also the higher proportion of reoperation for bleeding, pulmonary, GIT, and renal complications in these patients. This coincides with Engelman et al [11] and Thourani et al [20] who recorded a significantly higher proportion of mortality in patients with lower BMI. Stamou et al [18] recorded a significantly higher proportion of mortality in overweight patients compared to patient with normal BMI. Wigfield et al [19] and Moulton et al [5] did not find any significant difference between patients with different BMI regarding mortality.

Multivariate analysis of our results did not confirm the effect of BMI on the early clinical outcomes after cardiac surgery except for the higher risk of wound complications among overweight and obese patients in reference to the normal BMI patients. Stamou et al [18] demonstrated a lower risk for hemorrhage-related reexploration and operative mortality for the overweight than the normal BMI patients and a similar operative mortality and postoperative morbidity for obese compared with the normal BMI patients. Thourani et al [20] concluded that patients with BMI less than 24 had a significantly increased risk for in-hospital and long-term mortality after cardiac valvular surgery. Engelman et al [11] concluded that low BMI independently predicts increased morbidity and mortality after cardiac operations.

# STUDY LIMITATIONS

It is a retrospective not a randomized prospective study and it is a single-institutional study done by different surgical teams. There are a relatively small number of patients especially in the underweight group.

# CONCLUSION

Body mass index has no effect on the early clinical outcomes after cardiac surgery except for the higher risk of wound complications among overweight and obese patients.

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# **Concomitant DeVega's annuloplasty with mitral valve replacement: when to declamp the aorta?**

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<u>Objectives:</u> The objectives of this study is to compare the results of performing the DeVega's annuloplasty tricuspid valve repair before and after releasing the aortic cross clamp in patients with rheumatic heart disease indicated for concomitant tricuspid repair with mitral valve replacement.

<u>Methods</u>: Concomitant DeVega's annuloplasty with mitral valve replacement was always performed under arrested heart at our institution. Since January 2012 two surgeons started to perform the procedure after declamping the aorta. The first group in this study is constituted of 39 patients with declamped aorta DeVega's annuloplasty of the tricuspid valve with primary elective mitral valve replacement. Among these 39 patients there were 10 who had additional concomitant aortic valve replacement. This group was compared with the last 39 patients with arrested heart concomitant DeVega's annuloplasty with primary elective mitral valve replacement, including the last 10 patients with additional concomitant aortic valve replacement.

<u>Results:</u> The patients of group 1 had significantly shorter cardiopulmonary bypass time (106.93  $\pm$  12.6 minutes vs. 135.72  $\pm$  16.18 minutes, P <0.001 for patients with mitral valve replacement and 183.8  $\pm$  13.87 minutes vs. 228.4  $\pm$  26.65 minutes, P <0.001 for patients with double valve replacement) and total operative time (235.93  $\pm$  25.08 minutes vs. 266.62  $\pm$  62 minutes, P <0.001 for patients with mitral valve replacement and 312.5  $\pm$  19.8 minutes vs. 361.3  $\pm$  33.9 minutes, P= 0.001 for patients with double valve replacement). There were no significant differences between the two groups in the postoperative results including mortality (4 patients (10.26%) in each group), temporary pacemaker stimulation (14 (35.9%) in group 1 vs. 10 (25.64%) in group 2, P= 0.326) and permanent pacemaker implantation (3 patients (7.69%) in each group).

<u>Conclusions</u>: In concomitant tricuspid valve repair with mitral valve replacement, performing the DeVega's annuloplasty after declamping the aorta is safe and equally effective as performing the procedure under arrested heart. It has the advantages of significantly reducing the cross clamp time, cardiopulmonary bypass time and total operative time.

<u>Keywords</u>: DeVega's annuloplasty, Tricuspid valve, Beating heart, Tricuspid regurge, Tricuspid incompetence



t least 15.6 million people are estimated to be affected by rheumatic heart disease with a significant number of them requiring heart surgery in the next years [1]. Although all of the cardiac valves may be involved by the rheumatic process, the mitral valve is involved most prominently and in virtually all cases [2]. More than one third

of the patients with mitral stenosis have at least moderate tricuspid regurgitation [3]. Accordingly, concomitant tricuspid valve repair with mitral valve replacement is one of the most common open heart procedures performed in cardiac facilities in developing countries. Since the economic factors including the price of the tricuspid annuloplasty

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Codex : o3/04/1311

rings play a great role in these countries, DeVega's annuloplasty is still performed in the majority of cases of tricuspid repair.

Performing the tricuspid repair after releasing the aortic cross clamp has the clear advantage of reducing the myocardial ischemia. On the other hand, the advantages of performing the repair with the aorta clamped are the absence of blood flow through the coronary sinus and, theoretically, less pulmonary air embolisation. The clinical sequences of the advantages and disadvantages of both techniques have not been adequately studied and no specific indications for the preference of one technique over the other have been reported.

Although tricuspid valve repair using arrested heart vs. beating heart was studied in isolated tricuspid valve operations [4], to our knowledge, there are no studies comparing both techniques in concomitant tricuspid repair with mitral valve replacement, which is much more commonly performed than isolated tricuspid valve repair [5].

The objectives of this study is to analyse the results of performing the DeVega's annuloplasty tricuspid valve repair before and after releasing the aortic cross clamp in patients with rheumatic heart disease indicated for concomitant tricuspid repair with mitral valve replacement.

### **Patients and methods**

Concomitant DeVega's annuloplasty with mitral valve replacement was always performed under arrested heart at our institution. Since January 2012 two surgeons started to perform the procedure after declamping the aorta. From March 2012 till December 2013, this technique was used in 50 patients with concomitant DeVega's annuloplasty of the tricuspid valve with primary elective mitral valve replacement. To exclude the effect of learning curve, the first 10 patients were excluded from the study. These first ten patients had only one hospital mortality and no major complications. One more patient was excluded because he had concomitant coronary artery bypass. The remaining 39 patients constitute the first group of the study. Among these 39 patients there were 10 who had additional concomitant aortic valve replacement. The second group of patient is constituted of the last 39 patients with arrested heart concomitant DeVega's annuloplasty with primary elective mitral valve replacement, including the last 10 patients with additional concomitant aortic valve replacement. These patients were operated upon during the period from September 2010 till March 2012 by the same surgeons operating the first group.

All data were prospectively collected and retrospectively analysed. The study was approved by the ethical committee at our institution.

There were no significant differences between the two

groups regarding the demographic data and preoperative risk factors. (Table 1)

The indications for concomitant DeVega's annuloplasty were severe secondary tricuspid valve regurge or moderate secondary tricuspid valve regurge with dilated annulus (more than 40 mm). The decision to perform DeVega's annuloplasty, rather than tricuspid ring annuloplasty, was taken by the surgeon according to his own judgement.

All patients in both groups had rheumatic heart disease with severe mitral stenosis not suitable for open mitral commissurotomy. Additional mitral and aortic valves pathologies are shown in table 2.

The operations were performed through conventional median sternotomy, using standard techniques for cardiopulmonary bypass with mild systemic hypothermia. The left sided valves were replaced under cardiac arrest with antegrade cold crystalloid cardioplegia in all cases. All mitral valves were replaced through the trans-septal approach. The DeVega's annuloplasty was performed using a double row of 2-0 braided polyester suture. In group 1, the left heart side was de-aired and the aorta was declamped just before starting the DeVega's annuloplasty. In group 2, the DeVega's annuloplasty was performed and the right atrium was closed before releasing the aortic cross clamp.

Transesophageal echocardiography was performed shortly after weaning from cardiopulmonary bypass to assess the repair and to detect retained intracardiac air.

The statistical analysis was performed using version 5 of JMP Software (SAS Institute Inc.). The continuous variables are expressed as mean  $\pm$  SD and categorical variables were expressed as proportions. Continuous variables were compared using Student's *t* test. The categorical variables were compared using the  $X^2$  test or Fisher's exact test.

## Results

The patients of group 1 had significantly shorter cross clamp time (64.37  $\pm$  7.25 minutes vs. 84.38  $\pm$  11.02 minutes, P <0.001 for patients with mitral valve replacement and 120  $\pm$  7.83 minutes vs. 159.9  $\pm$  16 minutes, P <0.001 for patients with double valve replacement), cardiopulmonary bypass time (106.93  $\pm$  12.6 minutes vs. 135.72  $\pm$  16.18 minutes, P <0.001 for patients with mitral valve replacement and 183.8  $\pm$  13.87 minutes vs. 228.4  $\pm$  26.65 minutes, P <0.001 for patients with double valve replacement) and total operative time (235.93  $\pm$ 25.08 minutes vs. 266.62  $\pm$  62 minutes, P <0.001 for patients with mitral valve replacement and 312.5  $\pm$  19.8 minutes vs. 361.3  $\pm$  33.9 minutes, P = 0.001 for patients with double valve replacement). (Table 3, Figure 1)

The pulmonary artery could be clearly visualised by transesophageal echocardiography in 33 patients in group 1 (84.6%) and 31 patients (79.5%) in group 2. Retained air was detected in the pulmonary artery in all patients of both groups, whenever the pulmonary artery was clearly visualised. The air was detected in both bubbles and pooled forms in these patients. Unfortunately, it was not possible to quantify and compare the amount of retained air in both groups in a reliable way.

(10.26%) in each group), temporary pacemaker stimulation (14 (35.9%) in group 1 vs. 10 (25.64%) in group 2, P= 0.326) and permanent pacemaker implantation (3 patients (7.69%) in each group). (Table 4) All mortalities in both groups resulted as sequence of low cardiac output. Two patients in group 1 had transient hemiparesis. One patient in group 2 had permanent hemiplegia and another one had transient hemiparesis. CT scan of the brain confirmed the presence of ischemic infarction in the patient with hemiplegia and it was free in the other three patients.

There were no significant differences between the two groups in the postoperative results including mortality (4 patients

	Beating heart	Arrested heart	Р
Age (years)	$33.92 \pm 9.75$	$34.64 \pm 9.38$	0.741
Female	19 (48.72%)	15 (38.46%)	0.361
BMI	$27.03 \pm 4.7$	$26.38 \pm 4.23$	0.528
EuroSCORE (%)	$9.15 \pm 4.8$	$10.13 \pm 4.83$	0.374
EF (%)	53.38 ± 7.06	$52.49 \pm 5.6$	0.898
PP	60 ±16.99	$56.95 \pm 19.58$	0.465
TR	$3.54 \pm 0.51$	$3.46 \pm 0.51$	0.503
T Ann (mm)	$40.33 \pm 5.14$	$41.77 \pm 5.04$	0.217
AF	21 (53.85%)	23 (58.97%)	0.648
NYHA	$2.51 \pm 0.51$	$2.54 \pm 0.51$	0.823

EF=Ejection Fraction

BMI=Body Mass Index PP=systolic Pulmonary Pressure

T Ann=Tricuspid Annulus diameter

TR=Tricuspid Regurge severity

AF=Atrial Fibrillation

Table 1.	Demographic	and preoperative a	lata
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	Beating heart	Arrested	heart P
MS	10 (25.64%)	9 (23.08	8%)
MS+MR	19 (48.72%)	20 (51.2	8%)
MS+AS	3 (7.69%)	0 (0%	(o)
MS+MR+AS	2 (5.13%)	2 (5.13	
MS+AR	1 (2.56%)	0 (0%	(b) 0.40
MS+MR+AR	1 (2.56%)	2 (5.13	%)
MS+AS+AR	1 (2.56%)	3 (7.69	%)
MS+MR+AS+AR	2 (5.13%)	3 (7.69	%)
MS=Mitral Stenosis	MR=Mitral Regurge	AS=Aortic Stenosis	AR=Aortic Regurge

Table 2. Mitral and Aortic valves' pathologies

	Beating heart	Arrested heart	Р	Beating heart	Arrested heart	Р
	MVR	MVR		DVR	DVR	
CC mean	$64.37 \pm 7.25$	84.38 ± 11.02	< 0.001	$120 \pm 7.83$	$159.9 \pm 16$	< 0.001
CC range	49-74	63-105		110-134	137-177	
CC 25% p	59	75.5		115.75	140.5	
CC median	65	84		118.5	164.5	
CC 75% p	70.5	92		123.25	176.25	
CPB mean	$106.93 \pm 12.6$	$135.72 \pm 16.18$	< 0.001	$183.8 \pm 13.87$	$228.4 \pm 26.65$	< 0.001
CPB range	78-134	102-163		167-203	187-263	
CPB 25% p	98	122.5		171.25	198.75	
CPB median	106	139		182.5	240	
CPB 75% p	116.5	147		197	202.7	
OP mean	$235.93 \pm 25.08$	$266.62\pm62$	< 0.001	$312.5 \pm 19.8$	$361.3 \pm 33.9$	0.0014
OP range	184-292	223-307		286-356	303-402	
OP 25% p	216.5	246.5		300.25	336	
OP median	234	270		308.5	371	
OP 75% p	254.5	286		321	388.75	

CC=Cross Clamp time (minutes) MVR=Mitral Valve Replacment

CPB=Cardiopulmonary Bypass time (minutes) DVR=Double Valve Replacement

p = percentile

#### Table 3. Cross clamp, Cardiopulmonary bypass and total operative times (minutes)

	Beating heart	Arrested heart	Р
Mortality	4 (10.26%)	4 (10.26%)	1.000
Temporary PM	14 (35.9%)	10 (25.64%)	0.326
Permanent PM	3 (7.69%)	3 (7.69%)	1.000
Ventilation (hours)	$10.77 \pm 12.76$	$14.46 \pm 28.83$	0.467
ICU stay (days)	$2.46 \pm 1.25$	$2.79 \pm 2$	0.382
Hospital stay (days)	$9.26 \pm 2.53$	$9.41 \pm 2.91$	0.804
Neurologic deficit	2 (5.13%)	2 (5.13%)	1.000
Dialysis	1 (2.56%)	2 (5.13%)	0.552
Bleeding (ml)	$738 \pm 389$	$798 \pm 410$	0.506
Re-exploration	2 (5.13%)	1 (2.56%)	0.552
Low CO	8 (20.51%)	5 (12.82%)	0.36
TR	$1.15 \pm 0.74$	$1.15 \pm 0.81$	1.000
T Ann (mm)	$29.9 \pm 4.19$	$30.15 \pm 4$	0.783
PP	47.95 ± 17.55	$45.67 \pm 19.22$	0.586
Superficial infection	3 (7.69%)	4 (10.26%)	0.691

PM=Pacemaker TR=Tricuspid Regurge T Ann=Tricuspid Annulus

PP=systolic Pulmonary Pressure

CO=Cardiac Output

Table 4: Postoperative data

# Discussion

Clinical experience has demonstrated that up to 20% of patients undergoing mitral valve replacement receive a tricuspid annuloplasty [6]. The benefits and indications of concomitant tricuspid valve repair with mitral valve replacements in cases of significant tricuspid regurge are well established [7-12]. However, concomitant tricuspid and mitral valve operations are associated with increased mortality as well as longer postoperative length of stay compared with isolated mitral valve operations. These patients also have significantly higher incidence of postoperative prolonged ventilation, renal failure and new-onset hemodialysis [13]. On the other hand, mitral stenosis is a significant predictor for mortality in tricuspid valve operations [10]. Therefore, every effort should be done in these operations trying to minimize the operative risks. Performing the tricuspid repair after releasing the aortic cross clamp is one of the steps that can be taken trying to achieve this goal.

Despite modern techniques of cardio protection, aortic cross-clamp time is an independent predictor of mortality in patients with preserved preoperative contractile function [14]. Prolonged cardiopulmonary bypass time is a known risk factor for postoperative blood loss and transfusion of blood products [15, 16]. The total operative is an independent risk factor for both superficial and deep wound infections [17]. Our study demonstrates significant reduction in cross clamp time, cardiopulmonary bypass time and total operative time. However, these reductions were not associated with significant improvement in the outcome. This can be explained by the relatively small number of patients included in the study. Pfannmueller and coworkers [4] conducted a study comparing arrested-heart vs. beating-heart techniques in isolated tricuspid valve operations. Similar to our study, the total operative time was significantly shorter in the beating heart group. Interestingly, although their beating-heart patients needed no post-ischemia reperfusion, the cardiopulmonary bypass time was a little longer in the beating heart group. This difference was not statistically significant and the authors stated that this is an implication that beating heart technique is not more demanding than the arrested heart technique. Nevertheless, their two groups of patients were very heterogeneous and difficult to compare.

Trying to keep our two groups of patients as homogeneous as possible, we included only patients with secondary tricuspid valve regurgitation treated by DeVega's annuloplasty, the procedure mostly performed for the tricuspid valve at our institution. However, despite the absence of level I, there is growing evidence that ring annuloplasty is associated with significantly better results that DeVega's annuloplasty in terms of long-term survival, event free survival, reoperation and recurrence of tricuspid regurge [8, 18, 19]. On the other hand, DeVega's annuloplasty is easy, fast and cost effective. Many studies reported its very good results, even in comparison with ring annuloplasty [20-22].

Our intraoperative and postoperative echocardiographic results demonstrate the feasibility of performing the DeVega's annuloplasty after declamping the aorta with achievement of equally adequate repair in comparison with performing the repair with the heart arrested. In our experience, performing the repair after releasing the aortic cross clamp is not only technically feasible, but also we have the impression that assessment of the repair with warm saline is easier in comparison with the arrested heart technique. We also believe that the same feasibility is applicable to ring annuloplasty and tricuspid valve replacement. We currently perform both procedures after declamping the aorta with good results and without technical difficulties. However, Pfannmueller and coworkers [4] found higher incidence of dehiscence of a Carpentier-Edwards Classic Annuloplasty ring in the septal part of the annulus in the beating heart group in comparison with the arrested heart group, although this difference was not statistically significant and there was a limited number of patients with rigid rings. The possible explanation mentioned by the authors was the increase in shearing forces at the septal portion of the annulus during beating heart operations. This argument can be supported by addressing the dynamics of the native tricuspid annulus [23].

Postoperative atrioventricular block is an important issue in tricuspid valve surgery. Performing the procedure with perfused heart has the theoretical advantage of the immediate recognition and rectification of atriventricular node injury by a suture. This advantage is more relevant in isolated tricuspid valve repair, when the whole operation is performed while the heart is beating. Nevertheless, no significant difference in postoperative heart block was noted between beating heart and arrested heart techniques of isolated tricuspid valve operations [4]. In case of concomitant tricuspid repair with mitral valve replacement, we proceed with the repair just after releasing the aortic cross clamp without waiting for the heart to regain its rhythm. In our study we found no significant differences in postoperative temporary pacemaker stimulation or permanent pacemaker implantation.

One of the concerns about performing tricuspid valve operations with the aorta declamped is the pulmonary air embolism. Retained air in the pulmonary artery can be detected in all cases when the right atrium is opened, even with cardioplegic cardiac arrest [24]. The air can even pass the pulmonary circulation to reach the left side of the heart [25]. To our knowledge, there are no studies comparing pulmonary air embolisms in perfused heart vs. beating heart tricuspid valve operations. In our study, we could detect retained air in the pulmonary artery in all cases, whenever the pulmonary artery was clearly visualised. Unfortunately, we were not able to quantify the amount of air in order to make a comparison between the two groups. However, the blood gas analysis didn't show any sign of significant pulmonary embolism in any of our patients. In addition, we couldn't detect any possible consequences of increased transpulmonary passage of air emboli in the perfused heart group. Both groups were equal in the incidence of postoperative neurological complications.

We acknowledge that our study has several important limitations. In addition to the small number of patients, an important limitation of our study is that the pulmonary vascular resistance was not measured. This measurement could have added valuable information to the study. The main limitation of the study is its retrospective nature. Although retrospective studies can be associated with significant bias, the majority of evidence for tricuspid valve surgery is based on such studies because of small number of patients. Trying to avoid any selection bias, we included consecutive non-selected patients in both groups after exclusion of the first patients performed with the heart perfused to avoid the effect of the learning curve. As a result, we had two homogenous groups with very similar demographic data, cardiac pathologies and preoperative risk factors.

In conclusion, in concomitant tricuspid valve repair with mitral valve replacement, performing the DeVega's annuloplasty after declamping the aorta is safe and equally effective as performing the procedure under arrested heart. It has the advantages of significantly reducing the cross clamp time, cardiopulmonary bypass time and total operative time.

Conflict of interest: None declared

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# Short Term Evaluation of Clinical Outcomes of Ischaemic Left Ventricular Dysfunction Patients Undergoing On Pump CABG

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<u>Background</u>: Surgical revascularization in patients with left ventricular dysfunction has historically carried a high perioperative mortality and morbidity; however, with advances in surgical technique and myocardial protection the safety of CABG in select patients with ischemic cardiomyopathy has been demonstrated.

<u>Objectives</u>: To investigate the short term clinical outcome of the study group, who have LV dysfunction, after surgical revascularization using cardiopulmonary bypass technique (on-pump CABG).

<u>Patient and methods</u>: This study includes 90 patients with ischaemic heart disease and prepared for elective coronary artery bypass grafting. First group; 60 patients with a left ventricular function <0.40. Second group; 30 patients with a left ventricular function >0.50, all patients were subjected to conventional CABG. All patients' data were collected at the preoperative, operative, postoperative (Hospital stay) and 12months postoperative periods. Echocardiography was performed preoperatively and postoperatively after 12 months for all patients and dobutamine stress echocardiography for the LV dysfunction cohort preoperatively.

<u>Results</u>: There was a significant increase in ITU stay in LVD group (2.27±2.299 days versus 1.33±0.479 days in GEF group). There was non significant difference in mean of postoperative hospital stay, when both groups were compared. There was a significant improvement in NYHA class in both groups. There was a significant improvement in EF in both groups.

<u>Conclusion</u>: Patients with coronary artery disease and depressed ejection fraction benefit from coronary artery bypass grafting, and specific preoperative factors may help determine optimal treatment.

> atients presenting with left ventricular (LV) dysfunction undergoing primary isolated coronary artery surgery are at increased risk of perioperative morbidity and mortality. The present study investigates early outcomes in a consecutive series of patients with LV dysfunction undergoing coronary surgery<sup>(1)</sup>.

The main advantage of the on-pump technique is the ability it provides to perform complete revascularization, with low morbidity and mortality even in impaired LV function<sup>(2)</sup>.

Advances in anesthetic techniques and the surgical management of patients with left ventricular dysfunction have created an environment in which the majority of the coronary artery bypass patients undergo these procedures yearly with a low risk-adjusted operative mortality. Additional adjuncts utilized in these procedures such as transesophageal echocardiography, newer inotropic agents, and hemostatic agents have created a platform for continued growth and development of innovative techniques<sup>(3)</sup>.

Functional benefit of the left ventricle, however, appears to be time-limited, despite remarkable improvement in patient functional capacity<sup>(4)</sup>.

In patients with LV dysfunction, improvement of exercise capacity correlates with the extent of viable myocardium. Quality of life improves in most patients undergoing revascularization<sup>(5)</sup>.

Cardiovascular

In other studies, In-hospital mortality and morbidity in patients presenting with severe LV dysfunction is low with comparable results with both on- and off-pump coronary artery surgery. Midterm clinical outcome is encouraging and seems to justify surgical revascularization for this high-risk group of patients<sup>(6)</sup>.

Comparing the results of revascularization, in this particular group of patients, by on-pump CABG with PTCA reveals comparable results. For example, In selected high risk patients with severe LV dysfunction revascularization with drug eluting stent implantation offers comparable long term mortality and major adverse cardiac events rate to CABG patients<sup>(7)</sup>.

## AIM OF THE WORK

To investigate the short term clinical outcome of the study group, who have the LV dysfunction, after surgical revascularization using cardiopulmonary bypass technique (on-pump CABG).

# PATIENTS AND METHODS

This retrospective study includes 90 patients with ischaemic heart disease and prepared for elective coronary artery bypass grafting, the patients were operated in the period from April 2010 to April 2011 and patients were classified into two groups:

*First group:* 60 patients with a left ventricular function <0.40.

Second group: 30 patients with a left ventricular function >0.5.

## **Inclusion criteria**

- 1. Both sex and any age
- 2. Chronic stable angina
- 3. Single or multivessel disease
- 4. Patients with Left ventricular dysfunction EF<40%
- 5. Total revascularization for all patients.

### **Exclusion criteria**

- 1. Ischemic mitral regurgitation or any other valvular heart disease
- 2. Significant carotid artery disease
- 3. Emergency revascularization
- 4. Associated severe comorbidities

#### All patients had been studied as follow:

For each patient the following was done:

- 1. Preoperative evaluation:
- History and full clinical examination with assessment of NYHA and CCS scores.

 Investigations: Electrocardiogram, chest x ray, echocardiography, dobutamine echocardiography, coronary angiography, radio active isotope scanning if needed and routine laboratory investigations.

#### 2. Operative data:

- 1. Recording of ischemic time, bypass time and mode of myocardial protection.
- 2. The need for pharmacological support (inotropes) and/or mechanical support (IABP).

#### 3. Immediate post operative data:

Recording of ventilation time, ICU stay, and hospital stay including morbidity and mortality if any.

#### 4. Post operative follow up:

Reassessment of NYHA and CCS scores and echocardiography one year post operative.

#### **Statistical analysis:**

Statistical analyses were performed using the SPSS (Software Package for Science Statistics), version 16.0, computer program. A probability (p) value less than 0.05 was considered significant. Frequency and % values of categoric variables, and mean and standard deviation (SD) values of continuous variables were determined. Patient characteristics, operative data, and hospital outcomes were compared univariately using t-tests for continuous variables and the Chi-square or Fisher exact test for categoric variables.

## RESULTS

Tables (1) show demographic data of the study groups. There was non significant difference in age and sex when both groups were compared together. Table (2) shows angina and dyspnea status of the study groups, with non significant difference between both groups regarding comparison of CCS class and NYHA class.

As far as medical risk factors of the study groups were concerned, there was non significant difference in the incidence of diabetis, hypercholesterolemia, hypertension, hypothyrodism, respiratory disease, history of smoking, and history of previous cerebrovascular accident (CVA) when the two groups were compared together.

Table (3) shows coronary risk factors of the study groups. There was non significant difference in the incidence of preoperative MI, the number of attacks and history of previous percutaneous coronary intervention (PCI), when both groups were compared together. Table (4) shows preoperative extent of coronary disease of the study groups. There was non significant difference in the incidence of double vessel disease, triple vessel disease, Quadruple vessel disease and left main disease, when both groups were compared together.

Table (5) shows operative data of the study groups. There was a significant increase in mean of cardiopulmonary bypass time (min.) in LVD group (88.00±20.59 min. in LVD group versus 77.20±22.722 min. in GEF group). Also, there was a significant increase in aortic cross clamp time in LVD group (58.57±19.46 min. in LVD group versus 49.07±19.783 min. in GEF group). There was non significant difference in number of distal coronary anastomosis. There was non significant difference in the LIMA – LAD anastomosis site between both groups. Intra-aortic balloon pump (IABP) was used in 13.3% of LVD group and 3.3% of GEF group with non significant difference. All patients were subjected to antegrade intermittent warm blooded cardioplegia.

Table (6) shows postoperative morbidity of the study groups. The total incidence of postoperative complications was (41.7%) in LVD group and 30% in GEF group, with non significant difference. There were non significant differences in the incidences of pulmonary, neurological, renal complications, arrhythmia, sternal resuturing, reopening for bleeding and duration of ventilation between both groups. There was a significant higher incidence of patients with low cardiac output in need of inotropes in LVD group (40.0% versus 16.7% in GEF group). Table (7) compares preoperative and postoperative changes in left ventricular ejection fraction (EF) in both groups as well as end systolic and diastolic dimensions (ESD and EDD). There was a significant improvement in EF

in both groups and a significant decrease of ESD in LVD group.

Table (8) shows duration of ITU and hospital stay of the study groups. There was a significant increase in stay in ITU in LVD group (2.27 $\pm$ 2.299 days versus 1.33 $\pm$ 0.479 days in GEF group). There was non significant difference in incidence of mean of post-operative hospital stay, when both groups were compared. Table (9) shows univariate analysis of hospital mortality in 60 patients with LVD. All died patients had age  $\geq$  70 years versus (46.3%) of alive patients, with a significant difference. There was non significant differences as regard univariate comparison of other preoperative and operative risk factors.

Multivariate regression was done to estimate the independent predictors of hospital mortality in 60 patients with LVD. Age  $\geq$  70 years was a significant independent predictor of hospital mortality in LVD group.

One year survival of discharged patients was comparable in patients with low EF as compared to patients with EF greater than 50%. One –year survival rate was 78.3% for low EF patients versus 96.7% for patients with EF greater than 50%. Table (10) demonstrates a comparison between hospital mortality and one year mortality in LVD and GEF groups.

	LVD	GEF	Total	$\mathbf{X}^2$	P-value
Gender					
Female	No 13	3	16		
	% 21.7%	10%	17.8%		
Male	No 47	27	74	1.862	0.172
	% 78.3%	90.0%	82.2%		
Total	No 60	30	90		
	% 100.0%	100.0%	100.0%		
Age (mean±SD)	68.42±8.583	66.7±9.433		0.865#	0.389

\* : significant difference

 $# \cdot T$ -test

Variable	LVD (N=60)	GEF (N=30)	Z	P-value
CCS class	2.17±1.237	1.83±1.289	-1.33	0.184
NYHA class	1.73±0.821	1.43±0.728	-1.803	0.071

\* : significant difference

Table 2. Angina and dyspnea status of the study groups.

Preoperative MI	LVD (n=60)	GEF (n=30)	P-value
0	33	17	
1	20	11	
2	5	2	0.887
3	1	0	
4	1	0	
Preoperative stenting	ıg		
No	53	25	0.511
Yes	7	5	

Variable	LVD (N=60)	GEF (N=30)	P-value
Single vessel disease	2 (3.3%)	1 (3.3%)	1.00
Double vessel disease	11 (18.3%)	6 (20%)	0.849
Triple vessel disease	45 (75.0%)	23 (76.7%)	0.862
Quadruple vessel disease	2 (3.3%)	0 (0.0%)	0.312
Left main stenosis	24 (40.0%)	13 (43.3%)	0.762

\* : significant difference

\* : significant difference

Table 3. Coronary risk factors of the study groups.

Table 4: Preoperative extent of coronary disease of the studygroups.

Variable	LVD (N=60)	GEF (N=30)	P-value
Cardiopulmonary bypass time (min.)	88.00±20.59	77.20±22.722	0.026*
Aortic cross-clamp time (min.)	58.57±19.46	49.07±19.783	0.033*
No. of distal coronary anastomosis:			
1 graft	2 (3.3%)	1 (3.3%)	
2 grafts	16 (26.7%)	12 (40.0%)	0.442
3 grafts	32 (53.3%)	15 (50.0%)	0.443
4 grafts	10 (16.7%)	2 (6.7%)	
LIMA-LAD			
No	7 (11.9%)	3 (10.0%)	0.792
Yes	52 (88.1%)	27 (90.0%)	
Use of IABP	8 (13.3%)	1 (3.3%)	0.136

\* : significant difference

# Table 5. Operative data of the study groups.

Variable	LVD (N=60)	GEF (N=30)	P-value
Postoperative complications	25 (41.7%)	9 (30%)	0.282
Low cardiac output (need of Inotropes)	24 (40.0%)	5(16.7%)	0.026*
AF	14 (23.3%)	7 (23.3%)	1.00
Reoperation (for bleeding)	3 (5.0%)	1 (3.3%)	0.718
Sternal resuturing	2 (3.3%)	1 (3.3%)	1.00
Pulmonary complications	7(11.7%)	3 (10%)	0.813
Neurological complications	3 (5.0%)	0 (0.0%)	0.213
Renal impairment:			
Not requiring dialysis	17 (28.3%)	9 (30.0%)	0.869
Requiring dialysis	2 (3.3%)	0(0.0%)	0.312
Duration of ventilation	10.08±8.716	10.3±8.691	0.912
Postoperative EF	49.84±7.401	61.45±5.248	0.000*
Postoperative NYHA	1.16±0.621	1.17±0.759	0.925
Postoperative need for IABP	8 (13.3%)	1 (3.3%)	0.136

\*: significant difference.

Table 6. Postoperative morbidity of the study groups.

Variable	EF %	P-val	ue
	Preoperative	Postoperative	
LVD (N=60)	33.4±4.709	43.145.153±	0.001*
GEF (N=30)	58.62±6.95	61.45±5.25	0.001*
ESD			
LVD (N=60)	$3.588 \pm .6203$	3.34±.614	0.002*
GEF (N=30)	3.33±0.63	3.07±0.50	0.066
EDD			
LVD (N=60)	4.786±0.5977	4.666±0.6934	0.097
GEF (N=30)	4.600±0.5726	4.438±0.4739	0.149

ESD: End systolic dimension; EDD: End diastolic dimension; \*: significant difference.

 Table 7: Comparing preoperative and postoperative changes in left ventricular ejection fraction (EF), end systolic dimension (ESD) and end diastolic dimension (EDD) in both groups.

Variable	LVD (N=60)	GEF (N=30)	P-value
Stay in ITU (days)	2.27±2.299	1.33±0.479	0.008*
Total hospital stay (days)	8.83±6.465	8.27±5.583	0.683
*: significant difference.			

Table 8: Duration of ITU and hospital stay of the study groups.

Variable		Death (N=6)	Alive (N=54)	P-value
Age (years)	≥ 70	6(100.0%)	25(46.3%)	0.013*
	< 70	0(0.0%)	29(53.7%)	
Sex	Male	41(75.9%)	6(100.0%)	0.174
	Female	13(24.1%)	0(0.0%)	
CCS class	I-II	4(66.7%)	35(64.8%)	0.928
	III-IV	2(33.3%)	19(35.2%)	
NYHA class	I-II	5(83.3%)	43(79.6%)	0.830
	III-IV	1(16.7%)	11(20.4%)	
Previous MI	Yes	2(33.3%)	25(46.3%)	0.545
	No	4(66.7%)	29(53.7%)	
Diabetes mellitus	Yes	2(33.3%)	9(16.7%)	0.317
	No	4(66.7%)	45(83.3%)	
Hypercholesterolaemia	Yes	4(66.7%)	43(79.6%)	0.465
	No	2(33.3%)	11(20.4%)	
Hypertension	Yes	6(100.0%)	48(88.9%)	0.389
	No	0(0.0%)	6(11.1%)	
Cardiopulmonary bypass time (min.)	> 120	0(0.0%)	5(9.3%)	0.436
	≤ 120	6(100.0%)	49(90.7%)	
Aortic cross-clamp time (min.)	> 60	2(33.3%)	21(38.9%)	0.791

\*: significant difference.

Table 9: Univariate analysis of hospital (30 Days) mortality in 60 patients with LVD.

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Hosp mortality		LVD	GEF
Alive	No.	54	30
	%	90.00%	100.00%
Died	No.	6	0
	%	10.00%	0.00%
One year mortalit	у		
Alive	No.	47	29
	%	78.3%	96.70%
Died	No.	13	1
	%	21.7%	3.30%

Table 10: Comparison between hospital mortality and one year mortality in LVD and GEF groups

## DISCUSSION

It has been shown that CABG provides a survival benefit over medical therapy alone in patients with LV dysfunction and coronary artery disease<sup>(8)</sup>.

CABG offers the only feasible chance of improved survival for most patients with severe LV dysfunction <sup>(9)</sup>.

In our study, we did not investigate severe LV dysfunction per se as most of previous studies <sup>(10-12)</sup> who used the EF of less than or equal to 35% as a cut point to define low EF. In contrary, we investigated poor LV function as a more global term that includes patients with different grades of LVD (mild, moderate, and severe).

Regarding demographic data of the study groups. There was non significant difference in age and sex when both groups were compared together; similarly, the preoperative risk factors in both groups. These findings are due to the choice of age and sex matched groups, with exclusion of patients with major preoperative co-morbidity to avoid the influence of these factors on postoperative outcome and ascertain that the outcome will be related mainly to the disease condition of the patient.

Similar findings regarding the non significant differences in patient characteristics and preoperative risk factors were reported by Trachiotis et al. (1998), Darwazah et al. (2006) and Hillis et al. (2006)<sup>(10-13)</sup>.

Regarding the operative data of the study groups, there was a significant increase in mean of cardiopulmonary bypass time in LVD group (88.00±20.59min. in LVD group versus 77.20±22.722 min. in GEF group). Also, there was a significant increase in aortic cross clamp time in LVD group (58.57±19.46 min. in LVD group versus 49.07±19.783 min. in GEF group).

Similarly, Wu et al. (2006) reported significantly longer cardiopulmonary bypass time (147 $\pm$ 44 minutes vs 137 $\pm$ 40 minutes, p < 0.001) in patients with LVEF < 35%<sup>(14)</sup>.

However, Trachiotis et al. (1998), Darwazah et al. (2006), Hillis et al. (2006) found non significant differences in cardiopulmonary bypass time and cross clamp time between both groups<sup>(10,11,13)</sup>.

Similar to our finding of non significant difference between LVD and GEF groups regarding perioperative MI, Brat et al. (2004) didn't find any significant difference in the incidence of perioperative MI between groups<sup>(15)</sup>.

There were non significant differences regarding incidence of postoperative complications between LVD and GEF patients in our study, however, Wu et al. (2006) reported that patients with LVEF < 35% had significantly higher postoperative complications (23.3% vs 16.1%, p < 0.01)<sup>(14)</sup>. These findings obtained by those authors might be attributed to the significantly higher incidence of preoperative co-morbidities within LVD in their study.

In the present study, low cardiac output was the most common postoperative complications. There was a significant higher incidence of patients with low cardiac output in need to inotropes in LVD group 40.0% versus 16.7% in GEF group).

Similarly, in a recent study by Chong et al. (2007), up to 96% of patients with severe LVD had inotropic support postoperatively<sup>(16)</sup>.

In the present study, the incidence of postoperative arrhythmia was 23.3% in both LVD and GEF group with non significant difference.

Similarly, the recent study by Youn et al. (2007) reported postoperative arrhythmia in 22.6% of patients with LVD underwent on-pump coronary grafting. Also, Bouchart et al. (2001) reported postoperative arrhythmia in 28% of patients with LVD.<sup>(12,17)</sup>.

In the present study, postoperative renal impairment occurred in 19 patients in LVD group; 17 patients (28.3%) with renal impairment not requiring dialysis and 2 patients (3.3%) with severe impairment requiring dialysis. There was non significant difference in incidences of renal impairment in both groups.

The recent data obtained by Hillis et al. (2006) suggest that, among patients with significant LV systolic dysfunction undergoing CABG, renal function, measured using either serum creatinine or eGFR, is the single most powerful predictor of medium-term outcome<sup>(18)</sup>.

Regarding the comparison of preoperative and postoperative changes in left ventricular ejection fraction (EF) in both groups, there was a significant increase in EF in both groups. In LVD group, EF raised from  $33.4\pm4.709$  to  $43.14\pm5.153$ . In GEF group, EF raised from  $58.62\pm6.95$  to  $61.45\pm5.25$ .

Hernandez-Pampaloni et al. (2003) reported that LV ejection fraction increased significantly from  $30\pm10\%$  to  $42\pm13\%$ , in 25 patients with LVD<sup>(19)</sup>.

In the present study, hospital mortality was defined as death after the procedure before patient's discharge regardless of the duration of hospitalization. Patients who died after discharge from hospital but within 30 days after the procedure were also considered as hospital deaths<sup>(20)</sup>.

Mortality rate in patients with LVD was 10%. This rate is in agreement with the mortality and morbidity rates (2.7% to 33%) reported in multiple series <sup>(13,17,20)</sup>.

The improved mortality rate observed in our study is most likely related to multiple factors, including patient selection and perioperative management. Patient selection is, undoubtedly, a critical factor. Other key factors accounting for the low operative mortality observed in our series include liberal use of IABP, use of heparinbonded cardiopulmonary bypass circuits with reduced systemic anticoagulation, and insisting on complete revascularization.

In our study, 1 year mortality was 21.6% for LVD group compared to 3.3% for GEF group with multivariate logistic regression analysis showed that previous cardiac operation, peripheral vascular disease, chronic obstructive pulmonary disease, and congestive heart failure, were independent predictors of mortality during follow-up.

Overall, our findings and review of the literature suggest that patients with coronary artery disease and severely depressed ejection fraction benefit from coronary artery bypass grafting, and specific preoperative factors may help determine optimal treatment.

# CONCLUSION

In conclusion, our findings indicate that, despite LV dysfunction, the presence of HM confers low postoperative mortality and potential LV functional benefits to patients submitted to CABG. The advantage of CABG to perfuse functionally impaired myocardium in selected patients is obvious. Several preoperative factors, however, may account for transient LV recovery of function with subsequent determination of optimal treatment.

# **STUDY LIMITATIONS**

This series represents a retrospective non-randomized study. Patients were selected exclusively for CABG procedure and according to the presence of adequate amount of HM. Therefore, they were not randomly assigned to different type of therapeutic management.

Changes in operative strategies along the study course also occurred and, thus, may have influenced postoperative results and related data interpretation.

Postoperative assessment was not complete as regards to quality of coronary revascularization and graft patency since none of these patients ware subjected to recatheterization along the follow up which may affect the interpretation of the postoperative outcome.

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#### Cardiovascular

# **Effect of Patient Prosthesis Mismatch on Left** Ventriclar Function and Regression After Aortic **Valve Replacement For Aortic Stenosis**

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left ventricular (LV) hypertrophy and changes in the left ventricle function. The overall goal of aortic valve replacement (AVR) is to alleviate the pressure and volume overload on the left ventricle allowing myocardial remodeling and regression of left ventricular mass. The left ventricular geometrical shape also influences the outcome of AVR.

Introduction: Aortic valve disease is associated with eccentric or concentric

Patient and methods: 69 patients underwent aortic valve replacement for aortic stenosis at king Abdul-Aziz university hospital between June 2008- and May 2012, The aim of this study is to evaluate the left ventricular function and mass regression after aortic valve replacement, and effect of patient-prosthesis mismatch (PPM) on it.

Results: we found nine (13%) patients have post operative sever PPM, and sixteen (23.2%) patient have moderate PPM . In patients with moderate and severe mismatch ,effective orifice index area (0.85-0.65cm<sup>2</sup>/m<sup>2</sup>) there is mild improvement in symptoms of heart failure from 52% preoperatively to 36% postoperatively, also we observed significant improvement of EF% over first year post operative in patient without mismatch with p value 0.002; also we observed left ventricular mass regression with significant degree in those patients.

Conclusion: The effect of PPM on outcomes differs markedly depending on its severity as well as on the patient's preoperative status. Also the presence of PPM limits the LV regression and reduces EF % improvement. There is no effect of PPM on early survival especially in patient with good LV functions.

#### KEYWORDS: Mismatch, aortic stenosis, regression

Cardiovascular

ortic valve replacement (AVR) is now the second most commonly

performed cardiac operation and with an increasingly elderly population, the number of such procedures will inevitably continue to grow [1]. Aortic valve disease is associated with eccentric or concentric left ventricular (LV) hypertrophy and changes in the left

ventricle function [2]. The overall goal of AVR is to alleviate the pressure and volume overload on the left ventricle allowing myocardial remodeling and regression of left ventricular mass. The left ventricular geometrical shape also influences the outcome of AVR [3].

Another important objective of aortic valve replacement is to minimize postoperative gradients to optimize the normalization of left ventricular mass and function, and it has been well demonstrated that patient-prosthesis mismatch is, by far, the most frequent cause of high postoperative gradients in normally functioning prostheses [4]. Recent studies also suggest that mismatch could theoretically be predicted at the time of operation, but this remains to be determined [5].

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The concept of patient-prosthesis mismatch (PPM) was originally introduced by Rahimtoola in 1978, and defined " to be present when the effective prosthetic valve area, after insertion into the patient, is less than that of a normal valve." [6] In the last decade, however, as Pibarot and colleagues subclassified PPM more precisely according to the effective orifice index area (EOIA) of a prosthetic valve as mild >  $0.85 \text{ cm}^2$ /  $m^2$ , moderate (0.65–0.85 cm<sup>2</sup>/m<sup>2</sup>), or severe less than 0.65 cm<sup>2</sup>/m<sup>2</sup> [7]. Most patients undergoing prosthetic AVR will technically have some degree of PPM, but this is rarely severe and patients at the highest risk of significant PPM are those who are already at the highest risk from surgery. Although it is possible that severe PPM may result in a slight increase in operative mortality, and especially in the setting of pre-existing impaired ventricular function, there is general agreement that PPM, even when severe, does not adversely affect long term survival. Use of newer generation aortic prosthesis with superior hemodynamics may avoid the need for enlargement of the aortic root/annulus where significant PPM is likely [5].

## PATIENT AND METHODS

This study includes 69 patients underwent aortic valve replacement at king Abdul-Aziz university hospital,KSA between June 2008- and May 2012, all patients underwent isolated aortic valve replacement for aortic stenosis included mechanical and tissue valve, patient with aortic valve replacement with other cardiac operation (e.g. coronary artery bypass graft), were excluded from this study. In all patients a median sternotomy was performed. Standard moderate hypothermic cardio-pulmonary bypass was performed with a membrane oxygenator and by ascending aorta and bicaval cannulation. Aortic cross-clamp and antegrade intermittent cold crystalloid cardioplegic solution infusion was done with topical hypothermia. Aortic valve replacement with mechanical prosthesis done for fifty five patients and for fourteen patients tissue valve was used, seven patients had aortic root enlargement. The aim of this study is to evaluate the left ventricular function and mass regression after aortic valve replacement, and effect of patient-prosthesis mismatch on it. All data collected on personal computer, LV mass was calculated on line through ECHO web site [8], SPSS v16 was used for statistical analysis.

# RESULTS

Sixty nine patients were reviewed in our study, mean age is 47.9 year, range from 13-79 years, fifty three (76.8%) of patient were male, sixteen (23.2%) patient were female. The main presenting symptom was that of heart failure ( dyspnea, chest pain, and palpitation) in thirty (43.5%) patients, while twenty seven (39.1%) patients were asymptomatic. The mean EF%, LVESD, LVEDD were 51.92%, 4.26cm, 5.93cm respectively, table (1).

Variable	No = 69
AGE /y (Mean +SD)	47.9(13-79)±19.27
GENDER:	
- male %	53(76.8%)
- female %	16(23.2%)
SYMPTOMS: (%)	
- asymptomatic	27 (39.1 %)
- angina	9 (13 %)
- heart failure	30 ( 43.5 %)
- syncopy	3(4.3%)
ECHO: (Mean + SD)	
- ESD:	4.26±1.17
- EDD:	5.93±1.14
- EF%:	51.92±12.27
- AVA:	$1.52 \pm 1.37$
- Max G:	83.13±34.13
- Mean G:	61.76±18.24

#### Table (1) preoperative patient characteristics

Mechanical vale used in fifty five (79.7%) patients, and fourteen (20.3%) patients required tissue valve, valve size used 19(in 5 patients7.2%),21(in 24 patients34.8%), 23 (in 28 patients40.6%0, and 25(in 12 patients17.4%) with frequent use of 21 and 23 size. Seven (10%) patients had aortic root enlargement, none of them have postoperative PPM, table (2).

Variable	No.(%)
Valve Type:	
- Mechanical	55(79.7%)
- Tissue	14(20.3%)
Valve Size 19:	5(7.2%)
21:	24(34.8%)
23:	28(40.6%)
25:	12(17.4%)

## Table 2. Operative data.

All patients followed for development of any symptoms and transthoracic echocardiography done one year after operation, there is no mortality during follow up period, according to EOAI, we classified patients into three category, patient with no or mild mismatch with EOAI >0.85cm<sup>2</sup>/m<sup>2</sup>, patient with moderate mismatch with EOAI between 0.65-0.85cm<sup>2</sup>/m<sup>2</sup>, patient with EOAI less than 0.65cm<sup>2</sup>/m<sup>2</sup> considered as severe mismatch, forty four patients (63.8%) has no mismatch, sixteen (23.2%) has moderate mismatch, and nine (13%) patients has sever mismatch. table (3).

PPM	N(%)
No or mild mismatch	44 (63.8%)
Moderate EOAI of 0.65- $0.85 \text{ cm}^2/\text{m}^2$	16 (23.2%)
Severe < <b>0.65</b> $cm^2/m^2$	9 (13%)

#### Table (3) Incidence of postoperative mismatch.

In patients with moderate and severe mismatch EOAI (0.85 - 0.65cm<sup>2</sup>/m<sup>2</sup>) there is mild improvement in symptoms from 52% to 36% of patients, and mild Ejection Fraction improvement from 50.16% to 52.65% with p value 0.37, while in patients without mismatch there is marked improvement in symptoms from 65% to 14%, and there is marked improvement in EF% from 51.79 to 57.11 with significant p value 0.001. Also in patients with moderate and severe mismatch the mean preoperative LV mass was 335.7 gms with SD of 129.1 LV mass regressed to 309 gms (mean) with SD 122 gms) p value was 0.45. In patient without mismatch, pre operative mean left ventricular mass was 337.2 gms with SD 129.1, postoperatively In those patients, the left ventricular mass was significantly regressed to 286 gms (mean) with SD 121.1). p value for this group was 0.01 as in table(4).

## DISSCUSION

AVR reduces symptoms, increases long-term survival, and improves the quality of life in patients with aortic valve disease. LV hypertrophy regresses after AVR, but LV mass does not return to normal levels [9]. The time course of the regression of LV hypertrophy after AVR is controversial. The earliest documented evidence of consistent LV mass regression after AVR has varied between 6 weeks and 1 year [10]. In this study, we have observed the changes in the LV mass during first year after operation. Pre operative and one year post operative clinical and echocardiography evaluation done to observe the changes in the LV mass. During follow up period there is no mortality for all patient even with sever mismatch, but returning of heart failure symptom was marked in patient with mismatch, this associated with mild or no improvement or even worse left ventricular function in most of patients.

In the cardiac surgery literature there is no conclusive evidence of this supposed beneficial clinical effect of postoperative LVMI reduction. Although animal and clinical studies have suggested a deterimental effect of hypertrophy on LV performance, arrhythmia incidence, and susceptibility to ischemia [11]. The correlation between hypertrophy regression and clinical outcome has been not thoroughly investigated. In a review of the literature we identified only two studies which directly correlated the extent of LVMI regression after surgery with the post-operative outcome: a small retrospective study which reported some clinical benefits [12] and a large multicentre prospective series which gave the opposite results. However, both investigations had several methodological flaws and cannot be regarded as conclusive in this regard [13].

The presence of PPM worse the functional status and capacity, and reduce the regression of left ventricle, in our study we found nine (13%) patients have post operative sever PPM, and sixteen (23.2%) patient have moderate PPM. Some litratures reported that severe PPM occurs in 2-11% of patients after aortic valve replacement (AVR), whereas the prevalence of moderate PPM among these individuals is 20%-70% [14].

In our study we observed significant improvement of EF% over first post operative year in patients without mismatch with p value 0.002; also we observed left ventricular mass regression with significant degree in those patients. **Lamb J. and associates** demonstrated same results with improvement of EF% after AVR for aortic stenosis, also demonstrates regression of LV mass early after AVR for those patients [15], Strong evidence shows that patients with PPM have worse functional class and exercise capacity, reduced regression of left ventricular (LV) hypertrophy [14], as observed in our study, nine (36%) patient still have symptom post operatively, as compared to six (14%) patient without mismatch have symptoms,

	Mismato	ch n= 25	P value	No misma	ntch n= 44	Darahara
	Pre op	Post op	P value	Pre op	Post op	P value
Symptom	13(52%)	9 (36%)	0.64	29(65%)	6 (14%)	0.001
EF%	50.16±11.06	52.65±8.22	0.37	51.79±11.22	57.14±11.38	0.002
LVES	4.44±1.05	3.67±1.0	0.01	4.22±1.16	3.75±0.87	0.029
LVED	6.25±1.01	5.94±1.09	0.30	6.27±1.15	5.39±0.84	0.001
LVM	335.7+129.1	309±122	0.45	337.2±129.1	286±121.1	0.01
LVMI	185.1±34.8	170.7±29.1	0.11	186.8±18.2	136.3±24	0.001

Table (4) Comparison pre and post operative data in patients with mismatch and without Mismatch:

# Conclusion

The incidence of patient-prosthesis mismatch is repoted after aortic valve replacement for aortic stenosis, moderate mismatch is common, severe mismatch is rare, PPM is a prevalent and modifiable risk factor in patients who undergo AVR, and is associated with poor hemodynamic and symptomatic status,. The effect of PPM on outcomes differs markedly depending on its severity as well as on the patient's preoperative status. Also the presence of PPM limits the LV regression and reduces EF% improvement. There is no effect of PPM on early survival especially in patient with good Lv functions.

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# Inflow Occlusion: Is Their Still A Role In Modern Cardiac Surgery

Al Sayed M. Salem; MD

**Background:** Because of the safety and efficacy of cardiopulmonary bypass, performing open heart surgery on CPB is the standard method of current practice. However, inflow occlusion is still preferred in selected cases and several series have shown this to be a safe and effective method for performing brief open cardiac repairs.

<u>Patients and methods</u>: Eighteen patients underwent inflow occlusion for performing atrial septectomy and extraction of slipped devices. Of these patients; fourteen cases underwent atrial septectomy combined with extra cardiac procedures (pulmonary artery banding, cavopulmonary anastomosis and modified Blalok-Taussig shunt), four cases underwent extraction of PDA and ASD devices from LPA and aortic arch.

<u>Results:</u> Mean inflow occlusion time was 116 seconds, mean postoperative size of the ASD in patients underwent atrial septectomy was 11 mm, mean ventilation time was 6.4 hours and mean ICU stay was 4.3 days. Theire were two unrelated mortality cases and no significant residual neurological deficit.

<u>Conclusion</u>: Inflow occlusion is safe and effective and could be considered as a good alternative for selected patients performing atrial septectomy and extraction of slipped devices.

#### KEY WORDS: Inflow Occlusion, Beating heart, Cardiac surgery

he technique of normothermic caval inflow occlusion was introduced clinically by Varco in 1951[1], and several series have shown this to be a safe and effective method for performing brief open cardiac repairs. However, Because of the safety and efficacy of cardiopulmonary bypass, performing open heart surgery on CPB is the standard method of current practice and the inflow occlusion technique has been left with limited indications [2].

Nowadays, this technique is seldom preferred in cases such as pulmonary valvotomy, aortic valvotomy, atrial septectomy, cardiac injury, and extraction of intracardiac thrombus or foreign body [3-8]. These aforementioned operations could also be performed by using CPB. Perioperative problems secondary to the inflammatory process triggered by extracorporeal circulation that may be of concern in already septic patient (as patients with infected pacemaker leads, pneumonia), in neonates and small infants with bad general condition and emergency situations as foreign bodies and slipped devices make the sense that inflow occlusion technique is more save and effective in performing these brief intracardiac repairs [9,10].

Inflow occlusion interrupts the cardiac filling making the field to be more or less bloodless allowing the surgeon to do the required procedure but results in acute drop in the forward cardiac output and severe systemic hypotension. The coronary blood supply to myocardium is jeopardized during the inflow occlusion. Also, the brain is vulnerable to ischemia both due to systemic hypotension and rise in the cerebral venous pressure due to tightening the snares on major caval veins. However, Since inflow occlusion is always restricted to a brief duration (less than two minutes), myocardial and cerebral ischemia may be limited to a minimum extent and are well tolerated [11].

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### **Patients and methods**

This study was conducted in the national heart institute from January 2012 to December 2013. Eighteen patients underwent inflow occlusion for performing atrial septectomy and extraction of slipped devices. Of these patients; fourteen cases underwent atrial septectomy combined with extra cardiac procedures (8 combined with pulmonary artery banding for single ventricle physiology with increased pulmonary blood flow, 4 combined with cavopulmonary anastomosis and 2 combined with modified Blalok- taussig shunt for single ventricle physiology with decreasd pulmonary blood flow), three cases underwent extraction of PDA device slipped in LPA (combined with PDA closure), one case underwent extraction of ASD device closure slipped in the left side of the heart and migrated to the distal aortic arch and the surgeon did not find it during emergency ASD closure because TEE was unavailable and appeared in the chest X- ray in the ICU (figure 1).

#### Surgical technique:[12, 13, 14]

# The goal is to do quick, safe and effective procedure, this depends on some principles;

- Well organized and cooperated meticulous anaesthetic technique as well as careful, expeditious surgery.
- Duration of circulatory arrest should be < 2 minutes. If necessary, inflow occlusion can be repeated to allow completion of a cardiac surgery. If repeated, adequate time (at least three minutes) for complete recovery of the myocardium should be allowed between inflow occlusions.
- Keep temperature  $> 32^{\circ}$  C to avoid ventricular fibrillation
- Drugs, blood and volume replacement and equipment for full cardiac resuscitation should be available.
- Ventilation should be discontinued during inflow occlusion to prevent pulmonary blood from being pushed into the surgical field.
- Adequate de-airing the heart is a critical step at termination of venous inflow occlusion to avoid a fatal air embolus. This is accomplished by simultaneous release of one tourniquet and a large positive pressure breath (i.e. Valsalva) just prior to closure of the cardiac incision and opening the pre placed aortic root cannula with Gentle cardiac massage.
- Digital occlusion of the descending aorta after finishing the procedure helps direct the available cardiac output to the heart and brain.
- If ventricular fibrillation occurs, the heart should be defibrillated by direct electrical shock immediately after inflow occlusion is discontinued.
- Cardiac incisions are initially closed with vascular clamps to minimize the length of circulatory arrest times. After cessation of inflow occlusion and cardiac function is restored, the cardiac incisions are closed with sutures.

#### ..... The sequence of steps:

### (1) For atrial septectomy

The procedure was done in the operating room, under standard general anesthesia and complete CPB setup was available. After median sternotomy, the superior and inferior vena cavae were surrounded with nylon tapes. A longitudinal purse-string sutures was placed on the right atrium from the appendage to neer the IVC to control the edges of the incision befor closure (alternatively it could be controlled with a straight vascular clamp (to save the time of closure and shorten the ischemic period). Another purse string was placed at the aortic root to include an eighteen gauge cannula for future de-airing. At this stage, half the standard heparin dose was given and the patient was ventilated at an oxygen concentration of 100% for 5 min. After the occlusion of the venae cavae by snares, ventilation was stopped, the cross clamp was applied after 8 to 10 beats to evacuate the heart and a right atriotomy was made between the purse-string sutures. The ASD was enlarged or created by excising the septum primum with careful attention not to go outside the heart. The snares were loosened, ventilation was resumed and the aortic root cannula was opened, the right atriotomy was snared or clamped, the heart was gently massaged and aorta was declamped . The right atriotomy was closed using 4/0 polypropylene sutures after restoring acceptable hemodynamics either spontaneously or after pharmacologic resuscitation and/or DC.

#### (2) For PDA device extraction from the pulmonary artery

After initial digital palpation for adequate localization of the device that was found in the LPA, Similar steps were done for its extraction with the exception that the distal main pulmonary artery with the proximal LPA was opened instead of the right atrium and aortic root cannula was not needed.

#### (3) For ASD device extraction from the aortic arch

After initial digital palpation for adequate localization of the device that was found in the distal aortic arch at the level of the left subclavian artery, Similar steps were done for its extraction with the exception that the innominate and the left common carotid arteries were snared, the ascending aorta was clamped, the anterior surface of the arch was dissected and opened for device extraction, then de-aired befor closure.

#### (4) Special situations

- Glenn and MBT shunts were done befor the procedure to help in resuscitation after inflow occlusion but should be temporarily occluded with stopping the ventilation to prevent flooding the field with blood.
- PDA were closed befor opening the PA for the same reason.
- PAB was after septectomy for accurate adjustment and it may not be tolerated if done befor.

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# Results

The mean age of the eighteen patients was 13.5 months with range (1- 60 months). The mean body weight was 7.4 kg with range (3-24 kg). The mean inflow occlusion time was 116 seconds with range (94 - 124 seconds). The mean postoperative size of the ASD in patients underwent atrial septectomy was 11 mm with range (9-14 mm). The mean ventilation time was 6.4 hours with range 2-18 hours. The mean ICU stay was 4.3 days with range 2-13 days. No neurological deficit occurred for any patients but one patient underwent atrial septectomy with MBT shunt suffered three episodes of light fits observed mainly in the face during the day of surgery that was controlled by dormicum and epanutin infusion was given for two days to prevent recurrence. This patient was extubated on the second postoperative day with no residual neurological deficit. Thiere was two mortality cases for a two and three months infants underwent PAB with atrial septectomy and MBT shunt with atrial septectomy respectively, the cause of death for both cases was severe chest infection and repeated intubation.



*Fig. 1. postoperative chest x ray; ASD device migrated in the distal aortic arch.* 

# Discussion

Although inflow occlusion technique used to be a frequent technique before the CPB era and it has lost its popularity with the use of CPB in daily practice, it is still preferred in selected cases such as pulmonary valvotomy, aortic valvotomy, atrial septectomy, cardiac injury, and extraction of intracardiac thrombus or foreign body [3-8]. Also, there are many case reports published regarding the use of the inflow occlusion technique In removed a pacemaker lead from a patient with endocarditis and tricuspid valve endocarditis vegetectomy [10,11]. In our study, the technique enabled us to do atrial septectomy with sufficient ASD size (mean 11 mm) in this group of patients with complex anatomy and to extract slipped devices from the pulmonary artery or aortic arch in an urgent situations and in all cases the inflammatory response of CPB was avoided. The mean time of inflow occlusion remained within the safe limit (116 seconds). No mortality related to the technique or residual neurological deficit had occurred and both mortality cases were due to severe chest infection in low body weight patients with bad general condition and the ventilation time and ICU stay was satisfactory for us regarding our ICU status.

Since inflow occlusion is always restricted to a brief duration (less than two minutes), myocardial and cerebral ischemia may be limited to a minimum extent. If a patient can maintain a stable hemodynamics before surgery, a brief period of inflow occlusion may be endured well. Cardiac and neurological complications may be seen due to systemic and cerebral malperfusion, particularly in occlusions of more than 3 min [3]. In our study, we paid particular attention to not exceeding 3 min. With the application of such precautions, no complication was observed in a patient and target procedures were effectively done.

# Conclusion

Although using CPB remains the standard and preffered technique when doing intra cardiac repairs, inflow occlusion is safe and effective and could be considered as a good alternative for selected patients performing atrial septectomy and extraction of slipped devices.

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# Early Results of Minimal Invasive Video Assisted Mitral Valve Replacement Surgery "Evaluation of its Safety and Clinical Outcome"

Marwan H. Elkassas; MD\* Prof. Olivier Jegaden\*\* <u>Introduction:</u> Minimally invasive mitral valve surgery was first performed in the mid 1990s. Since then it has evolved as the standard technique at some specialized centers. Approaches and techniques for mitral valve surgery are changing. The development of new cardiopulmonary bypass technologies, special surgical instruments, as well as thoracic video systems facilitates mitral surgery via a small right minithoracotomy. With increased patients demand, and the up rising competition from percutaneous techniques, cardiac surgeons have great interest now a day in minimally invasive approaches for mitral valve surgery.

<u>Methods</u>: Since we begin our minimal invasive program at Sheikh Zayed Hospital in Cairo (June 2012), minimal invasive video assisted technique was carried out in 34 patients group (1), for mitral valve replacement. Our routine technique includes direct femoral cannulation, a right lateral minithoracotomy and a transthoracic aortic clamping using special cannulae and instruments, results was compared with another 34 patients group (2) of mitral valve replacement with conventional sternotomy that were done in our center in the same period. Data was collected and analyzed retrospectively.

<u>Results:</u> Among the 34 patients, 54% female and 46% males. The average age was  $34.27\pm7.95$  years. Mean length of incision was  $8.1\pm1.0.56$  cm ,Skin-to-skin mean operating time was  $3.5\pm1.2$  hours and aortic cross-clamp time was  $93.18\pm1.7$  min, total bypass time was  $139.73\pm1.6.8$  minutes, mean intensive care unit stay was  $21.18\pm4.87$  in group (1) hours vs.  $36.45\pm9.8$  hours in the conventional technique group (2) (p <0.01), and hospital stay was  $6.73\pm2.3$  days vs.  $8.8\pm1.2.1$  days in conventional technique (p <0.01), we had one case of in hospital deaths occurred at the 4th day (2.94%) in group (1). No conversion to median sternotomy occurred, no reexploration for bleeding, Postoperative echocardiography showed excellent valve function in all patients. Patient follow-up suggested minimal perioperative pain and rapid recovery.

<u>Conclusion</u>: minimal invasive lateral right minithoracotomy offers excellent exposure; visualization can be further enhanced when using endoscopic cameras, early results suggest that video-assisted minimally invasive mitral operations can be done safely. Patient will benefit from this method through less morbidity, and earlier discharge.

ince the first description of Minimally invasive mitral valve surgery (MIMVS) by Navia and Cosgrove<sup>(1)</sup>, various minimally invasive approaches have been reported including the right parasternal, ministernotomy, minithoracotomy, and totally endoscopic approaches<sup>(2-5)</sup>. However, despite the differences in surgical approaches, the shared goal

of all these MIMVS procedures is to avoid median sternotomy-related complications such as pain, excess blood loss, wound infection, blood transfusion, prolonged hospital stay, long recovery period <sup>(2-7)</sup>, and at the same time, to provide a safe and effective operation for mitral valve surgery with the clinical benefits associated with a minimal access approach. During the past years, several studies on outcomes of MIMVS have been published in the literature <sup>(7-10)</sup>.

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Codex : o3/08/1311

Minimally invasive mitral valve surgery (MIMVS) has been proven as a feasible alternative to conventional full sternotomy approach with low perioperative morbidity and short-term mortality <sup>(6-10)</sup>. As a result, MIMVS is being employed increasingly as routine approach in many centers worldwide with excellent short and long-term results <sup>(4-10)</sup>.

Later on, the success of laparoscopic operations in general surgery paved the way to use the video camera in cardiac surgery for better visualization, and hence appeared the technique of video assisted minimally invasive mitral valve surgery <sup>(7-10)</sup>. And so we begin our program in minimal invasive mitral valve surgery and we present the early result of this work to prove is it worth to shift our classic approach to this alternative one or not.

### Methods

In this study, 34 patients undergone video-assisted minimally invasive mitral valve surgery (MIMVS) between June 2012 and March 2013 in Sheikh Zayed Hospital in Cairo group (1), were evaluated retrospectively. Our patients had only mitral valve disease, with no aortic regurgitation and only mild to moderate tricuspid valve disease, with of coarse no concomitant coronary artery disease.

We compared our results of this technique with another 34 patients had conventional mitral valve replacement surgery in our center at the same period group (2), with no statistically significant difference as regards the demographic and the preoperative data between the two groups. We obtained informed consent after a detailed discussion of potential complications with the patient and family. We should mention that not all patients with isolated mitral valve disease, who were referred to our center, were offered a minimally invasive operation by that time as we could not have the supplies all the time and our main surgeon at the beginning of our program before totally transmitted the technique to us was only available every two months, and we should also mention that we fixed the surgical team in every case and we proud to say that the last 12 cases were operated by a totally Egyptian team. Statistical comparisons for all data were made with the use of a  $\chi^2$  analysis to calculate significance with respect to discrete variables. Operative and postoperative times were compared by means of a two-tailed t test. Data are shown as ± standard error of the mean.

#### **Operative technique**

#### Anesthesia

The necessary peripheral arterial and venous accesses were installed for patient hemodynamic monitoring. The patient was anesthetized in a supine position with the right side of the chest elevated 15 to 20 degrees, intravenous anesthesia with sufentanil, propofol, and pancuronium was administered, patient intubated with a single lumen endotracheal tube in the majority of the cases, but we used a left double-lumen endotracheal tube in the first twelve patients but later on we managed to operate without it, but it can be helpful in the patients of large chest diameter to perform a positive pressure ventilation on the left lung, so pushing the heart and the mediastinum to the right side for better visualization.

A standard 3-lumen (7.0 or 8.5 Fr) central venous line is used for drug administration and CVP monitoring. External defibrillator pads are placed on the patient's back and the lateral left chest.

Transesophageal echocardiography (TEE) probe is inserted for the percutaneous venous cannulation guidance and effective Dearing. The patient is draped exposing the left lateral border of the sternum, the anterior and right lateral chest wall and both groin zones, with the right arm away and slightly down the plane of the operating table. The skin is prepared with iodine solution and an aseptic strip is applied to the exposed areas.

## Surgery

The incision is placed on the right side of the chest in the inframammary fold over the fifth rib and the thorax entered through the bed of the fourth rib, after good hemostasis a soft tissue retractor was used for tissue protection and better visualization, then a minithoracotomy retractor was introduced to stabilize the field. In all the patients the right femoral artery and vein were surgically exposed through a 3 to 4 cm incision parallel to the inguinal skin fold. If all is ok, both the femoral artery and vein were cannulated, for arterial inflow we used either 18 or 20 Medtronic femoral cannulae, and for venous cannulation we used the Remote Access Perfusion (RAP, Estech, San Remon) cannulae of different sizes according to the patient surface area, both inserted over a guide wire by the Sildenger technique, venous cannula was placed in the femoral vein and advanced to the right atrium under Transesophageal echocardiography (TEE) control, in some but not all the cases we used the Vacuum-assisted oxygenator (Skipper, Euroset, Italy) for better drainage.

The 12 mm plastic trocar port was introduced and then the 10 mm (0-degree or 30-degree view) thoracoscopic camera is inserted through the port in the fourth intercostal space posterior to the thoracotomy incision. The camera port intercostal space is not selected until the superior pulmonary vein is identified. Co2 insufflations was used once we introduced the trocar through a side way connection by a flow of about 2 to 2.5 L/min, until we closed the left atrium and removed the cross clamp.

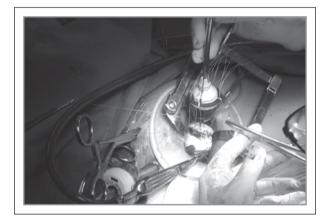
Then we begin the bypass machine, conventional cardiopulmonary bypass system with roller pumps and membrane oxygenator was used, then we stopped the ventilation and fully drained the heart, a traction suture to the diaphragm was done if needed, where it fixed transcutaneously at the chest wall, then a pericardial incision was done two cm parallel and superior to the phrenic nerve and three traction sutures were done routinely and fixed below the incision on the chest wall through the fifth intercostal space.

Cardiovascular

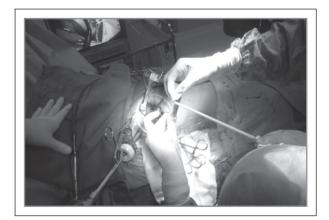
Inspection of the aorta was done, and 2-0 purse string prolene suture was applied at the aortic root slightly at the lateral side and as low as it possible using special long endoscopic instruments. A long single lumen antegrade cardioplegic cannula (MIAR cardioplegic cannula, Medtronic, USA) was introduced in the aortic root where cold blood antegrade cardioplegia was used after the cross clamp to arrest the heart, and this cannula served as an aortic vent for Dearing after cross clamp removal.

We used a transthoracic special aortic cross clamp (Chitwood aortic clamp) where it passed through the chest wall in the third intercostal space at the anterior axillary line, anterior to the superior vena cava through the transverse sinus just caudal to the right pulmonary artery. After cardiac arrest a left atriotomy was done and valve replacement was done in all the patients Pic. (1).

Systemic cardiopulmonary temperature perfusion was maintained between 28° and 30° C through out the arrest period.



*Pic.* (1): Minimal invasive mitral replacement through right minithoracotomy, the incision length was just bigger than the valve size.



*Pic.* (2): Minimal invasive mitral replacement during using the knot pusher with visualization of the knot and the valve on the video screen.

Most of the operation, including cross clamp placement, valve inspection, annular suture placement, and knot tying, was directed by thoracoscopic secondary vision. But atriotomy closure often was done by direct primary vision Pic. (2).

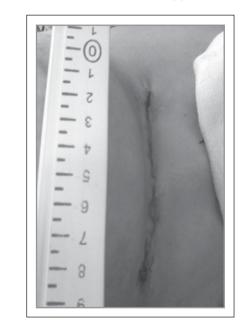
Both ventricular and aortic root vents were used for Dearing, after atrium closure cross clamp removal, and resuming of the heart beats, two pace maker wires were applied, with two small size intercostal tube drainage, direct muscle closure was done without any intercostal sutures traction. After protamine administration, removal of the femoral cannulae was done, and we conducted a direct surgical vessel repair technique using 5-0 prolene suture for the both femoral vessels.

# Results

34 patients were included in the study, 54 % were female, average age was  $34.27 \pm 7.93$  years, average body surface area was  $1.68\pm0.8$  m<sup>2</sup>, we did not exceed more than 1.79 m<sup>2</sup>, the results of both the demographic and preoperative data presented in table (1).

Most of the patients had rheumatic valve disease (88.2 %) predominantly mixed stenotic and regurgitant mitral valve lesion, with of coarse no aortic regurgitation, and only trivial regurgitation of the aortic valve in (8.8%). We did not operate any case with sever tricuspid regurgitation but (58.8%) of our patients had mild tricuspid regurgitation, while11.4 % of the patients had previous balloon mitral valvoplasty (table 2).

Mitral valve replacement was accessible in all cases; we have not transferred any case to median sternotomy, average length of the incision was 8.15 cm, Pic. (3).



*Pic.* (3): A less than 8 cm skin incision after minimal invasive mitral valve replacement.

We compared the post operative data of our group with the data of conventional surgery patients group (2) that have no statistically difference between the demographic or preoperative data (table 3). We found significant difference between the minimal invasive surgery patients and the conventional sternotomy patients as regards the total amount of blood drainage, the total hours of mechanical ventilation, length of ICU stay, incidence of infection, and the length of the days to recover (p <.005). While no significant difference between the two groups as regards the amount of blood transfusion, the post operative hemoglobin and hematocrite, and the total hospital stay (table 4).

We had one case of mortality on the 4<sup>th</sup> post operative day, this patient was transferred to the inpatient on day one postoperatively and every thing was good by that time, but on day 4 he developed dyspnea and sudden hemodynamic deterioration later on, once he was transferred to the ICU we diagnosed him as cardiac tamponade with the ECHO, but we did not have the time to save him, as he arrested few minutes later and despite we performed all the resuscitation measurements; except internal message and rapid pericardial evacuation which was not accessible to perform in the ICU in this technique and we were not prepared to such scenario in our early experience, also we have not the time to transfer him to the theater either to extend the incision or to perform a full sternotomy; we did not have a response, he passed off in the ICU.

Total Number	34
Sex (Female)	54%
Age (years)	34.27 ± 7.93
EDD	5.71 ± 0.31
ESD	3.63 ± 0.32
EF	54.32 ± 2.42
PAP (mmHg)	38.6±6.7
LA (cm)	4.5±0.36
EuroSCORE II	1.09±0.13 %
NYHA II	5 (14.7%)
NYHA III	22 (70.5%)
NYHA IV	3 (8.8%)
BSA m2	1.68±0.8

	Numbers(%)	
Rheumatic	30 (88.2%)	
Degenerative	4 (11.7%)	
Mitral lesion (stenosis)	6 (17.6%)	
Mitral lesion (reg.)	9 (26.5%)	
Mitral lesion (mixed)	18(52.9%)	
No /Trivial Aortic Reg.	31 (91.2%)	
Mild Aortic Reg.	3 (8.8%)	
Tricuspid Reg. (No)	6 (17%)	
Tricuspid Reg. (Mild)	20 (58.8%)	
Tricuspid Reg. (Moder.)	8 (23%)	
Previous B.V.P	4 (11.7%)	

 Table (2) Distribution of patients according to Valvular

 Lesions

Preoperative data	Minimal Invasive Group	Conventional Sternotomy Group	P -value
age	34.27±7.95	36.4±2.3	0.95
sex(female)	54%	52%	0.98
Hg	12.1±0.6	11.9±0.8	0.97
Hct	34.4±0.9	33.3±0.7	0.98
S. cr	0.9±0.2	$1.2 \pm 0.3$	0.85
INR	1.2±0.2	1.1±0.3	0.9
platelet count	236.3±23.4	243.6±32.5	0.91
AST	19.6±2.3	21.2±1.9	0.8
ALT	18.2±3.6	23.5±2.5	0.86
NYHA Class	2.4±0.5	2.5±0.7	0.9
EF	$54.32 \pm 2.42$	53.4±2.7	0.98
PAP	38.6±6.7	40.2±5.8	0.81
LA	4.5±0.36	4.8±0.78	0.85
EDD	5.71±0.31	5.8±1.6	0.89
ESD	3.63±0.32	3.5±0.49	0.92
Euro SCORE II	1.09±0.13	1.1±0.34	0.84
B.S.A.	1.68±0.8	1.72±0.86	0.9

Table (1) preoperative and demographic Data

 Table (3) Demographic and preoperative data of the two
 groups

Variables	Minimal Invasive	<b>Conventional Sternotomy</b>	P value
Total Drinage (ml)	268.18 ±67.8	530.91 ± 61.39	p < 0.001
Fresh Frozen Plasma (units)	$2.75 \pm 0.53$	$3.55 \pm 0.38$	p < 0.62
Packed Blood (units)	$2.3 \pm 0.45$	$3.08 \pm 0.65$	p < 0.23
Post Operative Hb %	11.56± 1.1	$9.04 \pm 0.8$	p < 0.5
Time of Ventilation (hrs)	$2.3 \pm 1.2$	$8.5 \pm 2.3$	p<0.001
ICU Stay (hrs)	$21.18 \pm 4.87$	$36.45 \pm 9.8$	p < 0.002
Total Hospital Stay (days)	6.73 ±2.3	$8.8 \pm 2.1$	p < 0.1
Average Skin Length Incision (cm)	$8.15 \pm 1.7$	$25.6 \pm 3.2$	p < 0.001
Cross Clam Time (min)	93.18 ± 13.7	$75.2 \pm 6.8$	p < 0.006
Total bypass Time (min)	139.73 ± 6.8	89.2 ± 7.9	p < 0.001
Days To Recover	$5 \pm 2.4$	$15 \pm 3.6$	p < 0.001
Icidense of Infection	0	3.4%	p < 0.001

Table (4) operative and postoperative Data

## Discussion

Minimally invasive procedures were introduced to reduce postoperative complications and morbidity related to full median sternotomy, pain, infection, hospital stay, recovery time, and cost while providing a favorable cosmetic result as compared with conventional surgery <sup>(4-8)</sup>.

We can see that our patients were young as the main pathology in our country is rheumatic valvular lesion, and the female are predominant as they 54% of the total number. We should say that we carefully chose our patients so that they had good ventricular function and low EuroSCOR, low body surface area to facilitate the venous drainage during the operation and to insure good result, as we did not have the experience to operate bigger than 1.79 m<sup>2</sup>, in whom they need a jugular vein cannulation as a second source of drainage and of sure more disposables and connections that we have not by this time.

More over we can see from our preoperative data that our patients had relatively low pulmonary pressure, and also relatively small atrial size, with no cases of severe tricuspid regurgitation, this is again as we carefully chose our patients in the beginning of our program to insure the best result, for building the trust to our team, and between us and the patients as minimal invasive mitral surgery is still in its first step in our country.

A less-invasive mitral valve operation has great appeal to patients, who often prefer a non sternotomy approach, but outcomes have never been critically evaluated in a prospective randomized fashion. Several published meta-analyses articles have concluded that MIMV operations are associated with fewer blood transfusions, shorter lengths of hospital and intensive care unit stays, but with longer cardiopulmonary bypass and cross-clamp times <sup>(6-9)</sup>. In our study we proofed that minimal invasive surgery is accompanied with lower blood loss, lower ventilation time, with definitely longer bypass and cross clamp time.

But we did not have a statistically significant difference as regard amount of blood transfusion, this is may be explained by that actually in our practice we have a trend to give our patients more units of blood products either fresh frozen plasma or red blood units even if it is not needed, and we conduct this policy in every patient for fear of reexploration which is usually not accepted by our population.

We do have significant longer bypass and cross clamp time, this is expected in this technique, and if we revised the data of the American centers regarding the difference in total bypass time and cross clamping time between the minimal invasive surgery and the conventional sternotomy we will find it longer in all times with statistically significant difference <sup>(6-7,9-10)</sup>, more over we just began our program less than one year ago, and of sure we will ameliorate our result in favor of shorter bypass and clamp time later on and step by step.

As regard the average skin incision length it is around 8 cm which is longer a little bit than other articles results which is around 4-6 cm  $^{(7.9)}$ , as we are still in our learning curve, and we are sure that we will have shorter incision later on.

If we look to the difference between the two groups as regards the post operative ventilation time, and the length of the ICU stay we will find it significantly lower in the minimal invasive group, which is similar to the results of other studies <sup>(5-7,10)</sup>. Mean while the total hospital stay between the two groups is not significant, this is may be explained by that we always

admit patients of minimal invasive surgery two days before the operation rather than the preoperative one day policy of the conventional group.

Lastly the number of the days needed for recovery (in term of performing the average activity with out pain and help), in the minimal invasive group is around 5 days rather than 15 days of the conventional group, which is statistically significant. We have not performed any analysis in terms of their return to work. But there is evidence that those patients, who were operated through the minimal invasive approach, do return to their regular daily activities faster than those operated with conventional approaches  $^{(4-6, 10)}$ .

We should mention that we learned a lot from our mortality case in the ICU with such previously mentioned scenario, that we should had more close inpatient follow up to those patients, we should had better way of postoperative pericardial drainage by a dependable pericardial drain or continuous low suction modality, early ICU post operative ECHO before inpatient discharge is mandatory, and lastly keep the special minimal invasive instruments ready or easily accessible to the ICU, as it is almost impossible to have a remote access to the heart or the pericardium without it.

The early results of minimal invasive mitral valve replacement surgery of our study proved to be superior to the conventional surgery in different ways; this is also supported by the consensus statement of the society of minimal invasive cardiac surgery <sup>(11)</sup>.

# Conclusion

We concluded that minimal invasive mitral surgery is safe, feasible operation, with very good early clinical out come.

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#### Cardiovascular

# Minimal Invasive Aortic Valve Replacement, Good Exposure And Better Postoperative Over All Results

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<u>Objectives:</u> Minimally invasive cardiac surgery has been developed to offer patients the benefits of open heart surgery with the least postoperative pain and limited skin incision. In this study we show the results of minimally invasive AVR compared to standard sternotomy.

<u>Methods</u>: From March 2011 to May 2013, 19 patients had isolated aortic valve replacement by either (reversed L-shaped or inverted T-shaped) ministernotomy (group 1). And 18 patients as a control group (group 2) were enrolled who underwent isolated aortic valve replacements by standard sternotomy in the same period. A retrospective comparative study was conducted to evaluate the results between the two groups.

<u>Results:</u> Mean ischemic time and entire operation time between the two groups showed no significant difference (P>0.05), but the mean total bypass time in group 1 was obviously longer than that in group 2 (P<0.01). Mean postoperative drainage was 253.18± 47.3 ml in group 1, 592.61 ± 51.29 ml in group 2 and the difference between the two groups was significant (P<0.05). Mean postoperative respiratory support time was 8.3 ± 1.3 h in group 1, and 9.5 ± 3.3 h in group 2, with no significant difference (P>0.05). Mean duration of hospital stay were 6.53 days in group 1, and 9.3 days in group 2, with significant difference (P<0.01).

<u>Conclusions</u>: The minimal invasive sternotomy provides good exposure to the aortic valve, and it is suitable for all kinds of aortic valve operations. More over decrease the post operative bleeding, time of the ICU and hospital stay, and provide better patient satisfaction.

ardiac surgery for different valve lesions had advanced considerably through improvement in various aspects as bypass machine, myocardial protection, and surgical instruments, led to the development of new different approaches which is called minimally invasive cardiac surgery.<sup>(1-4)</sup>

Aortic valve replacement has proven reliable, and improves long-term survival of patients with aortic stenosis and aortic regurgitation. During the last years, minimally-invasive techniques have been introduced in cardiac surgery. Minimally invasive aortic valve replacement uses small incisions, reduces surgical trauma, post operative blood loss, and postoperative hospital stay. <sup>(5-8)</sup>

Early and medium term results for minimally invasive aortic valve replacement approaches show a reduction in pain, improved patient satisfaction, and improved recovery and return to normal activity <sup>(9)</sup>

Minimally invasive valve surgery has been proven as a feasible alternative to conventional full sternotomy approach with low perioperative morbidity and better out come <sup>(6-10)</sup>. Concomitantly, there should be decreased cost and a decreased reliance on post-hospital rehabilitation. <sup>(7, 8, 11)</sup>

We here by presented the results of our work of minimal invasive aortic valve surgery in comparison to full median sternotomy.

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Codex : o3/09/1311

## **Methods:**

In this study, 19 patients had isolated aortic valve replacement by (reversed L-shaped or inverted T-shaped) ministernotomy (group 1) by minimally invasive aortic valve surgery between March 2011 to May 2013 in Sheikh Zayed Hospital in Cairo, Suez Canal University Hospital and Suez Insurance Hospital were evaluated retrospectively.

Our results of this technique were compared with another 18 patients had conventional full sternotomy aortic valve replacement surgery (group 2), with no statistically significant difference as regards the demographic and the preoperative data between the two groups. We obtained signed consent after a detailed discussion of potential complications with the patient and family. All the minimal invasive operations operated by one surgeon.

Statistical comparisons for all data were made with the use of a  $\chi 2$  analysis to calculate significance with respect to discrete variables. Operative and postoperative times were compared by means of a two-tailed t test. Data are shown as  $\pm$  standard error of the mean.

## **Operative technique**

#### Anesthesia

The necessary peripheral arterial and venous accesses are installed for patient hemodynamic monitoring. The patient is anesthetized in a supine position; a standard 3-lumen (7.0 or 8.5 Fr) central venous line is used for drug administration and CVP monitoring. External defibrillator pads are placed on the patient's back and the lateral left chest.

Transesophageal echocardiography (TEE) probe is inserted for the percutaneous venous cannulation guidance and effective Dearing. The patient is draped exposing the anterior chest wall and the both lateral borders of the sternum, both groin zones. The skin is prepared with iodine solution and an aseptic strip is applied to the exposed areas.

### Surgery

In all the patients the right femoral artery and vein were surgically exposed through a 3 to 4 cm incision parallel to the inguinal skin fold. If all is ok, both the femoral artery and vein were cannulated, for arterial inflow we used either (17 or 19 f, Medtronic) or (18 or 20 f, Medos) femoral cannulae, and for venous cannulation we used the Remote Access Perfusion (RAP, Estech, San Remon) cannulae of different sizes according to the patient surface area **Pic. (1)**, or the (Medos, Germany) in the small body surface area patient either 20 or 22 french, both inserted over a guide wire by the Seldinger technique after heparin administration and a target ACT more than 400 was reached, venous cannula was placed in the femoral vein and advanced to the right atrium under transosephageal echocardiographic (TEE) control, in some but not all the cases we used the Vacuum-assisted oxygenator (Admiral, Euroset, Italy) for better drainage.

A straight skin incision of approximately 7 to 8 cm is then made from the level of the head of the second rib in the midline over the sternum and extended down to the level of the head of the fourth rib. The skin and subcutaneous tissue are undermined up to the sternal notch at the upper end, and at the lower extent into the right fourth intercostal space to form reversed L-shaped sternal incision <sup>(2)</sup>, if exposure is not enough an extension to the other side at the same level on the left fourth space was done to form inverted T-shaped incision <sup>(5,9)</sup>. Either a regular saw or an oscillating one can be used, but it is essential to protect the mammary artery at both sides by incising the sternum from out side to the midline after opening the space and liberating the adhesions.

After good hemostasis, small Finocchietto retractor is inserted and the mediastinal tissues exposed. The thymic tissue is then dissected and excised if necessary providing the usual access to the upper anterior pericardium, the pericardium is then opened from the innominate vein to beneath the lower intact sternal table. Essential for good exposure is the use of multiple, heavy silk sutures on the pericardium to pull the aorta and right atrium into good view usually three sutures is used on both sides.

Then we begin the bypass machine, conventional cardiopulmonary bypass system with roller pumps and membrane oxygenator was used, Co2 insufflations was used by a flow of about 2 to 2.5 L/min, until we closed the aorta and removed the cross clamp.

A long single lumen antegrade cardioplegic cannula (MIAR, cardioplegic cannula, Medtronic, USA) was introduced in the aortic root where cold blood antegrade cardioplegia was used after the cross clamp to arrest the heart, and this cannula served as an aortic vent for Dearing after cross clamp removal, we used this technique for induction of cardioplegia in all cases, even if there is an aortic regurgitation then a direct osteal coronary cannulae were used later on during the procedure.

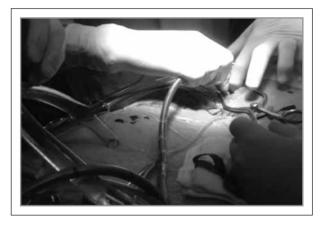
A standard angled or curved aortic cross clamp is applied and sits out of the surgical field as usual. Systemic cardiopulmonary temperature perfusion was maintained between 28° and 30° C throughout the arrest period.

For aortic valve procedures, the aortotomy incision was done as the usual hokey stick one extending in the noncoronary sinus, exposure of the aortic valve is aided by placing commissural sutures under tension. From this point the aortic procedure does not different from the standard until the deairing stages. The surgical field is kept dry by a suction vent in the left superior pulmonary vein (our preferred choice), main pulmonary artery or the bottom of the left ventricle (transaortic) all of which are easily accessible with this method.

After aortic closure cross clamp removal, and resuming

of the heart beats, two pace maker wires were applied, with two small sizes intercostal tube drainage, after protamine administration, removal of the femoral cannulae was done, and we conducted a direct surgical vessel repair technique using 5-0 prolene suture for the both femoral vessels.

The sternal edges are accurately opposed with steel wires taking care not to damage the internal thoracic arteries. For the L-shaped or inverted T-shaped sternotomy incision four wires between the two halves of the sternal table are sufficient. An additional wire for the horizontal limb of the L or T-incision was used to ensure sternal stability.



*Pic.(1): Femoral vessels cannulation with multistage venous cannula for better drainage.* 

## Results

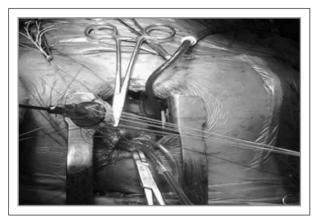
19 patients were included in the study, 42 % were female, average age was  $40.27 \pm 7.93$  years, average body surface area was  $1.69\pm0.6$  m<sup>2</sup>, we did not exceed more than 1.75 m<sup>2</sup>, the results of both the demographic and preoperative data presented in table (1).

Most of the patients in the minimal invasive group had rheumatic valve disease (78.94 %) predominantly mixed stenotic and regurgitant aortic valve lesion, with only pure aortic valve stenosis in (21%).As regards the prosthetic valves sizes, we had five cases replaced by aortic valve size 19, nine cases size 21, three size 23, and two by size 25.

Aortic valve replacement was accessible in all cases; we have not transferred any case to full median sternotomy, average length of the incision was 8.45 cm.

We compared the post operative data of our group with the data of conventional surgery patients that have no statistically difference demographic or preoperative data (table 2). We found significant difference between the minimal invasive surgery patients and the conventional sternotomy patients as regards the total amount of blood drainage, length of ICU stay, the total hospital stay, and the length of the days to recover (p <.005). While no significant difference between the two groups as regards the amount of blood transfusion, the post operative hemoglobin and hematocrite, and the postoperative hours of mechanical ventilation, or the cross clamp time (table 3).

We had no cases of reopening, with no cases of early valve failure or any paravalvular leak, we had no mortality.



Pic. (2): Ministernotomy incision, showing cardioplegia cannula after aortic clamp application, left ventricular vent appeared at the lower edge of the incision in the superior pulmonary vein.

Total Number	19
Sex (Female)	42%
Age (years)	40.8±8.73
EDD	6.71±1.36
ESD	4.63±1.32
EF	52.82±1.72
PAP (mmHg)	29.3±1.4
LA (cm)	3.5±0.35
EuroSCORE II	1.19±0.23 %
NYHA II	3 (15.78%)
NYHA III	14(73.68%)
NYHA IV	2 (10.52%)
BSA m2	1.69±0.6

Table 1. preoperative and demographic Data

Preoperative data	Minimal Invasive Group	<b>Conventional Sternotomy Group</b>	P -value
age	40.8±8.73	37.1±5.6	0.8
sex(female)	42%	48%	0.7
Hg	10.2±1.6	11.3±0.9	0.9
Hct	31.2±1.4	33.2±1.2	0.8
S. cr	$1.1 \pm 0.6$	$0.9 \pm 0.3$	0.75
INR	1.2±0.4	1.1±0.2	0.9
platelet count	220.1±33.4	223.4±42.5	0.93
AST	18.3±3.1	22.2±1.4	0.69
ALT	19.2±4.3	20.5±4.6	0.8
NYHA Class	2.6±0.4	2.5±0.3	0.9
EF	52.82±1.72	51.4±2.1	0.98
PAP	29.3±1.4	30.2±3.8	0.81
LA	3.5±0.35	3.8±0.71	0.9
EDD	6.71±1.36	6.8±1.3	0.89
ESD	4.63±1.32	4.5±0.89	0.9
Euro SCORE II	1.19±0.23 %	1.04±0.30	0.9
B.S.A.	1.69±0.6	1.72±0.4	0.9

Table (2) Demographic and preoperative data of the two groups

Variables	Minimal Invasive	Conventional Sternotomy	P value
Total Drinage (ml)	253.38 ±47.3	592.61 ± 51.29	p < 0.001
Fresh Frozen Plasma (units)	$2.85 \pm 0.32$	$2.65 \pm 0.58$	p < 0.62
Packed Blood (units)	$2.3 \pm 0.76$	$3.20 \pm 0.25$	p < 0.23
Post Operative Hb %	$9.53 \pm 1.4$	$9.4 \pm 1.8$	p < 0.5
Time of Ventilation (hrs)	8.3 ± 1.3	9.5 ± 3.3	p<0.7
ICU Stay (hrs)	$22.27 \pm 4.2$	34.35 ± 4.8	p < 0.002
Total Hospital Stay (days)	6.53 ±2.4	9.2 ± 3.1	p < 0.01
Average Skin Length Incision (cm)	8.45 ± 1.7	29.6 ± 3.2	p < 0.001
Cross Clam Time (min)	63.8 ± 13.7	58.2 ± 6.8	p < 0.6
Total bypass Time (min)	98.73 ± 6.8	73.4 ±7.9	p < 0.001
Days To Recover	$7 \pm 2.4$	$14 \pm 3.6$	p < 0.001
Incidence of neurological complications	0	0	NS

Table (3) operative and postoperative Data



*Pic.(3): Minimal invasive Aortic valve replacement with limited skin incision.* 

## DISCUSSION

Over the last decade, several studies have demonstrated excellent postoperative outcomes of the upper ministernotomy for aortic valve replacement <sup>(6-10)</sup>. But others concluded that partial upper median sternotomy failed to demonstrate clear advantages, apart for an increase in operating times, the surgical results are similar to those of a conventional median sternotomy with only improvement in the aesthetical aspect among patients undergoing minimally invasive cardiac surgery <sup>(13, 14)</sup>. It is well known that most of the incision-related complications of new techniques occur in the early period after the procedure. We performed this study to determine whether minimal invasive AVR offers better results than the standard approach in the early postoperative period or not.

Review of the outcome analysis of patients that had the upper T-shaped <sup>(15)</sup>, or reversed L ministernotomy approaches did not reduce the quality of the procedure, and that this technique is safe and effective for AVR <sup>(5,7-9,15)</sup>. Although some surgeons claimed that the minimally invasive valvular operations required significantly more cross clamp and machine times than conventional operations even with experienced surgeons <sup>(6)</sup>, other prospective randomized <sup>(10,12,13)</sup> and retrospective studies <sup>(8,9,14)</sup> demonstrated that the cross-clamp and machine times were almost the same for both approaches.

Our experience with the ministernotomy approach for AVR operations have demonstrated that cross-clamp time tends to be longer in minimal invasive approach but with statistically no significant result, and it may be because we just at our first stage of the learning curve which we hope to be better later on, but the bypass time was definitely longer, a possible explanation is that we adapted a technique of total femoral (arterial and venous) cannulation rather than an aortic cannulation as most of the other studies, justifying earlier and longer usage of the machine giving longer bypass time. The increased stability of the thoracic cage and integrity of pleural spaces allow patients to mobilize early and cough more efficiently <sup>(5,9)</sup>, more over there is direct relation between the sternal incision length, or any thoracic cage incision and the surgical trauma itself and the pulmonary function test during the first two weeks postoperatively <sup>(16)</sup>.

Our patients in the minimal invasive group showed a trend toward shorter ventilation time, but that variable did not reach statistical significance, while the total ICU stay time showed definite reduction in the minimal invasive group with statistically significant result. Retrospective analysis of our results showed a significant reduction in hospital stay in the ministernotomy AVR group. Several other studies have also demonstrated reduced hospital stay and cost for minimal access AVR when compared with conventional AVR <sup>(6-8, 11).</sup>

Duration of ICU and hospital stay is gaining more and more importance, because they are the most important determinants of costs in cardiac surgery <sup>(7, 11)</sup>. Therefore, all steps led to reduce time of patient's recovery in order to shorten hospital stay are greatly appreciated. Unfortunately, we cannot confirm that our group of patients that had ministernotomy approach had lower financial cost.

Mächler HE et al. <sup>(12)</sup>, made a very informative study comparing the results of both minimal invasive partial sternotomy versus conventional full sternotomy as regards total bypass time, cross clamp time, and postoperative bleeding, he confirmed that ministernotomy was associated with less post operative drainage. Our results showed a significant difference between the two groups as regards the amount of post operative drainage, with lower incidence of post operative blood loss in the minimal invasive group, but our results showed no significant difference between the two groups on the postoperative hemoglobin or hematocrite.

One of the main concern of ministernotomy is the difficulty of air removal from the heart at the end of the procedure <sup>(9,12, 13, 17)</sup>, it seemed that CO2 insufflations into the operation field, aortic needle aspiration, positive ventilation before clamp removal were sufficient to achieve good air removal from the left ventricle. In our study, no statistical difference in neurologic outcome has been reported between the two groups.

Cohn and colleagues <sup>(11)</sup> reported that one of the disadvantages of this technique was the use of the femoral area for cannulation and perfusion in many patients. In our study, there were no groin complications with femoral artery or vein cannulation. Femoral vein cannulation was used in all the ministernotomy group to improve exposure and comfort the surgeon during the operation. Although the use of femoral artery or vein cannulation slightly increases the cost, it is balanced with a certain amount of cost reduction because of the reduced duration of hospital stay, which is the major determinant of costs in cardiac surgery <sup>(7, 8, 11)</sup>.

We also observed a faster mobilization in patients of minimal invasive approach because of decreased pain from the incision, and assumed better pulmonary function parameter. And we had statistically significant difference between the groups as regards the time of recovery to more or less normal activity which is supported by most of the other studies <sup>(9, 11-13).</sup>

We are well aware of the limitations of the study as it is retrospective study, with limited numbers of patients, and both groups were none randomly assigned to treatment; however, there were no statistical differences between the groups in terms of preoperative patient characteristics. The proven advantages of ministernotomy were the reduced surgical trauma, decreased blood loss, shortened ICU and hospital stays.

**In conclusion**: We know that new surgical techniques require long experience before optimal results are achieved; however, if the same quality of operation can be performed safely through a less traumatic procedure with cosmetically better incision and with shorter hospital stay, then we support that the minimal access approach can be used on a routine basis for isolated primary aortic valve replacement.

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# Surgical Outcomes After Atrioventricular Septal Defect Repair: Modified Single Patch Versus Two-Patch Technique

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<u>Methods</u>: A retrospective study designed to include 81 patients who were referred for atrioventricular septal defect repair. Patients were grouped into modified single patch technique group (n= 48) and the two patch technique group (n=33). Preoperative, intraoperative, and postoperative data were analyzed and compared between the two groups.

Results: The preoperative results were statistically different between both groups regarding the mean size of ventricular septal defect which was 1.3±0.6mm in the two patch group versus 0.56±0.24 mm in single patch group (P value < 0.001) and mean preoperative pulmonary artery pressure which was 61.91±18.86 mmHg in the two patch group versus 53.15±13.68 mmHg in single patch group (P value = 0.02). The intraoperative data revealed that Rastelli type C was significantly more encountered in the two patch group (51%) and Rastelli type A was more in single patch group (93%) (P value <0.001). Mean aortic cross clamping time was 79.18±33.63 minutes in the two patch group versus 45.34±11.44 minutes in single patch group and mean cardiopulmonary bypass time was 116.2±50.9 minutes in the two patch group versus 72.36±18.6 minutes in single patch group (P value < 0.001). The mean intensive care unit stay was  $6\pm 2.3$  days in the two patch group vs. 4.9±2.4 days in single patch group (P value < 0.001) and the period of mechanical ventilation was 39±15.7 hours in the two patch group vs. 26.1±10.7 hours in single patch group (P value < 0.001). The overall in hospital mortality was 5 patients (6.2%), 2 patients (6%) in the two patch group and 3 patients (6.3%) in single patch group. Reoperation was required in 2 patients (6%) in the two patch group for fixation of sternal dehiscence and permanent pacemaker insertion, and in 2 patients (4.2%) in the single patch group for pacemaker insertion and for left ventricular outflow obstruction.

<u>Conclusion</u>: Although modified single-patch and the two-patch techniques have comparable results in surgical outcomes, the modified single patch technique appears more advantageous as regards shorter cross clamp and cardiopulmonary bypass times.



trioventricular septal defect (AVSD) comprises about 3% of congenital heart diseases. It represents a full spectrum of lesions, characterized by the absence of the atrioventricular (AV) segment of the cardiac septum with presence of common AV ring and both valve components stay undivided. According to Rastelli classification,

three anatomical subgroups can be classified based on the insertion of the chordae tendineae and the morphology of the superior bridging leaflet of the common AV valve. (1)

Down syndrome is an associated finding in approximately 75% of the patients with complete AVSD. (1) Associated lesions like secundum atrial septal defect (ASD) and persistent ductus arteriosus (PDA) are common. Mitral regurgitation and pulmonary hypertension, mostly due to unrestricted left to right shunt, are common findings. (2)

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Since Lillehei and colleagues performed first successful surgical repair of complete AVSD in 1954, various surgical procedures had evolved. The main principles of repair are septal defects closure, creating or maintaining two competent and non-stenotic AV valves, and avoiding AV block induced by damage of the AV node.

According to the technique used to close the interventricular communication, various techniques were described for repair of the complete AVSD, namely, classic one-patch technique (Rastelli technique) with division and reattachment of the valvular components, two-patches technique, "modified" single-patch technique, and no patch technique (3,4).

Despite the advances in the diagnosis, surgical techniques and in intensive care management that had led to significant reductions in mortality and morbidity, postoperative AV valve dysfunction and subaortic stenosis continues to be the most important early and late morbidity. (5)

This study aimed at reporting the short and mid-term outcomes after complete AVSD repair comparing the two-patch and modified single-patch techniques used in repair.

## **Materials and Methods**

After approval of local ethics committee and written informed consents from parents or guardians, 81 patients who were referred to the pediatric cardiac surgery center at Ain Shams University and Atfal Masr insurance hospitals for AVSD repair between January 2008 and June 2012 were retrospectively analyzed. Follow up was continued with a closeout date January 2013. The patients were grouped into two groups according to the operative technique where the modified single patch technique (SP) group included 48 patients and the two patch technique (TP) group included 33 patients. Patients who needed pulmonary artery banding (PAB), incomplete AVSD, or AVSD associated with unbalanced ventricles, double outlet right ventricle and tetralogy of Fallot were excluded. Diagnosis of all patients was based solely on the two dimensional echocardiography.

All operations were performed through median sternotomy and using the cardiopulmonary bypass (CPB), moderate hypothermia (28-30°C), Aortic cross clamping and intermittent antegrade cold blood cardioplegia infusion. In all cases, the PDA was immediately ligated after the start of CPB and a vent was inserted through right superior pulmonary vein.

AV valves morphology and competence were evaluated using cold saline injection. The opposition zone between the superior and inferior bridging leaflets was identified and closed using 5/0 or 6/0 interrupted simple prolene (Ethicon, Somerville, NJ) sutures and the test for competence was repeated using the cold saline injection. In some cases, a partial posterior annuloplasty of the left AV valve was done to avoid the central regurge and ensure the competence of the valve. In cases of two patch technique, a glutaraldehyde-treated autologous pericardial patch or a Gore-Tex patch (W.L. Gore& Assoc, Inc, Flagstaff, AZ), was used to close the ventricular septal defect (VSD) component and the ostium primum defect was closed by pericardial patch. All patches were sutured with continuous suture technique using 5/0 or 6/0 prolene sutures (Ethicon, Somerville, NJ) and there was no need to divide the bridging leaflets.

In cases of modified single patch technique, series of pledgeted 5/0 prolene sutures were placed on the right side of the crest of the ventricular septum and passed through the endocardium of the right ventricle then through the midportion of the common AV valve leaflet with no need to incise the bridging leaflets. The sutures were passed through a previously harvested autologous pericardial patch and tied resulting in obliteration of the VSD component by pulling the AV valve leaflet to the top of the ventricular septum. Then the ostium primum defect was closed by the pericardial patch using continuous 5/0 or 6/0 prolene suture. Coronary sinus was kept on the right side in all cases.

In the postoperative follow-up, the patients were assessed for the presence of residual VSD that needs further intervention, the competence of the left AV valve, the left ventricular outflow tract obstruction, and third-degree AV block (AVB) requiring permanent pacemaker implantation.

#### **Statistical methods**

Statistical analysis was done using the Statistical Package for Social Sciences version 17 (SPSS; SPSS Inc, Chicago, Illinois). The Shapiro-Wilk test was used to examine the normality of numerical variables. Numerical variables were presented as median (interquartile range), mean ± standard deviation (SD) and categorical variables as ratio or number (%). For intergroup comparisons, the Mann-Whitney U test was used to compare skewedly distributed numerical variables. The Pearson chi square test (or Fisher's exact test if appropriate) was used to compare nominal variables. Ordinal variables were compared using linear-by-linear association. P<0.05 is considered statistically significant.

#### Results

The preoperative characteristics of all patients and the comparison of the analyzed data are shown in table (1). Severe left AV valve regurge was more encountered in TP group (22 patients; 66.7%) and moderate regurge was more encountered in SP group (30 patients; 62.5%). The mean size of VSD component was approximately double the size in TP group ( $1.3 \pm 0.6$ cm in TP group vs.  $0.56\pm0.24$  cm in SP group; P value < 0.001). Although all patients had preoperative pulmonary hypertension, mean PAP was higher in TP group ( $61.91\pm18.86$  in TP group vs.  $53.15\pm13.68$  in SP group, P value = 0.02).

Variable	TP (n=33)	SP (n=48)	p-value
Age (months)			0.651
Median (range)	14 (10.75 - 25.5)	15.5 (8.5 - 24.0)	
Mean ± SD	$24.18 \pm 25.28$	$29.8 \pm 38.2$	
Gender (M/F)	16/17	21/27	0.674
Weight (kg)			0.569
Median (range)	8 (6.0 - 10.0)	8 (6.0 - 10.0)	
Mean ± SD	$9.18 \pm 4.35$	$10.4 \pm 6.5$	
Down's syndrome	17 (51.5%)	28 (58.3%)	0.544
Left AV valve regurgitation			0.005
Mild	0 (0%)	1 (2.1%)	
Moderate	11 (33.3%)	30 (62.5%)	
Severe	22 (66.7%)	17 (35.4%)	
Associated anomaly			0.233
Secundum ASD	5 (15.2%)	9 (18.8%)	
PDA	10 (30.3%)	7 (14.6%)	
MPAP (mmHg)			0.024
Median (range)	60 (48.0 - 71.25)	50 (40.0 - 65.0)	
Mean ± SD	61.91 ± 10,01	$53.15 \pm 13.68$	
ASD size (mm)			0.051
Median (range)	1.5 (1.2 - 1.7)	1.2 (1.0 - 1.5)	
Mean ± SD	$1.4 \pm 0.38$	$1.2 \pm 0.34$	
VSD size (cm)			< 0.001
Median (range)	1.2 (0.98 - 2.0)	0.5 (0.4 - 0.7)	
Mean ± SD	$1.3 \pm 0.6$	0.56±0.24	

Data are presented as median ((interquartile range)), mean  $\pm$  SD, or number (%). AV= atrioventricular, ASD= atrial septal defect, F=Female, MPAP= mean pulmonary artery pressure, M=Male, PDA= patent ductus arteriosus, VSD= ventricular septal defect.

#### Table 1. Pre-operative patient characteristics

Eighteen patients (22.2%) underwent previous PAB before repair, 10 patients (30.3%) in TP group and 8 patients (16.7%) in SP group. According to intraoperative assessment, morphologic features of the common AV valve consistent with Rastelli type C were more in TP group (51%) and Rastelli type A were more in SP group (93%). Mean aortic cross clamping time and CPB time were significantly shorter in SP group (79.18 $\pm$ 33.63 and 116.2 $\pm$ 50.9 min., respectively in TP group vs. 45.34 $\pm$ 11.44 and  $72.36\pm18.6$  min., respectively in SP group; P value <0.001), as shown in table (2). Annuloplasty of the left AV valve was done in 3 patients (9%) of TP group and 5 patients (10.4%) of SP group with no statistical difference between the two groups.

The mean ICU stay was  $6 \pm 2.3$  days in TP group vs.  $4.9\pm 2.4$  days in SP group (P value < 0.001) and the period of mechanical ventilation was  $39\pm 15.7$  hours in TP group vs.  $26.1\pm 10.7$  hours in SP group (P value < 0.001), as shown in table (3).

Variable	TP (n=33)	SP (n=48)	p-value
AV canal anomaly			<0.001
Rastelli Type A	15 (45.5%)	45 (93.8%)	
Rastelli Type B	1 (3.0%)	2 (4.2%)	
Rastelli Type C	17 (51.5%)	1 (2.1%)	
Aortic cross clamp time (min)	79.18±33.63	45.34±11.44	< 0.001
CPB time (min)	116.2±50.9	72.36±18.6	< 0.001

Table 2. Operative data

Variable	TP (n=33)	SP (n=48)	p-value
AV valve regurgitation			0.940
Mild	23 (69.7%)	30 (62.5%)	
Moderate	7 (21.2%)	16 (33.3%)	
Severe	3 (9.1%)	2 (4.2%)	
Duration of ventilation (h)			< 0.001
Median (range)	40 (24 - 52)	22.5 (20 - 30)	
Mean ± SD	39 ± 15.7	$26.1 \pm 10.7$	
CU stay (days)			< 0.001
Median (range)	5 (5 - 12)	5 (4 - 15)	
Mean ± SD	$6 \pm 2.3$	$4.9 \pm 2.4$	

Data are presented as median (interquartile range), mean ± SD or number (%).AV= atrioventricular. ICU= intensive care unit.

#### Table 3. Early postoperative outcome

The early postoperative complications are presented in table (4); however, there was no statistical significance between both groups. The complete heart block encountered in one patient from each group necessitated permanent pacemaker insertion. The first degree heart block encountered in one patient in TP group had resolved spontaneously on 5th postoperative day.

Early postoperative echocardiography revealed mild degree of left AV valve regurge in most of the patients of both groups (69.7% in TP group and 62.5% in SP group). However, 3 patients (9.1%) in TP group and 2 patients (4.2%) in SP group were having severe degree of left AV valve regurge with no statistical difference between both groups, as shown in table (3). Residual VSD was found in two patients of TP group (6%), yet, it was small (0.2mm) and in 2 (4.2%) patients of SP group and it was 0.3 and 0.4mm with no significant difference between the two groups.

Three patients needed reoperation in the early postoperative period. In TP group, one patient was 6 months old Down syndrome who had unstable sternum on the 15th postoperative day and needed sternal fixation. The other patient was having complete heart block and needed epicardial permanent pacemaker insertion. In SP group, reintervention was needed for a patient who had complete heart block for epicardial pacemaker insertion.

The overall in-hospital mortality was 5 patients (6.2%). Two mortalities occurred in TP group (6%), one of them was suffering severe pulmonary hypertension, and developed hypertensive crisis with subsequent refractory cardiogenic shock and died at the first postoperative day. The other mortality had occurred at the 20th postoperative day due to pneumonia. Three mortalities had occurred in SP group (6.3%), two mortalities were also due to acute hypertensive crisis with cardiogenic shock at first postoperative day and the third mortality was due to low cardiac output at 12th postoperative day.

Complete follow up was available for 62 patients (77.5%). Mean follow up period was 27.8  $\pm$  13.95 months (range 6-48 months). All residual VSD in both groups healed spontaneously and didn>t need further intervention. Left AV valve regurge was improved from severe to moderate in one patient (3%) in TP group and from moderate to mild in one patient (2%) in SP group. However the remaining patients with moderate to severe regurge were controlled medically and none needed reoperations. One patient in SP group developed LVOT obstruction after 1 year of operation with peak gradient across LVOT of 65 mmHg and needed reoperation.

Variable	TP (n=33)	SP (n=48)	p-value
Pulmonary hypertension	26 (78.8%)	35 (72.9%)	NS
Chest infection	4 (12.1%)	7 (14.6%)	NS
Junctional tachycardia	5 (15.2%)	6 (12.5%)	NS
Heart block			NS
First degree	1 (3%)	0	
Complete	1 (3%)	1 (2%)	
Sternal dehiscence	1 (3%)	0	NS

Data are presented as number (%). NS= non significant.

Table 4. Early postoperative complications

Variable	TP (n=33)	SP (n=48)	p-value
AV valve regurgitation			0.634
Mild	23 (69.7%)	31 (64.6%)	
Moderate	8 (24.2%)	15 (31.2%)	
Severe	2 (6.1%)	2 (4.2%)	
Data are presented as number (%). AV= atrioventricular.			

Table 5. Follow up data

## Discussion

Surgical correction of complete AVSD can nowadays be achieved with excellent short- and mid-term results. The improvement in understanding the morphologic anatomy, the advances in surgical technique, and better postoperative care leads to a reduced mortality rate of less than 4% even in young children, as reported by Tweddell and Dragulescu and their coauthors (6, 7). Mortality in our study was slightly higher (6.2%) with no significance between both groups. This is can be attributed to the difference between centers in the facilities and resources.

Different surgical techniques have been introduced for repair of the defect involving the use of either a single patch or two patches. Whether modified single patch or two patch technique is superior in repair of AVSD is still controversial. Many studies reported comparable results of both techniques; however, they recommended the modified single patch technique because of its advantage of relative simplicity and shorter ischemic time and cardiopulmonary bypass time. (2, 8, 9)

Despite the feasibility and the advantages of the modified single patch technique, Dragulescu and his coworkers reported, in their experience, no advantage using this modified single-patch technique. (3) Also, its potential to obstruct the left ventricular outflow tract and to cause increased AV valve regurgitation that led to more re-operations has been claimed by many authors. (3, 10)

However, the supporters of the technique reported that the incidence of reoperation for late left AV valve regurgitation with the modified single-patch technique was lower (8, 9, 11). Moreover, Piccoli, Jeong and their coauthors reported actual rate of the left ventricular outflow tract obstruction was only about 7% (7, 11) and current literature reported the incidence of significant LVOT obstruction after AVSD repairs requiring reoperations is 2.7% to 5.6 %. (5, 13, 14)

In our study, there was one patient (2%) with significant gradient across LVOT in modified single patch group requiring reoperation after one year of follow up. There were only two patients with severe left AV valve regurgitation in each group and they were treated conservatively with no re-operations needed during follow-up period.

Nunn reported good outcomes after modified single patch technique with a 1.6% mortality rate in 128 patients, no reoperations for residual ventricular septal defects or LVOT obstruction, no conduction abnormalities, and the incidence of mitral valve reoperation was very low at 2.3%. (11) Jonas has also reported excellent results with the modified single-patch in his study on 34 patients. There were no deaths and no reoperations for LVOT obstruction or left AV valve insufficiency. (15)

Our results are supporting the advantages of the modified single patch technique in form of shorter cross clamping time, CPB time, mechanical ventilation duration, and ICU stay. There was no difference between both groups in the degree of left or right AV valve regurge, residual VSD, or occurrence of heart block or other postoperative complications.

Many reports support the concept of early surgical intervention before the development of pulmonary vascular obstructive disease which subsequently decreases the incidence of pulmonary hypertensive crises. (1, 5, 6, 16-18) This may explain our results of high incidence of persistent postoperative pulmonary hypertension as the median age of our patients was 14 months in two patch group and 15.5 months in single patch group. The tendency to correct AVSD at earlier ages would make the simplified single-patch technique more advantageous in smaller children, because the lack of the ventricular patch decreases the difficulty of the procedure (1).

The use of the modified single patch repair, without the use of a VSD patch may not be applicable to large VSD components as recommended by many authors. (2, 8, 9) Our statistical analysis was consistent with these reports as the patients of the modified single patch group had smaller VSDs (median size was 5mm) and there was only one patient (2.1%) who had Rastelli type C of the AVSD which tend to have larger ventricular septal component of the defect, while the patients of the two patch group had larger VSDs (median size was 1.2 cm), and there were 17 patients having (51.5%) Rastelli type C of the AVSD with significant difference between both groups.

Our study reported chest infection in 13.6 % and complete heart block in 3.7 % of patients with no difference between both groups. These results are similar to Backer and coworkers who reported 3.5% of patients required permanent pacemaker due to heart block (19). The incidence of sternal dehiscence in our patients was 3% which is consistent with Ando and coworkers who reported 2% of patients had wound infections and dehiscence. (20)

The limitation of this study is that the patients were not randomized, with small study group. Another limitation is the relatively short follow-up, which may not be enough to comment on late LVOT obstruction or the AV valve regurge and the need for reoperation for such sequalea.

In conclusion, modified single-patch and two-patch techniques can both be utilized with comparable mortality and morbidity. However, the modified single patch technique appears more beneficial as regards shorter aortic cross clamp and CPB times.

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# Routine Reinforcement of Bronchial Stump After Lobectomy or Pneumonectomy With Pedicled Pericardial Flap (PPF)

# Thoracic

Hesham Alkady; MD \* Yasser Ahmad Boriek; MD \*\* Yasser Shaban Mubarak; MD\*\*\* <u>Introduction</u>: Bronchial reinforcement has been strongly supported in highrisk patients'. However; it is still unclear whether reinforcement of the bronchial stump should be performed as routine in every patient and whether that would be of particular value for prevention of bronchopleural fistula after lobectomy or pneumonectomy.

<u>Patients and Methods</u>: The results of 29 cases underwent a pedicled pericardial flap coverage for the bronchial stump after lobectomy or pneumonectomy were compared with those of 34 patients who received no coverage for the bronchial stump. Operative time as well as perioperative mortality and morbidities were recorded, and patients were followed up for a mean of  $6\pm 1.5$  months.

<u>Results:</u> In Group A (pedicled pericardial flap-Group), Perioperative mortality occurred only in one patient (3.4%), while in group B occurred in 2 patients (5.8%). The mean operative time in Group A was 190± 30 minutes for lobectomies and 160± 20 minutes for pneumonectomies , while in Group B was 180± 25 minutes for lobectomies and 150± 15 minutes for pneumonectomies. In Group A, no case of BPF occurred during the entire outpatient follow-up period, while in Group B BPF occurred in 4 patients (11.7%). Supraventricular tachyarrhythmia occurred in 2 patients (6.8%) of Group A and in one patient of Group B (2.9%)

<u>Conclusion</u>: Bronchial stump reinforcement should be routinely performed in all patients who are undergoing a lobectomy or pneumonectomy . This technique is proved to be feasible, safe and effective; also it does not increase much operative time.

<u>KEYWORDS</u>: Bronchial stump,re-enforcement, pedicled pericardial flap (PPF), bronchopleural fistula (BPF).



lthough bronchopleural fistula (BPF) is a rare problem, occurring in 2% of cases of lung resection (up to 10% after pneumonectomy), yet it is associated ,when it occurs, with mortality ranging from 15% to 75%, significant morbidity, and increased hospital stay for those who survive.<sup>(1-3)</sup> It leads to a number of life-threatening situations,

such as aspiration of infectious fluid from the pleural cavity, pneumonia of the remaining lung, and infection of the pleural cavity followed by empyema<sup>(4)</sup>.

Many factors have been implicated in the development of postresection bronchopleural fistula. Local factors such as empyema, pneumonia and bronchiectasis impair wound healing and end up in fistula formation. Prolonged postoperative mechanical ventilation or systemic infection with adult respiratory distress syndrome, as well as steroids, malnutrition, and age over 60 years are other predisposing factors.<sup>(5)</sup>Technical factors thought to be associated with the development of bronchopleural fistula include devitalization and devascularization by excessive peribronchial dissection, excessively tight closure, and long bronchial stump. There is controversy regarding the contribution of mediastinal node dissection and the difference between stapled and handsewn closure of the bronchus as risk factors <sup>(6&7)</sup>.

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Codex : 04/01/1310

The usefulness of bronchial stump reinforcement with viable tissues after a lobectomy or pneumonectomy procedure has been well documented. Different biological materials such as pleura, intercostal muscle, pericardial fat , diaphragm, azygos vein in case of a right-sided pneumonectomy , and pericardiophrenic pedicles have been used for such a prophylactic coverage<sup>(8&9)</sup>.

The use of a flap of pericardium in thoracic surgery was first described as an alternative method to the pericardial fat graft by Brewer and associates <sup>(10)</sup>as early as 1953. Anderson and Miller <sup>(8)</sup> later on have used this technique in different clinical situations, such as repair of tracheoesophageal fistulas, sleeve lobectomies, tracheal anastomosis, and extended pneumonectomies.

Bronchial reinforcement has been strongly supported in high-risk patients such as patients with bronchogenic carcinoma especially before administration of neo-adjuvant therapy, diabetic patients and patients with a highly morbid pathology, such as tuberculosis<sup>(11,&12)</sup>. However, it is still unclear whether reinforcement of the bronchial stump should be performed as routine in every patient and whether that would be of particular value for prevention of bronchopleural fistula after lobectomy or pneumonectomy.

#### **Patients and Methods**

The aim of this retrospective study was therefore to analyze the results of bronchial stump coverage with pedicled pericardial flap (PPF) for prevention of bronchopleural fistula .

To investigate the efficiency of bronchial stump coverage with pedicled pericardial flap (PPF),63 patients were included in the study. These patients received either lobectomy or pneumonectomy in the period between January 2011 to Mach 2013 by the same team in different hospitals. We divided the patients into2 groups: Group A consisting of 29 patients in whom the bronchial stump was covered with a pedicled pericardial flap and group B consisting of 34 patients in whom the bronchial stump was not covered with any tissues. Operative and perioperative complications were recorded, and patients were followed up for a mean of  $6 \pm 1.5$  months.

In **Group A** (PPF-Group) 17 were males (58.6%) and 12 were females (41.4%) with a mean age of 54.5 years. Diabetes mellitus was present in 10 patients (34%). Lobectomy was done in 23 of these patients (79%) and pneumonectomy was done in 6 cases (20.5) .Indications for lobectomy or pneumonectomy were lung malignancies in 20 cases (69%) and benign diseases (e.g. bronchiectasis) in 9 cases (31 %) .Of the malignancy patients, 14 cases (48%) received some form of additional therapy (irradiation or chemotherapy), either alone or in various combinations.See table (1)

ITEM	Group A (29)
Sex	17 males & 12 females
Age (mean)	54.5
Diabetes mellitus	10 (34%)
Operations	
Lobectomy	23 (79.5%)
Pneumonectomy	6(20.5%)
Indications	
Malignancies	20 (69%)
Benign diseases	9 (31%)
Additional therapy	14 (48%)

While in the other group 20 were males (58.8%) and 14 were females (41.2) with a mean age of 52.8 years. Diabetes mellitus was present in 10 patients (29.5%).Lobectomy was done in 25 of these patients (73.5) and pneumonectomy was done in 9 cases (26.5%).Indications for lobectomy or pneumonectomy were lung malignancies in 24 cases (70.5%) and benign diseases (e.g. bronchiectasis) in 10 cases (29.5%).Of the malignancy patients, 16 cases (47%) received adjuvant therapy (irradiation or chemotherapy), either alone or in various combinations.See table (2)

ITEM	Group B (34)
Sex	20 males & 14 females
Age (mean)	54.5
Diabetes mellitus	10 (29.5%)
Operations	
Lobectomy	25 (73.5%)
Pneumonectomy	9(26.5%)
Indications	
Malignancies	24 (70.5%)
Benign diseases	10(29.5%)
Additional therapy	16 (47%)

Tumor negativity of resection margins was ensured by histologic examination of all patients in both groups. No patient in both groups had positive bronchial stump for malignant cells (free stumps).Cases of pulmonary tuberculosis were excluded from this study. Regarding the previous data, there was no statistical difference between the two groups (P value > 0.05).

### **Surgical Technique**

#### **Closure of the bronchus:**

Bronchial stump closure was performed with simple interrupted sutures using non-absorbable sutures (Ethibond 3/0) in all patients, approximating the membranous and the cartilaginousportions of the bronchus. The bronchial stump was then checked for air leakage with 30 cm H<sub>2</sub>O sustained airway pressure.

#### **Coverage of the bronchus in Group A:**

A flap of the anterolateral pericardium, pedicled at its cranial, caudal or medial parts (according to the location of the stump) without inclusion of the phrenic vessels and measuring approximately 4 ×10cm, was prepared. The flap was attached caplike over the bronchial stump with numerous simple stitches of 4/0 proline. (Fig1). In all patients, the resulting defect in the pericardium was not reconstructed.

#### **Statistical Analysis:**

All analyses were done using the statistical software SPSS (SPSS Inc, Chicago, IL).In addition, univariate statistics using either an  $\alpha 2$  analysis or a Fisher exact test were obtained comparing the variables: age, sex, mortality, Diabetes mellitus, operatons, indications and additional therapy. A significant difference was indicated at p < 0.05. Data were statistically described in terms of relative frequencies (percentages), mean and standard deviation values (SD). All statistical calculations were done using Microsoft excel 7 computer program (Microsoft cooperation, NY, USA).

## **Results**

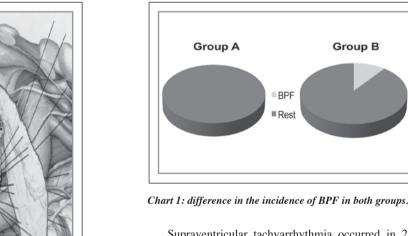
In Group A (pedicled pericardial flap-Group), Perioperative mortality occurred only in one patient (3.4%) who died from pulmonary embolism on the 6th postoperative day. In the other group, Perioperative mortality occurred in 2 patients (5.8%). In these patients, causes of death were: tumor progression in one patient, and renal failure in the other patient. There was no statistical difference between both groups regarding the perioperative mortality.

The mean operative time in Group A was 190± 30 minutes for lobectomies and  $160\pm 20$  minutes for pneumonectomies. while the mean operative time in Group B was 180±25 minutes for lobectomies and  $150 \pm 15$  minutes for pneumonectomies.

This difference was due to the time needed to prepare the pericardial flap and to cover the bronchial stump which required about 10 to 15 minutes.

Group A, no case of bronchopleural fistula occurred during the entire outpatient follow-up period. While in Group B bronchopleural fistula occurred in 4 patients (11.7%), of which 3 cases were lobectomies and one case was a left pneumonectomy. This difference was of statistical significance (P value < 0.05). It worse mentioning that one of those 4 patients developed a BPF on the 10th postoperative period with 2ry hemorrhage after right upper lobectomy and was managed by 2ry suturing and re-enforcement of the bronchial stump with PPF. The other patients developed empyema but fortunately responded successfully to chest tube drainage and vigorous parental antibiotic therapy. See chart 1.

Group B



Supraventricular tachyarrhythmia occurred in 2 patients (6.8%) of Group A and in one patient of Group B (2.9%) with no statistically significant difference. All cases were successfully managed pharmacologically in both groups. Also no patient in Group A showed signs of pericarditis due to spread of infection into the pericardial sac including precordial pain, fever and ST segment changes in ECG. See table 3

RPF

■ Rest



Fig.1 Bronchial Stump Coverage With a Pedicled Pericardial Flap: An Effective Method for Prevention of Postpneumonectomy Bronchopleural Fistula (13). Ann Thorac Surg 2005;79:284-288

RPF

Rest

Postoperative results	Group A	Group B
Perioperative mortality	1 (3.4%)	2 (5.8%).
Mean operative time	190± 30 min. (lo- bectomies)	180± 25min.(lobec- tomies)
	160± 20 min. (pneumonectomies)	150±15 min. (pneumonectomies)
Bronchopleural fistula	0	4 (11.7%)
Supraventricular tachyarrhythmia	2 (6.8%)	1 (2.9%)

Table 3: Summary of postoperative results

## **Comment and Discussion**

The development of a BPF remains one of the most devastating complications that may arise after pneumonectomy. During the last decade, significant improvements in surgical technique, antibiotic usage, postoperative care, and adjuvant therapy have lead to a decrease in the incidence from 28% to about 2%.<sup>(1)</sup> However, this complication remains a major concern for thoracic surgeons because of its significant associated morbidity and mortality.<sup>(14)</sup>

A large number of publications have dealt with the problem of bronchial fistula after lobectomy or pneumonectomy, and many emphasized on the need for bronchial stump coverage especially in high risk patients <sup>(14)</sup>. Several years ago, experience with routine coverage of the postresection bronchial stump with various tissues was reviewed <sup>(15)</sup>. No consensus has been reached on the ideal material to use including pleura, azygos vein, intercostal muscle, pericardial fat pad, and pericardial flaps.

In the last years we concentrated on adequate closure of the bronchial stump after pulmonary resections in all patients we operated, but with the increase of our personal experience with bronchopleural fistula after lobectomy or pneumonectomy we began to re-enforce the bronchial stump in all cases, as avoidance of this problem is always better than its treatment. Since then, our preferred technique for bronchial stump coverage has been the routine use of a pedicled pericardial flap and the purpose of this paper is now to review the results achieved with this particular technique in a much larger group of patients.

The potential side effects that can be expected from such a procedure are arrhythmias in the postoperative period, spread of infection to the pericardium, and cardiac tamponade in case of tight reconstruction<sup>(16)</sup> In this series, these specific complications occurred at a low rate. The incidence of postoperative supraventricular tachyarrhythmia occurred in 2 patients (6.8%) of Group A and in one patient of Group B

(2.9%) with no statistically significant difference which was within the range described in literature.

All cases were successfully managed pharmacologically in both groups. No patient in Group A showed signs of pericarditis and in all these patients, the resulting defect in the pericardium was not reconstructed to avoid cardiac tamponade.

Most bronchial stump fistulas are usually preceded by an air leak and occur early after lung surgery. The average length until BPF development has been reported as 15 to 30 days post-operatively .In our study Group A, no case of bronchopleural fistula occurred during the entire outpatient follow-up period. While in Group B bronchopleural fistula occurred in 4 patients (11.7%). This difference was of statistical significance (P value < 0.05).

### Conclusion

According to our experience bronchial stump reinforcement should be routinely performed in all patients who are undergoing a lobectomy or pneumonectomy. This technique is proved to be feasible, safe and effective; also it does not increase much operative time.

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# Carcinoid tumors of the lung. Surgery of no predetermined plan

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Carcinoid tumors of the lung are an uncommon group of neoplasms of neuroendocrine origin and account for 1% of all primary tumors of the lung. Total resection should be the primary goal of any form of surgical therapy. Lymph node dissection should accompany resection. While the most commonly used procedures are formal lobectomy, segmentectomy, or pneumonectomy, a variety of parenchymal-sparing bronchoplastic procedures, including sleeve resections, has been utilized with good long-term results. Patients with marginal pulmonary reserve may be good candidates for complete resection and cure if a bronchoplastic or parenchymal-sparing procedure can be performed Aim of this study is to highlight results of different surgical techniques for the management of typical and atypical bronchial carcinoids at different sites. We have retrospectively reviewed the hospital records of 37 consecutive patients who underwent surgical treatment for carcinoid tumors of the lung between 2001 and 2013 admitted to Alexandria University Hospitals in Egypt. The surgical technique used was according to site of the neoplasm. The patient group comprised 37 patients 20 females and 17 males, (mean age  $56 \pm 11$  years, range 21-76, Right lower lobes were the most affected, lobectomy was performed in 20 cases, pneumonectomy in 5 cases, bronchotomy and excision in 10 cases.Survival of carcinoid tumors was favorable. Surgery remains a mainstay for the treatment of both types of carcinoids.

# <u>KEY WORDS</u>: Carcinoid, pulmonary, lung cancer, neuroendocrine tumor, typical carcinoid, atypical carcinoid, Surgery

ronchial carcinoid tumors are an uncommon group of pulmonary neoplasms that are characterized by neuroendocrine differentiation and relatively indolent clinical behavior. Although originally referred to as bronchial adenomas, these tumors are now recognized as malignant neoplasms because of their potential to metastasize. The

2004 World Health Organization (WHO) classification recognizes 4 major types of lung neuroendocrine tumors (NETs): typical carcinoid (TC), atypical carcinoid (AC), large cell neuroendocrine carcinoma (LCNEC), and small cell lung cancer (SCLC). These tumors are further grouped in a 3- tiered grading system as low grade (TC), intermediate grade (AC), and high grade (LCNEC and SCLC) NETs.<sup>(1)</sup>

The Lung is a common site of carcinoid tumors, which account for 30% of welldifferentiated NETs in the body. Lung is second only to tubular gastrointestinal tract and is more common than pancreas in incidence of well differentiated NETs. Carcinoid tumors were first described in the gut by Oberndorfer in 1907. <sup>(2)</sup> Thorson et al subsequently explained carcinoid syndrome as the constellation of flushing, fainting, diarrhea, bronchospasm, right heart valvular disease in patients with carcinoid tumors. <sup>(3,4)</sup> Most carcinoids are indolent tumors that typically follow a benign course. More aggressive subtypes may develop local or distant metastases. However, these metastases generally have a more favorable prognosis than carcinomas. Carcinoid tumors of pulmonary origin were first described by Hamperl in 1937. <sup>(5)</sup> Pulmonary carcinoids comprise 10% to 33% of all carcinoid tumors, and, unlike their nonpulmonary counterparts, they rarely produce carcinoid syndrome. <sup>(6)</sup>

The clinical presentation of patients with bronchopulmonary carcinoid is variable. Airway obstruction, hemoptysis, and pneumonitis are the most common presenting

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Codex : o4/02/1311

signs in the pediatric age group, <sup>(7)</sup> while adults most frequently present with pneumonitis, hemoptysis, and cough. Less common symptoms are weakness, nausea, weight loss, chest pain, and carcinoid syndrome.

Careful preoperative evaluation of patients with suspected bronchopulmonary carcinoid is crucial for accurate staging and surgical treatment planning. In asymptomatic patients (up to 65%), plain Chest X-ray is first-line investigation. It provides the earliest indication of thoracic neoplasm. The characteristic plain radiographic feature of carcinoids is that of a solitary, well-demarcated radiopaque mass. The lesion is typically round or oval and may occur in any lung field, with or without associated atelectasis. Central endoluminal tumors may be very subtle on plain chest radiography and require careful inspection of the tracheobronchial air column for evidence of airway tumor. Approximately 4% of tumors show radiographic evidence of calcification. <sup>(8)</sup> Computerized tomography (CT) can provide information about tumor proximity to lobar bronchi and the presence of mediastinal lymphadenopathy that is important for precise surgical planning.<sup>(9)</sup> Recently, positron emission tomography (PET) has been a useful tool for evaluating radiographically indeterminate pulmonary nodules and screening for distant metastases. (10)

Biopsy remains the diagnostic procedure for the diagnosis which is done via CT guidance, fiberoptic or rigid bronchoscopy with additional confirmation of the site of the tumor. Easy bleeding on touch is a diagnostic sign for carcinoid tumors. All patients with suspected bronchopulmonary carcinoid should undergo diagnostic flexible bronchoscopy by the attending surgeon. In addition to obtaining diagnostic tissue, bronchoscopy provides valuable anatomic and spatial information that is critical for precise operative planning.

### Aim of The Work

This study was undertaken to highlight different surgical techniques for the management of carcinoid tumor of the lung at different sites.

## **Patients and Methods**

This study is a retrospective cross sectional study, done in Alexandria University hospitals, Department of Cardiothoracic Surgery in Alexandria, Egypt.

We included 37 patients diagnosed with operable pulmonary carcinoid tumors who presented to Alexandria University Hospitals during the period 2001 to 2013. We excluded patients who were unfit for general anesthesia, All patients after obtaining written consents were taken for the surgery and included in the study. We excluded the results of participants who refused to be included in our study. Recorded variables included age, sex, smoking history, environmental exposure, family history of lung cancer or carcinoid, presenting signs and symptoms, radiologic tests, diagnostic laboratory tests, treatment (surgical, chemotherapy, or radiation) and detailed pathologic description.

**Preoperative Evaluation:** recorded data about history taking, and complete physical examination that were done for all patients. Plain Chest radiographs as well as Computerized tomography were done for all cases. We did Rigid and fiberoptic bronchoscopy for the diagnosis of the site, the extent of the tumor as well as biopsy taking. Pathologic confirmation of bronchial carcinoid was based on routine light microscope sections, argyrophilic staining techniques (Grimelius) and the demonstration of neurosecretory granules by transmission electron microscopy in selective cases. In Our sample Chest CT findings were a single nodule with well-defined, round or ovoid boarder. Sometimes were lobulated. Usually 2-5 cm in size and may contain calcifications (eccentric mostly) (Figure 1,2).

**Surgical technique:** The operative procedure performed were as follows: Pneumonectomy, 5; lobectomy, 20; segmental resection, 2; bronchotomy and excision with safety margin 9, combined bronchotomy and lobectomy in one patient.

Our follow up protocol included CT Chest scan in immediate postoperative period, another scan after 1 month, 3 Months, then after 6 months. Recurrent cases were referred for laser ablation. No long term follow up records were available.

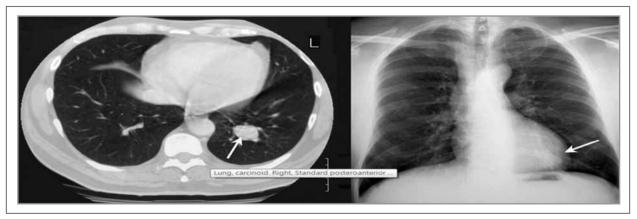


Fig. 1: Plain Chest X-ray and High resolution CT scans (lung window) shows a well-defined round, partially endobronchial nodule (arrow) in the lateral subsegmental branch of the anterior segmental bronchus of the left upper lobe. (c) On a contrast-enhanced CT scan (mediastinal window) the nodule (arrow) demonstrates marked contrast enhancement and mimics a vascular structure



Fig. 2: Bronchoscopic appearance of Bronchial carcinoid

Statistical Analysis: After data collection, the results were tabulated as frequency distribution for different qualitative and quantitative values, it was assessed with SPSS 22.0 (IBM Inc., Chicago, IL). The statistical analyses was carried out using t-test for independent samples and  $\chi^2$ -test.

## Results

Our sample of 37 consecutive patients operated for bronchopulmonary carcinoids had a mean age  $56 \pm 11$  years (range 21-76), 20 females and 17 males were included in our study. No statistical significance between gender and histopathological type. The most common presentations were dyspnea, cough and hemoptysis. The presenting signs and symptoms and diagnostic laboratory tests are shown in tables 1 and 2. The radiologic evaluation and method of diagnosis are shown in tables 3 and 4.

Univariate analysis found no significant association of survival with the patient's age, smoking history, family history of lung carcinoid, reported environmental exposure or hemoptysis. However, there was improved survival for female sex, asymptomatic presentation, lack of systemic symptoms (weight loss, anorexia, bone pain, generalized weakiness, or neurologic changes), normal serum serotonin or urinary

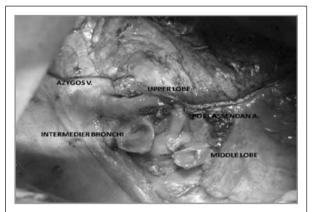


Fig. 3: relation of the Right lower lobe to the Azygos Vein

hydroxyindoleacetic acid, peripheral location of the primary tumor, pathologic stage I or II, primary tumor less than 3 cm in diameter, histologically negative lymph nodes, and typical histology.

Lobectomy was done in twenty cases, the most common site of the tumor was the right lower lobe (21.6%) followed by the right upper lobes and left lower lobes (13.5% each), left upper lobes were the least affected (5.26%). Segmental resection was done in two cases with right upper lobar tumors. Pneumonectomy was done is Five cases, Right pneumonectomy was done in three cases. Completion pneumonectomy was done in three patients who developed recurrence at the site of resection, two on the right and one on the left. We had no cases who underwent sleeve resection. Bronchotomy and excision of endoluminal tumors with safety margin was done in 24.3% of our cases with no cases of recurrence. Right main bronchotomy was done in seven cases. We used combined approach in one case where Bronchotomy along with left lower lobectomy. (Table 5)

We also found a statistical significance for tumors arising at the RLL which might raise the possibility of the relation of these tumors to the course of the Azygos vein. (Figure 3)

Symptom	Number of patients	Percentage
Nonproductive cough	11	29.7%
Productive cough	14	37.8%
Hemoptysis	12	32,4%
Weight loss	9	24.3%
Dyspnea	8	21.6%
Chest pain	7	18.9%
Sweating/flushing	5	13.5%
Diarrhea	4	10.8%
Bone pain	1	2.7%
Asymptomatic	16	43.2%

Table 1: Percent Distribution of the presenting symptoms in patients with bronchial carcinoid tumors (Data are not mutually exclusive).

Test	Number of patients	<b>Elevated/Total</b>
Liver enzymes (ALT, AST)	30	4/30
Urine hydroxyindoleacetic acid, and Serotonin	15	4/15
Serum serotonin	12	4/12

Table 2: Laboratory tests

Radiologic procedure	Number of patients	Positive/Total
Chest radiography	37	36/37
Chest CT	35	35
Bone scan	5	1/5

Table 3: Radiological procedures

Procedure	Number of patients	Positive/Total
Bronchoscopy	37	
Bronchial brush/washing	16	3/16
Bronchial biopsy	12	7/12
Transthoracic needle biopsy	10	7/10
Thoracotomy	20	20/20

#### Table 4: Diagnostic methods

	Site of The Tumor	No. of patients (%)
Segmental resection	Upper Lobe	2 (5.26%)
	RUL	5 (13.5%)
Labortomy	RLL	8 (21.6%)
Lobectomy	LUL	2 (5.26%)
	LLL	5 (13.5%)
D	RP	3 (8.1%)
Pneumonectomy	LP	2 (5.26%)
	Right main bronchotomy	7 (18.92%)
Bronchotomy and excision with safety margin	Left main bronchotomy	2 (5.26%)
Combined Approaches	Bronchotomy and left lower lobectomy	1 (2.7%)
	TOTAL	37 (100%)

Table 5: Percent distribution of cases according to Surgery performed

## Discussion

Carcinoid tumors have an incidence of 1% to 2%. In some series, this incidence is higher in the male population (2:1), while in other series it is higher among females (3:2). <sup>(11)</sup> In our series, we found no significant differences in distribution by sex (54% females and 45.9% males). The age of presentation is quite variable. In our series, the mean age was  $56 \pm 11$  years—similar to that of other series—and the range was from 21 to 76 years. <sup>(12)</sup> Some authors report that the emergence of carcinoid tumor occurs, on average, about 10 years before the emergence of bronchial carcinoma. Only 12 cases were reported in childhood in the literature. <sup>(13)</sup>

Preoperative fiberoptic or rigid bronchoscopy performed on all of the patients found lesions in 80% of the cases. Domingo et al, <sup>(14)</sup> have asserted that the macroscopic image of the lesion

often suggests the diagnosis, although they support needle aspiration of the lesion because it has a diagnostic yield of 80%.

Carcinoid syndrome, defined as the presence of facial flushing, hypertensive crisis, or diarrhea is described in 6.7% to 10% of cases. Its emergence is more common in carcinoids restricted to the intestine, in which the presence of liver metastasis is necessary to confirm diagnosis. Liver metastasis is not a requisite in the case of bronchial carcinoids, however. Moertel et al, <sup>(15)</sup> in a series of 209 patients, found carcinoid syndrome in 6.7%, a figure that rose to 15% when metastasis was present. In our series, 5 patients had carcinoid syndrome (13.5%)

Some studies report that carcinoid tumors are located in the left hemithorax in up to 75% of the cases. <sup>(16)</sup> In our series, the lower right lobe of the right hemithorax was the most common location.

Lead Author	Year	Number of Patients	тс	AC	LCNEO
Okike[2]	1976	203	94%	57%	
Rea(15)	1989	60	93%	66%	
Dresler[48]	1997	40			13%
Perkins[29]	1997	79	79%	39%	
Ducrocq[24]	1998	139	92%		
Travis[6]	1998	200	87%	56%	27%
Carretta[31]	2000	44	93%		
Beasley[23]	2000	106		61%	
Garcia-Yuste[49]	2000	326	96%	72%	21%
Fink[18]	2001	142	89%	75%	
Filosso[50]	2002	126	97%	77%	
yoda[13]	2002	133	100%	90%	32%
Takei[10]	2002	87			57%
Skuladottir[17]	2002	347	87%	44%	15%
Divisi[14]	2005	42	96%	68%	
Asamura[27]	2006	383	96%	78%	40%
AC = atypical carcinoi	d; LCNEC =	large-cell neuroend	ocrine carcine	oma; TC = typ	cical carcinoi

			Stag	e	
Histology	Series	1		m	IV
AC	Beasley[23]	71%	46%	37%*	37%
LCNEC	Dresler[48]	18%			
	Takei[10]	67%	75%	45%	0%

 Table 6. Review of literature discussing five year survival rates

 in neuroendocrine neoplasms of the lung

Jamal et al, <sup>(12)</sup> observed that 16% of the patients with carcinoid tumor had nodal involvement; this percentage increased to 28% for atypical carcinoids. Other studies have found mediastinal lymph node involvement in up to 30% to 50% of the cases of atypical carcinoids.

The clinical significance of lymph-node involvement in typical carcinoid tumors is still a matter of debate. <sup>(17)</sup> This might be because the use of sublobar resections and the lack of systemic nodal dissection in some studies can prejudice its correct assessment. Some authors preferred lesser resection, such as sublobar resections, due to their excellent results with good long-term survival and extremely low recurrence rates. <sup>(18,19)</sup> Others granted the importance of systemic lymphadenectomy, although they recommended lung-sparing surgery. <sup>(19,20)</sup> Typical carcinoids are generally considered as tumors associated with a fairly benign behavior and therefore they are often treated with relatively conservative surgical approach. Furthermore, the importance of long-term clinical follow-up is also likely to be underestimated. In our study, there were no patients with mediastinal lymph-node involvement and follow-up period

was relatively short; however, studies found no significant correlation between nodal involvement and carcinoid related mortality, a finding consistent with reports from Froudarakis et al, <sup>(21)</sup> that the prognosis was no worse for patients with nodal involvement. They also found no relation between nodal involvement and the type of tumor.

According to the WHO classification of lung tumors, (22) neuroendocrine proliferation can be divided into a spectrum of lesions ranging from neuroendocrine cell hyperplasia to tumor lets and carcinoid tumors. When pulmonary neuroendocrine cells extend beyond the basement membrane, this proliferation is identified as a tumorlet, which is by definition a nodular proliferation of neuroendocrine cells constituting a nodule <5 mm.<sup>(23)</sup> However, the real significance of tumorlets is not completely understood and it is still controversial whether they may represent an early stage of typical carcinoid. Furthermore, their small dimensions reportedly resulted in underestimation of their real incidence, because appropriate serial sections were not performed during examination of the surgical specimen. <sup>(24)</sup> Ferolla et al. <sup>(25)</sup> reported that the possibility that tumorlets were found in the resected specimen became approximately three times when palpation and serial sections of the surgical were performed systematically. Likewise, specimens multicentric carcinoid lesions have been reported, but their real incidence and prevalence remain to be assessed

To date, two studies have reported that there were multiple lesions in approximately 10% of the patients with carcinoid tumors.<sup>(24,25)</sup> Interestingly enough, one study stated that multicentric lesions demonstrated poor prognosis.<sup>(24)</sup> In some series, up to 30% of cases involve the presence of distant metastasis, mainly in cases located in the colon, small intestine, or bones. In atypical carcinoid tumors, cases with cerebral and thyroid involvement have been described. <sup>(26)</sup> In our series, 8% of the cases (n=5) had distant metastasis

The surgical treatment of central bronchopulmonary carcinoids may present a complex and challenging problem. The technique of resection should be based on combined radiographic, endoscopic, and intraoperative findings. Due to the common presentation of typical carcinoid tumors in the central airways, Pneumonectomy is often considered necessary for complete surgical resection by surgeons not familiar with or proficient in bronchoplastic surgery. (11) Although Pneumonectomy is occasionally necessary, in experienced hands, it is avoidable in the vast majority of endobronchial carcinoid tumors. This difference is paramount in the care of patients with central carcinoid tumors. These patients are frequently young, otherwise healthy individuals who have the tragic and avoidable consequences of pneumonectomy, including increased mortality, postpneumonectomy bronchopleural fistula and empyema, and a lifelong decrease in lung function and pulmonary reserve. Endobronchial coreout or laser debulking of obstructing endobronchial tumors can reestablish distal airway patency and facilitate resolution of postobstructive pneumonia and subsequent parenchymasparing resection. Parenchymal preservation is generally feasible when careful operative planning and well-executed bronchoplastic techniques are used. Mediastinal lymph node sampling should also be performed in these patients, but the role of this procedure in TCs is somewhat controversial. For obstructive lesions, an endobronchial laser resection can provide palliation, although this should not be used definitively, as most lesions spread extraluminally and adequate margins would not be attainable using this approach.<sup>(27)</sup>

Surgery remains a mainstay for the treatment of both types of carcinoids, but the extent of surgical resection tends to be less for typical carcinoids due to their pathological features and predilection for the central bronchial trees. Complete surgical resection remains the most effective treatment of bronchopulmonary carcinoids. The technique of resection is determined by tumor size, location, and relationship to adjacent structures. Because these tumors are generally slow growing, localized malignancies, parenchymal sparing procedures are preferred over more extensive operations. The most common surgical treatment was lobectomy. Segmentectomy was considered valid for high risk surgical patients with a small tumor located in the periphery of the lung parenchyma and without mediastinal or hilar lymph node involvement because segmental resection fails to remove local lymphatic channels and intrapulmonary (N1) lymph nodes, lobectomy should be performed in all cases of atypical carcinoid. Typical carcinoids may be amenable to less extensive procedures due to the low propensity for lymph node or distant metastases. Authors such as El Jamal et al, (12) citing the slow growth of carcinoid tumors,(28) have argued in favor of conservative resection regardless of the tumor type; on the other hand, others favor routine excision of the lobe or lung and the area around the lymph nodes.<sup>(29-31)</sup>

Endoscopic resection of endobronchial tumors has been described, although recurrence—later requiring excision according to usual practice—has been observed after this procedure. <sup>(12)</sup> For this reason, most authors reserve this treatment for patients ineligible for surgery. <sup>(32)</sup>

Long-term results vary in the literature (table 6): Todd and colleagues (33) in a study conducted in 65 patients with carcinoid tumors, reported a survival rate of only 65% at 5 years, whereas Stamatis et al, (34) in 210 patients with typical carcinoids, reported 5-year and 10-year survival rates of 98% and 95%, respectively. The 10-year survival in our atypical group is similar to that reported by Okike et al, (35) which reached 57%. We have reviewed a series of 640 cases the literature in the last 20 years (1984 to 2000) with sufficient data. Mean age is 52 years, and the male to female ratio is 1.1 in favor of the female patients. Location in most series is central (64%), and typical carcinoid is reported in 81% of cases. Lobectomy was sufficient in 42 to 69% of cases, and pneumonectomy was performed in 6 to 16% of cases. As seen, prognosis is excellent in most series, and survival is approximately 88% at 5 years and 81% at 10 years. (36)

A study conducted by Ducrocq (37) examined factors determining long-term survival after resection of typical carcinoid tumors. It failed to demonstrate any prognostic significance for sex, tumor size (T1 versus T2), tumor location (central versus peripheral), and type of resection. The study confirms a good prognosis after complete resection of typical carcinoid tumors, including those with lymph node metastasis. Parenchyma-saving resections should be preferred for a typical carcinoid tumor. Patients who have an atypical carcinoid tumor with a consequent higher rate of nodal involvement should receive a radical surgery. (37) Published in 2010, a retrospective study of 126 patients treated surgically for a carcinoid tumor showed that the survival at 10 years was 79.8%. The main prognostic factors are histology (with a significantly higher survival for typical carcinoid tumors), lymph node, and metastasis. (38) In 2007, in another study of 661 patients treated surgically for a carcinoid tumor, the overall five-year survival was 97% for typical carcinoid tumors (100% for those with nodal involvement, but no significant difference) and 78% for atypical carcinoid tumors (60% with positive lymph nodes, with a statistically significant difference). The histology and lymph node involvement were the main prognostic factors for these patients. Lymph node dissection during surgery is important.<sup>(39)</sup> Endobronchial removal should be reserved for much selected typical carcinoid tumor with endobronchial structures without an extension through the cartilaginous area.<sup>(40)</sup>

Although typical carcinoid tumors generally have benign characteristics, their malignant features, such as nodal involvements, multiple forms, and recurrences after resection should be kept in mind to deal with this entity of tumors appropriately. Furthermore, effective chemotherapy and/or radiotherapy for carcinoid tumors are not expected. At this point, in bronchopulmonary typical carcinoid tumors, major surgical resection should be necessary.

There are several limitations in this retrospective study. The largest limitation is the relatively small size of the study in number and the difficulty of reaching some of the record details. Larger-scale prospective study with multiple institutions is absolutely needed.

## Conclusions

Complete tumor resection with preservation of uninvolved pulmonary parenchyma remains the fundamental goal in the surgical treatment of this unusual clinical entity. Current practice of pulmonary resection of bronchopulmonary typical carcinoid tumors in our institution was seemingly justified although there were one case of recurrent carcinoid tumors and another case of multicentric carcinoids in the resected specimen. Our results supported the idea that bronchopulmonary typical carcinoids might require major surgical procedures and that complete pulmonary resection of such tumors could expect long-term survival. Furthermore, a careful search for multifocal lesions and a careful follow-up should always be performed.

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- 41. RUL: right upper lobectomy; LUL: left upper lobectomy; RLL: right lower lobectomy; RML: right middle lobectomy.

# **Comparative Study between Surgical Fixation and Conservative Management of Flail Chest Injuries**

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<u>Objectives:</u> The objective of this study was to compare the short-term outcome of internal fixation of flail chest with the conservative non-surgical treatment.

Methods: This was a non-randomised trial carried out on 34 patients admitted to cardiothoracic surgery department at Menofia University Hospitals with traumatic flail chest between May 2011 and May 2013. The patients were divided into two groups; group A: was managed by conservative treatment using analgesia, endo-tracheal intubation and mechanical ventilation when needed, and group B: was managed by internal fixation of the ribs under general anaesthesia using plates and/or stainless steel wires.

<u>Results:</u> The average number of days of mechanical ventilation was significantly less in the surgically managed group (average 3.6 days) than the conservatively managed group (average 8.64 days) (p=0.014) with the complications of mechanical ventilation significantly higher in the conservatively managed group (p=0.018). The average number of days spent in intensive care unit was significantly more in group A (average 8 days) than in group B (average 3.4 days) (p=0.048). Also, the total number of days spent in the hospital was significantly more in group A (average 13.9 days) than in group B (average 8.2 days) (p=0.032). In group A, 62%of patients had significant deformity on discharge from the hospital whereas in group B only 8% of patients had significant deformity, with the difference being statistically highly significant (p=0.002). There was no statistically significant difference between both groups regarding the mortality rate (14% in group A and 8% in group B, p=0.562).

<u>Conclusion</u>: Surgical management of flail chest is associated with improved outcome in the form of reduced length of mechanical ventilation, length of stay in the ICU, pain and deformity. That all was reflected on the overall length of hospital stay and cost and postoperative recovery.

#### KEYWORDS: Flail chest, Chest trauma, Rib Fixation

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lail chest injury is a condition resulting from high-energy trauma to the chest causing multiple rib fractures with segmental chest wall instability and leading to significant morbidity and mortality [1, 2]. It occurs in approximately 10% of patients with chest trauma and its presence alone carries an associated mortality rate of 10%-15% [2].

The standard of care of flail chest in most institutions has been selected ventilatory support and tracheostomy when indicated, aiming at 'internal splinting' of the flail segment to prevent paradoxical movement and hence improve gas exchange [3, 4]. However, this technique required prolonged time on the ventilator, resulting in secondary chest infections and persistently high mortality rates of 10-36% in some series [5, 6]. Additionally, positive pressure ventilation is not always able to reduce and stabilise the bony injury, resulting in painful fracture non-union or symptomatic chest wall deformity in 64% of patients in one study [6].

Several authors have reported excellent results using open reduction and internal fixation to manage flail chest injuries [7-10]. These reports suggest that the pulmonary improvement resulting from this technique shortens the duration of intubation, decreases ICU Length of stay, lowers the incidence of pneumonia, improves pulmonary function

Thoracic

testing, restores chest wall continuity, and allows patients to return to work more quickly [7-10]. However, this technique is still considered under-used [11].

The objective of this study was to compare the short-term outcome of internal fixation of flail chest with the conservative non-surgical treatment.

## **Patients and Methods**

This was a non-randomised trial carried out on 34 patients admitted to cardiothoracic surgery department at Menofia University Hospitals through the accident and emergency department with traumatic flail chest between May 2011 and May 2013.

On admission all patient underwent primary and secondary survey and resuscitation with full history taking and clinical examinations. All patients had plain chest radiogram on admission and most of them had computed tomography of the chest as well. Additional investigations were done depending on the suspected associated injuries. The selection of mode of treatment depended mainly on the surgeon preferences, the severity of injury and the suitability of patients to undergo general anaesthesia.

The patients were divided into two groups; (group A) was managed by conservative treatment using analgesia, endotracheal intubation and mechanical ventilation when needed. Tracheostomy was done on all patients who needed mechanical ventilation for more than seven days. The other group (group B) was managed by internal fixation of the ribs under general anaesthesia using plates and/or stainless steel wires.

The outcome of treatment in both groups including; complications, mortality, need of mechanical ventilation and tracheostomy, duration of intensive care unit and hospital stay, was compared and statistically analysed.

#### Results

This study included thirty-four patients 29 males and five females. Twenty-one patients was treated conservatively (Group A) while thirteen patients was surgically managed with internal fixation of the ribs (Group B).

#### 1-Epidemiology

There was no statistically significant difference regarding the age between Group A (mean age was 48.0 years) and Group B (mean age was 45.8 years). Males constitute the majority in both groups (86% of Group A and 85% of Group B) with no statistically significant difference between the two groups.

There was no statistically significant difference between both groups regarding; the weight, the height and the body mass index.

Also there was no statistically significant difference between both groups regarding smoking history and history of chronic chest problems (COPD and Asthma). History of Diabetes Mellitus, Hypertension, Ischaemic heart disease, and liver Impairment showed no statistically significant difference between both groups.

#### 2-Trauma

The main cause of trauma was road traffic accident in both groups. It was the cause of trauma in fifteen patients in Group A (71%) and eight patients in Group B (62%). Other causes of trauma was hitting by heavy object or fall from height. There was no statistically significant difference between both groups regarding the cause of trauma.

There was no statistically significant difference between both groups regarding the side, the site or the number of rib fractured. The site of fracture was anterolateral in nearly half of the patients in either group (48% in group A and 46% in group B). The average number of fractured ribs was 6.1 and 6.2 in group A and group B consecutively.

There was no statistically significant difference between both groups regarding associated chest injuries (e.g. presence of haemothorax, pneumothorax or lung contusion), or other associated injuries (e.g. abdominal visceral injuries, neurological injuries or other skeletal injuries).

#### **3- Management and Outcome:**

Although almost half of the patients in each group (52% in group A and 54% in group B) needed mechanical ventilation, the number of days of mechanical ventilation was significantly less in the surgically managed group (average 3.6 days) than the conservatively managed group (average 8.64 days). The complications of mechanical ventilation were significantly higher in the conservatively managed group.

Three patients in group A and none in group B needed tracheostomy, with no statistically significant difference between both groups regarding the need for tracheostomy.

The number of days spent in intensive care unit was significantly more in group A (average 8 days) than in group B (average 3.4 days). Also, the total number of days spent in the hospital was significantly more in group A (average 13.9 days) than in group B (average 8.2 days).

The pain was significantly better controlled (as measured by the average analogue pain score) in group B (average analogue pain score 4.5) than in group A (average analogue pain score 6.1).

In group A, 62% of patients had significant deformity on discharge from the hospital whereas in group B only 8% of patients had significant deformity, with the difference being statistically highly significant (p-value=0.002). There was no statistically significant difference between both groups regarding the mortality rate (14% in group A and 8% in group B).

	Group A	Group B	P value
Number of patients	21	13	
Sex			0.930
Male	18 (86%)	11 (85%)	
Female	3 (14%)	2 (15%)	
Age (years) (mean ± SD)	$48.0 \pm 15.7$	$45.8 \pm 17.4$	0.717
Weight (kg) (mean ± SD)	$85.3 \pm 14.0$	$82.0 \pm 10.4$	0.471
Height (metres) (mean $\pm$ SD)	$1.73 \pm 0.10$	$1.70 \pm 0.10$	0.175
BMI (mean ± SD)	$28.8 \pm 5.5$	$29.2 \pm 4.6$	0.814
Smoking			0.407
Current Smoker	14 (67%)	8 (62%)	
Ex-Smoker	4 (19%)	1 (8%)	
Non Smoker	3 (14%)	4 (31%)	
Previous chest disease			0.367
None	16 (76%)	8 (62%)	
COPD	5 (24%)	4 (31%)	
Asthma	0 (0%)	1 (8%)	
Other past history			0.876
None	11 (52%)	7 (54%)	
Diabetes Mellitus	4 (19%)	1 (8%)	
Hypertension	5 (24%)	3 (23%)	
Ischemic Heart Disease	2 (10%)	1 (8%)	
Liver Impairment	4 (19%)	4 (31%)	

## Table 1. Epidemiology

	Group A	Group B	P value
Mechanism of Trauma			0.735
RTA	15 (71%)	8 (62%)	
Hit by heavy object	2 (10%)	1 (8%)	
Fall from height	4 (19%)	4 (31%)	
Side of fractured rib			0.730
Right	10 (48%)	7 (54%)	
Left	9 (43%)	5 (38%)	
Both	2 (10%)	1 (8%)	
Number of fractured ribs (mean $\pm$ SD)	6.1±1.2	6.2±1.2	0.98
Site of fractured ribs			0.969
Anterolateral	10 (48%)	6 (46%)	
Posterolateral	3 (14%)	2 (15%)	
Anterior	2 (10%)	2 (15%)	
Lateral	3 (14%)	2 (15%)	
Anterior, lateral. Posterior	3 (14%)	1 (8%)	
Associated chest injuries			0.940
None	4 (19%)	3 (23%)	
Hemothorax	4 (19%)	3 (23%)	
Pneumothorax	3 (14%)	1 (8%)	
Hemopneumothorax	4 (19%)	2 (15%)	
Lung contusion	1 (5%)	0 (0%)	
Hemothorax & lung contusion	5 (24%)	4 (31%)	
Other associated injuries			0.999
None	8 (38%)	5 (38%)	
Liver	2 (10%)	1 (8%)	
Spleen	2 (10%)	1 (8%)	
Subdural hemorrhage	1 (5%)	1 (8%)	
Vertebral injury	2 (10%)	1 (8%)	
Fracture Pelvis	1 (5%)	1 (8%)	
Fracture femur	2 (10%)	1 (8%)	
Fracture leg bones	1 (5%)	1 (8%)	
Fracture humerous	1 (5%)	0 (0%)	
Fracture clavicle	1 (5%)	1 (8%)	

Table 2: Trauma

	Group A	Group B	P value
Need for Mechanical ventilation (MV)	11 (52%)	7 (54%)	0.934
Duration of MV (days) (mean ± SD)	8.64±4.7	3.6±1.5	0.014
Complications of MV			0.018
None	2 (18%)	6 (86%)	
Chest infection	7 (64%)	1 (14%)	
ARDS	2 (18%)	0 (0%)	
Need for tracheostomy	3 (14%)	0 (0%)	0.154
ICU stay (days) (mean ± SD)	8.05±7.9	3.4±2.7	0.048
Average analogue pain score (mean $\pm$ SD)	6.05±1.8	4.5±2.1	0.033
Hospital stay (days) (mean ± SD)	13.9±8.8	8.2±2.9	0.032
Return to work (weeks) (mean $\pm$ SD)	5.86±3.6	3.5±1.0	0.032
Deformity	13 (62%)	1 (8%)	0.002
Mortality	3 (14%)	1 (8%)	0.562

Table 3: Management and Outcome

## Discussion

The treatment of flail chest injuries has evolved over the last decades from immediate endotracheal intubation with or without tracheostomy until there was no movement of the flail segment, to the present when every effort is made to provide good analgesia and avoid intubation. Some have advocated operative fixation of a flail segment so that there is no motion.

In our study almost half of the patients in each group (52% in group A and 54% in group B) needed mechanical ventilation, however, the number of days of mechanical ventilation was significantly less in the surgically managed group (average 3.6 days) than the conservatively managed group (average 8.64 days). There was statistically significant difference between both groups regarding the complications of mechanical ventilation.

These results are in accordance with a study done by Z. Ahmed and Z. Mohyuddin in which 21 of 26 patients with flail chest treated with internal fixation were weaned from the ventilator in an average of 1.3 days [8]. The nonoperative group in the same study was managed by endotracheal intubation and ventilation alone and spent an average of 15 days on the ventilator [8]. Also Peter L. Althausen et al reported an average ventilator duration of 4.14 days of patients treated operatively and an average ventilator duration of 9.7 days in non-operatively managed patients, this was a statistically significant difference with a p-value of 0.007. Immediate post-operative extubation was possible in 18.2% of patients [12].

A study done by Nirula et al, demonstrated an average decrease of 6.5 day in ventilator duration in patients treated with operative stabilisation [13]. In a study by Lardinois et al, immediate postoperative extubation was possible in 47% of patients and median postoperative intubation was 2.1 days [14]. Voggenreiter et al determined that early chest wall stabilisation

within 48 hours permits extubation after a mean ventilator duration of 6.5 days [15].

In our study, three patients in group A and none of the patients in group B needed tracheostomy, with no statistically significant difference between both groups regarding the need for tracheostomy. Peter L. Althausen et al, reported in their cohort of operatively treated patients, 3 (13.64%) of 22 patients required tracheostomy, whereas 11 (39.29%) of 28 patients of the nonoperative cohort required tracheostomy. This was a statistically significant difference with a p-value of 0.042 [12]. In the study of Ahmed and Mohyuddin, 11% of operatively treated patients required tracheostomy, whereas 37% of non-operatively treated patients required it [8]. This is a clear advantage of operative fixation as it avoids this secondary surgical procedure with its complications.

In our study, there was a significant difference in the ICU length of stay between operatively and non-operatively treated groups; the ICU length of stay in non-operatively managed group was an average of 8 days, compared to the operatively managed group which was an average of 3.4 days. Also the total number of days spent in the hospital was significantly more in the non-operatively managed group (average 13.9 days) than the operatively managed group (average 8.2 days).

In the study done by Peter L. Althausen et al, there was a significant difference in the ICU length of stay between operatively and non-operatively treated patients. Operatively managed patients spent a mean of 7.6 days in the ICU, whereas non-operatively managed patients spent 9.7 days. This was statistically significant with a p-value of 0.018, decreasing the overall costs of treatment [12]. The average ICU length of stay in the study done by Ahmed and Mohyuddin was 9 days for operatively managed group and 21 days for non-operatively managed group [8]. In our study the pain was significantly better controlled (as measured by the average analogue pain score) in group B (average analogue pain score 4.5) than in group A (average analogue pain score 6.1). In a study done by Marc de Moya the need for analgesia was significantly reduced after rib fixation and was reflected on a significantly shorter ventilator period and ICU stay, lower incidence of pneumonia, better pulmonary function tests at one month, and a higher percentage returned to full employment at six months than the nonoperative group [16].

Our results showed that, 62% of non-operatively managed patients had significant deformity on discharge from the hospital whereas only 8% of operatively managed patients had significant deformity, with the difference being statistically highly significant (p=0.002). Ahmed and Mohyuddin demonstrated, fractured ribs treated conservatively undergo progressive displacement during the healing phase, which results in considerable deformity, volume loss, and atelectasis [8]. Thomas et al and Moore P, have independently reported that progressive chest wall collapse leading to ventilator insufficiency is particularly common with non-operatively managed postero-lateral flail injuries [17, 18]

Also Peter L. Althausen et al demonstrated long-term outcome studies of patients with flail chest injuries indicate that 50%-60% of patients develop long term morbidity, the most common problems being persistent chest wall pain or deformity [12]. Mayberry et al concluded that operative repair of severe chest wall injuries is associated with low long-term morbidity and pain, as well as health status equivalent to the general population [19]. In contrast, many studies have shown that patients treated conservatively develop chronic pain and disability and do not return to work or their pre-injury quality of life [19].

## Conclusion

Surgical management of flail chest is associated with improved outcome in the form of reduced length of mechanical ventilation, length of stay in the ICU, pain and deformity. That all was reflected on the overall length of hospital stay and cost and postoperative recovery.

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# Prospective randomized trial of intrapleural bleomycin versus cisplatin via pig tail in the palliative treatment of malignant pleural effusions

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<u>Background</u>: Malignant pleural effusions are a common complication of endstage malignancy, severely impairing quality of life. Most effusions do not respond to systemic chemotherapy, and the treatment is generally palliative.

<u>Objectives</u>: To compare intrapleural bleomycin and cisplatin administered through a small pore 14 French pig tail in the palliation of malignant pleural effusions.

<u>Patients and methods</u>: One hundred sixty patients with rapidly recurrent malignant pleural effusion were randomly assigned to intrapleural bleomycin (80 patients) or cisplain (80 patients administered through a small pore 14 French pig tail, and pleural effusion was completely drained before starting the treatment. Bleomycin 0.75 mg/kg was administered as a single dose. Cisplatin 25 mg was administered through a small pore 14 French pig tail, An additional dose was given if daily fluid output did not drop to less than 100 ml/day within 3 days. Thirty-day and long-term responses were evaluated under the intention-to-treat principle.

<u>Results:</u> In the bleomycin arm, 76 received a single dose of the drug, 4 received a further dose after 3 days, as daily fluid output remained higher than 100 ml . In cisplatin arm, 5 patients received another dose. Response rate was nearly equal in the bleomycin arm B with complete response of 40% and partial response of 43% and in cisplatin arm A, 12 patients had complete response and 45% of patients achieved partial response with an overall response rate of 80%. Median time to progression was 93 days in the bleomycin arm, and 90 days in the cisplatin arms, respectively.

<u>Conclusion</u>: Intrapleural bleomycin and cisplatin were an effective agent for the palliative management of massive, rapidly recurrent pleural effusions in patients with advanced neoplastic disease with acceptable toxicities the decision should thus be affected by the cost benifiet.

KEYWORDS: Bleomycin, cisplatin, palliation, malignant pleural effusion

alignant pleural effusions are common in patients with cancer, most frequently in cancer of the breasts or lungs and in lymphoma. In most malignancies, the presence of a malignant effusion portends a poor prognosis, with survival measured in months<sup>(1)</sup>.
 The effusions do not respond to systemic chemotherapy, and

the treatment is generally palliative. The treatment can be achieved by drainage of pleural fluid, but rapid return of the effusion often occurs. If life expectancy is not short, pleurodesis is the most recommended treatment<sup>(2,3)</sup>.

The complete drainage of pleural effusion by tube thoracostomy before instillation of sclerotic material is considered to play the main procedure in successful pleurodesis <sup>(2-4)</sup>.

Malignant pleural effusions are exudative and result from increased capillary permeability or impaired pleural resorption of normally produced pleural fluid due, typically, to pleural metastasis or lymphatic obstruction by tumor<sup>(5)</sup>. The pleural effusion is often associated with dyspnea, cough, and chest pain<sup>(6)</sup>. The majority of Malignant

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Codex : 04/04/1311

pleural effusions are symptomatic with 96% presenting with dyspnea and 56% having complaints of pleuritic chest pain<sup>(7,8)</sup>.

The malignant pleural effusion is a debilitating complication associated with numerous types of advanced oncologic diseases. In the United States, there are more than 150,000 new cases of Malignant Pleural Effusions each year. Two previous studies demonstrated the etiology to be lung cancer in 35 to 40% of patients and breast cancer in 23 to 26% of patients<sup>(2-4)</sup>.

The prognosis of patients with Malignant pleural effusions is poor, with the average survival time after diagnosis being 3 to 6 months<sup>(5)</sup>. Mortality is 54% at one month and 84% at 6 months<sup>(3,4)</sup>. Survival is slightly longer, averaging 9.6 months, in patients whose malignant effusion is the initial manifestation of cancer<sup>(9)</sup>.

Patients with breast cancer with Malignant pleural effusions commonly live for one year or more, but those with primary ovarian tumors have an expected survival of 9 months. MPEs associated with lung and gastric primary tumors have a shorter patient survival<sup>(10)</sup>.

Intrapleural treatment using hypotonic cisplatin solution (cisplatin solution diluted by distilled water) effectively controlled malignant pleural effusion. According to experimental data, hypotonic cisplatin solution demonstrated a significantly greater antitumour activity than either isotonic cisplatin or distilled water alone<sup>(11)</sup>.

Bleomycin is the most widely used antineoplastic agent for pleurodesis, and intrapleural instillation is usually well tolerated<sup>(12)</sup>.

This randomized study was planned to compare the palliative efficacy of intrapleural bleomycin and cisplatin after complete drainage of the effusion by a small-bore chest tube.

## PATIENTS AND METHODS

Patients were included who met the following criteria:

- 1. Age greater than 18.
- 2. Symptomatically,
- 3. histopathologically, or cytologically confirmed Malignant pleural effusions.
- 4. Total leucocytic count count more than 3000, hemoglobin more than 8 gm/dl, platelet count more than 100,000/mm<sup>3</sup>; serum creatinine less 1.8 mg/dl; total bilirubin within normal limits, transaminases (alanine aminotransferase and/or aspartate transaminase) up to 1.5 institutional upper limit of normal.
- 5. Negative serum or urine pregnancy test for women of childbearing age.

Patients characteristic	No of patients of bleomycin	No of patients of cisplatin	P value
Gender			
Male	50	55	0.405
Female	30	25	
Age			
Mean ±SD	61.5±5.5	61.3±2	0.915
Range	59 (55-68)	61 (58-64)	
Type of cancers			
Breast	25	23	
Lung	32	37	0.025
Renal	3	3	0.925
Ovarian	12	10	
Lymphoma	8	7	
Previous treatment			
Surgery	45	37	0 767
Chemotherapy	58	54	0.767
Radiotherapy	12	8	
Performance status ECOG			
PS0	0	0	
PSI	55	57	0.910
PSII	16	13	0.819
PSIII	9	10	
PSVI	0	0	

6. Informed consent.

Table (1). Patients characteristics

#### ECOG performance status. (14)

- 0: Fully active, able to carry on all pre-disease performance without restriction
- 1: Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2: Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 : Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
- 4 : Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
- 5: Dead

#### **Exclusion criteria**

They included prior ipsilateral pleurodesis, bilateral malignant pleural effusions, and a history of hypersensitivity reaction to both drugs.

#### **Treatment methods**

All procedures were done at the bedside under local anesthesia and without radiologic guidance. Salient technical aspects of pigtail catheter insertion include appropriate use of local anesthetic and needle insertion that barely "walks over" the top of the rib to avoid the intercostal bundle. We typically employ a small (22 gauge) "finder needle" before inserting the larger needle provided with the kit. Pleural fluid should be easily withdrawn with the needle, and passage of the guidewire into the pleural space should be virtually effortless. Development of an adequate tract with the dilator and insertion of the pigtail so that the sideholes are well within the pleural cavity are important for proper function. The pigtail catheter is attached to a standard thoracic drainage system and suction applied for pneumothoraces.

Pre- and post-placement radiographs were reviewed by a thoracic radiologist who determined effusion or pneumothorax volume before and after catheter placement. Therapeutic success was defined as freedom from a second intervention (repeat pigtail placement, tube thoracostomy, or operation) within 72 hours after removal of the pigtail catheter.

The 160 patients were randomized into 2 groups, Arm A for cisplatin and Arm B for bleomycin from Clinical Oncology Department and Cardiothoracic Department, Zagazig University. First, premedications, intramuscular injection of 15 mg of pentazocine and intrapleural administration of 10 ml of 1% lidocaine were performed. Thereafter, 25 mg of cisplatin in 500 ml of distilled water was instilled through a small pore 14 French pig tail. The hypotonic cisplatin solution was prepared as follows: 50 ml cisplatin solution containing 25 mg cisplatin

was injected into the bottle containing distilled water of 500 ml. The pig tail was clamped for one hour. The patients were then asked to change position (supine and bilateral decubital) for 15 minutes to each position time to time during the treatment regimen, and then the pig tail was declamped and allowed to drain under a negative pressure of 10-15 cmH<sub>2</sub>. An additional dose was given if daily fluid output did not drop to less than 100 ml/day within 3 days. Thirty-day and long-term responses were evaluated under the intention-to-treat principle.

When the drainage effusion was less than 100 ml a day, the pig tail was removed. Any patient whose drainage effusion continued for over 2 weeks was withdrawn from the trial versus bleomycin 0.75 mg/kg in 50 ml of normal saline. The response was assessed according to the criteria of **Paladine et al.**<sup>(13)</sup>:

- Complete response was defined as no re-accumulation of fluid.
- 2. Partial response, as asymptomatic fluid recurrence less than 50% of the original effusion, not requiring thoracentesis.
- 3. No response, as fluid recurrence greater than 50% of the original effusion, requiring thoracentesis.
- 4. Global response was defined as complete response plus partial response.
- 5. Treatment failure was defined as no response, plus deaths before 30 days, plus dropouts. Thirty-day responders were then sonographically monitored every 2 weeks until death or progression, defined as fluid recurrence requiring thoracenthesis.
- 6. Time to progression was defined as the time from the chest tube removal to the first posttreatment thoracentesis, or the death for patients not requiring thoracenthesis. The number of thoracenteses performed until death was recorded for all patients, including treatment failures.
- 7. The overall survival was defined as the time from enrolment until death from any cause.

A chest radiograph in responding patients was taken at least every month in order to monitor the condition of the controlled pleural effusion. The response and duration of response were determined by an extramural review committee.

Toxicities were evaluated according to ECOG common toxicities criteria<sup>(14)</sup>.

#### **Treatment coast**

The cisplatin dose coast was around 50 le while the coast of bleomycin is 128.5 le

### Statistical analysis

Data were collected and analyzed using Epi-Info 6 and SPSS (Statistical Package for the Social Sciences) version 19. Data were presented as mean  $\pm$  standard deviation (SD),

median, range for quantitative variables & number and percentage for qualitative variables. Comparison of variables between the two groups was performed by the Chi-square test and student's t test.

#### Level of significance

- P value of > 0.05 indicates non-significant results.
- P value of < 0.05 indicates significant results.

All statistical analyses were performed under the intention to-treat principle. Thirty-day response and long-term response in the two treatment arms were compared using  $\chi^2$  test. Time to progression and overall survival were analyzed using the Kaplan and Meyer non-parametric test, and the outcomes in the two groups were compared using the log-rank test. The median number of thoracentesis performed in the two treatment arms until patient death was compared using the non-parametric Mann-Whitney test.

## RESULTS

Eighty patients were assigned to the cisplatin arm A, and 80 were assigned to the bleomycin arm B. The two groups were well-matched for sex, age, type of tumor, and amount of pleural fluid drained before intrapleural treatment. Table 1 shows patient characteristics. In the bleomycin arm, 76 received a single dose of the drug, 4 received a further dose after 3 days, as daily fluid output remained higher than 100 ml. In cisplatin arm, 5 patients received another dose.

Response rate was nearly equal in the bleomycin (83%) arm B with CR of 40% and PR of 43% and in cisplatin (80%) arm A, 12 patients (35%) had CR and 45% of patients achieved PR with an overall response rate of 80% (95% confidence interval, 74-91%), with previous response we started treatment of chemotherapy according to type of cancer for systemic control (**Table 2 & Figure 1**).

In **Table 3, Figure 2**, Median time to progression was 93 days (range, 79 to 385 days) in the bleomycin arm, and 90 days (range, 74 to 347 days) in the cisplatin arm.

Median survival was 134 days (range, 107 to 393 days) and 121 days (range, 98 to 373 days) in the bleomycin and cisplatin arms, respectively.

Fifty-two patients in the bleomycin group and 39 in the cisplatin group did not require thoracentesis until death; 16 and 3, respectively, needed thoracentesis only in the last 2 weeks of life (p = 0.001). Toxicity was mild in both groups. In the bleomycin arm, self-limiting fever occurring within 12 hours of the drug administration was observed in 41 patients, vomiting was seen in 5 patients, and moderate chest pain treated with minor analgesics was present in 14 patients.

Neither the haematological toxicity of any grade nor of grade 4 non haematological toxicity was observed in all 160 eligible patients. Grade 3 non-haematological toxicities were observed, including nausea (4%), vomiting (3%), dyspnoea (1%) and empyema (**Table 4 & Figure 3**).

	Number	Percentage	Complete response	Partial response	P value
Bleomycin	66	83%	40	43	0.588
Cisplatin	64	80%	45	35	0.388

Table 2. Response rate of Bleomycin versus Cisplatin.

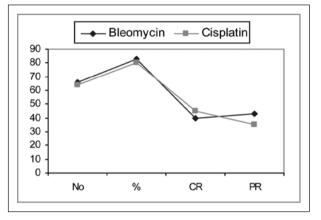


Fig 1. Response rate of Bleomycine versus Cisplatin No: number, %: percentage, CR: complete response, PR: partial response.

	Bleomycin Median (range)	Cisplatin Median (range)	p. value
Median time to progression	93	90	
Median survival	134	121	0.721

Table 3. Thirty-days response and survival

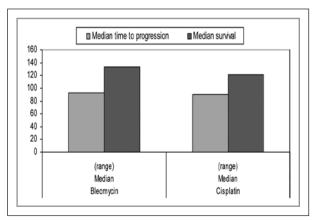


Fig. 2. Thirty days response and survival.

	Number	Percentage
Nausea	6	4.0
Vomiting	5	3.0
Dyspnea	2	1.0
Empyema	2	1.0

Table 4. Non-hematological toxicities

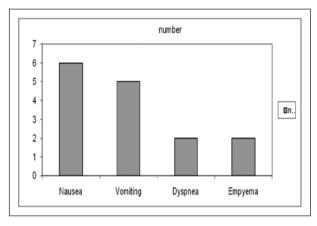


Fig. 3. Non hematological toxicities.

# DISCUSSION

Recurrent pleural effusions are a common clinical problem in patients with advanced neoplastic disease, and the treatmentis mostly palliative. When life expectancy is not too short, pleurodesis is considered the most valid option<sup>(2)</sup>.

However, despite the evaluation of a wide variety of sclerosing agents, to date, no ideal agent exists. Comparison of sclerosing agents is hampered by the lack of large randomized trials, different eligibility criteria, and disparate criteria for measuring response and end points<sup>(2,3)</sup>.

Traditional sclerosing agents such as talc, bleomycin, and tetracycline derivatives have been used for the treatment of MPEs. Although talc pleurodesis has been shown to be highly effective in apposing lung parenchyma to the chest wall, its limitations include severe pain from instillation and complications ranging from acute pneumonitis, granulomatous pneumonitis, and acute respiratory distress syndrome<sup>(15, 16)</sup>.

The incidence of major complications after talc pleurodesis has widely varied from study to study, ranging from 0.7% to  $33\%^{(17)}$ .

Intrapleural bleomycin has been studied extensively as a sclerosing agent. It is well-tolerated, and its systemic absorption is limited.but its ability to provoke inflammation and fibrosis has been questioned<sup>(18,19)</sup>.

In our study, response rate was nearly equale in the bleomycin (83%) arm B with CR 40% and PR 43% and in cisplatin (80%) arm A 12 patients (35%) had CR and patients (45%) achieved PR with an overall response rate of 80% (95% confidence interval (74-91%). Median time to progression was 93 days (range, 79-395 days) in the bleomycin arm, and 90 days (range, 74-347 days) in the cisplatin arm. Median survival was 134 days (range, 107-393 days) and 121 days (range, 98-373 days) in the bleomycin arms, respectively with minimal toxicities.

# CONCLUSION

Our study shows that intrapleural bleomycin and cisplatin were an equally effective agent for the palliative management of massive, rapidly recurrent pleural effusions in patients with advanced neoplastic disease with acceptable toxicities yet coast effectivness is in favour of cisplatin.

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# Single Port Video Assissted Thoracoscopy For Loculated Thoracic Empyema

Ayman A. Gabal

<u>Background</u>: The treatment of empyema with pleural drainage is a widely accepted surgical procedure. Currently, thoracoscopy often is used to treat this disease in some thoracic surgery centers. This study aims to present the authors experience with the treatment of loculated pleural empyema using single port thoracoscopic technique.

<u>Methods</u>: From janurary 2006 to may 2013, 29 patients with a diagnosis of pleural empyema were treated in thoracic surgery unit, King Saud Hospital, AlQaseem area, Saudi Arabia. Surgical management involved performing thoracoscopy for all the patients before pleural cavity drainage. This study group consisted of 21 males and 8 females, mean age was 30.7years (range 18 to 75years).

<u>Results:</u> A total of 29 patients with loculated pleural empyema were included in this study. Intraoperatively, double chamber empyema was recognized in 11 patients (38%), and multichamber empyema in 18 patients ( 62%), complete debridement of pleural cavity was atchieved in twenty six of our cases.

Three of 29 patients (10.3%) required partial pleurectomy. Median operation time was 55 minutes (range from 40 to 105 minutes).

There were no intraoperative complications, and no intraoperative or postoperative death. Chest tubes were removed after a median time of 12 days ( range from 5 to 40 days ). The diagnosis of biopsy specimens collected intraoperatively was a non specific inflammatory process in 25 patients (86.2%), and a specific inflammatory process ( TB) in 3 patients (10.3%). Chest neoplasm was the diagnosis in the remained one patient.

<u>Conclusion</u>: Thoracoscopy offers the possibility of good visualization and cleansing of the empyema chamber even in patients with advanced stages of the disease.We concluded that the minimal invasive single port video assisted thoracoscopic approach is safe and efficient. However, prospective multicenter trials on this topic are required to make firm conclusions.

#### <u>KEY WORDS</u>: Single port thoracoscope-pleural empyema.



he introduction of minimally invasive video surgical techniques enabled visualization and evaluation of the empyemal cavity as well as application of additional treatment procedures before placement of drainage. Numerous benefits from the thoracoscopic treatment of pleural empyemas are mentioned in the recent literatures.(1)(2)

Drainage of pleural pus has always been regarded as the key to its successful management. However, it is still a matter of debate what the best approach to multiloculated empyema is, when and how to intervene, although it is generally recommended to do an early intervention.(3)

In recent years, several reports documented the superiority of intrapleural fibrinolysis over simple chest tube drainage but when intrapleural fibrinolysis fails, there is the need for mechanical adhesiolysis which can be done by video assisted thoracoscopic surgery with pleurectomy.(4)

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Another way of performing mechanical adhesiolysis is via VAT in local anesthesia and good sedation which is called medical thoracoscopy. It is a less invasive technique used throughout Europe since 1910 to diagnose and treat pleural diseases including thoracic empyema.(5) The role of medical thoracoscopy for

This study aimed to evaluate the safety and efficacy of an original technique of single port video assisted thoracoscope in patients with loculated pleural empyema.

the treatment of pleural empyema is not established yet.(3)(5)

# METHODS

From janurary 2006 to may 2013, 29 patients with a diagnosis of pleural empyema were treated in thoracic surgery unit, King Saud Hospitl, Saudi Arabia. Surgical management involved performing thoracoscopy for all the patients before pleural cavity drainage.

This study group consisted of 21 males and 8 females, mean age was 30.7years (range 18 to 75years).Empyema was defined as frank pus on thoraccentesis with or without positive smear and bacteriologic culture findings, or PH < 7.2 with signs of infection.The diagnosis had to be confirmed by chest radiography and contrast enhanced chest CT, which was done for all our patients.

I exclude any patient with free empyema with no loculation.

All patients initially received emperic antibiotic treatment according to current practice guidelines with adaptation depending on the results of the microbiological workup.

#### Thoracoscopy technique:

The thoracoscopic procedure was performed directly after establishment of the final diagnosis and location of the empyema, no later than 72 hours after admission to the hospital. The operation was performed with the patient under general anesthesia lying on his or her side using a double lumen endotracheal tube.

The site of thoracoscope insertion was established on the basis of early x-ray, and CT scan. Pleural cavity puncture performed directly before the beginning of thoracoscopy, usually it was at the sixth or seventh intercostal space in the mid or posterior axillary line.

Through the single access(fig. 1), a video-camera and standard thoracoscopy instruments were simultaneosly introduced to perform deloculation, debridement and lavage of the pleural cavity.Pulmonary mobilization and partial decortication was necessary in seven cases with advanced stages of empyema.

In all cases, the following were performed : bacteriologic examination as well as histopathology of fibrin tissue and pleural segments. At the end of the procedure, two drains (32F size) were inserted and connected to underwater seal suction.

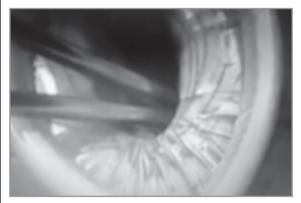


Fig. 1 : Single port access

In five patients intrapleural administration of streptokinase (250.000 IU), in 100ml of normal saline solution was needed once daily during the first 3 to 5 days postoperatively.All patients received IV antibiotics (Tienam 1 gm twice daily)for at least five days after the procedure.

# RESULTS

A total of 29 patients with loculated pleural empyema were included in this study of whom 72.5% (21 of 29) were males, mean age was 30.7 years (range from 18 to 75 years).

The etiology of loculated thoracic empyema is presented in table (1).Intraoperatively, double chamber empyema was recognized in 11 patients (38%), and multichamber empyema in 18 patients (62%), complete debridement of pleural cavity was atchieved in twenty six of our cases.

Three of 29 patients (10.3%) required partial pleurectomy, and five patients (17.2%) needed another port for completion of the procedure, (Table 2). Median operation time was 55 miutes (range from 40 to 105 minutes).

There were no intraoperative complications, and no intraoperative or postoperative death. Chest tubes were removed after a median time of 12 days ( range from 5 to 40 days ),(Table 3). Intrapleural streptokinase (250000 IU ) was used daily up to five days postoperatively in five patients (17% ).

The diagnosis of biopsy specimens collected intraoperatively was a non specific inflammatory process in 25 patients (86.2%), and a specific inflammatory process (TB) in 3 patients (10.3%). Chest neoplasm was the diagnosis in the remained one patient, this patient had history of thyroidectomy for papillary carcinoma.

Postoperatively three patients (10.3%), presented shortly after discharge from the hospital with fever and chest pain,

those patients were diagnosed as relapse of empyema with pleural thickening, and subjected later on for decortication through open thoracotomy.

Etiology	No.	%
Parapneumonic	24	82.75
Tuberculous	3	10.3
Neoplastic	1	3.4
Post-traumatic inf.	1	3.4

Table 1. Etiology of empyema

Variable	No.	%
Single port access	24/29	82.75
More than one port	5/29	17.2
Double chamber empyema	11/29	38
Multichamber empyema	18/29	62
Intra-operative complications	Zero	
Table 2. Operative data		
ICT stay time(days)	No.	%
< 7 days	6	20.7
7 to 10 days	13	44.8
>10 days	10	34.5

Table 3. Post-operative drainage time

# DISCUSSION

The goal of surgical treatment of empyema is to control infection, prevent persistent and recurrent disease, and restore pulmonary function by obviating restrictive lung function. Pleural cavity drainage is the fundamental procedure for pleural empyema.(6,7)

The issue to be decided about single port video assisted thoracoscopic management of loculated thoracic empyemaare as follows : a-Is it effective ?, b-Is it safe?, c-Was it indicated for patients included in this study?

The literatures published during the past few years emphasizes minimally invasive techniques such as video assisted surgery and thoracoscopy, which have changed the view concerning empyema treatment.(8)The introduction of thoracoscopy enabled an efficacious method of treatment during every stage with minimal trauma from surgical intervention.(5,9) Single port thoracoscope in our study influence the decision concerning early surgical intervention. The insertion of a single trocar in this study was sufficient to perform the whole surgical procedure with the camera within the same working canal for twenty four patients. Martinez-Ferro and coworkers,(10) described the same method in his study.

Multichambered empyema patients predominated in our study (62 %), which was confirmed intraoperatively with marked overlying fibrin on visceral and parietal pleura.

A second trocar for evacuation of overlying fibrin was inserted in five cases and it was needed also as partial decortication was difficult in these cases.

Histopathologic examination was an advantage of thoracoscopy which enabled diagnosis of three cases of TB, and one case of metastatic neoplasm, and this was concommittent with other studies.(8,11)

The duration of surgical intervention varied between 40 and 105 minutes depending on the stage of empyema as well the need for intraoperative procedures. In some published studies delaying the thoracoscopic intervention in advanced stages of empyema increases unfavorable results and often leads to the need for a thoracotomy to obtain efficient lung decortication and decompression(10,11), and this was the condition for three patients in our study.

Doski and his associates, revealed better results for patients who underwent initial thoracoscopy in their treatment, as drainage in those patients was 3 days shorter and hospitalization 5 days shorter than for patients treated by means of drainage and fibrinolytic agents. The necessity of open thoracotomy in Doski JJ, study was significantly greater for patients treated only by means of drainage .(12)

Proper postoperative management in this study was the same like other studies (12) including antibiotics, vitamines, and possibility of adminstring a fibrinolytic agent to the pleural cavity, which causes fibrinolysis of accumolated fibrin.

Based on our analysis of 29 patients treated for pleural empyema, we confirmed that single port thoracoscopic intervention accelerated recovery and established proper diagnosis of its causes, and this was concommittent with other studies(6,12).

# CONCLUSION

Thoracoscopy offers the possibility of good visualization and cleansing of the empyema chamber even in patients with advanced stages of the disease, and enables collection of materials not only for bacteriologic, but also for histopathologic examination.

We concluded that the minimal invasive single port video assisted thoracoscopic approach is safe and efficient. However, prospective multicenter trials on this topic are required to make firm conclusions.

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# Outcome of Wedge Resectionversus Lobectomy of Stage 1 Non Small Cell Lung Cancer.

Yasser Shaban Mubarak; MD\* Yasser Ahmad Boriek; MD\*\* Hesham Alkady; MD\*\* <u>Background and Aim</u>: Surgical resection of stage 1 non-small lung cancer (NSCLC) is a curative management. The outcome of wedgeresection (non anatomic resection) in the surgical management of stage I (T1-T2N0M0) non-small cell lungcancer against the gold standard of lobectomy (anatomic resection) continues to be debated. We balance between the increased risk for local recurrence and adequate cardiopulmonary reserve.

<u>Patients and Methods</u>: Between 2005 and 2013, We analyzed the outcome of (86) patients with pathologic stage I (T1-T2N0M0) non-small cell lungcancer who underwent openwedgeresection (53), and lobectomy (33) to assess morbidity, locoregional recurrence, and 5- year survival rate. There were (66) males and (20) females with a mean age of 57.8 years.

<u>Results:</u> The mean hospital stay was significantly less in the wedgeresection groups. There were no operative deaths among patients having neither wedge resection nor lobectomy. Kaplan-Meier survival curves were nearly identical at 5-year (squamous to adenocarcinomaopenwedgeresection89.3% - 96%, lobectomy 92.3% - 90%). Postoperative follow-up was every 6 months for loco regional recurrence or distant metastasis.At 5 years disease freewas 0% for patients having openwedgeresection, and 16.7% for those having lobectomy.

<u>Conclusions</u>: The wedgeresectionofstage 1 NSCLC is an easy, fast and safe technique forunfitpatients, who can't tolerate major resection. Also, it presents not only a low morbidity and mortality, but also a nearly similar survival.

<u>KEYWORDS</u>: Wedge resection, lobectomy, non-small cell lung cancer, sublobar resection.

tage I non-small cell lung carcinoma (NSCLC), as defined by American Joint Committee, consisting of a T1 or T2 primary tumor and no evidence of hilar or mediastinal nodal disease (N0) or metastatic spread (M0). Medically fit patients in this clinical stage should be considered for aggressive local therapy, and curative treatment is possible. Surgical resection is the accepted treatment for patients with this stage, and lobectomy rather than sublobar (wedgeresection, segmentectomy) resection is strongly suggested. The performance of a systematic sampling or full mediastinal lymph node dissection may improve pathologic staging but is unproven therapeutically. The use of neoadjuvant or adjuvant chemoradiotherapy in stage I NSCLC is of unproven benefit. Primary radiation therapy should be considered for inoperable patients. (Smythe, et al., 2003).

Surgical resection remains the cornerstone in the treatment of patients with stages I NSCLC. The role of sublobar resection (SLR), either anatomic segmentectomy or nonanatomic wedgeresection (WR), in patients with small peripheral nodules may become important. (Gorenstein, et al., 2011).

Wedgeresections are frequently performed for small peripheral lesions in patients unfit for a more extensive resection, (**Mediratta, et al.,2013**).Sublobar resections spare pulmonary function compared to lobectomy in stage I NSCLC and thereby offer a method of increasing resection rates in patients with limited pulmonary function who would not tolerate a lobectomy, (**Wulf S, et al.,2008**). In regard to limited resection, sublobar resection (wedgeresection and segmentectomy) may yield a good long-term outcome in selected cases, as doe's lobectomy,(**Endo, et al., 2003**).

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Codex : o4/06/1311

The aim of this study is to evaluate the outcome of wedge resection versus lobectomyin stage 1 NSCLC patients unfit for major resection for disease free interval and 5-year survival rate.

# **Patients and Methods**

This study was conducted at Cardiothoracic Surgery Departments in MiniaUniversity and Cairo University hospitals during the period Jan.2005 to Juli2013.NSCLC stage1 patients (86)underwent a wedge resection(53) and lobectomy(33). Patients were (66)males and(20) femaleswith a mean age 57.8 years. The preoperative workup included compete physical examination, laboratory tests, pulmonary function tests and cardiological evaluation. Further workup for metastatic disease included computed tomography (CT) of the chest, brain and upper abdomen. No patient had distant metastasis.

Fine Needle Aspiration Biopsy (FNAB)was done to obtain diagnosis.CT chest revealed lesions of any size less than 3 cm, peripheral but completely surrounded by lung parenchyma, with no evidence of atelectasis or pneumonia in the lung parenchyma distal to it together with absence of mediastinal lymphadenopathy.Pulmonary lung function was defined poor in presence of a FEV1 <1.5 or <50% predicted. Poor cardiopulmonary status (CPS) was defined as the simultaneous presence of two or more of the following factors: age >75 years, WHO Performance status >3, poor pulmonary functions (FEV1 <1.5 or <50% of predicted), co-morbid factors (previous myocardial infarction, current angina, and uncontrolled diabetes), poor nutritional status, and previouslungresection.

In this study we present our research in performing wedge resection against lobectomy analyzing long-term outcome.

#### Technique

Anesthetic technique was standardized in all patients, under general anesthesia with a double-lumen endotracheal tube. All patients underwent resection through a mini-thoracotomy in case of wedge resection and through the 5th or 6th intercostal space posterolateral thoracotomy in case of lobectomy. After opening the pleural cavity, we performed an examination of the hilum. The completeness of resection was based on ensuring at least 2 cm palpable tumor free margins.Wedgeresections were performed by excision of the tumor using electrocautery or scissors. The resulting parenchymal defect was closed by resorbable 4/0 running sutures. In case of lobectomy, the bronchial stump was re-approximated transversely with interrupted non-absorbable suture in a single layer suture No 3/0 or 4/0 polyproprolene. The bronchial stump was covered with a pleural flap. Two intercostal chest tubes were inserted in the pleura and the thoracotomy incision was closed according to standard procedures. The patients were extubated and transferred to intensive care unit (ICU) for the first 6-12 hr. postoperatively. Thesurgically resected specimens were sent to pathological examination. The surgical and pathologic reports of all patients were carefully reviewed to ensure that no residual tumor was left behind, and that no involved regional nodes (N1 and N2) were present.

Follow-up studies included physical examination, chest X-ray, chest CT, abdominal sonography, and full laboratory tests in a 3-month interval for the first 2 years then every 6-12 months for 5 years.

Recurrent NSCLC was diagnosed based on a physical examination and diagnostic imaging such as chest CT. Treatment for recurrence included systemic chemotherapy.

#### **Statistics**

Survival estimates were made with the Kaplan–Meier model and compared with the log-rank test. Statistical significance was admitted for any value of P less than 0.05.

#### **Results**

This study was done between Jan.2005 toJune 2013 at Minia and Cairo University hospitals.That included (86) patients with NSCLC stage I (T1-T2N0M0) and had (66) males and (20) females with a mean age of 57.8Years. We observed outcome of wedge versus lobectomy.

The average postoperative hospital stay was 7 days (range 5 - 14 days). There was no atelectasis, bronchopleural fistula or empyema. There was air leak lasting for more than 7 days in 5 patients after wedge resection mainly due to emphysematous lung. There was no in hospital mortality. Early death (4 patients) within the 1st 2 months was due to coronary artery disease and heart failure. Late death (3 patients) in less than 1 year was due to respiratory failure.

5 -year survival of wedge resection to lobectomy was 89.3% to 92.3% in squamous cell carcinoma and 96% to 90% in adenocarcinoma. We observed that the difference in 5-years survival between wedge to lobectomy range from 3% - 6%, which considered accepted and better than non-surgical intervention when patients had high risk and unfit for major resection, (Table 1)

		T ( 1		Ś	Survive	
Pathology	Resection	Total	Death	Ν	Percent	
<i>a</i> 11	Wedge	28	3	25	89.3%	
Squamous cell carcinoma	Lobectomy	13	1	12	92.3%	
	Overall	41	4	37	90.2%	
Adenocarcinoma	Wedge	25	1	24	96.0%	
	Lobectomy	20	2	18	90.0%	
	Overall	45	3	42	93.3%	
Overall	Overall	86	7	79	91.9%	

Table 1. Five-year survival according to type of resection and pathological type

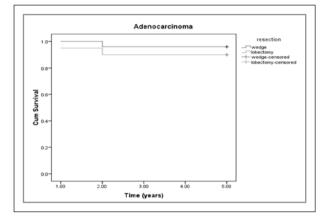


Fig. 1. Cumulative five-years survival according to type of resection in patients with adenocarcinoma using Kaplan-Meier survival analysisafter limited resection

We observed 5-years survival in wedge resection was better than lobectomy in cases of adenocarcinoma .So, we observed, that unfit patients for lobectomy, wedge resection can be performed with well survival rate.

We observed 5-years survival in lobectomy better than wedge resection in cases of squamous cell carcinoma.

Time (years)	Wedge	Lobectomy
1	93.9%	86.7%
2	71.4%	66.7%
3	22.4%	43.3%
4	0.02%	20%
5	0%	16.7%

Table 2. Five-year disease free according to resection

Five-year disease free was better with lobectomy than wedge resection. Disease free period was up to 3 years in wedge resection but up to 5 years in lobectomy, (Table2). Disease free

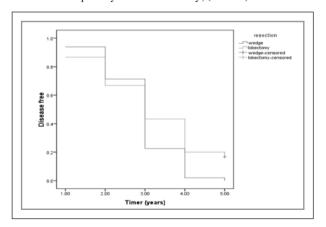


Fig. 3. Cumulative five-years disease free period according to type of resection using Kaplan-Meier survival analysis.

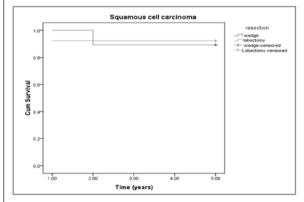


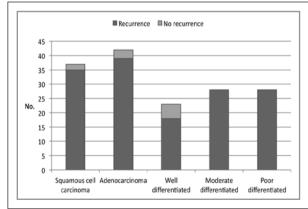
Fig. 2. Cumulative five-year survival according to type of resection in patients with squamous cell carcinoma using Kaplan-Meier survival analysis

was similar after 3 years in wedge resection and 5 years in lobectomy. So with limited resection there is a higher incidence of recurrence.

Variable		Recurrence	No re- currence
Pathological	Squamous cell carcinoma	35	2
type	Adenocarcinoma	39	3
	Well differenti- ated	18	5
Differentiation	Moderate differ- entiated	28	0
	Poor differenti- ated	28	0

# Table 4. Recurrence according to pathological type and differentiation.

Recurrence was more in adenocarcinoma than in squamous carcinoma, and more in less differentiated than well differentiated carcinoma either in wedge resection or lobectomy.



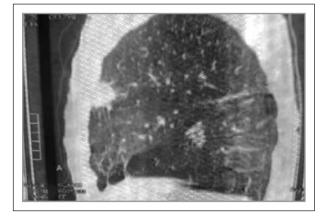


Fig. 5. Photo was showing CT chest with small peripheral lung nodule and emphysematous lung

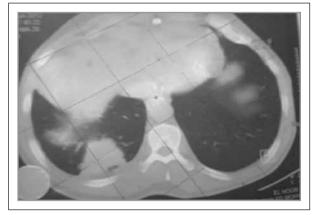


Fig. 6. Photo was showing CT chest with peripheral NSCLC stage 1 in right lower lobe

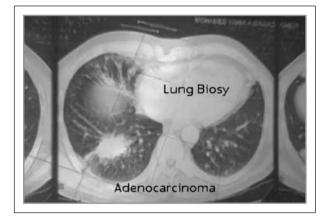


Fig. 7. Photo was showing NSCLC stage 1 adenocarcinoma in right lower lobe in patient with IHD.



Fig. 8. Photo was showing cut section of wedge lung resection from patient with NSCLC stage 1 squamous cell carcinoma.

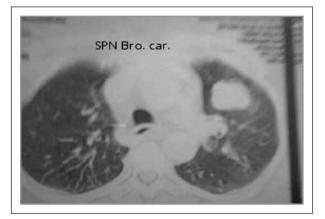


Fig. 9. Photo was showing CT chest with NSCLC stage 1

### Discussion

Lung cancer is the leading cause of cancer related deaths worldwide. The treatment of non-small cell lung cancer (NSCLC) depends on the stage of the disease. Lobectomy with radical lymph node dissection remains the standard initial therapy for patients with stage I, II, and IIIA NSCLC, but limited resection has also been performed for early stage NSCLC. The Lung Cancer Study Group performed a pivotal study comparing limited resection (segment or wedge) with lobectomy for clinical stage (c-stage) IA NSCLC and found inferior overall survival and three times the local recurrence rate in the limited resection group, (**Hiroaki**, et al., 2013).

Standard lobectomy with mediastinal lymph node sampling has been described as the gold standard operation for stage I lungcancer with a free survival at 5-year of 80%.

Limited lungresection for cancer patients with compromised pulmonary or cardiac reserves continues to be a controversial matter. Several authors have been in favor ofusing lesser formofresection such as wedgeresection in patients who would not tolerate a lobectomy. There was an increased risk of locoregional recurrence with limited resection, but they felt that since most patients with locoregional recurrence died of distant metastases, survival was not affected.(**Balakrishnan,et al., 2004**).

There is ongoing controversy as to the extent of resection necessary for stage I NSCLC. The Lung Cancer Study Group showed that for stage IA NSCLC, patients who underwent a limited resection (segmentectomy or wedge) had a higher recurrence rate and lower survival than did those treated by lobectomy, (Ginsberg, et al., 1995). Miller and associates demonstrated that for NSCLC measuring 1 cm or less, patients who underwent lobectomy had significantly improved survival and fewer recurrences than did those having limited resection, (Miller, et al., 2002). However, other authors have suggested that limited resections are adequate treatment for early-stage disease, (Okada, et al., 2001).

Recently, **Okada et al** revealed that wedgeresections with lymph node sampling yield a disease-free and overall survival equivalent to segmentectomies and lobectomies in patients with stage IA NSCLC  $\leq 2$  cm who could even tolerate a lobectomy. Indications for these sublobar resections were limited pulmonary function or severe cardiac co-morbidity. The choice between segmentectomy and wedgeresection was at the discretion of the surgeon, (**Okada, et al., 2006**).

In Lee and associates study, only 10 patients (12%) had limited resection, mainly because of poor pulmonary reserve and/or associated comorbidities. There was no significant difference in overall survival between patients with limited resection and those with anatomic resection. In the 67 patients with stage IA tumors, 8 patients had limited resection. No recurrence was noted in either the limited resection or the anatomic resection group during the follow-up period. Although the survival of patients with limited resection in this series suggests that limited resection for 1 cm or less tumors may have equivalent results to lobectomy, the small sample size examined precludes any definitive conclusions, ( Lee, et al., 2006 ).

In our study, 5 –year survival of wedge resection to lobectomy was 89.3% to 92.3% in squamous cell carcinoma and 96% to 90% in adenocarcinoma. We observed that the difference in 5-years survival between wedge to lobectomy range from 3% - 6%, which considered accepted and better than non-surgical intervention when patients had high risk and unfit for major resection. Five-year disease free was better with lobectomy than wedge resection. Disease free period was up to 3 years in wedge resection but up to 5 years in lobectomy, so there is higher incidence of recurrence with limited resections.

Segmentectomy was associated with a significantly better cancerrelated 5-year survival than wedgeresection in stage IA (71% vs 48%, respectively; p = 0.016; log-rank test). Occurrence of distant metastasis was equal between segmentectomy and wedgeresection, however, wedgeresection was associated with a significantly increased local recurrence rate compared to segmentectomy (55% vs 16%, respectively; p = 0.001; log-rank test),(Wolf, et al., 2008).

The rate of morbidity and mortality in elderly patients were similar to those observed in younger patients. However, perioperative management should be cautiously performed while taking into account the risk factors for morbidity especially in elderly patients because they frequently have various co-morbidities, (**Kazuya, et al., 2011**).

Limited resection may be sufficient to control pure ground glass adenocarcinoma of the lung. It is doubtful that mediastinal lymph node dissection has additional therapeutic effect in those patients, (Choi, et al.,2013).So, we did not perform mediastinal lymph node dissection as a routine.

Regardingpatients with adenocarcinoma, males have a significantly reduced long-term survival compared to females. No difference existed in patients with squamous histology subtype. This reinforces the importance of a preoperative histological diagnosis in the decision process, (**Mediratta, et al., 2013**) In our study, Male to female ratio was nearly similar in adenocarcinoma patients whose were performed wedge resection and lobectomy, so gender did not has any effect on 5- years survival.

Stereotactic ablative radiotherapy (SABR) and sublobar resection (SLR) are both reasonable alternatives to lobectomy in high-risk surgical patients. SABR is associated with reduced local recurrence (4 vs 20%; P = 0.07) and lower toxicity. SABR studies are needed to reach a firm conclusion on this debatable topic, (Sarah, et al., 2013).

Lobectomy is still recommended for younger patients with adequate cardiopulmonary function. Although limited resection carries a decreased rate of complications and shorter hospital stays, it may also carry a higher rate of loco-regional recurrences, (Maya, et al., 2012).

In our study, shorter hospital stays more in patients had performed wedge resection than lobectomy, inspite of they had many risk factors.

Video-assisted thoracoscopic surgery (VATS) for wedgeresection in lungcancer performed safety use and shortly hospital stay than open thoracotomy, (**Howington, et al., 2012**). We hope to Perform VATS for either wedge resection or lobectomy later on to decrease hospital stay, pain, and to at chive progress in minimal invasive thoracic surgery.

The increased long-term mortality associated with wedgeresection is mainly due to non-cancer deaths, reflecting a higher risk patient group with many comorbid conditions, (**Themistokles, et al., 2009**). In our study, Most ofdeaths were due to non surgical problems but due to associated comorbid conditions e.g., CAD or COPD.

Thoracic

The 5-year survival rates after curative resection for nonsmall-cell lung cancer (NSCLC) have improved remarkably from 52.6% for patients who underwent resection in 1994 to 61.4% in 1999 and 69.6% in 2004. This improvement is believed to be a consequence of the increase in the detection of small-sized lung cancers, thanks to improvements in diagnostic imaging, such as computed tomography (CT) and <sup>18</sup>F-fluorodeoxyglucose positron emission tomography (FDG-PET), as well as other factors, such as the standardization of adjuvant chemotherapy.

Chemotherapy for recurrence is routinely administered based on the recommended regimen for unresectable advanced NSCLC. However, patients with postoperative recurrent disease can be anticipated to have a poor organ function and old age. This improvement likely reflects the effect of new anticancer agents. This change in lung cancer chemotherapy can also be expected to have exerted an effect on prognostic factors for recurrent NSCLC, (**Shinsuke, et al., 2013**). In our study, 5-year survival rates for patients who underwent resection had nearly 90%. Inspite of, recurrence in squamous was 35\41 case and in adenocarcinoma 39\45, advanced of new lines of chemotherapy had a direct effect on improving life-style and increasing survival rate.

When surgeons have to take the controversial decision of whether to offer resection to octogenarians, they should base their choice first on the stage of the disease, and then on an accurate assessment of the general clinical conditions, rather than on pulmonary function alone.(**Olivi**, et al., 2011), so in our study, we performed wedge resection in patients with poor pulmonary function and had a good results on improving survival.

Our study has some limitations. First, this study analyzed only a small number of patients, and this number was lower than those included in previous studies. Because of most patients were diagnosed in more advanced stage, so we only had a small sample size in our study. We recommend early survey especially in suspected or high risk groups.

# Conclusion

Wedge resection is a safe and effective surgical option for patients presenting with stage 1 bronchogenic carcinoma (T1NOMO) with poor cardiopulmonary reserve. 5-years survival and disease free survival improved but with a relatively high incidence of late recurrence.

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# Comparative study between epidural morphine versus epidural morphine-haloperidol combination for post thoracotomy pain releif

Ayman M. Abdel-Ghaffar \* Wesam Abdel-Galil \*\* <u>Background:</u> The addition of haloperidol to epidural morphine has been assumed to provide good analgesia following severely painful operations including thoracotomy with subsequent decrease in the analgesic consumption. Reduction in the incidence and severity of pruritis, postoperative nausea and vomiting (PONV) could be achieved without cardiac, respiratory or central nervous system side effects.

<u>Objective</u>: This study was to evaluate the effect of haloperidol on the incidence and severity of pruritus, PONV caused by epidural morphine as well as its effect on urinary retention and sedation , besides evaluating its effect on the duration and potency of morphine analgesia as an attempt to improve the quality of post operative analgesic condition of patients undergoing thoracotomy.

<u>Methods:</u> In our study, 60 patients were scheduled for elective thoracic surgery and were allocated into two equal groups;30 patients each. Morphine group MG where (5 mg) morphine was given epidurally and Morphine-haloperidol group MHG where (5 mg) morphine plus (2.5 mg) haloperidol given epidurally. The severity of pruritis, PONV, pain and sedation are evaluated at (1, 6, 12 & 24 hours) postoperatively by an anesthesiologist who is blinded to the study.

<u>Results:</u> Along the 24 hours postoperative period study, no significant differences were detected between both groups as regard the respiratory rate and the hemodynamic values. However a significant decrease in the incidence and severity of the unwanted side effects of epidural morphine like pruritis, PONV on addition of haloperidol to epidural morphine in the second group. No significant difference was observed between both groups as regard the postoperative urinary retention. Although the analgesic quality did not show a significant difference between the two groups by visual analogue scale (VAS), significant reduction in the analgesic consumption was observed in the haloperidol group together with significant decrease in the cortisol level in the same group. All patients in the haloperidol group had experienced mild to moderate degree of sedation.

<u>Conclusion</u>: This study concluded that, adding haloperidol to epidural morphine when certain safety measures are taken is safe, feasible and helpful technique for better postoperative analgesia, lesser analgesic consumption and significantly decrease the unwanted side effects of epidural morphine for adult patients undergoing thoracotomy.



horacotomy is one of the most painful operations. Regardless of the underlying pathology, most of chest diseases requiring thoracotomy need early patient mobilization and adequate lung ventilation, unfortunately severe pain usually preventsboth events<sup>1</sup>.

Epidural opioids provide significant postoperative analgesia; however, their use is often limited by side effects such as nausea and pruritus<sup>2-3</sup>, or they require the addition of epidural local anesthetics with possible side effects of motor block and hypotension<sup>4</sup>.

Many drugs had been studied to be added to epidural morphine in order to enhance their action, decrease analgesic consumption and alleviate or decrease the associated unwanted effects<sup>3,5</sup>. There are many evidences that epidural butyrophenones may achieve these goals<sup>4</sup>.

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Codex : o4/07/1311

# **Material & methods**

After approval of ethical committee and informed consent from patients, this prospective, randomized, double blind clinical trial was conducted in Sohag University Hospital on 60 patients scheduled for elective thoracic surgery (pneumonectomy, lobectomy, wedge resection, lung biopsy, decortication and mediastinal mass excision) (Fig.1). They were randomly allocated into two equal groups, 30 patients each.

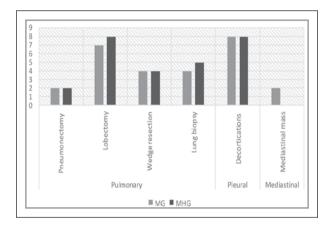


Fig. 1. Surgical procedures

Before surgery, the respiratory condition of the patients was optimized, all patients were given midazolam (0.1mg/kg) via IV route in the recovery room. Then, in the sitting position, an epidural catheter was applied at (T7-8) and advanced 5 cm using the paramedian approach and loss of resistance technique and a test dose of (3 ml) lidocaine 2% with epinephrine 1:200000 were given.

In the operating room, patients in both groups were given general anesthesia using fentanyl (2ug/kg), propofol (6mg/kg) for induction and rocuronium (0.6 mg/kg) for muscle relaxation and anesthesia was maintained by using propofol infusion (2mg/kg/hr) and fentanyl infusion (2 ug/kg/hr). Tracheal intubation with a double-lumen tube was carried out to avoid contralateral spillage of pus and secretions in cases of infected lung conditions and to facilitate pulmonary resections.

Patients are randomly allocated to one of two groups (30 patients each); (Group MG) Patients received postoperative epidural injection of Morphine (5 mg) in total volume of 10 ml; (Group MHG) Patients received postoperative epidural injection of Morphine (5 mg) plus Haloperidol (2.5 mg) in total volume of 10 ml.

The severity of pruritis, (PONV), pain and sedation are evaluated at (1, 6, 12 & 24 hours) postoperatively by anesthesiologist who was blinded to the study treatment.

# The severity of pruritis is assessed by using a four-point scale:<sup>6</sup>

#### 0= Absent

- 1= Mild (localized to one area such as the face or arms and not troubling the patient).
- 2= Moderate (affecting a larger area such as the face and the arms or the face and the anterior surfaceof the thorax, but not disturbing the patient and therefore not requiring treatment)
- 3= Severe (extensive or generalized, often disturbing the patient to the point that treatment was indicated)

When patients experienced a severe pruritis, (propofol 10 mg) was injected IV as a rescue medicine.

# The severity of PONV was assessed by using a four point scale:<sup>3</sup>

- 0= Absent (no nausea or vomiting)
- 1= Mild (Mild nausea/ vomiting, patient not requesting an antiemetic)
- 2= Moderate (nausea/ vomiting, patient requesting an antiemetic)
- 3= Severe (nausea/ vomiting, resistant to antiemetic)

When severe PONV occurred, (metoclopramide 10 mg) or (ondanestron 4mg) was given IV as a rescue medicine.

#### Pain was assessed by

- Visual Analogue Scale (0 to 10: 0 represent no pain at all & 10 the worst imaginable pain)
- Measurement of serum cortisol level.

#### Insufficient analgesia was treated as follows:

- Intolerable pain (VAS equals or more than 7) and plasma cortisol level (more than 200 mg/dl): subsequent dose of epidural morphine (3mg) in total volume of 10 ml
- Mild to moderate pain (VAS ranges from 3-7) with plasma cortisol level (between 50-150 mg/dl): 30 mg of ketrolac is given IV.

#### Sedation was assessed by using four-point scale:<sup>7</sup>

- 0= Alert or drowsy but easily aroused by verbalcommands alone
- 1= Sleeping and aroused by verbal commands
- 2= Sleeping, not aroused by verbal stimuli but aroused by tactile stimulation
- 3= Sleeping and not aroused by tactile stimulation.

#### **Operative technique**

After intubation, the patient was placed in the appropriate lateral decubitus position with proper padding to the elbows and the knees.

The inferior angle of the scapula, its spinal and axillary borders are palpated and outlined. The standard incision follows the course of the underlying ribs, and extends from a point located at 3 inches from the mid-spinal line to the anterior axillary line. The incision is deepened through the subcutaneous tissue and superficial fascia until the fascia overlying the latissimus dorsi and trapezius muscles are exposed. Total transection of the latissimus dorsi is performed using the electrocautery unit. The division of the trapezius muscle must be avoided.

The serratus anterior and the rhomboid muscles are exposed; the inferior border of the rhomboideus and the posterior border of the serratus are facing a fatty triangle. The latter is separated from the muscles to get access to the ribcage. When this dissection is properly performed, the serratus can be elevated and retracted anteriorly, thus avoiding its transection.

Selection of the appropriate intercostal space can be guided by counting ribs. The desired intercostal space either fifth or sixth space is located and the pleural space is entered after dividing of intercostal muscles with the electrocautery. The incision is pushed as far as possible anteriorly to allow for easy retraction of the ribs. A large rib spreader is inserted, placing the larger blade in front of the scapula. The rib spreader is always opened slowly and progressively, sometimes posterior transection of the rib to avoid fracture was done.

Closure of the incision starts by inserting pericostal sutures. Each of the two musculofascial layers is closed with an absorbable running suture after intercostal tube(s) insertion.

#### **Statistical analysis**

Numerical data were expressed as Mean  $\pm$  Standard deviation (M $\pm$ SD) or as median (interquartile range), and categorical data were expressed as number (percent). SPSS program version 19 was used for data analysis. Categorical variables were analyzed using the Chi-squared test (or Fisher's exact test). Mann Whitney test was used for numeric variables. P-values <0.05 were considered statistically significant.

### Results

Of 60 patients who were allocated to the study, 3 patients were excluded due to failure of epidural catheterization and 3 patients because they found to be addicts. Therefore, only 54 patients completed the trial (Table 1). The two patient groups were demographically comparable.

The heart rate, systolic blood pressure, diastolic blood pressure and respiratory rate were measured postoperatively at fixed intervals and compared (Table 2). We found no significant differences between the two groups or within the same group.

	MG ( <i>n</i> =27)	MHG ( <i>n=27</i> )	P-value
Age (years)	36±12	39±11	0.37
M/F ratio	2.5:1	3:1	0.58
Weight (Kg)	79±12	88±23	0.15
Height (cm)	168±8	167±2	0.38

P-value <0.05 considered significant

Table 1. Demographic data

Variable	Casua	1 <sup>st</sup> h	our	6 <sup>th</sup> h	our	12 <sup>th</sup> 1	hour	24h	ours	Р
variable	Group	Mean	P value	Mean	P value	Mean	P value	Mean	P value	value
HR	MG	89±20	0.56	90±12	0.28	90±9	0.27	$88 \pm 10$	0.23	0.43
пк	MHG	89±14	0.30	87±9 0.28 86±7	86±7	0.27	85±7	0.25	0.45	
SBP	MG	119±14	0.66	119±8	0.49	122±13	0.43	118±8	0.52	0.38
SDP	MHG	120±14	0.00	1104± 0.49	118±7	0.43	117±8	0.52	0.58	
DBP	MG	77±11	0.43	76±9	0.78	78±9	0.39	79±9	0.51	0.19
DBP	MHG	74±9	0.45	74±7 0.78	77±8	0.39	77±7	0.51	0.19	
RR	MG	17±2	0.64	17±4	0.73	17±3	0.65	17±3	0.38	0.53
KK	MHG	16±2	0.04	16±2	0.75	16±1	0.05	16±2	0.58	0.55
VAS (modion)	MG	2(1-4)	0.56	2(1-3)	0.02	2(1-5)	0.62	3(1-6)	0.17	0.07
VAS (median)	MHG	3(1-5)	0.30	1(0-3)	0.02	1(1-4)	0.02	2(0-4)	0.17	0.07

HR: Heart rate, SBP: systolic blood pressure, DBP: diastolic blood pressure, RR: respiratory rate, VAS: visual analogue scale

Table 2. Postoperative data

Using the visual analogue scale (VAS) for pain assessment, and Mann-Whitney test for statistical analysis, the following data were collected and presented as median (M) and range (R)

**<u>1. At first hour postoperatively:</u>** The median VAS in morphine group MG was 2(1-4) and in the morphine haloperidol group MHG was 3(1-5).

<u>2. At the sixth hour postoperatively</u>: The VAS in morphine group MG was 2(1-3) and in the morphine haloperidol group MHG was 1(0-3).

<u>3. At the 12 hour postopratively:</u> The VAS in morphine group MG was 2(1-5) and in the morphine haloperidol groupM-HG it was 1(1-4).

**<u>4. At the 24 hour postoperatively:</u>** The VAS in morphine group MGwas 3(1-6)and in the morphine haloperidol group MHG was2(0-4)

We found significant decrease in VAS at 6 hours in both groups (P-value <0.02), while no significant difference between the two groups (P-value=0.07). Serum cortisol level was compared between the two groups, showing significant reduction in haloperidol group(P-value= 0.012) (Table 3).

	<200 mg/dl	>200mg/dl	
MG	12(44.4)	15(55.6)	0.012
MHG	21(77.8)	6(22.2)	

#### Table 3. Serum cortisol level

In both groups, most analgesic consumption was in the first hour. In the first postoperative hour, analgesic consumption was significantly higher in MG . Six patients in MG (22.2%) received ketorolac and one patient (3.7%) needed morphine as rescue analgesia. While, 2 patients in MHG (7.4%) needed ketorolac and no one needed morphine (Table 4).

At 6-12 hour, analgesic consumption regressed in both groups. Again ketorolac was received by 6 patients in MG while no patients was in need in MHG.

At 24 hour, analgesic consumption retuned to its maximal value in MG (22.2%) while no patient in MHG needed analgesia.

	1 <sup>st</sup> hour	6 <sup>th</sup> hour	12 <sup>th</sup> hour	24 <sup>th</sup> hour
MG	6(22.2%)	1(3.7%)	5(18.5%)	6(22.2%)
MHG	2(7.4%)	0	0	0

#### Table 4. Analgesic consumption

The total incidence of occurence of nusea and vomitting was (77.7%) in MG and (48.1%) in MHG (P-value=0.034). (Table 5)

Severe vomitting occurred in (33.3%) of MG and (3.7%) of MHG (P-value = 0.008).

Complication		MG	MHG	Р
Nausea and/or	No	6(22.207)	14(51.007)	value 0.034
vomiting		6(22.2%)	14(51.9%)	(S)
, enning	Mild	12(44.4%)	12(44.4%)	
	Sever	9(33.3%)	1(3.7%)	
Opioid in-	No	5(18.5%)	21(77.8%)	0.002
duced pruritis	Mild	14(51.9%)	6(22.2%)	(HS)
	Sever	8(29.6%)	0	
Sedation	No	16(59.3%)	0	< 0.001
	Mild	9(33.3%)	24(88.9%)	(HS)
	Moderate	1(3.7%)	3(11.1%)	
	Severe	1(3.7%)	0	
Urinary reten-	No	3(11.1%)	4(14.8%)	0.83
tion	Retention	21(77.8%)	19(70.4%)	(NS)
	Catheter	3(11.1%)	4(14.8%)	

#### Table 5. Post operative complications

#### Data are expressed as no.( percentage)

The pruritis was compared in both groups. In morphine group MG, the overall incidence of pruritis was (81.5%) and (22.2%) in MHG. While non of MHG suffered severe pruritis, 9 patients (51.9%) in morphine groupMG had the severe degree.

There was significant decrease in postoperative pruritis in morphine haloperidol group MHG (P-value =0.002)

The sedation was compared in both groups. In morphine group MG, one patients suffered severe sedation (3.7%) and non of MHG. Patients experienced no sedation at all were 16 (59.3%) in MG while all patients in MHG experienced some degree of sedation.

The urinary retention was compared in both groups. In morphine group MG, retention occurred in 21 patients (77.8%) and 10 patients (37%) needed catheterization to relief it. 19 patients in MHG (70.4%) suffered from urinary retention and9 patients (33.3%) needed catheterization, but this was not significant.

There was no significant decrease in postoperative retention in morphine haloperidol group MHG (P-value = 0.83)

In MG group, one patient (3.7%) had fever, while five patients (18.5%) had fever in MHG group.

# Discussion

This study focused on evaluating the effect of epidural haloperidol on the incidence and severity of pruritis, urinary retention, nausea and vomiting caused by epidural morphine; besides evaluating its effect on analgesic consumption and sedation. We used (5 mg) of epidural morphine, a relatively large dose, because it is our standard practice and to achieve a satisfactory analgesic effect to our painful thoracotomy operations for encouragingpatients to mobilize early and breath smoothly.

In contrast with most studies which used droperidol, as a member of butyrophenone to minimize epidural morphine side effects, we used haloperidol (2.5 mg) because of its availability in our market. Unlike droperidol, previous studies on haloperidol are lacked and deficient.

In our study, heart rate, systolic, diastolic blood pressures and respiratory rate showed no significant differences between the two groups and within the same group along the 24 hrs study. On the other side, some studies had significant hemodynamic changes after addition of butyrophenone to epidural morphine. *Horta et al*<sup>8</sup>.confirmed that hypotension occurred in (44%) of droperidol group; they anesthetized the patients using a single epidural injection of 150 mg (30 mL) of 0.5% bupivacaine for cesarean section, a dose might cause serious cardiovascular compromise even in non pregnant patients. Other studies as *Sanansilp et al*<sup>5</sup>, (43%) of droperidol also showed hypotension and needed ephedrine in comparison to (36.3%) in morphine group. This may be because their studies done on patients undergoing cesarean section.

Pruritis was the most prominent side effect of morphine in our study. We found that the overall incidence of pruritis was (81.5%) of patients in morphine group, this incidence was reduced down to (22%) by using epidural haloperidol. In agreement with us, all relevant studies proved significant antipruritic effect of epidural butyrophenone. Horta et al<sup>8</sup>, who studied patients undergoing CS, had close results to our study; the incidence of pruritus in their study was (74%) and this incidence was reduced to half on droperidol addition. A similar study of Naji et al<sup>2</sup>, also showed significant reduction in the incidence of pruritis from (55%) in morphine group to (25%) in morphine droperidol group. The lower incidence of pruritis in MG in their study maybe attributed to the relatively smaller dose of morphine they used (4 mg) as well as the higher mean age of their patients  $(64 \pm 11)$  compared to our patients  $(36 \pm 12)$ . The more significant reduction in pruritis incidence in our study could reflect stronger antipruritic properties of haloperidol than droperidol.

As regard PONV; in our study, the total incidence of occurrence of nausea and vomiting after using epidural morphine was (77.7%) and reduced in the haloperidol group to (48.1%). Moreover, epidural haloperidol significantly decreased the severity of vomiting. So, while the severe degree of vomiting represented (33.3%) of morphine group, its incidence was only (3.7%) in the haloperidol group. There is some controversy about the effectiveness of droperidol in the treatment or prevention morphine induced PONV in other studies. *Naji et al*<sup>2</sup>, showed more significant reduction in the incidence of nausea and vomiting from (65%) in morphine group to (35%) in morphine droperidol group. On the other hand *Sanansilp et al*<sup>5</sup>, who used similar morphine dose for PO analgesia for CS failed to demonstrate a significant reduction in the incidence of occurrence of nausea and vomiting by epidural droperidol; this might be explained by the additive dose of pethadine (75mg) given in this study for treatment of shivering (24.2%) in MG, (34.4%) in droperidol group.

The fact that pain is a highly subjective experience and the poor educational level of most of our patients made the pain assessment using (VAS) really challenging to us. Pain scores were lower with epidural haloperidol, but a significant enhancement of the analgesic effect of morphine by epidural haloperidol was not confirmed within the 24-h study design. In agreement with our results, *Naji et al*<sup>2</sup>, showed no significant differences in pain score among the two groups.

However, Serum cortisol measurements ensured better pain control in haloperidol group in our study. It revealed that (77.8%) of haloperidol group had serum cortisol level less than (200 mg/dl) in comparison to (44.4%) of morphine group. Relevant studies were not concerned with serum cortisol level. Lower serum cortisol in MHG might explain why analgesic consumption was much higher in morphine group, (66.7%) required poster analgesia despite insignificant differences in VAS among the two groups. Significant sedation experienced by patients in MHG might result in less analgesic consumption; only (7.4%) required poster analgesia.

All haloperidol patients experienced some degree of sedation in our study (100%), but non of them had been severely sedated. This was highly significant when compared to morphine patients, as only(39.7%) experienced variable degrees of sedation, while (59.7%) did not experience any degree of sedation . in agreement with our study; Horta et al8. reported a significant increase in somnolence with (5 mg) epidural droperidol (35%). Bach et al<sup>9</sup> reported a significant increase of sedation (26%) with epidural droperidol. The great variabilityin the incidence demonstrate the difficulty in assessing sedation in patients given neuroleptics. These compounds induce a state of quiescence, with reduced movements, diminished expressed anxiety and a degree of indifference to the surroundings. This could easily be mistaken for sedation especially because we had no previous experience with such drugs. The stronger neurosuppressant effect of haloperidol than droperidol might be a cause, as well.

Urinary retention was less with epidural haloperidol but this difference was not statistically significant (P-value=0.83). Likewise, *Naji et al*<sup>2</sup>, reported insignificant reduction in retention with droperidol.

In MG group, one patient (3.7%) had moderate degree offever (38.5 C), while five patients (18.5%) had fever in MHG group. No other studies had focused on such finding. This couldn't simply be attributed to drug induced fever without excluding the other causes of fever in our study, which needs further investigations. Although we did not observe other respiratory, cardiac or central nervous system side effects, further studies are recommended as regard this issue.

# Conclusion

This study concluded that, adding haloperidol to epidural morphine when certain safety measures are taken is safe, feasible and helpful technique for better postoperative analgesia, lesser anesthetic consumption and significantly decrease the unwanted side effects of epidural morphine for adult patients undergoing thoracotomy.

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# Surgical Internal Fixation versus Conservative Treatment by Mechanical Ventilation for Management of Flail Chest

Mohamed Abul-Dahab; MD\* Tamer Fouda; MSc\* Pierre Zarif; MD\*\* The strategy for treatment of flail chest remains controversial. Debate between MV and surgical fixation persisted for years.

<u>Methodology</u>: Twenty patients were randomized into two groups, group I: was managed by MV. Group II was treated by surgical internal fixation. Both groups received thoracic epidural analgesia when feasible and mechanical ventilation with lung protection strategy was achieved. In group I, age ranged from 18-65 with mean  $34.4 \pm 13.38$ , while in group II age ranged from 21-69 with mean  $44.2 \pm 19.46$ . We used plates for fixation together with screws and stainless steel wires with which we observed more stability than the mere use of wires or absorbable sutures alone.

<u>Results</u>: There was no statistically significant difference as regards the age, sex, associated injuries in both groups, the stability gained one month after the trauma, but there was significant difference regarding the mean duration of mechanical ventilation, ICU stay and incidence of chest infection in both groups. There was no statistical significant difference between both groups regarding hospital stay, morbidity and mortality although it is lower in the surgical group.

<u>Conclusion</u>: Surgical fixation is a successful treatment modality in patients with traumatic flail chest as it avoids long term mechanical ventilation, resulting chest infection and allows early discharge from ICU with less mortality.

#### KEY WORDS: Flail, mechanical ventilation, surgical fixation



lail chest complicates about 10% to 20% of patients with blunt chest trauma and is associated with a mortality rate ranging from 10% to 35%. Flail chest is included to the major, often life-threatening decelerational injuries along with sternal fracture serving as a marker of significant intrathoracic injury [1].

The management of severe flail chest has gradually changed over years, as a consequence of improved ventilatory techniques and better understanding of the pathophysiology of the complex traumatic acute respiratory failure syndrome. Internal pneumatic stabilization with mechanical ventilation is the standard treatment for patients with flail chest and respiratory failure, or when associated head and/or abdomen injuries require mechanical ventilation [2, 3].

The treatment of flail chest injuries has evolved over the last 4 decades from immediate endotracheal intubation for at least 7–10 days with a mandatory tracheostomy until there was no movement of the flail segment, to the present when every effort is made to provide good analgesia and avoid intubation [4]. The use of epidural analgesia is limited in the trauma population due to numerous exclusion criteria. However, when feasible, epidural analgesia is associated with a decrease in the rate of nosocomial pneumonia and a shorter duration of mechanical ventilation after rib fractures.[5]

In patients with isolated blunt chest trauma who have severe flail chest without significant pulmonary contusion, prolonged internal pneumatic stabilization is not suitable because of the risk of ventilator-related infectious complications. Moreover, mechanical ventilation is not always successful in preventing chest wall deformities that may result in a subsequent respiratory restrictive dysfunction [3, 6].

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stabilization) may result in shorter intensive care unit stay with lower morbidity and prevention of pulmonary restrictive complications resulting in working incapacity [3], [5]. Moreover, prolonged paradoxical motion of the chest wall before spontaneous stabilization occurs can lead to additional mechanical impact on the contused lung area by the flail segment. Furthermore, the broken rib tips may disrupt the lung parenchyma [7]. This is because fractured ribs treated conservatively undergo progressive displacement during the healing phase, which results in considerable deformity, volume loss, and atelectasis. Endotracheal intubation and ventilation may not be able to prevent rib cage distortion [7]. Early surgical stabilization can prevent additional injury as well as promote earlier weaning from the ventilator [4].

The primary end point for this clinical situation is the prevention of late chest restriction due to an anatomically deformed spontaneous stabilization. Surgical stabilization of a flail chest is also mandatory when the trauma patient is undergoing a thoracotomy for associated thoracic lesions. In this situation, chest wall stabilization does not add significant surgical morbidity [3].

Although surgical management of patients with severe flail chest is at present controversial, we think that surgical stabilization is strongly indicated in specific clinical situations regarding reduction in morbidity and mortality, ICU stay, hospital stay, and the early return of the patient to work. The aim of this study is to compare two methods used for stabilization of the chest wall: the conservative method by mechanical ventilation and the method of surgical fixation of the flail segment. Through a prospective comparative study, the early results and the results at one month after trauma of both modalities of treatment will be compared together with their effect on morbidity and mortality.

# **Patients and methods**

20 patients of flail chest with respiratory failure undergoing this randomized study, 10 of them to be managed by surgical fixation versus 10 managed by internal pneumatic stabilization (mechanical ventilation).

Inclusion criteria include all the patients with blunt chest trauma associated by severe flail chest (flail chest with respiratory failure, tachypnea RR>30, PO2<50 either with or without PCO2>50 inspite of good analgesia) requiring mechanical ventilation or already on mechanical ventilation.

Exclusion criteria include:

 Patients presenting to emergency room unconscious due to other causes as severe head trauma because these patients need mechanical ventilation whether they had the internal fixation or not. But if the patient regained his consciousness, he is considered in the study.

- Patients with severe lung contusion as these patients require mechanical ventilation whether fixed or not.
- Patients with history of pre-existing lung disease; e.g., bronchial asthma.
- · Patients with pre-existing chest wall deformities.
- Exclusion criteria for thoracic epidural include; any acute spine fracture or pre-existing spine deformity, severe traumatic brain or spinal cord injury, or severe altered mental status such that pain could not be assessed, unstable pelvic fracture or open abdomen that would preclude positioning for epidural placement, ongoing cardiac instability or coagulopathy, active chest wall infection, and acute thoracic aortic transection.

On arrival to the ER, routine medical history and full general and local examination are done to assess the effect of trauma on different body organs and to exclude the presence of any chest diseases or chest wall deformities with immediate and appropriate management for keeping the patient vital signs stable; resuscitation in shocked patient and management of concomitant lesions.

All patients are admitted after that to the intensive care unit and received general and local examination together with radiological assessment in the form of chest X-ray and CT chest if possible. Routine labs were done to detect the presence of baseline hemoglobin and total leucocytes count or any organ dysfunction or coagulopathy together with ABGs to detect any present or ongoing respiratory failure.

Intercostal chest tube was inserted in those who have pneumothorax or pleural collections or hemopneumothorax.

Narcotic analgesics were given in doses that do not produce respiratory center depression and if possible epidural analgesia is applied. Patients are randomized either for conservative treatment (group I) or for surgical treatment (group II).

**Group I patients** were considered to be the conservative group to be managed by mechanical ventilation. Patients in this group will stay on mechanical ventilation till fixation occurs or till weaning from mechanical ventilation can be done with good arterial blood gases and deep breathing can be done by the patient.

These patients were put on continuous monitoring by CVP, urinary catheter, noninvasive arterial blood pressure and frequent daily arterial blood gases with follow up by daily chest X-rays. Fluid balance was observed with some sort of fluid restriction for the concomitant lung contusion keeping the patient with negative balance or at least to be balanced in the first few days. Some medications were added for aiding in the management of lung contusion; e.g., diuretics and corticosteroids.

Pulmonary toilet and hygiene were done by frequent suction, positioning and frequent percussion on the back with

the use of mucolytics either given through the Ryle used for feeding or given intravenously.

Follow up for pneumonia and chest infection was kept in mind by observing the patients' temperatures for the possibility of occurrence of fever with follow up of total leucocytic count and its shift to the left together with doing daily chest X-rays.

Postoperative pain control through thoracic epidural, if possible, using bupivacaine 0.125% together with fentanyl( $2\mu/m$ ) to be infused continuously (3-5ml/hr) till the patient become pain free after extubation. If epidural analgesia cannot be applied; e.g., in cases of fracture spine, narcotic drugs (morphine)are given in doses so that not to affect respiration.

Patients were fed through Ryle with adjustment of patients electrolytes by lab follow up.

Frequent positioning was done to avoid the occurrence of bed sores with the use of elastic stocking and anticoagulants in prophylactic doses against DVT after the stabilization of the lungs condition regarding the presence of contusions.

**Group II patients** were managed by surgical fixation preferably after 24 to 48 hours after admission to ICU (some patients were fixed after being on mechanical ventilation for 4-5 days with ongoing bad arterial blood gases or failure of weaning from the ventilator).

These patients were managed initially as the conservative group regarding monitoring, IV lines, labs, frequent daily ABGs, chest X-rays and if possible CT chest including bone window with 3D reconstruction of the thoracic cage which helps greatly in identifying the number and accurate sites of the fracture ribs. The thoracic epidural analgesia was applied if possible.

Under general anasthesia with epidural analgesia if possible or intercostals nerve block, the patient was positioned according to the site of fracture ribs and the decision planned; i.e., supine in cases of anterior flail undergoing fixation parasternally alone or with fixation of sternal fracture if present. In case of anterolateral, lateral or posterolateral flail, the patient is positioned in lateral position with the side occupying the fracture undergoing fixation upwards.

The incision was individualized according to the site of the fracture and the plan put; i.e., in case of anterior flail, midline skin incision was done with doing pectoral flap for fixation of the ribs fractured parasternally with fixation of fractured sternum if present.

In cases of anterolateral, lateral or posterolateral flail, lateral thoracotomy was done and extended according to the need. Dissection is tailored to the ribs undergoing fixation and muscle cutting was avoided.

Assessment of the severity of flail chest regarding the number and sites of fracture ribs. Removal of any bone fragment due to comminuted fracture, if present, was done. Recording and management of any associated lesions was done; e.g., evacuation of blood clots, repair of lung tears, control of torn intercostals ...etc. Reduction of the fracture ends to be fixed was done after that. We adopted fixation of one fracture site only in each rib leaving the other site of rib fracture to be managed as simple one. However, if the two fracture sites in the same rib were accessible through the incision, both of them were done. Fixation was done in ribs from 4-9 because fracture of the upper 3 ribs has little role in hampering the respiration and the same for fracture of those below the 9<sup>th</sup> one in addition to the limited accessibility of these ribs through the thoracotomy.

Fixation was carried out using different techniques. In some patients we used stainless steel wires alone. In others we used plates and screws that in some patients were associated with stainless steel wires for fixation. In one patient only we use vicryl and stainless steel wire only for fixation.

The advantage of using stainless steel wire alone or with vicryl is that it is easier. The needle is inserted into one of the fracture ends and to be delivered through the other. However, the stability gained by this method was limited if compared to the method of using plates along the fractured rib.

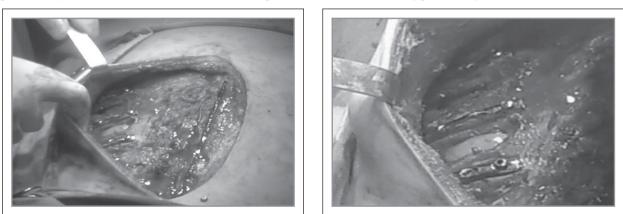


Fig. 1. A, B: A case of anterior flail, midline skin incision was done with doing pectoral flap for fixation of the ribs fractured parasternally using plates and screws

The more difficult but the more efficient method we used was the fixation using the plates and screws or plates and circlage instead of the screws if the rib thickness is thin compared to the smallest screw which may result in loose fixation. We used stainless steel one third tubular plates with cancellous screws (3.5mm) of different sizes (10, 12, 14 and up to 20mm).

Using the power drill, drill holes were made in the rib before and after the fracture site. 2-3 holes at least are made on each side to give maximum stability. This was done with the plate kept on the rib surface using the plate holder. After drilling the rib, sizer was inserted in each hole to decide the size of each screw. Then the screws were inserted and tightened. In case of thin ribs, the smallest screw will protrude through the rib into the chest cavity. To avoid this, we pass stainless steel wire in the holes within the plate on each side of the fracture site to be twisted tightly leaving the knot to the outside surface of the rib to be buried adequately in the surrounding tissues. Plates give the highest degree of stability.

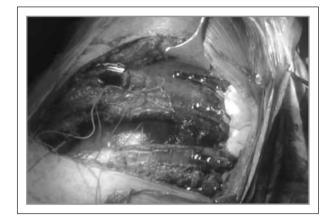


Fig. 2. The ribs after fixation. Proper hemostasis was done, chest tube was put in the chest cavity and drains were left under the dissected muscle flaps

This procedure was repeated with each fractured rib. If some of the fractured ribs were inaccessible, we avoided excessive dissection or muscle cutting incisions by fixing the fractured middle ribs in the flail area leaving one or two ribs above or below so that the flail island was interrupted converting the case from owing flail chest to simple fracture ribs. Finally after the achievement of fixation planned and gaining the stability required, closure in layers was done after meticulous hemostasis to avoid the occurrence of hematomas within the wound. We left one chest tube in the thoracic cavity and one or two suction drains underneath the muscle flap made during dissection.

The incision should be made in the middle area of flail segment to give accessibility to most or all of the fractured ribs.

Postoperatively, patients were planned to be kept for 12-24 hours entubated. Epidural analgesia was kept even after extubation for 2-3 days. During this period the patient was left in the ICU. Supplemental doses of narcotics were given to assist the patient to cough and breathe as deep as possible. Frequent ABGs and daily chest X-rays were done. The patients were discharged to the department where they stay for several days. During the ICU and department stay the patients were followed for fever, leucocytosis and signs of wound infection, dehiscence or the occurrence of hematoma. Chest tube was removed after 48 hours and suction drains were removed once they stop drainage.

Both groups were followed weekly in the first month after discharge to assess the patients generally and locally; i.e., the progress of healing of the fractured ribs (in both groups) and wound healing (in group 2). After 6-8 weeks, the patients were followed by general and local examination together with chest X-rays. Assessment of the degree of deformity left was done in each of the two groups to compare between the two modalities of treatment.

#### **Statistical analysis:**

Quantitative data are presented as the mean  $\pm$  standard deviation (S.D.). Statistical analysis of the data was performed using the unpaired t-test, Chi-square test. For all the statistical comparison, a *P*-value less than 0.05 (*P*-0.05) was considered significant.

### Results

The mean age of the 20 patients was 39.3 years (range, 18-69) and the male/female ratio was 19:1. Associated injuries were found in 18 (90%); to the head in 2(10%), to the abdomen in 1(5%), to soft tissues and bones in 5(25%) and to the thoracic cavity in 17(85%).

Balanced or negative fluid status for pulmonary contusion and vigorous pulmonary toilet was attempted in all patients. Chest tube drainage was carried out in 6 patients (30%) with pneumothorax, 2(10%) with hemothorax and 9(45%) with hemo-pneumothorax. Tracheostomy was performed in 4 patients (20%) needing entubation for longer than 12 days and those with failed extubation.

The causes of flail chest were traffic accidents in 14(70%) cases, falling from height in 4(20%) and crushing industrial injuries in 2(10%).

13 patients (65%) received thoracic epidural analgesia, the other 7 (35%) didn't receive this type of analgesia and received narcotic drugs because one of them had spinal fracture; other 6 were technically difficult because they were entubated.

Epidural analgesia was 6-8ml/hr of 0.125% bupivacaine mixed with fentanyl to be infused continuously. Ventilatory support was required in all cases with variable durations.

Pulmonary contusions occurred in 19 patients (95%). 5 patients (25%) died.

Among the ten patients in **the surgical group**, 1 patient (10%) were unconscious on admission because of extradural hematoma, 1(10%) had undergone abdominal surgery, 1(10%) had fracture in upper and lower extremities.

Fractures in the surgical group were anterior in 2(20%), anterolateral and lateral in 7(70%) and posterolateral in 1(10%). Midline incision was done in 2(10%) while lateral thoracotomy was done in 8(80%).

Indications for fixation of flail chest were concomitant thoracic operations that allowed simultaneous repair of the flail segment in 1(10%), gross instability of a large segment of the chest wall in 6(60%) and failure to wean from the ventilator in 3 (30%). Indications for thoracic operations that allowed simultaneous repair of a flail segment were lung tear and major air leak together with bleeding causing hypovolemic shock.

1 patient (10%) was operated upon during the 1<sup>st</sup> 12 hours due to associated injuries. All the others except 3 patients were operated within 48hrs of trauma. 2 of these 3 were entubated on the  $2^{nd}$  day after the trauma while they were hospitalized due to impaired breathing. On the  $3^{rd}$  to  $4^{th}$  day after ventilation they underwent open fixation because of ABG deterioration. The 2 were weaned from the ventilator after 3 and 5 days successively and got discharged from the hospital after 15 and 30 days successively because of the presence of concomitant lesions (abdominal surgery and fracture femur). 1 patient (10%) was entubated from the start and because of ABG deterioration and failure to wean from the ventilator; the patient had an operation on  $6^{th}$  day to have extubation after 10 days and was discharged from the hospital after 30 days.

Pain control was achieved in all patients in the surgical goup using epidural analgesia postoperatively, together with the use of narcotic drugs. Ventilatory support was done in all patients and duration of ventilation ranged from 12hrs to 19 days with mean of 2.15 days. The hospital stay ranged from 5 to 30 days with mean 13.4 days.

Morbidity in this group was due to wound infection in 1 patient (10%), deformity in 1(10%), local pain 2 months after the operation in 5 (50%) and chest infection in 1 (10%) while tracheostomy was done in 1 patient (10%).

Methods of fixation were plates and screws in 2 (20%) with stainless wires, stainless steel wires and vicryl in 1(10%) and plates with circlage in 7 (70%).

All the 10 patients in **the conservative group** were admitted within the 1<sup>st</sup> day of trauma causing flail chest and all were conscious. None had undergone non thoracic operation before admission. Fractures were anterior in 2 (20%), lateral or anterolateral in 7 (70%), bilateral in 1 (10%). 3 patients (30%) received effective pain control with epidural analgesia together with narcotic and non-narcotic parentral analgesia.

	Befor	re management	After management	P-value
Conservative group	PO <sub>2</sub>	58.6±8	$89.2 \pm 7.6$	<0.001
	PCO <sub>2</sub>	$50.1 \pm 4.3$	$30.9 \pm 2.5$	< 0.001
	$O_2$ saturation	87.2±2	$96 \pm 1.6$	<0.001
Surgical group	PO <sub>2</sub>	56.2±9.2	98.6 ± 21	< 0.001
	PCO <sub>2</sub>	$40.2 \pm 6.3$	$31.2 \pm 5.9$	0.004
	$O_2$ saturation	85.1±3.4	96.8 ± 3	< 0.001

Partial pressure of oxygen (pO<sub>2</sub>), partial pressure of carbon dioxide (pCO<sub>2</sub>). Not significant (N.S.).

Table 1.	Blood ga	s analvsis	in 20	patients	with tr	raumatic	flail chest

Post management data	Conservative group	Surgical group	P-value
Mechanical ventilation Number of patients (%)	ALL	ALL	
Mean duration of mechanical ventilation (days)	$9.6 \pm 5.98$	$2.15 \pm 3.15$	0.003
Mean ICU stay (days)	12.8 ± 8.35	4 ± 5.27	0.011
Mean hospital stay (days)	$15 \pm 10.12$	$13.4 \pm 9.19$	N.S.

Not significant (N.S.).

Table 2: Post-management data in 20 patients with traumatic flail chest

The mean duration of paradoxical chest wall movement was 6.6 days (range 3-21 days) and ventilatory support ranged from 1-18 days (mean 9.6 days). The mean hospital stay was 15 days (range 1-25 days) and morbidity was in 8 (80%) in the form of pneumonia which was diagnosed by high fever (>39c), infiltration on chest X-ray, leucocytosis. Atelectasis persisted during ventilatory support and after weaning. ARDS occurred in 2 (20%). Bed sores occurred in 4 patients (40%). Tracheostomy was done in 3 patients (30%). Chest deformity occurred in 3 (30%).

Mortality occurred in 4 patients (40%). 2 died because of respiratory failure from ongoing lung contusion 24 hours after admission. The other 2 died from ARDS with high  $CO_2$  despite respiratory treatment.

# Discussion

The treatment of flail chest injuries was and still controversial and the lines of treatment described since 1950s till now are full of debate. One reason for the controversy concerning treatment is that mortality for flail chest has not changed in certain centers over the past several decades. This is despite obvious advances in the overall care of trauma victims and marked improvements in ventilator support techniques [4], [7]. However, decreases in mortality from 30%–40% in 1976 to 11%–60% in the 1980s have been reported; which still significant. The treatment has evolved over the last 4 decades from immediate endotracheal intubation for at least 7–10 days with a mandatory tracheostomy until there was no movement of the flail segment, to the present when every effort is made to provide good analgesia and avoid intubation [4].

It is obvious that the major injury requiring ventilatory support is underlying pulmonary contusion and not the motion of the chest wall. Some have advocated operative fixation of a flail segment so that there is no motion, but others see that this greatly over simplifies the pathophysiology of the problem [4]. We see that it is not the paradoxical movement that causes the respiratory failure but its impact on the lungs with the resulting lung contusions together with the hypoventilation and restriction of respiration on top of pain; which result also from the paradoxical respiratory failure. We evaluated the patients on the basis of the severity of flail chest and the underlying pulmonary injury, especially pulmonary contusion, with the effect of both on respiratory status and applied appropriate treatment.

Early surgical stabilization can prevent additional injury as well as promote earlier weaning from the ventilator. Less analgesia may be required postoperatively, and these factors may lower morbidity for isolated flail injuries [4,5,9]. Moreover, open fixation of the chest wall may be a good alternative for patients who have deteriorated under ventilatory treatment because it shortens the ventilator time and decreases mortality [4, 9]. Many studies showed that the obvious indication for a surgical approach is an internal injury requiring a thoracotomy. In our opinion, this is the correct approach; but surgical intervention should also be considered in patients with excessive paradoxical movement, deteriorating clinical status, or unremitting pain hampering respiration.

In our study we did a randomized study on patients with flail chest requiring mechanical ventilation for respiratory failure. Each group was managed by either mechanical ventilation or surgical fixation. Patients in this study had fulfilled the inclusion and exclusion criteria while the surgeon's experience was saved for the methods used for fixation and the appropriate technique.

The major cause of mortality and morbidity is respiratory failure resulting from contusion or laceration by a detached rib fragment. With large flail segments, mediastinal shift is possible, with accompanying decreased venous return to the heart. Depressed rib segments impart a crushing injury and may penetrate the diaphragm, lung, heart or aorta [4]. Increases in routinely performed tracheostomy with long-term ventilation until the flail segment stabilized or until the pulmonary contusion was no longer present on the chest radiograph led to a high incidence of nosocomial infections and tracheostomy complications that resulted in severe disability or death[4, 8]. Pneumonia was an important cause of mortality.

Placement of a thoracic epidural catheter was problematic in some patients of the study because it was difficult to put patients with flail chest in the proper position to place the catheter; this is why we did not use it in all of the patients, but it was of great benefit in those we used it with them regarding the marked relief of pain.

Among the disadvantages of operative stabilization is the required general anesthesia which is inherently risky for patients who have sustained multiple and severe trauma, or the presence of associated severe injuries such as myocardial contusion. Techniques of stabilization can be difficult, time consuming, and the additional dissection required to accomplish these repairs may increase local tissue injury. Implanted foreign bodies can contribute to chronic osseous and soft tissue infections [6, 10].

Different methods have been used for the stabilization of fractured segments, all of which have been reported to be successful. We used fixation with stainless steel wires passed through plates and tied firmly to give more stability. The use of plates and screws; if the rib can withstand the screws, give more and more stability but the problem that in some instances the rib is too thin to hold the smallest screwed nail. In these situations we either used stainless steel wire alone or preferably with plates. We noticed that the use of plates gave the best stability if compared to fixation without their use

In the case of a very large defect with instability involving the anterolateral part of the chest wall, Carbognani and associates in 2000 suggested that the use of an extrapleural long bar, associated if necessary with other standard devices, can be very useful [10]. The Sea Gull Wing Prosthesis, which is self-retaining and easily removable, has been proposed by Actis Dato and associates in 1999 [10]. Mayberry and his associates reported in 2003 about their preliminary experience with absorbable plates for rib fracture repair with good clinical results as an option for rib fracture repair [12].

As regards the stability of the chest wall after surgical fixation, our results with 90% stability are coinciding with those reported in the literature. Andreas Granetzny and associates in 2005 used Kirschner wires, stainless steel wire, or both with 85% stability obtained [6]. Fabbri and associates in 1996 managed flail chest surgically by osteosynthesis of the ribs using small plates and reported that 87.5% of their patients were stabilized as regards paradoxical motion of the chest wall [13]. In 1995 Ahmed and Mohyuddin used Kirschner wires for fixation of the flail parts achieving stability in 87.5% of their patients [14]. Reber and his colleagues in 1993 used plates for fixation of the flail segment and the stability was achieved in all patients without secondary dislocation [15]. Lardinois and his colleagues in 2001 used 3.5 mm thick reconstruction plates as used for pelvic stabilization and obtained fixation in nearly all their patients [6].

Chest wall injury may result in a variety of delayed sequelae. The most common late problems are chronic pain two months after surgery and chest wall deformity (Stove-in chest) in 10% of patients. This was in agreement with Reber and his associates in 1993 who reported that stability of the chest wall without chest wall deformity was achieved in all the survivors with flail chest who were surgically fixed [15]. In 1995 Ahmed and Mohyuddin stated that 12.5% of their patients who were surgically treated had minimal chest wall deformity [14]. Andreas Granetzny and associates in 2005 stated that 5% of their surgically treated patients had chest wall deformity

In our study tracheostomy was done in 30% of conservative group patients compared to only 10% in the surgical group. In 1995 Ahmed and Mohyuddin stated that tracheostomy was required in 37% of patients in the ventilated group whereas only 11% of the patients in the surgically treated group required this procedure [14].

In our study chest infection and pneumonia occurred in 80% of conservative group patients compared to only 10% in the surgical group. In 1995 Ahmed and Mohyuddin stated that chest infection occurred in 50% of the conservative group patients while the prevalence of chest infection was much lower in the surgically treated group (15%) [14]. Andreas Granetzny and associates in 2005 stated that 10% of their surgically treated patients had chest infection compared to 50% of the ventilated group [7].

Mean duration of mechanical ventilation was 9.6 days (range 1-18) in the conservative group while was 2.15 days (range from 12hrs to 19 days) in the surgically treated group. Balc1 and his colleagues in 2004 had mean duration of mechanical ventilation 3.1 days while the non- surgically treated patients had mean duration of ventilatory support of 7.2 days [4]. Andreas Granetzny and associates in 2005 had mean duration of ventilatory support of 2 days compared to 12 days in conservative group [6]. Lardinois and his colleagues in 2001 reported a mean duration of postoperative intubation was 2.1 days, ranging from 0.5 to 26 days [5]. In 1995 Ahmed and Mohyuddin study, patients from the ventilated group required the use of a ventilator for an average of 15 days. Against this, patients from the surgically treated group received assisted ventilation for an average of 3.9 days [14].

The ICU stay mean was 4 days in the surgical group whereas 12.8 days in the conservative group. Andreas Granetzny and associates in 2005 had ICU stay mean of 9.6 days in the surgically fixed group while mean stay was 14.6 days in the conservative group [6]. In Lardinois and his colleagues study in 2001, the patients were transferred from the intensive care unit to the ward after an average of 6.8 days (range 1–48 days) [6]. In 1995 Ahmed and Mohyuddin study, patients from the ventilated group required ICU stay of average 21 days. Against this, patients from the surgically treated group stayed in the ICU for an average of 9 days [14].

The hospital stay ranged from (5 to 30) days with mean 13.4 days in the surgical group compared to 15 days (range 1-25) in the conservative group and this is because 2 cases died within 24 hours after admission in the conservative group while there were 2 cases of the surgical group who stayed in the hospital for 30 days because of concomitant non thoracic injuries. Balc1 and his colleagues in 2004 had mean duration of hospital stay of 18.3 days (range 9 to 32 days) in surgical group while was 19.6 days (range 8–33 days) in conservative group [4]. Andreas Granetzny and associates in 2005 had 11.7 days as mean hospital stay in the surgical group while mean stay was 23.1 in the conservative group [7]. In Lardinois and his colleagues study in 2001, mean hospital stay was 17.4 days, with a range of 8–60 days [6].

The mortality rate was 30% in our patients who were treated conservatively. Similar results were reported in the literature with a 21% mortality rate among the patients who were treated conservatively and required ventilator support. On the other hand, mortality rate in our surgically treated patients was 10%. This coincided with the results of other centers, who reported an 8–12% mortality rate in surgically treated patients. Lardinois and his colleagues in 2001 reported mortality about 11% in their surgically treated patients, while Granetzny and associates in 2005 mentioned 10% mortality in their patients [6], [7]. In 1995 Ahmed and Mohyuddin had mortality rate of 29% among the conservative group compared with 8% in patients in the surgically treated group [14]. Balc1 and his colleagues did a study in 2004 and revealed mortality of 11% compared to 27% in the conservative group [4].

In conclusion we suggest that surgical fixation of a flail segment with an individualized management approach is a method of great value in the treatment of flail chest. In this modality of treatment, stability without deformity of the chest wall is achieved. Patients surgically stabilized had a significantly smoother course during the intensive care unit and hospital stays, had a significantly decreased rate of complications, and had almost no residual chest wall deformity.

Although the groups did not fulfill statistical comparability criteria, mortality seemed to be lower in the surgically managed group, duration of ventilation was shorter, less ICU stay, less incidence of respiratory tract infection but the hospital stay and morbidity were similar to those in the nonsurgical groups. It was concluded that surgical fixation is a successful treatment modality in patients with traumatic flail chest.

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**Case Report** 

# Ectopic Mediastinal Thyroid Tissue A Case Report and Review of The Literature

Raed Mostafa Alareeni Mahmoud El batawi <u>BACKGROUND</u>: Ectopic intra-thoracic thyroid is a very rare presentation of a mediastinal mass, comprising 1-3% of retrosternal goiters and about 1% of Mediastinal tumors.

*Case presentation:* A case of 59-year – old Femele with a mediastinal mass that proved to be ectopic intra thoracic thyroid tissue is presented.

The mass was completely excised through a right postero– lateral thoracotomy and pathological examination confirmed multinodular goiter associated with colloid cyst formation and secondary hyperplesia. Relevant literature is briefly reviewed.

KEY WORDS: Ectopic thyroid, middle mediastinum, thoracotomy.

urgical removal relieved symptoms, excluded malignancy and provided definite diagnosis of mediastinal mass Ectopic intrathoracic thyroid is a very rare presentation of a mediastinal mass, comprising 1-3% of retrosternal goiters and about 1% of mediastinal tumors<sup>(1)</sup>. Ectopic thyroid tissue way be found between the foramen ceacum and the normal position of thyroid gland.

The most frequent locations are along the midline from the base of the tongue to the mediastinum<sup>(2)</sup>. Ectopic thyroid tissue has been described in the submaudibular region, trachea, heart, lung, duodenum, Adrenal gland an parotid Salivary gland<sup>3</sup>.

A case of a -59- year old Femele with a middle mediastinum mass that proved to be ectopic intra thoracic thyroid tissue is presented through a right posterolatral thoracotomy and pathologicl examination confirmed multinodular goiter associated with colloid cyst formation and secondary hyperplasice.

# **CASE PRESENTATION**

A 59-year – old Femele presented to our department for management of a mediastinal mass. She had a history of cough, dyspnea, and dysphagia over the last six mounths. Physical examination was normal. She had undergone subtotal thyroidectomy 30 years earlier, and had not been placed on thyroid supplement ever since. Thyroid function tests done a week prior to admission were normal. Chest radiography revealed a mass in the superior mediastinum with trachea deviation (Figure 1) computerd tomographic scan of the chest showed a round mass 70 x 60 mm in size, at the patient side of the middle mediastinum (Figure 2) Abdomen, brain and bone scan was negative for metastasis disease subsequently, the patient was subjected to surgery. Atypical Rt postero lateral thoracotomy was performed. Intra operativele findings revealed a firm and encapsulated mass with in the middle mediastinum next to superior vena cava and trachea (Figure 3) extended to the Rt apex of lung and next to azygaus vein.

The mass derived its blood supply from RT snbclavian vseless. The mass was Completele exciased. (Figure 4-5).

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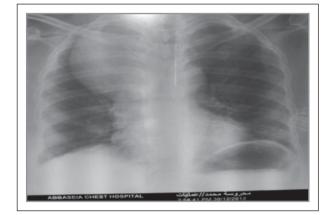


Fig. 1. Chest x-ray revealed a mass in the superior mediastinum with tracheal deviation.

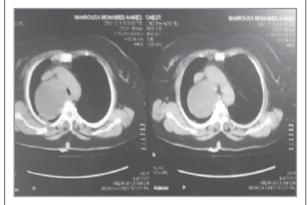


Fig. 2. Computed tompgraphic scan of the chest showed a round mass,  $70 \times 60$  mm in size, at the right side of the middle mediastinum

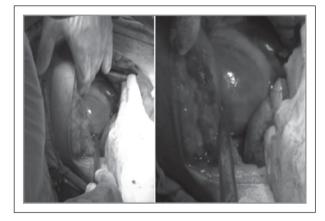


Fig. 3. Intraoperative findings revealed a firm and enapsulated mass in the superior mediastinum next to the superior vena cava aand the trachea.



Fig. 4. Macroscopic appearance of the reseeted specimen



Fig. 5. Macroscopic appearance of the reseeted specimen

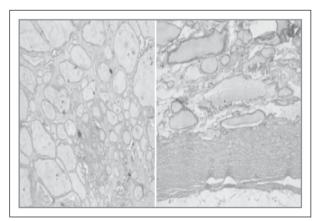


Fig. 6. Histopathologic examination of the mass, using hematoxylin -eosin revealed multinodular with colloid cysts.

Histo-pathological examination of the mass using hematoxylineosin, revealed multinodular goiter with colloid cyst (Figure 6) the postoperative period was uneventful.

# DISCUSSION

Ectopic thyroid tissue has been found along the midline from the base of the tounge to the mediastinum. Ninety percent of the reported cases are found at the base of the tounge, while 10% lie in the anterior aspect of the neck superficial to the hyoid bone. Ectopic thyroid tissue is rarely faund in other locations<sup>(3.4)</sup>.

Heterotopic thyroid tissue in the anterior mediastinum has probably originated embryological from rudiments of developinq thyroid dragged into the chest during the descent of the heart and great vesseles with the development of the embryonic neck and the unfolding of the embryo<sup>(5)</sup>.

Ectopic intra thoracic thyroid can be distinguished from retrosternal goiter or secondary intra thoracic goiter from the fact that the former receives its basal supply from mediastinal vessels rather than neck and is not connected to the cervical thyroid except from a thin band of conective tissue. patient with intra-thoracic thyroid are usually asymptomatic with the tumor reported as an incidental finding on chest radiography. They are usually euthyroid as in the present case. Some times they may present with respiratory symptoms similar to the those of this dysphagia, weight loss, chest pain superior vena cava syndrome.

Chest x-ray is usually diagnostic for a soft tissue mass. Other findings include tracheal displacement, tracheal compression or calcifications.

Chest computed tomography and magenetic resonance imaging provide important information abaut location of the ectoptic thyroid tissue and its relation with the great vessels and other mediastinal structures. Scintiqraghy, when intra thoracic thyroid is suspected, its useful and effective for differential diagnosis of other mediastinal tumors.

However, uptake of I<sup>131</sup> is not always observed in ectopic thyroid tissue and scintigraphy is not always diagnostic<sup>(6)</sup>. True malignant transformation in ectopic thyroid tissue is extremely rare<sup>(7)</sup>. Nevertheless these masses should be resected surgically due to the risks of malignant transformation, progressive enlargement, hemorrhage within the mass causing respiratory failure, and compression of neighboring vital mediastinal organs<sup>(8)</sup>.

With regards to the surgical approach, thoractomy provides both surgical convenience and allows a complete resection with easy access and better visuallitation<sup>(9)</sup>. Axillary thoracotomy although muscle sparing is not indicated for surgical treatment of mediastinal masses, especially in cases with no definite preoperative diagnostic thoracoscopic excision has also been reported with excellent results<sup>(10)</sup>. Operability must be determined early and in many cases is not able to be confirmed until after thoracotmy or sternotomy.

Surgery has a very low mortality rate (0-2%) and an acceptable morbidity<sup>(11)</sup>.

Prognosis following a successful surgical excision is excellent.

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**Case Report**