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Comparison of Braided Polyester Versus Standard Stainless Steel Wire Sternal Closure in Open Heart Patients

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ABSTRACT

Background: Postoperative complications associated with poor sternal fixation can result in morbidity, mortality, and considerable resource utilization. Ideal sternal closure is not the only but an important factor to decrease postoperative morbidity and mortality. The ideal sternal closure should ensure stability, reduced rate of postoperative complications, and a short hospitalization period, alongside cost-effectiveness. **Objective:** To compare two sternal closure techniques; steel wire closure vs braided polyester No.5 sutures, regarding sternal stability, early and late postoperative pain, reoperation for bleeding, sinus formation, and superficial and deep sternal infection. **Patients and Methods:** This was a prospective, non-randomized, comparative study that enrolled a total of 118 patients who underwent open heart surgery via sternotomy, divided into 2 equal groups: **Group A:** 59 Patients with sternum closure by braided polyester No.5, and **Group B:** 59 patients with sternum closure by standard stainless-steel wire. **Results:** Group A showed no sinus complications compared to group B in which 4 patients developed postoperative sinus, p value = 0.03, reoperation rate for bleeding was one patient in Group A (1.7%) vs four patients in Group B (6.8%), p value = 0.045, and frequency of late postoperative pain (one patient in group A (1.7%) vs four patients in group B (6.7%), P value 0.03, the difference proved to be statistically significant. In Group A, one out of 58 patients (1.7%) had sternal instability, while in group (B) 3 out of 59 (5.0%) were found unstable, and difference was statistically insignificant (P value 0.648). **Conclusion:** We found that braided polyester sutures No.5 can be used as a safe alternative to standard stainless-steel wire. Beside this material has proven lower rate of sinus formation and less late complications.

Keywords: Braided polyester, Cardiac surgery, Ethibond 5, Sternal stability, Sternum closure.

INTRODUCTION

In 1957, median sternotomy became the standard incision for cardiac procedures and has remained so until today[(1)]. The sternum is responsible for the stability of the chest, once divided, it has to be stabilized properly to allow healing under the continuous stress of respiratory and scapular movements[(2)]. An unstable sternum can result in catastrophic morbidities such as wound infection and mortality[(3)].

Although sternotomy closure is straight forward, it is not without complications. Although stainless steel wire has proven the most reliable and widely used sternotomy closure material[(4)], however, steel wire closure isn't without complications, it's associated with risk of sternal dehiscence, wound infection, sinus formation, bleeding, pain early and late postoperatively. Alternative materials are needed with reduced risk of complications. No experimental studies have compared a large variety of closing materials in a human model; a sternal closure method that's easy to apply and associated with less complications. Still some trials have been done to find another material providing more stability.

The purpose of this study was to compare the hospital outcome and short term results (3 months) of two closing materials used for median sternotomy incision, using the braided polyester No. 5 and standard stainless steel wire regarding sternal stability, wound infection, mediastinitis and rewiring rate.

PATIENTS AND METHODS

This is a prospective comparative study including 118 patients, who underwent adult cardiac surgeries in National Heart Institute and Cairo University Hospitals, from the first of January 2019 till the end of July 2019. Patients were divided into 2 groups: Group A: 59 Patients with sternum closed by braided polyester No.5, and Group B: 59 patients with sternum closed by standard stainless steel wire.

The following data are recorded in each group:

Age, Gender, Ejection fraction (EF), Body Mass Index (BMI), presence of COPD (Chronic Obstructive Pulmonary Disease), current smoking status, type of surgery, total bypass time, aortic cross clamp time, duration of mechanical ventilation, length of ICU stay, length of hospital stay, surgical reopening, early serous discharge

The exclusion criteria were preexisting autoimmune diseases, connective tissue disorders, uncontrolled diabetes mellitus with glycated hemoglobin higher than 8. Sternal closure was performed with braided polyester No. 5 sutures - Ethibond, (Ethicon, Somerville, NJ) (Group A) or with conventional stainless steel wire, (Group B). All patients in both groups were followed for three months, and assessed clinically for occurrence of superficial or deep wound infection, sternal stability, late development of seroma, appearance of sinus discharging pus, and late sternal pain. The study endpoint was to compare the frequency of superficial infection, mediastinits, sternal dehiscence, pain severity post sternotomy as well as rewiring rate in the intervention and control groups. All participants gave written informed consent.

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All patients received 2 grams intravenous (IV) ceftriaxone every 24 hours at the time of induction until chest tube removal. Moreover, patients undergoing on pump coronary artery bypass grafting also received 1 gr IV amikacin at the time of intubation and 24 hours after, this is the institution routine because internal mammary harvesting predisposes sternal wound infection.

Surgical Technique:

The surgeon on duty on the day of surgery performed both the conventional median sternotomies and the sternal closures in either group. In one group (Control group), two figure of 8 conventional stainless steel wires were placed through the manubrium and another two through the body of sternum to coapt the sternum (Figure 1). Similarly, in the intervention group, four figure of 8, Ethibond number 5 sutures were placed through the manubrium and body of the sternum, sliding knots were used to ensure tight sternal coaptation (Figure 2). The soft tissue and skin were closed in a routine manner in both groups. Same postoperative care was given in both groups.

In the intensive care unit, criteria for extubation were: hemodynamic stability, fully conscious status, arterial blood gases met the criteria for extubation, and no significant bleeding from the chest drains.

Patients were discharged from the intensive care unit after stopping inotropes and chest drains removed.

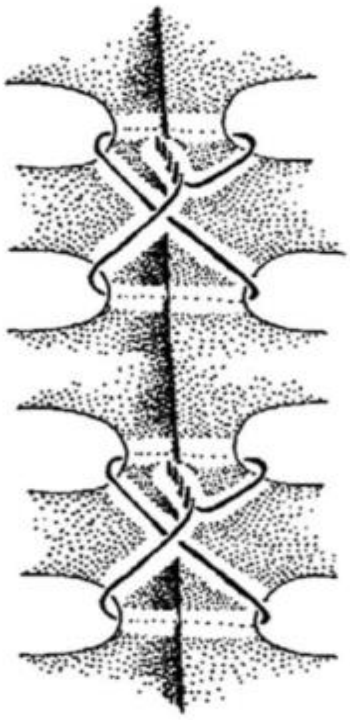

Figure (1): Technique of sternal closure using four figure-of-8 steel wire [5].

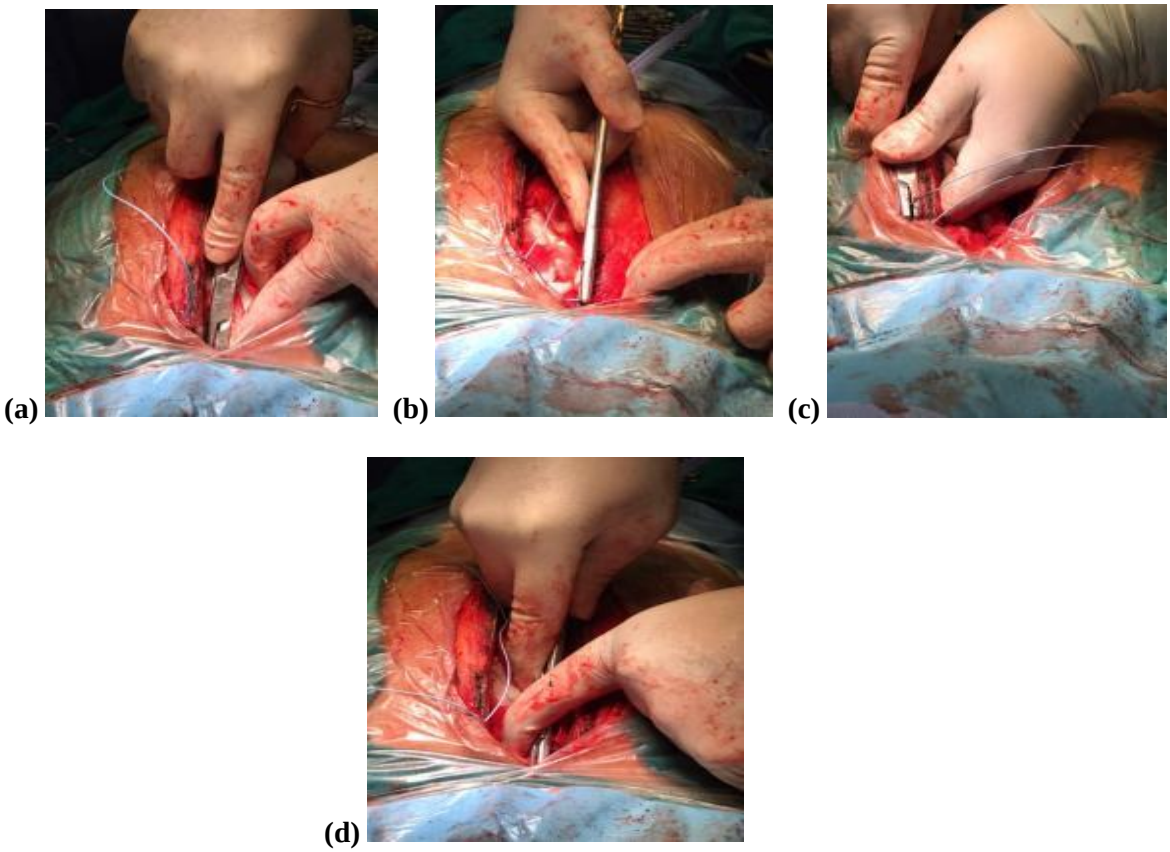

Figure (2): Surgical technique of sternotomy closure, using figure of 8 stitches of braided polyester no.5 sutures; (a) passing the needle at left manubrial half, (b) receiving the needle, (c) after the needle passed through the right manubrial half, it's passed again at the left manubrial half – the suture is seen making a second loop, (d) receiving the needle at the left manubrial half again.

Follow-Up:

After discharge, patients were followed postoperatively up to 3 months after discharge, checking for postoperative complications including pain severity, wound dehiscence, incisional infections (superficial or deep), and organ/space infection (mediastinitis or osteomyelitis), and surgical rewiring.

The diagnosis of incisional and organ/space infection was made according to the Guideline for Prevention of Surgical Site Infection[6]. Incisional infections are divided into superficial and deep infections. Superficial wound infections refer to those involving only skin and subcutaneous tissue (Superficial Surgical Site Infection (sSSI)). Deep infections refer to those involving deeper soft tissues of the incision (Deep Surgical Site Infection (dSSI)) and Organ/Space SSI refers to involvement of any part (e.g., organ or space) other than incised body wall layers that were opened or manipulated during the operation. All cases suspected for infection were referred to a single cardiac surgeon for confirmation and determining plan of management in association with the operating surgeon. Patient's postoperative pain was measured by the use of a 0–10 visual analog scale (VAS) [7], a patient was considered to have early or late pain if patient gave a score equal to or above four (denoting moderate to severe pain, interfering with daily activities) [5].

In our study, the assessment and diagnosis of sternal dehiscence was made based on clinical findings of sternal click or evidence of sternal instability during respiration or coughing and was confirmed by CT chest.

Ethical consent:

An approval of the study was obtained from Cairo University Academic and Ethical Committee. Every patient signed an informed written consent for acceptance of participation in the study. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical Analysis

The sample size was calculated using sample size formula[8]. We considered $\alpha = 0.05$ and power = 80% with 59 subjects on each group.

For statistical analysis, results were presented as mean ± standard deviation (SD) for quantitative variables and were shown as absolute frequencies and percentages for categorical variables. Categorical variables were compared using chi-square test or Fisher's exact test. Continuous variables were compared using t test or non-parametric Mann-Whitney test whenever the data did not appear to have normal distribution. All statistical analysis was performed using SPSS software (version 21.0, SPSS Inc., Chicago, Illinois). $P<0.05$ was considered significant.

RESULTS

Preoperative characteristics:

The preoperative characteristics in both groups shows no statistically significant difference between both groups (Table 1).

Table (1): Preoperative characteristics of patients undergoing sternotomy closure by either braided polyester No.5 or conventional steel wire, following open heart surgery

Characteristics	Group A (Polyester) 59 patients	Group B (Conventional) 59 patients	P – value
Male gender	**38 (64.4%)**	**34 (35.6%)**	**0.3**
Age, year	**38± 11.8**	**40±13.4**	**0.07**
BMI, kg/m^2	**26.8± 3.6**	**26.9±4.7**	**0.8**
EF <45%	**15 (25.4%)**	**14 (23.7%)**	**0.56**
Diabetes Mellitus	**9 (15.9%)**	**11 (18.2%)**	**0.62**
COPD	**5 (9.1%)**	**6 (13.1)**	**0.81**
Current smoking	**3 (5%)**	**2 (3.5%)**	**0.52**

Data are presented as mean±standard deviation or as frequency and percentage

BMI; Body mass index, EF; Ejection Fraction, COPD; Chronic Obstructive Pulmonary Disease.

Operative assessment: (Table 2)

Type of surgery:

In group A: 18 patients underwent MVR one of them was Re-do, 8 patients MVR+TV repair one of them was Re-do, one patient MVR+ASD repair, 4 patients underwent DVR, 4 patients underwent on pump CABG, 4 patients underwent off pump CABG, 9 patients underwent AVR, 4 patients underwent ASD closure, one patient underwent ASD closure + MV repair, 2 patients underwent drainage via resternotomy for pericardial effusion evacuation, 2 patients underwent pericardiectomy, 2 patients underwent myxoma excision.

In group B: 12 patients underwent MVR one of them was Re-do, one patient underwent MVR+TV repair, one patient underwent MVR+ASD closure, 5 patients underwent DVR, 3 patients underwent DVR+TV repair, 10 patients underwent on pump CABG, one patient underwent off pump CABG ,14 patients underwent AVR, one patient underwent single graft +AVR, one patient underwent CABG+MV replacement (ischemic MV), 4 patients underwent ASD closure, 3 patients underwent myxoma excision, one patient underwent AVR+ supracoronary AA replacement post MVR, one patient underwent supracoronary AA replacement, one patient underwent pulmonary valve replacement post Fallot repair.

There was insignificant difference between both groups regarding the cardiac surgical procedures performed.

Table (2): Operative characteristics of patients undergoing closure of sternotomy using either polyester or steel wire

Characteristics	Group A (Polyester) 59 patients	Group B (Conventional) 59 patients	P – value
Operation:			
MVR	27 (46.1%)	15 (25.1%)	0.43
AVR	9 (15.3%)	15 (25,4%)	0.083
ASD	5 (9.1%)	4 (6.9 %)	0.67
DVR	4 (6.8%)	8 (13.6%)	0.06
CABG	8 (13.5%)	11 (18.2%)	0.12
Others	6 (13.4%)	6 (13.4)	0.29
Total bypass time (minutes)	54.57± 24.265	63.60± 32.943	0.56
Cross clamp time (Minutes)	33.08 ±16.830	38.4± 21.085	0.152

Data are presented as mean±standard deviation or as frequency and percentage

MVR*:* Mitral valve replacement. AVR: Aortic valve replacement. ASD: Atrial septal defect. DVR: Double valve replacement. CABG: Coronary artery bypass graft surgery

Postoperative assessment: (Table 3)

Polyester sternal closure was associated with no significant postoperative bleeding with a single case of postoperative reopening, and this case was reclosed by polyester sutures, while steel wire closure was associated with more postoperative reopening due to high mediastinal drainage > 1000 ml blood in 1st 24 hours, and this difference was statistically significant. There was significant difference between both groups as regard duration of mechanical ventilation.

Early serous discharge was found in slightly less patients in group A compared to group B, and it was statistically insignificant. Wound discharge in group A was sterile in all patients, while, in group B, all patients who had positive cultures were sensitive to antibiotics, no patient had multi drug-resistant strains. Sternal dehiscence was found slightly higher in Group B than in Group A (1.7% vs 5%), and this was proved by both chest X-ray (CXR) and CT chest, the difference was statistically insignificant. In group (A) immediate postoperative pain (on numeric rating scale of 1 to 10) was less than the conventional sternal closure group. This difference was statistically insignificant. Superficial wound infection was slightly higher in the polyester group, however no patient in this group progressed to sternal rocking, while 2 patients with SWI in the steel wire group progressed to sternal dehiscence.

Despite the insignificant difference between both groups regarding deep sternal wound infection (DSWI), it should be mentioned that the 3 cases in group (B) who suffered from DSWI, had poor outcomes even after good debridements and applying vacuum therapy to control infection, the 3 cases required reoperation for 2nd surgery pectoral flap, one of them failed and developed sternal click, which was managed conservatively for 30 days, and patient finally improved and got back to normal daily activities.

Late follow up: (Table 3)

All patients were followed up clinically for three months postoperatively. Despite the almost equal incidence of seroma formation in both groups, no patient in group A progressed from seroma to sinus formation, but one patient in group B did.

Group B showed a statistically significant higher rate of sinus formation and chronic sternal pain compared to group A.

Table (3): Postoperative characteristics and complications of 2 groups undergoing sternal closure by either steel wire, or polyester after a various open heart surgical procedure

Characteristics	Group A (Polyester) 59 patients	Group B (Conventional) 59 patients	P – value
Duration of mechanical ventilation (> 10 hours)	29 (49.1%)	20 (33.8%)	0.09
Reopening (due to high drainage)	1	4 (6.7%)	0.045
Length of ICU stay (>2 days)	16	20	
Length of hospital stay (> 10 days)	1 (1.7%)	4 (6.7%)	0.07
Early serous discharge	9 (15.3%)	11 (18.6%)	0.37
Early pain	5.7±1.6	5.8 ±1.36	0.04
Chest X-ray suggesting sternal dehiscence	1	3 (5%)	0.08
CT chest (retrosternal collection)	1 (1.7%)	2 (3.3%)	0.09
Superficial wound infection	4 (6.8%)	7 (11.9%)	0.373
Positive culture	1 (1.7%)	4 (6,8%)	0.12
Deep sternal wound infection	0	3 (5%)	0.07
Late seroma	2 (3.4%)	2 (3.4%)	0.28
Sinus discharging pus	0	4 (6.78%)	0.03
Sternal instability (clinical and radiographically)	1 (1.7%)	3 (5%)	0.648
Late sternal pain	1 (1.7%)	4 (6.7%)	0.03

Data are presented as mean± standard deviation or as frequency and percentage

DISCUSSION

Median sternotomy incision (first described by **Julian *et al*.** in 1957)[9], is considered the golden classic exposure of the heart and the great vessels. Although closure of a sternotomy incision is usually a simple procedure, however, sternal dehiscence is a serious complication which leads to a high degree of morbidity or mortality after open heart surgery. Here, we describe our experience comparing two materials of sternal closure; the braided polyester No.5, versus the classic method using standard stainless steel wire after adult cardiac surgeries.

All techniques claim to maximize sternal stability, but it is difficult to differentiate between the merits of various techniques scientifically. Moreover, no median sternotomy closure technique is entirely free of the risk of sternotomy dehiscence[10].

Regarding the postoperative drainage, our study showed that there was statistically significant difference between both groups concerning high (> 1L) mediastinal drainage in 1st 24 hours, and this result is concordant with what **Malhotra and his colleagues** found[5].They stated that bleeding was less with polyester sutures.

Concerning early postoperative pain, our study showed no statistical difference between both groups, similar to what **Al-naser *et al.*[11]** found in their study conducted on 128 patients[11]. On the other hand, the study conducted by **Malhotra and his colleagues**[5] found in their study over 94 patients, where using polyester sutures in closing sternum increased wound pain significantly in the first 10 days, however pain in both groups didn't exceed 5 over a scale of 10.

In our study, we didn't find statistically significant difference between both methods of closure regarding the incidence of sternal dehiscence and superficial wound infections (P > 0.05). Other studies showed sternal dehiscence with mediastinitis in 1%–5% of cases. Sternal dehiscence is associated with significant morbidity and mortality rates of 14%–50%[3, 12, 13].

We believe that the stability of sternotomy closure lies in the equidistance of wire insertion, the technique of wire-twisting that secures the uniform distribution of the traction forces throughout the whole body of the sternal bone, in agreement with **Casha and his colleagues** [14]. Moreover, in our study there was no statistically significant difference between the 2 groups regarding the length of ICU stay, prolonged mechanical ventilation.

The duration of postoperative hospital stay is one of the most important factors in dealing with patients with sternum instability. They represent a burden to the resources of the health care system regarding the cost of management and the failure of the patient to return to his work at the proper time. Our study showed that length of hospital stay is unrelated to the sternal closure technique used. This is concordant to what both **Malhotra *et al.* [5] and Al-naser *et al.*[11]** found in their studies

In this study, wound infection was similar between both study groups, this is in agreement with **Al-naser and his colleagues**[11]. However, **Malhotra *et al.***

[5] found in their study deleterious effect of using polyester for sternal closure, with significantly increased risk of infection, but in their study they didn't state the percentage of patients who had diabetes in both groups, also they didn't state the body mass index for both groups (only body weight was mentioned) and we believe those are important risk factors for infection.

Regarding late follow up:

We found that the risk of developing a sinus discharging pus is higher in the steel wire closure group, and the difference was statistically significant. Also, the risk of developing chronic sternal pain was affected by the method of closure, reporting significantly less late pain in the polyester group. That was contrary to what **Malhotra *et al.*** [5] found**,** as they stated that using polyester sutures increases late complications, while **Al-naser *et al.*** [11] reported the closure technique didn't affect the risk of pain.

When we tried to compare our results with other studies, some differences made this comparison difficult. For instance, there are only few studies done to compare the results of polyester sutures and standard wire in closing sternotomy, some of them focus on certain age groups as elderly or infants, and others were done on cadavers.

This study found that braided polyester sutures No.5 could be used safely as an alternative to standard stainless steel wire in closing sternotomy incisions in adults post cardiac surgery as this was not associated with increased complications or patient discomfort, on contrary it was associated with less postoperative surgical reexploration for bleeding. Moreover it showed less risk of late complications, namely less sinus formation, less late pain.

Limitations:

One of this study limitations that it needs to be applied on a bigger scale of population and to be compared with other studies. Another limitation is the relatively lower BMI profile of the study population, that may limit applying the results to patients with BMI higher than 37.

CONCLUSIONS

Braided polyester sutures No.5 can be used as a safe alternative to standard stainless steel wire, moreover, this material has proven lower rate of reexploration for bleeding and less late complications (sinus formation and late pain). Another plus is that braided polyester does not interfere with MRI post sternotomy.

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