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ORIGINAL RESEARCH

A Randomized Trial to Assess the Contribution of a Novel Thorax Support Vest (Corset) in Preventing Mechanical Complications of Median Sternotomy

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ABSTRACT

Objectives: Mechanical complications of median sternotomy may cause significant morbidity and mortality in cardiac surgical patients. This study was aimed at assessing the role of Posthorax support vest (Epple, Inc., Vienna, Austria) in the prevention of sternal complications and the improvement of anatomical healing in patients at high risk for mechanical sternal dehiscence after cardiac surgery by mean of median sternotomy.

Methods: A prospective, randomized, study was performed and 310 patients with predisposing factors for sternal dehiscence after sternotomy for cardiac surgery were included. The patients were divided into two groups: patients who received the Posthorax support vest after surgery, and patients who did not. Primary variables assessed included the incidence of mechanical sternal complications, the quality of sternal healing, the rate of re-operation, the duration of hospitalization, rate and duration of hospital, re-admission for sternal complications. Secondary variables assessed were the post-operative pain, the number of

In memory of Marcus Vinicius Ferraz, dear friend, colleague and gentleman.

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requests for supplemental analgesia and the quality of life measured by means of the EQ-5D format.

Results: Patients using vest demonstrated a lower incidence of mechanical sternal complications, a better anatomical sternum healing, lower hospital stay, no re-operations for sternal dehiscence before discharge and lower re-admissions for mechanical sternal complication. In addition, patients using a vest reported a better quality of life with better freedom from limitations in mobility, self-care, and pain.

Conclusions: Our findings demonstrate that the use of the Posthorax vest reduces post-sternotomy mechanical complications and improves the healing of the sternotomy, the clinical course, and the post-operative quality of life.

Keywords: Postoperative care; Quality of life; Sternum; Surgery complications; Wound healing; Dehiscence

INTRODUCTION

Mechanical complications of median sternotomy are less frequent than infective complications, but are a significant cause of morbidity and, occasionally, of mortality in patients undergoing cardiac surgery [1, 2]. These complications can lead to a prolonged hospitalization and sometimes require surgical sternum revision [1, 2]. The increased utilization of resources in terms of the duration of hospitalization, staff work-hours, use of materials and of infrastructure, result in higher health care costs [1, 3]. The limitations imposed on the reimbursement of health care expenditures, especially in recent years, have heightened the importance of preventing post-sternotomy induced complications and the need to reduce re-admissions and mean hospitalization times whilst, at the same time, be able to provide the best patient recovery and subsequent quality of life [4]. Furthermore, anatomically imperfect sternal healing may cause chronic pain and affect the chest mobility for many subsequent years [5–7].

The present research has a particular focus on mechanical sternal dehiscence [8], a topic only marginally treated by other papers [9–11].

We have adopted the Posthorax support vest (Epple, Inc., Vienna, Austria) as its design stabilizes the sternum following sternotomy, relieves pressure on the suture wires and reduces pain when breathing, coughing, and during rehabilitation.

The aim of this study was to assess the prevention of mechanical complications of median sternotomy and the improvement of the anatomical sternum healing by means of the utilization of the Posthorax support vest and to evaluate its impact on in-hospital recovery in a group of patients at high risk for sternal dehiscence.

METHODS

Eligibility Requirements and Recruitment

All procedures followed were in accordance with the ethical standards of the responsible national and institutional committee on human experimentation and with the Helsinki Declaration of 1964, as revised in 2013. Informed consent was obtained from all patients for being included in the study. From February 15, 2010, to September 15, 2014, a prospective, randomized, study was conducted. The CONSORT flow diagram [12] was adopted in order to assess the number of eligible patients

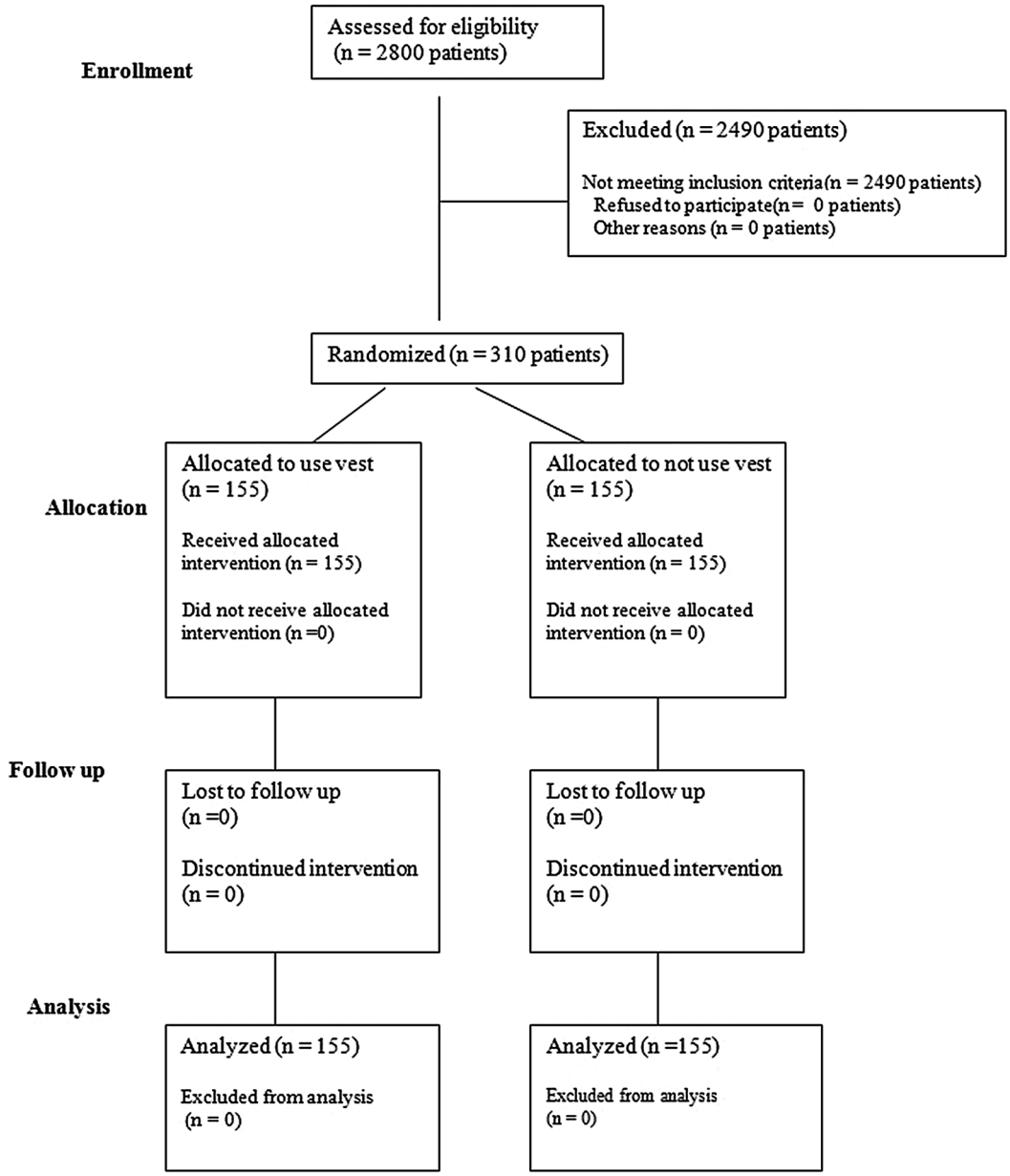

Fig. 1 The CONSORT diagram showing the flow of participants through each stage of a randomized study

who underwent a cardiac surgical procedure with a median sternotomy (Fig. 1). We assess for eligibility 2800 consecutive patients. Out of this group, 2490 patients were excluded and 310 patients were included for randomization. Exclusion criteria were the removal of the chest drains after the 4th post-operative day, the re-admission to the intensive care unit, the need for adoption of mechanical ventilation for any cause and the re-operation for non-mechanically induced complications of sternotomy including mediastinitis, wound, sternal infection, or secondary sternal wound infection and bleeding.

Within the cohort of 310 patients, 155 patients were allocated in group A (GA), in

whom the Posthorax support vest was used following the removal of the chest drains for their entire hospitalization and until 90 days after discharge, whereas the remaining 155 patients were allocated in group B (GB), in whom no support vests were used after surgery.

A power analysis was performed to determine the adequate sample size. Based on preliminary study results [9, 10], and an estimated incidence of cumulative complication rates of 3% for group A and 10% for group B, we have obtained a power value of 0.7 with a sample size of 152 patients.

The follow-up has been 100% complete and 100% of patients have been included in statistical analysis. Both groups had identical inclusion criteria and were deemed at high risk for mechanically induced sternal dehiscence if they presented at least one of the following recognized risk factors for complications of median sternotomy: any type of diabetes mellitus (regardless of duration of disease requiring diet modification, oral or insulin therapy), obesity [body mass index (BMI) $\geq$25], bilateral internal mammary artery (BIMA) harvesting, and chronic obstructive pulmonary disease (COPD). The latter was defined as chronic lung disease (emphysema, chronic bronchitis) of any severity (FEV_1 <75% of predicted, and/or on chronic steroid or bronchodilator therapy) preoperatively diagnosed by a respiratory specialist [9–11, 13].

Randomization of patients and assignment to each study group was performed immediately after the chest drains removal via a random number generator program. The study variables recorded for both groups were: the need for re-operation for mechanically induced sternum complications, the number of requests for analgesic supplementation, the quality of life as measured by the EQ-5D format [14], which was administered to patients at the moment of discharge, the duration of hospitalization (in days), the number of patients that were re-admitted only for post-sternotomy mechanically induced complications at any time from the start of the study until the end of follow-up and their length of stay following re-admission (in days).

Being that this an monocentric study, no trial registry was created to perform our analysis; data were deposited in/or recovered from patients' medical records.

Sternum Closure

Routine sternum closure as per institutional practice was followed in all patients. Seven stainless-steel sternum wire sutures were passed though the sternum at approximately 1 cm apart on each side and were tied and twisted avoiding excessive tension. No patient underwent sternum closure by means of Robicsek's technique [15]. Patients received an identical peri-operative prophylactic antibiotic regime with cefuroxime 3000 mg/day (adjusted accordingly with renal function) until the removal of the central venous line usually on the second post-operative day.

Any activity precaution after sternotomy was given to patients in according with well-established clinical and therapeutical practices.

Analgesia Protocols

All patients in both groups received a similar analgesic protocol, which included 4 mg of morphine sulphate IV and 500 mg of paracetamol IV every 8 h with 4 mg of ondansetron IV every 12 h during the first 48 h post-operatively. Subsequently, the patients received 500 mg paracetamol IV every 8 h only. The additional on-demand analgesic

supplementation to the standard analgesic protocol was 500 mg of paracetamol IV up to a maximum total of 2500 mg/day and afterwards 30 mg of ketorolac IV every 12 h. Pain levels were assessed every time a patient requested supplemental analgesia by using the visual analogue scale (VAS) to obtain a score [16].

Anatomical Recovery Evaluation

All patients underwent a routine anterior-posterior chest radiograph at discharge in order to assess anatomical sternum recovery by evaluating the sternotomy line. Findings such as a mid-sternum line of lucency >2 mm indicating sternum diastasis [17], any sternum wire displacement, or any obvious interruption/dislocation were recorded. Given that the maximum dehiscence risk occurs during the first post-operative week, a single chest radiogram at discharge was deemed adequate to assess sternum diastasis and in addition to inspection of the thorax to evaluate the sternum instability and/or pain at coughing. The physician involved in evaluating the chest X-rays was blinded according to treatment group.

During the 90-day follow-up period after discharge, patients were monitored at their visits to the outpatient clinic or by telephone interviews focusing on sternal wound problems after discharge.

Posthorax Support Vest

The Posthorax sternum support vest (Posthorax® sternum support vest; Epple, Inc., Vienna, Austria) is of a patented design with pressure and stabilization aimed specifically towards the sternum. It provides anterior-posterior stabilization of the thorax, instead of simple lateral compression, while holding the two halves of the sternum in place. Two pads placed longitudinally on each side of the sternum, ergonomically fitted for males and females, prevent intrinsic movement of the two sternum halves and serve as shock absorbers when the patient coughs or breathes deeply, and also support the sternum when mobilizing in and out of bed. Its design is non-restrictive so as to allow for maximal respiratory effort and expectoration without significantly contributing to respiratory complications such post-operative pneumonia. Moreover, the build-in individual sizing and upper strap supports stop the vest from sliding into and compressing the abdomen.

Statistical Analysis

Continuous, normally distributed variables are presented as mean ± standard deviation (SD). Categorical variables are expressed as absolute numbers and percentages. Comparisons between patient groups were performed using the χ^2 test and Fisher's exact test for categorical variables, while for continuous variable the unpaired t test or the Mann–Whitney U test were used. In addition to direct group comparisons, subgroup comparisons according to individual variables of interest (age $\geq$ 70, weight $\geq$ 80 kg, BMI $\geq$ 25, males, BIMA harvesting and those with COPD) were performed. p values less than 0.05 were considered statistically significant. For all statistical comparisons, the SPSS statistical software package for Windows (SPSS Inc., Chicago, IL, USA) was used.

RESULTS

Patient clinical and operative characteristics are shown in Table 1. The average number of requests for supplemental analgesia was lower in group A compared to group B but the difference did not reach statistical significance (1.6 ± 0.4 vs. 2.0 ± 0.5, $p = \text{NS}$) (Table 2). However, a subgroup analysis demonstrated a significant decrease in requests for supplemental analgesia in favor of group A in the following subgroups: those of age <70 years (1.4 ± 0.1 vs. 2.3 ± 0.2, $p = 0.002$), males (1.3 ± 0.2 vs. 2.1 ± 0.1, $p = 0.005$), patients

Table 1 Patient clinical and operative characteristics (% or mean ± SD)

	Group A (*n* = 155)	**Group B (*n* = 155)**
Age (years)	67.5 ± 12.0	70.4 ± 14.0
Male	109 (70%)	101 (65%)
Female	46 (30%)	54 (35%)
Weight (kg)	84.3 ± 17.2	78.4 ± 13.4
BMI	30.0 ± 11.1	28.0 ± 8.2
COPD	57 (37%)	61 (39%)
Procedural subgroups		
CABG	74 (48%)	70 (45%)
1 graft	24 (15%)	25 (16%)
2 grafts	21 (14%)	23 (14.8%)
3 grafts	28 (18%)	24 (15%)
4 grafts	8 (5%)	6 (4%)
LIMA graft	41 (26%)	43 (28%)
BIMA grafts	40 (26%)	35 (23%)
AVR or MVR	57 (37%)	60 (39%)
AAR	8 (5%)	7 (5%)
Combined surgery	16 (10%)	18 (12%)

BMI body mass index, *BIMA* bilateral mammary arteries, *COPD* chronic obstructive pulmonary disease, *AVR* aortic valve replacement, *CABG* coronary artery bypass grafting, *MVR* mitral valve replacement or repair, *LIMA* left internal mammary artery, *AAR* ascending aorta and/or arch replacement

Table 2 Average number of requests for supplemental analgesia (mean ± SD)

	Group A (*n* = 155)	**Group B (*n* = 155)**	***p* value**
Overall mean	1.6 ± 0.4	2.0 ± 0.5	0.07
Clinical subgroups			
Age ≥70	1.8 ± 0.7	1.7 ± 0.8	0.085
Age <70	1.4 ± 0.1	2.3 ± 0.2	0.002
Sex			
Male	1.3 ± 0.2	2.1 ± 0.1	0.005
Female	1.9 ± 0.6	1.9 ± 0.9	–
Weight ≥80 kg	1.7 ± 0.1	3.6 ± 0.2	0.001
Weight <80 kg	1.4 ± 0.3	1.6 ± 0.3	0.066
BMI ≥25	1.6 ± 0.2	3.3 ± 0.3	0.005
BMI <25	2.0 ± 0.2	1.8 ± 0.2	0.074
COPD	1.9 ± 0.1	4.2 ± 0.2	0.001
Procedural subgroups			
CABG	1.4 ± 0.3	1.6 ± 0.5	0.082
1 graft	1.2 ± 0.2	1.4 ± 0.4	0.073
2 grafts	1.4 ± 0.3	1.8 ± 0.6	0.065
3 grafts	1.6 ± 0.4	1.6 ± 0.5	–
4 grafts	1.4 ± 0.3	1.6 ± 0.5	0.082
LIMA graft	1.7 ± 0.6	2.3 ± 0.7	0.055
BIMA grafts	1.4 ± 0.1	3.2 ± 0.2	0.001
AVR	1.6 ± 0.2	1.9 ± 0.4	0.070
MVR	1.6 ± 0.7	1.7 ± 0.3	0.089
AAR	1.9 ± 0.4	2.1 ± 0.7	0.078

Table 3 Visual analog scale (VAS) pain scores (mean ± SD)

	Group A ($n = 155$)	Group B ($n = 155$)	p value
Overall mean	2.4 ± 0.3	3.4 ± 0.6	0.02
Clinical subgroups			
Age ≥70	2.4 ± 0.4	2.5 ± 0.8	0.086
Age <70	2.4 ± 0.2	4.3 ± 0.4	0.001
Sex			
Male	2.2 ± 0.1	3.6 ± 0.3	0.005
Female	2.6 ± 0.5	3.2 ± 0.9	0.059
Weight ≥80 kg	2.1 ± 0.3	4.2 ± 0.1	0.001
Weight <80 kg	2.7 ± 0.3	2.6 ± 1.1	0.071
BMI ≥25	2.3 ± 0.2	4.3 ± 0.2	0.001
BMI <25	2.5 ± 0.4	2.5 ± 1.0	–
COPD	3.1 ± 0.5	4.7 ± 0.6	0.002
Procedural subgroups			
CABG	1.8 ± 0.4	3.1 ± 0.6	0.01
1 graft	1.6 ± 0.2	2.3 ± 1.0	0.061
2 grafts	2.0 ± 0.6	2.8 ± 1.2	0.057
3 grafts	1.7 ± 0.8	2.4 ± 0.4	0.072
4 grafts	1.9 ± 0.6	2.9 ± 0.8	0.05
LIMA graft	1.8 ± 0.7	1.6 ± 0.5	0.077
BIMA grafts	1.8 ± 0.1	4.6 ± 0.7	0.001
AVR	2.8 ± 0.4	3.7 ± 0.2	0.05
MVR	2.4 ± 0.2	3.4 ± 0.4	0.02
AAR	2.8 ± 0.3	3.6 ± 1.1	0.05
Combined surgery	2.3 ± 0.3	3.4 ± 0.3	0.02

For the legend, see Table 1

with weight ≥80 kg (1.7 ± 0.1 vs. 3.6 ± 0.2, $p = 0.001$) or with a BMI ≥25 (1.6 ± 0.2 vs. 3.3 ± 0.3, $p = 0.005$), those with COPD (1.9 ± 0.1 vs. 4.2 ± 0.2, $p = 0.001$), and those which underwent BIMA harvesting (1.4 ± 0.1 vs. 3.2 ± 0.2, $p = 0.001$) (Table 2). The mean VAS pain score was significantly lower in group A than in group B (2.4 ± 0.3 vs. 3.4 ± 0.6, $p = 0.02$), a difference which in the subgroup analysis was more pronounced in the following subgroups: those of age <70 years (2.4 ± 0.2 vs. 4.3 ± 0.4, $p = 0.001$), males (2.2 ± 0.1 vs. 3.6 ± 0.3, $p = 0.005$), patients with weight ≥80 kg (2.1 ± 0.3 vs. 4.2 ± 0.1, $p = 0.001$) or with BMI ≥25 (2.3 ± 0.2 vs. 4.3 ± 0.2, $p = 0.001$), those with COPD (3.1 ± 0.5 vs. 4.7 ± 0.6, $p = 0.002$), and those which underwent BIMA harvesting (1.8 ± 0.1 vs. 4.6 ± 0.7, $p < 0.001$) (Table 3). Given the overall significant difference demonstrated that there was a significant reduction in pain scores between group A and group B across all types of surgery including coronary artery bypass grafting (CABG), (1.8 ± 0.4 vs. 3.1 ± 0.6, $p = 0.01$), aortic valve replacement (AVR), (2.8 ± 0.4 vs. 3.7 ± 0.2, $p = 0.05$), mitral valve replacement or repair (MVR), (2.4 ± 0.2 vs. 3.4 ± 0.4, $p = 0.02$), ascending aorta/arch replacement (AAR), (2.8 ± 0.3 vs. 3.6 ± 1.1, $p = 0.05$), and in combined surgery (2.3 ± 0.3 vs. 3.4 ± 0.3, $p = 0.02$) (Table 3). The EQ-5D analysis of post-operative quality of life demonstrated significantly better results in terms of freedom of limitations in mobility (70 vs. 30%, $p = 0.001$) and self care (73.5 vs. 46.4%, $p = 0.002$), in totally limited activity (10.3 vs. 24.5%, $p = 0.005$), in freedom from pain (43.2 vs. 10.3%, $p = 0.001$), and in absence of anxiety (49.7 vs. 29.6%, $p = 0.05$) in group A compared to group B (Table 4). At discharge there were no cases of re-operation for mechanically induced sternum complication in group A vs. seven cases in group B (Table 5). At discharge, a sternotomy stripe of lucency >2 mm was observed in seven patients in group A and in 31 patients in group B (4.5 vs. 20%, $p = 0.005$), and a clear

Table 4 EQ-5D category distribution (*n*%)

	Group A (*n* = 155)	Group B (*n* = 155)	*p* value
Mobility			
Free of limitations	108 (70%)	47 (30%)	0.001
Partially limited	47 (30%)	62 (40%)	0.058
Totally limited	0	46 (30%)	–
Self care			
Free of limitations	114 (74%)	72 (46%)	0.002
Partially limited	41 (27%)	44 (28%)	0.32
Totally limited	0	39 (25%)	–
Usual activities			
Free of limitations	77 (50%)	61 (39%)	0.062
Partially limited	62 (40%)	56 (36%)	0.12
Totally limited	16 (10%)	38 (25%)	0.005
Pain/discomfort			
Absent	67 (43%)	16 (10%)	0.001
Moderate	88 (57%)	102 (66%)	0.24
Extreme	0	37 (24%)	–
Anxiety/depression			
Absent	77 (50%)	46 (27%)	0.05
Moderate	78 (50%)	87 (56%)	0.19
Extreme	0	22 (14%)	–

interruption/dislocation of the sternotomy line was observed in eight patients in group B and none in group A (5.2 vs. 0%) (Table 5). The average days of in-hospital stay were significantly lower in group A compared to group B (7 ± 2.7 vs. 12 ± 3.4, $p = 0.02$) (Table 5). None of the patients in group A vs. three patients of group B developed post-operative pneumonia. In group B, 16 patients were re-admitted during the follow-up period for post-sternotomy mechanically induced complications vs. six patients in group A (3.9 vs. 10.3%, $p = 0.05$) (Table 5). The mean post re-admission hospital stay was significantly lower in group A (8 ± 3.2 days) vs. group B (24 ± 7 days, $p = 0.05$) (Table 5). There were no other complications of any kind reported with the usage of the Posthorax sternum support vest in group A patients. The mean follow-up was 2.4 ± 2.1 years (range, 0.83–5.25 years). Freedom from mechanical events at 5 years was 95.8 ± 6.1 in GA and 84.7 ± 5.3 in GB ($p < 0.001$).

DISCUSSION

The Posthorax vest is the latest technological generation of sternum support corsets [18]. It has been designed to stabilize the sternum following sternotomy so as to avoid excessive stress on the sternum wires during bone healing [17]. It differs from other previous vest designs because its structure is open in the front and is not based on a circumferential elastic band design making it less restrictive [18]. This open structure is also more hygienic, as it avoids compression and contamination of the skin wound. The non-elastic band structure avoids harmful continuous compression on the thorax and interference with respiratory effort and only provides support during excessive chest stress such as when coughing, mobilizing, or performing rehabilitation exercises [18]. In other words, the patient's chest is free to move during breathing and is only supported during excessive or non-physiological movement, thus reducing the potential risk of respiratory complications. None of the patients who utilized the Posthorax support vest in our series developed post-operative pneumonia or any other kind of complications associated with its use. Our findings concerning the incidence of respiratory complications with Posthorax support vest adoption is not statistically

Table 5 Outcomes (number event or mean ± SD)

	Group A ($n = 155$)	Group B ($n = 155$)	p value
Post operative length of stay (days)	7 ± 2.7	12 ± 3.4	0.02
Re-admission for mechanical complications	6	16	0.05
Re-operation for mechanical complications	0	7	–
Length of stay following re-admission	8 ± 3.2	24 ± 7.0	0.05
Sternotomy line >2 mm at discharges	7	31	0.005
Dislocation of sternotomy line	0	8	–
Follow-up (mean, 2.4 ± 2.1 years, range, 0.83–5.25 years)	95.8 ± 6.1	84.7 ± 5.3	0.001
5 years freedom from mechanical events (%)			

significant. Statistically significant clinical advantages were observed in the group of patients that used the Posthorax support vest following sternotomy, such as less mechanical complications, better sternal healing, lower hospitalization, less pain and lower analgesic medication requirements, better comfort, and earlier mobilization and autonomy. These clinical improvements may be attributed to the improved sternum stability in group A that is provided by the Posthorax support vest without limitation on breathing and this can be translated in better patient comfort and mobility and lower incidence of mechanically induced sternum complications, but quite importantly in our "economic conscious" age can mean lower associated healthcare costs. Our findings are supported by other randomized studies from the literature [9, 18, 19]. However, these studies are multicentric and included infective and non-infective sternal complications and furthermore they did not do an extensive subgroup analysis on patients with a high risk for sternal complications. As recently reported by Heilmann et al. [19], superficial healing disorders occur in 3.3% of unselected patients after sternotomy for cardiac surgery, while 2.5% developed deep wound complications and 7.9% of them died in-hospital. No pathogen was identified and the wound appeared uninfected in 21% of all deep complications or 0.05% of all patients.

Study Limitations

The study presents a number of limitations: firstly, we used EQ-5D format only as a descriptive tool because the time of observation of the study has been limited only to the hospital stay in order to eliminate bias related with differences in managing or behavior of patients after discharge from the hospital. To overcome this problem, we assumed the EQ-5D of the control group as the baseline. Furthermore, the use of baseline data inside the groups is not proper if we consider the fast changes of health status during the early postoperative period, a factor that makes EQ 5 as not reliable. Another limitation might be the antalgic protocol of the study. Our institution has not arbitrarily implemented this protocol, but it followed the directives of the "Hospital without pain" project that has been established by the Italian National Health Service (NHS) within all specialties for all hospitals. A further potential limitation is the

exclusion of all events at risk for infections and mediastinitis. It should, however, be stressed that the end point of the study is the prevention of mechanical complications of sternotomy with this vest and it has been adopted because the vest only acts mechanically. Thus, we have decided to eliminate this potential bias for powering the study. As mediastinitis is now a rare complication in cardiac surgery, the exclusion of mediastinitis is not a significant limitation of the study when we consider the dimension of our series. Finally, the lack of information regarding the techniques of sternal closure, we feel this aspect is not a significant limitation because both groups have been managed by the same surgical staff so that distributions of surgeon-dependent and patient-dependent criteria have been "de facto" random. Furthermore, it should be considered that in the same patient, the surgeon could use both kinds of wires in different segments of the sternotomy for technical reasons.

To follow patients in their use of the Posthorax vest during 90 days after discharge is very difficult and this may be considered another important limitation point. Indeed, during this period we have asserted the continuous use of the vest by outpatient visit or telephone interview. Of course, this procedure may be considered to be affected by limited veracity; however, the results obtained in the present study seem to indicate a continuous use of the vest by the patients.

CONCLUSIONS

The data of the present study show that mechanical sternal complications play a significant role in the genesis of poststernotomy complications and confirm they remain a challenge to cardiac surgery so that more efforts seem mandatory to decrease their significant morbidity and the costs of prolonged treatment. The original design of this study allows to evaluate for the first time without bias the effectiveness of this new sternal support corset to prevent mechanical sternal complications, to reduce pain and hospitalization, and to increase the quality of life in the postoperative period.

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Compliance with Ethics Guidelines. All procedures followed were in accordance with the ethical standards of the responsible national and institutional committee on human experimentation and with the Helsinki Declaration of 1964, as revised in 2013. Informed consent was obtained from all patients for being included in the study.

Data Availability. The datasets generated and analyzed during the current study are available from first author of the study (P. Caimmi: pcaimmi@gmail.com) or from corresponding author on reasonable request.

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