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A newly designed thorax support vest prevents sternum instability after median sternotomy☆

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Abstract

Objective: Sternum infection remains one of the primary causes of postoperative morbidity and mortality after median sternotomy. We report the clinical efficacy for primary reinforcement of the sternum with a new design of thorax support vest. **Methods:** A prospective randomized study including 455 patients was started in September 2007 to evaluate the effectiveness of the Posthorax® sternum vest (Epple Inc., Vienna, Austria). One hundred and seventy five patients were treated with the sternum dressing postoperatively (group A), 227 patients did not receive the vest (group B) and 53 patients refused it (group C). Several clinical and operative data were evaluated. All patients were recorded using the STS risk scoring analysis for mediastinitis after cardiac surgery. **Results:** The median age and gender distribution were comparable in both groups. Preoperative data like renal failure, chronic obstructive pulmonary disease, peripheral artery disease, and myocardial infarction were not significant. There were more patients with diabetes in group A and C (A: 39.4%, B: 29.1%, C: 43.4%, $p = 0.036$). A total of 55.8% underwent coronary bypass grafting, 15.4% aortic valve replacement, 7.7% mitral valve repair and 21.1% concomitant cardiac procedures. The median risk factor analysis and body mass index were comparable. In the follow-up period up to 90 days, in group A we observed 0.6% sternum wound complications, in group B 4.9%, and in group C 9.4% (group A vs B: Fisher's exact test $p = 0.0152$ and group A vs C: $p = 0.0029$). **Conclusions:** The use of the Posthorax® sternum vest shows a favourable outcome to prevent sternum instability after cardiac surgery. There was one reoperation in patients treated with this sternum vest compared to 16 in the control groups.
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Keywords: Sternum instability; Thorax vest; Mediastinitis; Infection

1. Introduction

Sternal instability caused by dehiscence or infection is still a serious complication after cardiac surgery. Sternal wound dehiscence occurs in up to 10% [1,2], and infections in 1—4% after sternotomy [3—5]. Their consequences are severe with an in hospital mortality up to 25% [6,7], high morbidity, prolonged hospital stay and additional cost estimated to be 2.8 times [4] higher compared to uncomplicated post-operative course.

Several risk factors and causes associated with sternal complications have been examined in studies [8—15] presenting obesity, age, diabetes, chronic obstructive pulmonary disease (COPD), use of bilateral mammary arteries, duration of surgery, prolonged mechanical ventilation and re-exploration for bleeding as related factors for the development of sternum infections.

Sternum wound problems (complications) become clinically apparent between 4 and 90 days postoperatively [16], remarkably, 49% of sternal wound infections were diagnosed post-discharge [17].

This study was established to evaluate the clinical efficacy for primary reinforcement of the sternum with the Posthorax® vest (Epple Inc., Vienna, Austria) in prospective, randomised controlled study.

2. Materials and methods

Four hundred and fifty five patients were included in this study conducted in our department since September 2007. The work was approved by the local ethics committee, each patient providing informed consent. Patients were randomised immediately after operation, the sternum vest was put on within 24 h. All patients received an identical perioperative

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antibiotic regime consisting of cephazoline 1 g eight hourly for 72 h. Seven gauge stainless steel wires (Assut Medical Sàrl®, Pully-Lausanne, Switzerland) were used for sternum closure, synthetic absorbable braided sutures (3-0 Vicryl, Johnson&Johnson®, Langhorn, PA) were used subcutaneously. The wound closure was made according to surgeon's choice either intracutaneously (4-0 Vicryl*Plus, Johnson&Johnson®, Langhorn, PA) or simple interrupted sutures (3-0 Dafilon, B. Braun®, Melsungen, Germany). Bone wax (Ethicon Bone Wax®, Johnson & Johnson Gateway Inc., Norderstedt, Germany) was used in 11.4% of patients, which was equally distributed in all groups.

All patients were stratified using a modified STS risk score analysis for major infection after cardiac surgery [18], demonstrated in Table 1; postoperatively the pain score was evaluated daily using the visual analog scale [19]. Exclusion criteria were age under 20 years, congenital cardiac defect, mechanical reanimation, and irradiation of the thorax. Patients who refused the sternum vest were analysed in a separate group ($n = 53$). Patients who refused the sternum support were complaining about the close fit and slipping of the vest.

Patients were followed for the prevalence of sternal dehiscence or wound infection for 90 days after cardiac surgery. Sternal wound infections included superficial infections, involving skin and subcutaneous tissue of the incision, and deep infections. Infection data were collected during hospitalisation using medical records. After discharge patients were monitored by visiting the outpatient clinic or by telephone questionnaire concerning sternal wound problems during the 90-day follow-up period.

2.1. Design of the thorax support vest

The Posthorax® sternum vest (Epple Inc., Vienna, Austria) provides anteroposterior stabilisation of the thorax. Two pads placed on each side of the sternum, ergonomically fitted for males and females, prevent intrinsic movement of the two sternum halves (Fig. 1). Lateral flaps are designed for optimum fit, allow for normal breathing and stop over-extension. The individual sizing and upper straps stop the thorax support vest sliding to the abdominal region.

Table 1
Modified infection risk score for sternum infection.

Variable	Points
Age (1 point/5 years above 55	1
BMI 30–40 kg/m^2	4
BMI above 40 kg/m^2	9
Diabetes	3
Chronic renal failure	4
Congestive heart failure	3
Peripheral artery disease	2
Female gender	2
COPD	2
Cardiogenic shock	6
Acute myocardial infarction	2
Concomitant surgery	4
Perfusion time 100–200 min	3
Perfusion time 200–300 min	7
Intra-aortic balloon pump	5

Fig. 1. The Posthorax® sternum vest provides stabilisation with its two pads in the front and lateral flaps.

3. Statistical methods

Statistical analysis was performed using Software StatXact®-8 with Cytel Studio™ (Cytel Inc., Cambridge, MA) and Statistica V 8.0 Statsoft® (StatSoft Inc., Tulsa, OK).

Differences between the patient groups, with respect to sample size were analysed using Fisher–Freeman–Halton test comparing all groups and Fisher's exact test calculating differences between particular groups. The alpha value was lowered with Bonferroni correction to avoid spurious positive significance levels (alpha/3 = 0.0167). Kruskal–Wallis ANOVA test was used to determine mean values including standard deviation as shown in Table 2. The Mann–Whitney *U* test was used to assess the distribution between length of hospital stay and ventilation time between patients with or without sternal wound complications. p Values of <0.05 were considered to indicate significance.

4. Results

Patient characteristics including risk factors such as diabetes, chronic renal failure, peripheral artery disease, chronic obstructive pulmonary disease, acute myocardial infarction (<21 days), and cardiogenic shock are summarised in Table 2. The two randomised groups (vest [group A] and non-vest group [group B]) were well matched on demographic and comorbidity features with the exception of diabetes, which was more prevalent in patients who received (39.4%) and who refused (43.4%) the support vest [group C] ($p = 0.036$). The mean age was 68.6 ($\pm$10.5 SD, range 34–87) years, 79% male in the non-vest, 73.1% in the vest group, and 71.7% in the group who refused the vest.

The New York Heart Association (NYHA) classification was median 3 in all groups, the body mass index (A: median 27.2 vs B: 27.6 vs C: 26.9), infection risk score (A: 9 ± 4.6 vs B:

Table 2
Patient characteristics.

	Vest group (n = 175)	Non-vest (n = 227)	Refused vest (n = 53)	p value
Age	68 (±10.4)	68 (±10.6)	68.8 (±11.4)	0.923
Male	128 (73.1%)	159 (70.0%)	38 (71.7%)	0.788
Women	47 (26.9%)	68 (30.0%)	15 (28.3%)	0.788
Diabetes	69 (39.4%)	66 (29.1%)	23 (43.4%)	*0.036*
CRF	20 (11.4%)	29 (12.8%)	10 (18.9%)	0.356
COPD	28 (16%)	34 (15.0%)	13 (24.5%)	0.233
PAD	8 (4.6%)	7 (3.1%)	2 (3.8%)	0.684
MCI	28 (16%)	27 (11.9%)	13 (24.5%)	0.063
Cardiogenic shock	1 (0.6%)	1 (0.4%)	0	1.000
Weight	80 (±14.7)	82 (±14.1)	75 (±17.9)	0.130
BMI	27.2 (±4.5)	27.6 (±4.0)	26.9 (±5.2)	0.225
Infection risk score	9 (±4.6)	8 (±4.8)	10 (±5.4)	0.102
NYHA	3 (±0.6)	3 (±0.6)	3 (±0.7)	0.184
EuroSCORE linear	5 (±3.6)	5 (±3.8)	5 (±3.2)	0.970
EuroSCORE logistic	3.4 (±5.5)	3.2 (±10.9)	3.9 (±6.1)	0.907

Variables were expressed as number (%), or mean ± standard deviation. Variables were compared with Fisher–Freeman–Halton test or Kruskal–Wallis ANOVA test. $p < 0.05$ was considered statistically significant. CRF, chronic renal failure; COPD, chronic obstructive pulmonary disease; PAD, peripheral artery disease; MCI, myocardial infarction; BMI, body mass index.

Table 3
Operative data.

	Vest group (n = 175)	Non-vest (n = 227)	Refused vest (n = 53)	p value
CABG	96 (54.8%)	127 (55.9%)	24 (45.3%)	0.507
CABG bimammaria	3 (1.7%)	3 (1.3%)	1 (1.9%)	0.876
AKE	23 (13.1%)	35 (15.4%)	12 (22.6%)	0.243
MKE/R	13 (7.5%)	17 (7.5%)	5 (9.4%)	0.797
Concomitant surgery	40 (22.9%)	45 (19.9%)	11 (20.8%)	0.950
p100	79 (45.1%)	97 (43.4%)	23 (43.7%)	0.901
p200	5 (2.9%)	5 (2.2%)	5 (9.4%)	0.045
Ventilation hours	12 (±110.3)	12 (±122.3)	12 (±261.1)	0.539
LOS	12 (±7.8)	11 (±12.6)	12 (±15.6)	0.532

Variables were expressed as number (%), or mean ± standard deviation. Variables were compared with Fisher–Freeman–Halton test or Kruskal–Wallis ANOVA test. $p < 0.05$ was considered statistically significant. CABG, coronary artery bypass graft; CABG bimammaria, CABG using both mammary arteries; AKE, aortic valve replacement; MKE/R, mitral valve reconstruction/replacement; p100, perfusion time 100–200 min; p200, perfusion time 200–300 min; LOS, length of stay in hospital.

8 ± 4.8 vs C: 10 ± 5.4), linear (A: 5 ± 3.6 vs B: 5 ± 3.8 vs C: 5 ± 3.2) and logistic EuroSCORE (A: 3.4 ± 5.5 vs B: 3.2 ± 10.9 vs C: 3.9 ± 6.1) were comparable and statistically not significant.

Operative and perioperative details shown in Table 3 reached no statistical significance including ventilation hours, concomitant surgery (e.g. valve and coronary artery bypass grafting), and length of hospital stay. In group C there were more patients with perfusion time between 200 and 300 min (A: 2.9%; B: 2.2%; C: 9.4%; $p = 0.045$).

Of the 227 patients without sternum vest, sternal wound complications developed in 11 (4.9%). Deep sternal infections occurred in seven patients (three, 1%), sternum dehiscence in one (0.4%), and superficial sternal wound complications in three (1.3%). Of the 175 randomised patients with the sternum support vest only one superficial sternum complication was detected (0.6%). Of the 53 patients who refused the vest 5 developed complications (9.4%) including 4 deep sternal infections (7.5%) and 1 superficial wound problem (1.9%). All complications needed surgical revision and were treated by surgical debridement, VAC-system implantation, and, if necessary, recerclage.

These findings show highly significant differences in sternal complications between the groups (Fisher–Freeman–Halton test $p = 0.0026$). After Bonferroni correction (alpha/3 = 0.0167) there is still a significant difference between the vest group and the non-vest or refused vest group (group A vs B: Fisher's exact test $p = 0.0152$ and group A vs C: $p = 0.0029$). In the analysis comparing the non-vest group with the group refusing the vest there was no statistical difference (Fisher's exact test $p = 0.1961$). Interestingly, four (25%) patients developed sternal wound complications after hospital discharge up to 90 days.

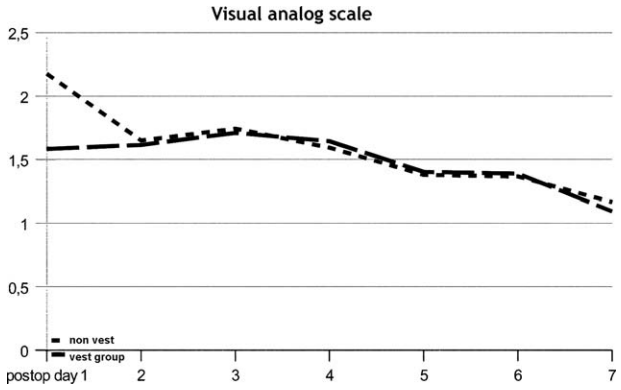

Fig. 2. Postoperative pain analysed with the visual analog scale (p = n.s.).

The postoperative pain was analysed with the visual analog scale. It showed no difference between the vest and non-vest group (Fig. 2).

The length of hospital stay was significantly longer in patients with complications (Mann—Whitney *U* test 22 days ± 19.6 SD) compared to patients without complications (11 days ± 10.7 SD). Taking the increased use of antibiotics and vacuum assisted devices in patients with sternum complications in account the cost effectiveness in the vest group is three-fold.

5. Discussion

The aim of this prospective randomised study was to prove the effect of the thorax support vest to prevent sternal wound complications. Prior to and in consideration of different variables causing sternum infections we changed our process of care. To prevent this complication we use proper antibiotic prophylaxis, attention to sterile technique and antibiotic covered suture material. Thus the rate of infections could be reduced in the past and is comparable with the findings of other study groups [1—5], but with 3.6% deep sternum infection it is still not satisfactory. There was no death in the entire cohort caused by infection, which can be accounted to early recognition and aggressive treatment of sternal wound complications.

The association of obesity, diabetes, chronic obstructive pulmonary disease, NYHA score >3, peripheral vascular disease, use of bilateral internal mammary arteries, duration of operation and ventilation with increased risk of sternal wound complications were reported in several studies [2,6—9,13,14]. The identification of reliable risk factors is important to carefully select patients needing special attention in perioperative and postoperative periods.

We used a risk scoring system created by Fowler et al. [18] to identify patients undergoing cardiac surgery, who are at high risk of major infection. This risk score estimates that probability of infection at nine points is more than 3%. There was no difference between the vest and non-vest group in the identified risk score values, the mean risk score was 8 and 9, which underline that both groups were well matched in this prospective, randomised study.

In our study the prevalence of wound infection after hospital discharge was 25%. In the literature sternal wound infection occurs between 4 and 30 days after cardiac surgery [3,4,20]. Other authors support 90 days postoperative surveillance for a reliable assessment of wound infections since up to 48% of sternal wounds infections were diagnosed after hospital discharge, with a median time of 26 days after hospital stay [16,17]. This long time interval suggests that the late onset of sternal infection is not operation or surgeon related but influenced by postoperative wound management [17,21].

The special attention to postoperative wound care leads to the need for an adequate stabilisation of the sternum after sternotomy. A few experimental studies compared the mechanical stability of the sternum using a variety of wiring techniques and other sternotomy closure material [22,23]. Measurement focusing on increased intrathoracic pressure showed a sternal separation of 2 mm at 46.8 mmHg of pressure. Strong coughing during extubation periods or postoperative course increases the intrathoracic pressure to 300 mgHg [24]. This produces shearing forces in the anterior-posterior and lateral directions.

In conclusion the thorax support vest is designed to avoid tilting of the sternum halves and prevents pressure to the wires. The clinical findings indicate a significant reduction of sternum wound complications. We suppose that the vest supports the mechanical stability after sternotomy and prevents separation and consecutive postoperative dehiscence. Subsequent biomechanical studies are mandatory to evaluate geometrically forces provided by the thorax support vest.

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Appendix A. Conference discussion

Dr G. Varela (*Salamanca, Spain*): I found the topic really interesting and many comments come to my mind, but due to time restrictions, I will only give three of them for your consideration.

The first one is related to the study population and randomisation methods. I have been a little bit surprised by the fact that the control group included around 100 cases more than the experimental one. Then the chance of outcomes in this group is increased simply because of the numbers. Could you tell us something more about the randomisation methods?

My second comment refers to the outcome definition. The aim of any external support after sternotomy is to avoid separation of both sternal halves due to shearing stress. Sternal movement leads to fluid accumulation from the bone up to the wound surface without any infection. I wonder in how many cases in your series you obtained a positive bacterial culture, since in such cases it could be suspected an intraoperative contamination that couldn't be avoided supporting the sternum.

And finally, did you analyse the effect of the device on postoperative pain? Unfortunately, I couldn't find information on the analgesia protocol or on the time when the pain was measured and if it was related to cough or deep inspiratory movements. Then, to my mind, your conclusions on the effect of the device on pain are highly questionable.

Dr Gorlitzer: To your first question, there is a difference between the two groups, because if a patient refused the support vest he was automatically switched to the non-vest group. It is a patients' decision, if a patient wants to wear the vest or not. This has to be accepted. A patient who refuses comes into the non-vest group. This is the reason that 280 patients are in the non-vest and 175 patients in the vest group. I think in the future a balance between both groups will be processed, especially in the multicenter study.

We didn't include or exclude any factors prior to randomisation to avoid any kind of bias, for example the risk factor diabetes. This is a prospective randomised study with a computer-based randomization.

Dr Varela: A number of patients, 50 or 70 patients, refused to enter the study. It could be suspected that these patients were reluctant to co-operate with the nursing and the physiotherapy team. Shouldn't they have been excluded from the study?

Dr Gorlitzer: I don't think so, because they didn't get the vest. So they are automatically in the non-vest group. That is widely accepted in prospective randomised studies.

I come to your second question. The bacteriological cultures were initially positive testing only in two patients. In my opinion sternum complications start with movement and instability of the sternum, subsequently we find an infection. In very rare cases we find a bacteriological problem at the beginning of the sternal wound complications, especially in patients who develop sternum problems within the first days. Remarkably most of the sternum wound complications appear after 7 or 10 days, or even later. I think in these patients the primary cause is mechanical and secondary a bacteriological.

Concerning your question about the pain measurement: the pain measurement using the visual analogy scale was made twice per day. That is when the nurses changed their duty in the morning and in the evening.

Dr G. Lutter (*Kiel, Germany*): As you are aware, it has been a very interesting project to analyse. For those who refused the vest or were rejected, were their results similar to the other ones? Did you look at the outcome? Did they have more sternal infections than the other ones? Why did they refuse it? It is a secure vest that is even used in the police department. So they should be aware of its safety.

Dr Gorlitzer: You are completely right, it is made for the security of the patients, but it is definitely the patient's choice to wear or to refuse the treatment. In the analysis there was no difference between the patients who refused the vest and the non-vest group.,

Dr K. Denk (*Mainz, Germany*): We already have experience with this vest, and also mostly women, but we had the problem that the vest didn't fit. So they moved and it was not fitting. So we stopped using the vest. And I ask you, what could be the problem?

Dr Gorlitzer: There were many series of the vest until we developed the final version. There are three different sizes in small, medium, large now available I recommend to ask the company for support starting to use the vest, because there are some things to pay attention for perfect fitting.

Dr Denk: In your experience, if the vest fits correctly there are no problems when patients move?

Dr Gorlitzer: Sometimes there is problem of proximal movement, but if you tie the vest correctly you can avoid any undesirable slipping.

Dr B. Szafron (*Zabrze, Poland*): I was surprised by very high numbers seen on the first slide, I mean, morbidity rates. It was 10% for sternal instability and 4% for deep sternal infection. In your cohort it was 3.6. These are very high numbers. Can you comment on this?

Dr Gorlitzer: Sorry. Can you repeat the last sentence?

Dr Szafron: These are very high numbers, I mean, 3.6% for deep sternal infection occurrence. I think it should be lower than 1.5.

Dr Gorlitzer: The follow-up period of this study is 90 days. There are just a few comparable studies with a 90-day observation period. This is the reason for the increased rate of sternal infections. You will not find a 3.6% sternal infection rate in the American literature because the hospital discharge is usually after four days in the U.S. with no further evaluation concerning sternum instability. I think it is very important to provide a follow-up time longer than the in hospital stay.

Dr Lutter: It would be interesting to know if you put the vest on very tightly and also correctly. Do you think it interfered with any functional lung tests? Patients should breathe very deeply after the operation. Do you have any observations about that?

Dr Gorlitzer: We didn't measure any functional lung test. This is a very good suggestion for the future. The sternum support vest did not affect breathing significantly. All patients had sufficient oxygen saturation.

Dr Lutter: It might help to find out how tightly and closely it should be worn.

Dr Gorlitzer: We developed pressure detectors to find out the effective tightness. This study is already initiated and we expect data concerning this issue in the near future.