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Posthorax® Prevents Sternal Dehiscence and Instability: Preliminary Results of a Prospective Randomized Multicenter Trial

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ABSTRACT

Aim: A Prospective Randomized Multicenter Trial is ongoing to evaluate Posthorax and prevention of sternal dehiscence/instability: clinical percept is optimistic for Posthorax use. The aim of this mono-center analysis is to give a preliminary result of Posthorax support vest after sternotomy. Methods: One hundred and eighty three cases elective patients were consecutive operated and included in this study conducted in our department since June 2009. Patients were randomized as following: 68 patients were treated with the Posthorax support vest and 115 received a standard bandage postoperatively. The primary endpoints were the Infective Events. Secondary endpoints included a composite of postoperative clinical variables and mortality. Results: The two groups are homogeneous for these characteristic except sex (more women in Control Group, $p = 0.022$). Operative data were comparable in both groups. Deep sternal infections occurred in four patients, all in Control Group (3.5% vs 0%, $p = 0.153$). At Follow up, we recorded 2 cases of superficial infection in the control group versus 0 (1.7%, $p = 0.394$) and 1 case of wound dehiscence always in Control Group versus 0 (0.9%, $p = 0.628$). Cumulative Infective Events are statistically more in Control Group (7 cases 6.1% versus 0 cases, $p = 0.036^*$). According to the secondary endpoints, there were also no differences between the two compared groups except length of hospitalization (10.6 ± 4 days versus 13.4 ± 9.5, $p = 0.019^*$). Conclusion: Preliminary results show the Posthorax sternum support vest as a valuable adjunct to prevent sternum-related complications: We record a statistical reduction of length of hospital stay and infective events using the support vest in a 3-month follow-up.

Keywords: Chest Wall; Device; Wound Dehiscence; Wound Infection; Postoperative Care

1. Introduction

In cardiac surgery, sternal instability caused by dehiscence or superficial/deep infection weigh on 1% to 10% [1-7]. Their consequences are an increase of morbidity and mortality (up to 10% and 40% respectively) and additional hospital costs [6,8-10]. Several factors (pre-, intra- and postoperatively) are associated with sternal dehiscence and the development of sternal wound infection [11-19]. The Posthorax is a newly designed thorax support vest for prevention of sternum instability. The design of Posthorax® support vest (Epple Inc, Wien, Austria) (**Figure 1**) ensures anterior-posterior stabilization of the thorax: two pads placed on each side of the sternum, preventing intrinsic movement of the two sternum halves. Lateral flaps are designed for optimum fit and allow for stopping over-extension but guaranteed normal breathing. Posthorax vest is ergonomically made to fit, both male/female as individual, for both thorax and abdominal region by supporting it with upper straps [20]. The design of Posthorax® support vest could be usefull follow any kind of sternotomy both in cardiac surgery and in thoracic surgery.

The literature shows a clinical efficacy for primary reinforcement of the sternum [20] and is ongoing prospective, randomized controlled multicenters study our Center as well [21]. The aim of this mono-center analysis is to give a preliminary result of Posthorax® support vest after sternotomy.

2. Material and Methods

From June 2009 to August 2009, 183 elective patients were consecutive operated and included in this study conducted in our department. The study was approved by the central ethics committee (Epple-Posthorax Maurer

Figure 1. Posthorax® support vest.

Langegasse 74, 1230 Vienna, Austria) and each patient providing informed consent.

All patients were stratified using a modified STS and LogEuroScore risk score analysis for cardiac surgery [22] and patients with age of under 20 years, congenital cardiac defect, mechanical reanimation, and irradiation of the thorax were excluded.

Patients were randomized immediately before operation by automatic central system in Epple Posthorax Maurer Langegasse 74, 1230 Vienna, Austria.

Patients were randomized as follows: 68 patients were treated with the Posthorax® support vest (Posthorax Group) and 115 received a standard bandage postoperatively (Control Group).

All patients received an identical perioperative prophylactic antibiotic treatment with 2 gr Cephazolin.

No patients underwent left and right internal mammary artery preparation at the same time. Internal mammary artery preparation was always non-skelletonized.

The technique of wound closure and disinfection protocol was regulated: at the operating room, the skin is disinfected with alcohol solution preoperatively and with iodine solution postoperatively. We changed the gloves after the disinfection and after every suspect rupture.

Stainless steel wires (Assut Medical SrlW, Pully-Lausanne, Switzerland) were used for sternum closure: four or more "figure-of-eight" sutures passed trans-sternal or peri-sternal. Trans-sternal sutures passed approximately 1 cm on each side. The suture wires were crossed, pulled, and twisted. Care was taken that knotting only occurs at the point where desired, and is not tied under tension. No patients undergoing Robicsek sternum closure [23].

The method for wound suturing was the same for both groups: synthetic absorbable braided sutures 2 - 0 Vicryl were used subcutaneously. Going from deep up to the surface, the pre-sternal fascia was closed with 0 Vicryl sutures in a "U" stitch type. The wound closure was made intra-cutaneously with 4 - 0 Monocryl (Ethicon Inc., Somerville, NJ).

Postoperatively the pain score didn't evaluated daily using the visual analog scale but Cough and Sneeze events were recorded with a 4 steps scale (1 = no event, 2 = few events with few pain, 3 = often enough with pain, 4 = many events with pain) [24].

Patients have Posthorax vest on in Intensive Care Unit as soon as they have a haemodynamic stability (usually 6 hours after extubation).

Patients who preoperatively refused the sternum vest were analyzed in the Control Group (n = 16) (**Figure 2**). Patients who refused the sternum support were complaining about the close fit and slipping of the vest.

Patients' data were collected during hospitalization using medical records and by telephone questionnaire after discharge during the 90-day follow-up period.

The primary endpoints were the Infective Events: incidence hospital sternal dehiscence requiring reoperation as well as the rate of sternal dehiscence or wound infection for 90 days after cardiac surgery requiring re-hospitalization. Sternal wound infections included superficial infections, involving skin and subcutaneous tissue of the incision (SSWI), and deep infections (DSWI). The DSWI were defined according to the criteria proposed by the Centers for Disease Control as follows: 1) bacteria can be isolated from cultures of mediastinal tissue or fluid; 2) evidence of mediastinitis is seen during surgery; and 3) one of the following con-

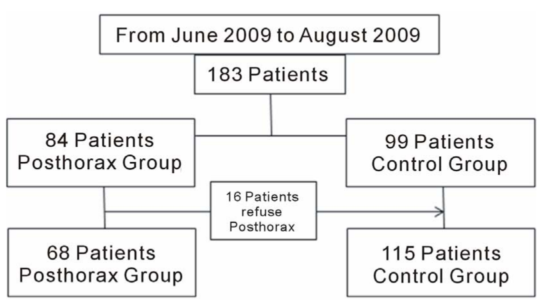

Figure 2. Flow diagram of the trial.

ditions: chest pain, sternal instability, or fever (≥38˚C) are present, and there is either purulent discharge from the mediastinum or bacteria can be isolated from a blood culture of drainage originating from the mediastinal area [25].

Secondary endpoints included a composite of postoperative clinical variables and mortality. Baseline characteristics and perioperative variables were recorded. The SPSS statistical software package 15.0 for Windows (SPSS Inc., Chicago, IL) was used. The continuous and normally distributed data are presented as means ± SD. Categorical data were expressed as percentages.

Differences between the patient groups were carried out by using the χ^2 and Fisher exact tests for categorical variables, and unpaired t test or Mann-Whitney U test for continuous variables.

A p value less than 0.05 was considered to indicate statistical significance

3. Results

Preoperative patient characteristics including risk factors such as Age, Log EuroSCORE, NYHA class, STS score, BMI (Body mass Index), diabetes, chronic renal failure, peripheral artery disease, chronic obstructive pulmonary disease, myocardial infarction and Heart failure are summarized in **Table 1**. The two groups are homogeneous for these characteristic except sex (more women in Control Group, see **Table 1**). Operative data were comparable in both groups (**Table 2**). Postoperative non-infective details shown in **Table 3** reached no statistical significance including ventilation hours, mortality and non-infective morbidity, except of length of hospital stay. Three patients died (1 for Low Output Syndrome, 1 for Pulmonary Insufficence, 1 for MOF post-Sepsis) and 2 were in Posthorax Group but these never vest dressed. Follow up was 100% complete. Deep sternal infections occurred in four patients, all in Control Group (3.5% vs 0%, p = 0.153). These infections are related to S. Aureus in 2, to E. Faecalis in 1 and S. Epidermidis in 1 case. All these patients needed surgical revision and were treated by surgical debridement, VAC-system implantation. In hospital no cases of superficial infection or wound dehiscence were recorded. At Follow up no cases of Deep sternal infections occurred but we recorded 2 cases of superficial infection in Control group versus 0 (1.7%, p = 0.394) and 1 case of wound dehiscence always in Control Group versus 0 (0.9%, p = 0.628). Of the 65 patients with sternum vest, sternal wound complications developed in 0 (0%). Cumulative Infective Events are statistically more in Control Group (7 cases 6.1% versus 0 cases, p = 0.036^*) (**Table 4**).

According to the secondary endpoints, there were also no differences between the two compared groups except length of hospital stay (10.6 ± 4 days in Posthorax Group versus 13.4 ± 9.5 days in Control Group p = 0.019^*).

4. Discussion

The aim of this mono-center analysis is to give a preliminary result of Posthorax support vest after sternotomy. Prevention of sternal dehiscence/instability has a difficult solution in consideration of different variables causing sternum: to prevent these complications majority cardiac surgery centers use proper antibiotic prophylaxis, made attention to sterile technique and use antibiotic covered suture material. Thus the rate of infections in the most important study groups result in 3.6% deep sternum infection [3-7]. There was only 1 death in our entire cohort caused by infection, which can be accounted to early recognition and aggressive treatment of sternal wound complications. Several study reports of a increased risk of sternal wound complications with obesity, diabetes, chronic obstructive pulmonary disease, NYHA score > 3, peripheral vascular disease, use of bilateral internal mammary arteries, duration of operation and ventilation [4, 8-12,16,17,20]. As well we record same pre-operative variable except for sex, Body Weigh and Body Height: no results show that women have more infective risk then men, and Body Weight/Height are higher in Posthorax Group (probably because more men) but BMI (indicative for obesity and more risk for infection) is not different between the two groups. 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.* [22] to identify patients undergoing cardiac surgery, who are at high risk of major infection (STS score). 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.

In our study the cumulative prevalence of wound infection after hospital discharge was 3.8%. In the literature sternal wound infection occurs between 4 and 30 days after cardiac surgery [5,6,26]. 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 [27,28]. That is our choice for 90 days follow up. This long time interval suggests that the late onset of sternal infection is not surgeon or operation related but linked to postoperative wound care [28-30]. The special attention to wound management leads to the need for an adequate stabilization of the sternum after sternotomy: the key factor in preventing sternal dehiscence and infection is a stable sternal approximation. Bacterial contamination in

Table 1. Preoperative variables.

	Posthorax	Control	p
	68 patients	115 patients	
Log EUROscore (mean ± Standard deviation)	5.8 ± 8.5	7.5 ± 8.8	0.196
Age (mean ± Standard deviation)	64.9 ± 11.1	67.8 ± 11.6	0.101
Female [number (percentage)]	15 (22.1)	45 (39.1)	0.022*
NYHA class (mean ± Standard deviation)	2.6 ± 0.9	2.7 ± 0.8	0.240
STS score (mean ± Standard deviation)	11.9 ± 5.8	11.8 ± 6.3	0.919
Diabetes [number (percentage)]	16 (23.5)	29 (25.2)	0.472
Diabetes ID [number (percentage)]	7 (10.3)	10 (8.7)	0.454
Diabetes NID [number (percentage)]	9 (13.2)	19 (16.5)	0.355
Chronic pulmonary disease [number (percentage)]	5 (7.4)	18 (15.7)	0.077
Body weigh (Kg) (mean ± Standard deviation)	85 ± 16.6	80 ± 13.8	0.033*
Body height (cm) (mean ± Standard deviation)	172 ± 9.3	169 ± 8.5	0.006*
BMI (Body mass index) (mean ± Standard deviation)	28.4 ± 4.8	28.1 ± 4.6	0.625
Creatinine ≥ 2 mg/dL [number (percentage)]	7 (10.3)	14 (12.2)	0.449
Heart failure [number (percentage)]	8 (11.8)	17 (14.8)	0.368
Myocardial infarct > 4 weeks [number (percentage)]	22 (32.4)	20 (17.4)	0.017*
Myocardial infarct ≤ 4 weeks [number (percentage)]	5 (7.4)	9 (7.8)	0.576
Extracardiac arteriopathy [number (percentage)]	11 (16.2)	21 (18.3)	0.442

* indicates values with statistical significance.

Table 2. Operative variables.

	Posthorax	Control	p
	68 patients	115 patients	
Cross-clamp time [min (mean ± Standard deviation)]	54.5 ± 26	55.8 ± 30	0.776
Cardiopulmonary bypass time [min (mean ± Standard deviation)]	99.8 ± 42	98.3 ± 46	0.834
Off-pump surgery [number (percentage)]	3 (4.4)	7 (6.1)	0.453
On-pump surgery [number (percentage)]	65 (95.6)	108 (93.9)	0.480
Coronary surgery [number (percentage)]	46 (67.6)	63 (54.8)	0.059
LIMA use for coronary graft [number (percentage)]	50 (73.5)	75 (65.2)	0.158
RIMA use for coronary graft [number (percentage)]	1 (1.5)	2 (1.7)	0.689
Mitral valve surgery [number (percentage)]	11 (16.2)	22 (19.1)	0.385
Aortic valve surgery [number (percentage)]	7 (10.3)	20 (17.4)	0.137
Aortic aneurysma surgery [number (percentage)]	1 (1.5)	0 (0)	0.372
Combinated surgery [number (percentage)]	49 (72)	77 (67)	0.291
Other surgery [number (percentage)]	10 (14.7)	17 (14.8)	0.585

LIMA: Left Internal mammary artery; RIMA: Right Internal mammary artery.

the face of sternal separation and instability can then progress to DSWI [31]. On the other hand, the initial instability derives from the basic mechanism of an osteomyelitis: this is the ground upon which the feared infection develops [32]. Experimental studies compared the mechanical stability of the sternum using a variety of wiring techniques and other sternotomy closure material [33,34]: several methods of sternal closure have been described in literature, for example, additional steel band at the third intercostal space [35], double crisscross [36], and double wires [32]. Measurement focusing on increased intrathoracic pressure showed a sternal separa-

Table 3. Postoperative variables.

	Posthorax	Control	p
	68 patients	115 patients	
Mortality (3 months) [number (percentage)]	2 (2.9)	1 (0.9)	0.311
Redo-surgery for Bleeding [number (percentage)]	2 (2.9)	4 (3.5)	0.604
Redo-surgery not for Bleeding or Infection [number (percentage)]	0 (0)	1 (0.9)	0.628
Blood unit transfusions (mean ± Standard deviation)	0.7 ± 1.3	9.9 ± 1.6	0.234
Plasma transfusion use [number (percentage)]	9 (13.2)	26 (22.6)	0.085
Platelets transfusion use [number (percentage)]	3 (4.4)	9 (7.8)	0.283
IABP use [number (percentage)]	0 (0)	6 (5.2)	0.059
Delirium/Mental confusion [number (percentage)]	7 (10.3)	19 (16.5)	0.172
Intubation time [hours (mean ± Standard deviation)]	13.7 ± 19	27.7 ± 66	0.092
Intensive care unit stay [days (mean ± Standard deviation)]	2.8 ± 2.6	3.4 ± 3.4	0.202
Hospital stay [days (mean ± Standard deviation)]	10.6 ± 4	13.4 ± 9.5	0.019*
Renal failure/Dialysis [number (percentage)]	3 (4.4)/1 (1.5)	10 (8.7)/3 (2.6)	0.217/0.524
Inotropic drugs use [number (percentage)]	65 (95.6)	112 (97.5)	0.396
Cough scale (mean ± Standard deviation)	2.2 ± 1.2	1.9 ± 0.9	0.096
Sneeze scale (mean ± Standard deviation)	0.93 ± 0.4	0.99 ± 0.4	0.327

* indicates values with statistical significance.

Table 4. Infective outcome.

	Posthorax	Control	p
	68 patients	115 patients	
Hospital SSWI [number (percentage)]	0 (0)	0 (0)	/
Hospital DSWI [number (percentage)]	0 (0)	4 (3.5)	0.153
Follow up SSWI [number (percentage)]	0 (0)	2 (1.7)	0.394
Follow up DSWI [number (percentage)]	0 (0)	0 (0)	/
Follow up wound dehiscence [number (percentage)]	0 (0)	1 (0.9)	0.628
Infective events [number (percentage)]	0 (0)	7 (6.1)	0.036*
SSWI: superficial sternal wound infections			
DSWI: deep sternal wound infections			

* indicates values with statistical significance.

tion of 2 mm at 46.8 mmHg of pressure: strong coughing during extubation periods or postoperative course increases the intrathoracic pressure to 300 mmHg [37]. Posthorax produces shearing forces in the anterior-posterior and lateral directions. We suppose that with a traditional method of sternal closure the Posthorax ensures anterior-posterior stabilization of the thorax and prevent intrinsic movement of the two sternum halves. It was not our intent to establish multiple preoperative, intraoperative, and postoperative risk factors associated with an increased risk for sternal wound complications; these have been done by several other authors and could even be confirmed in this study [1,8,22,38-40]. This study contains the obvious limitation of missing documentation use of Bone wax (our policy is a sporadic use, of course in <10% patients).

5. Conclusion

The Posthorax® design avoids tilting of the sternum and prevents sternum-related complications after cardiac surgery. Plausibly, the key factor in preventing sternal dehiscence/infection is a stable sternal: we believe that Posthorax supports the sternum stability get by separation and consecutive postoperative dehiscence. Of course, careful attention to hemostasis and meticulous surgical technique remain the main reasons of prevention and must include precise sternal alignment and stable closure and subsequent biomechanical studies are mandatory to evaluate geometrically forces provided by the thorax support vest. Nevertheless, in the 90 day follow-up period, a significant impact on the reduction of infective events and of length of hospital stay using the "support vest was observed.

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