Efficacious prevention of deep sternal wound complications post cardiac surgery by the posthorax® vest

Final results of a prospective randomized multicenter trial in 2600 patients.

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Background Literature

- Deep sternal infections: up to 5%
- Mortality up to 25%
- Prolonged hospital stay
- Estimated additional cost 2.8 times higher

Braxton et al.: Postoperative survival rate after mediastinitis
Observation period: 4 years - 15,906 patients

Orthopedic Literature:
Rabbit tibial fracture inoculated with S.aureus. Infection rates:
Compr. Plate (stable fixation): 35%
Loose rod (unstable fixation): 71%

Aim of the Study

- Examine, if additional sternal stabilization by a specially designed sternal support vest, prevents wound complications (WHC) after median sternotomy
- Develop a risk score for postoperative sternal complications (dehisence, mediastinitis etc.) based on a prospective randomized data collection

Posthorax® sternum support vest

Sternum Support Vest Design

Anterio - posterior sternum fixation
Study Design

- Prospective randomized
- 90 days follow-up
- Target: \( n \geq 2000 \)
- Vest use for 6 weeks (24hrs/day)
- Exclusion criteria:
  - secondary thorax closure
  - Inability to carry the vest <72 hrs
- Study endpoint: Incidence of WHC
- Analysis: ITT (Intention to Treat)

Study Groups

ITT Analysis

- NO VEST: 202
- VEST: 216
- VEST REFUSED: 933
- VEST NOT RECEIVED: 1188
ITT: Risk Profile
Vest – No Vest

Results:
Overall Incidence of WHC

Superficial (SWI) and deep sternal wound infections (DSWI)

VEST (INCL NOT RECEIVED & REFUSED)
NO VEST

p = n.s.
Incidence of Sternal Dehiscence & Mediastinitis

Deep sternal wound infections (DSWI) & mediastinitis

- VEST (INCL. NOT RECEIVED & REFUSED)
- NO VEST

p < 0.0136

Time Pattern of WHC

Graph showing the time pattern of wound healing complications (WHC) with bars for SWI and DSWI across different postoperative days.
Incidence of WHC: Subgroup Analysis

Deep sternal wound infections (DSWI) & mediastinitis

- NO VEST: 2.27%
- NOT RECEIVED: 3.24%
- REFUSED: 3.46%
- VEST: 0%

Subgroup Analysis
Preoperative Risk Profile

- MALE
- FEMALE
- AGE
- BMI
- DIABETES
- COPD
- PER VAS DIS.
- MI
- COMPLEX SURG.
- CRON BEND.

VEST
REFUSED VEST
NOT RECEIVED

* P<0.05 vest not received vs. vest
**Subgroup Analysis: Surgical Risk Profile**

- VEST
- REFUSED VEST
- NOT RECEIVED

*p<0.05 vest not received vs. vest*

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**Risk Factors for WHC: Multivariate Log. Regression Analysis**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Regression Coefficient</th>
<th>Standard Error</th>
<th>WaldZ-Value (Beta=0)</th>
<th>Wald Prob. Level</th>
<th>Odds Ratio Exp (B)</th>
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</thead>
<tbody>
<tr>
<td>1 WHC no vest</td>
<td>1.35387</td>
<td>0.42151</td>
<td>3.212</td>
<td>0.00132</td>
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<td>2 ComplexSurg.</td>
<td>0.57975</td>
<td>0.31481</td>
<td>1.842</td>
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<td>1.78560</td>
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<td>3 Perif.Vasc.Disease</td>
<td>0.62841</td>
<td>0.35527</td>
<td>1.769</td>
<td>0.07693</td>
<td>1.87463</td>
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<td>4 Diabetes</td>
<td>0.49811</td>
<td>0.30341</td>
<td>1.642</td>
<td>0.10065</td>
<td>1.64560</td>
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<tr>
<td>5 Age</td>
<td>0.02863</td>
<td>0.01661</td>
<td>1.724</td>
<td>0.08479</td>
<td>1.02904</td>
</tr>
</tbody>
</table>

BMI - no significance | 0.00335 | 0.00572 | 0.586 | 0.55803 | 1.00336 |
Use of the Posthorax® vest
- led to a significant reduction, if worn according to protocol even eliminated sternal dehiscence and mediastinitis
- led to a significant reduction of infection related hospital stay

Patient refusing the vest had identical preop. and surgical risk profile – key issue seems to be non-compliance

Preoperative factors seem less important for the development of WHC

Key risk factors rather related to prolonged surgery and postop. complications
Sternal instability seems to be the single most
important factor for deep wound healing infections
and mediastinitis post cardiac surgery
EFFICACIOUS PREVENTION OF DEEP STERNAL WOUND COMPLICATIONS POST CARDIAC SURGERY BY THE POSTHORAX® VEST – FINAL RESULTS OF A PROSPECTIVE RANDOMIZED MULTICENTER TRIAL IN 2600 PATIENTS

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Objective:
Analyzing efficacy of a specifically designed vest (Posthorax) to prevent sternal wound infections post cardiac surgery and identify risk factors.

Methods:
From 07/2008 until 03/2010 n=2632 patients undergoing cardiac surgery via median sternotomy were randomized to receive or not a Posthorax® vest. Patients were instructed to wear the vest postoperatively 24 hrs/day for at least 6 weeks, follow-up was 90 days. Protocol drop out occurred if no vest was applied within 72 hrs. postoperatively. Main statistics are based on an intention-to-treat (ITT) analysis. Further analysis involved all subgroups including drop out patients.

Results:
Complete data were available for n=2539 patients (age 67±11 years, 45% female). N=1351 were randomized to a vest versus n=1188 no vest. There was no significant difference between groups regarding age, gender, diabetes, BMI, COPD, renal failure, logEuroScore, surgery indication and bilateral mammary artery. Incidence of deep wound complications (dWC: mediastinitis, sternal dehiscence) was statistically significantly lower in vest n=14 (1.04%) vs. n=27 (2.27%) in no-vest (ITT, p<0.01), superficial complications(sWC) were no different between groups. Subanalysis of vest patients revealed only n=933 (Gr.A) wore the vest according to protocol, while n=202 (Gr.B-refused) refused wearing the vest (non-compliance), n=216 (Gr.B-drop out) dropped out of study (failed vest application <72 hours). All observed dWC occurred in groups B-refused (n=7) and B-drop out (n=7) despite identical preoperative risk profile with Gr.A. Postoperatively Gr.B-drop out revealed statistically elevated intubation time, length of ICU stay, use of IABP, incidence of COPD and percentage of patients with prolonged surgery.

Conclusion:
Consequent application of the Posthorax® vest eliminated deep sternal wound complications. Expected risk factors for wound complications did not prove to be relevant whereas complicated intra- and postoperative course seem of outstanding importance.