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BEST EVIDENCE TOPIC

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ADULT CARDIAC

Do external support devices reduce sternal wound complications after cardiac surgery?

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Abstract

A best evidence topic in cardiac surgery was written according to a structured protocol. The question addressed was whether external support devices reduce sternal wound complications after cardiac surgery with sternotomy. Altogether 116 papers were found using the reported search, of which six presented the best evidence to answer the clinical question. The author, year, journal, study type, patient group studied, relevant outcomes, results and study weaknesses are tabulated. Six randomized controlled trials investigating the effect of external chest support devices on sternal wound complications in adult patients undergoing sternotomy for cardiac surgery were selected. These studies demonstrate a significant reduction of deep sternal wound complication on comparing external support with no support. Non-elastic devices were more effective in reducing sternal complication compared with the elastic bandage (four trials). Three studies reported significant reduction of mean hospital stay in patients receiving non-elastic chest support devices. We conclude that early post-sternotomy use of an external non-elastic sternal support device reduces overall sternal wound complications and may reduce the hospital length of stay.

Keywords: Postoperative complication • Wound infection • Cardiac surgical procedures • External chest support • Review

INTRODUCTION

A best evidence topic was constructed according to a structured protocol. This protocol is fully described in the *ICVTS* [1].

CLINICAL SCENARIO

During the morning HDU round, the consultant surgeon suggests using an external thoracic support device on a male patient with moderate chronic obstructive pulmonary disease (COPD) who underwent a triple vessel coronary artery bypass surgery yesterday. The nurse accompanying you promptly applies the device but on the following day, you find the patient not wearing the device. On direct questioning, the patient says that the device is uncomfortable and would wear it only if there was sufficient evidence to support reduced sternal wound complication with its use. Therefore, you resolve to search the literature to find the evidence.

THREE-PART QUESTION

Do [external support devices] reduce [sternal wound complications] in patients undergoing [cardiac surgery with sternotomy]?

SEARCH STRATEGY

MEDLINE and EMBASE until April 2016 using the OVID interface.

[exp. Cardiac surgical procedures/OR exp. thoracic surgery/OR exp. sternotomy/OR exp. sternum/OR thorax.mp.] AND [exp. dehiscence/OR exp. postoperative pain/OR infection.mp./OR instability.mp./OR mediastinitis.mp./OR wound.mp.] AND (corset.mp./OR brace.mp./OR harness.mp./OR bra.mp./OR vest.mp./OR external support.mp./OR thorax support.mp./OR chest support.mp./OR binder.mp./OR Stern-E-Fix.mp./OR Posthorax.mp./or elastic bandage.mp./or Cardibra.mp./or Sternshield.mp.]

SEARCH OUTCOME

The search returned 136 articles and after de-duplication 116 articles remained, of which 6 were included in the BET analysis reported below. The relevant papers are presented in Table 1.

COMMENTS

Six clinical studies, all randomized controlled trials (RCTs), involving 5826 adult patients were found suitable. These studies

Table 1: Best evidence papers

Author, year, journal, study type	Population group	Outcome	Key results	Comments
Gorlitzer *et al.* (2009), *Eur J Cardiothorac Surg* [2] Randomized controlled trial, single centre	455 patients, male and female gender, randomized immediately after cardiac surgery with sternotomy to receive Posthorax vest or no vest Group A: Vest group (n = 175) Group B: No Vest group (n = 227) Group C: Refused after randomization (n = 53) Exclusion criteria: Less than 20 years old, congenital heart defects or mechanical reanimation or previous chest irradiation Follow-up: 90 days	All sternal wound complications Sternal wound dehiscence Superficial sternal complication Deep sternal wound infection Postoperative pain (visual analogue scale) Length of hospital stay (days)	With vest = 0.6% Without vest = 4.9% A versus B (P = 0.015) Refused vest = 9.4% A versus C (P = 0.003) With vest = 0 Without vest = 0.4% Refused vest = 0 With vest = 0.6% Without vest = 1.3% Refused vest = 1.9% With vest = 0 Without vest = 1% Refused vest = 7.5% No difference (numerical data not provided) With vest = 12 Without vest = 11 Refused vest = 12 (P = 0.53)	Sternal closure technique and perioperative use of antibiotics similar Vest was applied within 24 h Diabetes mellitus was significantly lower in the 'No vest group' Method of randomization not mentioned 23.2% of patients refused to wear the vest due to comfort issues
Celik *et al.* (2011), *J Thorac Cardiovasc Surg* [3] This paper reports 2 studies. *Study 1* Retrospective cohort *Study 2* Randomized controlled trial, single centre	*Study 1* 842 patients who had undergone elective cardiac surgery with sternotomy Group 1a: COPD (n = 328) Group 1b: No COPD (n = 514) *Study 2* 221 patients with moderate to severe COPD undergoing cardiac surgery with sternotomy Group 2a: Vest group (n = 100) Group 2b: No vest group (n = 121) Patients followed for 6 months postoperatively	*Study 1* Sternal dehiscence and deep sternal wound infection *Study 2* All sternal wound complications Sternal wound dehiscence Superficial sternal complication Deep sternal wound infection Duration of hospital stay (days) Number needed to treat	*Study 1* Significantly higher in COPD group (7.9 vs 1.2%; P < 0.001) COPD severity had significant effect (P = 0.002) *Study 2* With vest = 1% Without vest = 11.6% (P = 0.002) With vest = 1% Without vest = 2.5% (P = 0.628) With vest = 0 Without vest = 2.5% (P = 0.253) With vest = 0 Without vest = 6.6% (P = 0.009) With vest = 13.7 Without vest = 17.8 (P = 0.03) 15 patients with moderate to severe COPD	*Study 1* Figure-of-eight wire closure used in all patients *Study 2* Robiscek closure for all patients Well-matched groups Well powered for deep sternal wound complications Highlights the impracticality to adjust the device for use in obese female patients
Naismith and Street (2005), *Eur J Cardiovasc Nurs* [4] Randomized controlled trial, single centre	20 female patients with bra cup size ≥C cup were randomly allocated into Cardibra or regular bra after cardiac surgery Group 1: Cardibra (n = 10) Group 2: Regular bra (n = 10) Exclusion criteria: Previous mastectomy, pregnancy, emergency, unable to comply with follow-up protocol (6 weeks)	Pain scores (Likert scale) Sternal wound dehiscence or infection Swelling Comfort	No significant difference None in either group No swelling in treatment group Control group 27 mm^2 at 7 days and 10.6 mm^2 at 42 days No significant difference. (P-values not provided)	Extremely small sample size limiting statistical analysis Cardibra applied immediately after surgery, regular bra applied 3 days postoperatively Use of analgesia not analysed Comfort scores were primitive and could be more sophisticated

Continued

Table 1: (*Continued*)

Author, year, journal, study type	Population group	Outcome	Key results	Comments
Gorlitzer *et al.* (2010), *Interact CardioVasc Thorac Surg* [5] Randomized controlled trial, multicentre	1814 patients, male and female gender, randomized immediately after cardiac surgery with sternotomy to receive Posthorax vest or elastic chest bandage Group A: Chest elastic bandage (*n* = 905) Group B: Thorax vest 909 allocated 254 excluded (*n* = 655) 1560 included in final analysis No significant differences between demographic or risk factors of groups and STS infection risk score equally distributed Exclusion criteria: <20 years old congenital heart defects or mechanical reanimation or irradiation Follow-up: 90 days	Total complication rate: (Patients requiring additional sternal procedures) Sternal dehiscence Superficial wound infections Deep sternal infections Hospitalization time (days) ICU time (days)	Vest = 0.61% Bandage = 3.87% (*P* = 0.047) Vest = 0 Bandage = 0.77% (*P* = 0.046) Vest = 0.61% Bandage = 1.11% (*P* = 0.42) Vest = 0 Bandage = 1.99% (*P* = 0.0001) Vest = 14.8 Bandage = 17.3 (*P* = 0.04) Vest = 3.1 Bandage = 2.6 (*P* = 0.12)	Multicentre trial Cefazolin 1 g given IV for 48–72 h or until chest drain removed Vest applied after 48 h and patients advised to wear vest for 6 weeks Patients who failed to use vest were excluded (27.9%) Rate of AVR higher in elastic bandage group
Tewarie *et al.* (2012), *J Cardiothorac Surg* [6] Randomized controlled trial, single centre	750 male patients undergoing cardiac surgery with sternotomy Group A: Stern-E-Fix corset (*n* = 380) Group B: Elastic thorax bandage (*n* = 370) Mean follow-up = 8 weeks	Superficial sternal wound infections Deep surgical wound infection Sternal dehiscence requiring reoperation Mean ventilation time Mean hospital stay	Corset = 8 patients Bandage = 6 patients (*P*-value not provided) Corset = 4 patients Bandage = 7 patients (*P*-value not provided) Corset = 1 patient Bandage = 22 patients (*P*-value not provided) Corset = 1.28 days Bandage = 2.5 days (*P* = 0.01) Corset = 12.5 days Bandage = 18 days (*P* = 0.002)	No female patients Renal failure and ventilation time higher in elastic bandage group Patients received support devices for 6 weeks, given from first postoperative day and 96% patients were pleased Similar sternal closure and antibiotic protocol
Gorlitzer *et al.* (2013), *Interact CardioVasc Thorac Surg* [7] Randomized controlled trial, multicentre	2539 patients, male and female gender, randomized immediately after cardiac surgery to receive Posthorax vest or elastic chest bandage Group A: Vest group (*n* = 1351) Received vest within 48 h = 933 Did not receive in 48 h = 216 Refused vest = 202 Group B: Elastic chest bandage (*n* = 1176)	Superficial wound infection Deep sternal complications Relative risk reduction of suffering a deep sternal complication after vest application	Vest = 1.55% Bandage = 1.09% (*P* = 0.388) Vest = 1.04% Bandage = 2.27% (*P* = 0.017) All deep sternal complications occurred in patients not receiving or refusing Posthorax vest 54% lower in vest group	Intention-to-treat analysis Patients wore the vest for 6 weeks and monitored by specially trained nurse Perioperative antibiotic protocol, red cells and plasma transfusion similar for both groups Method of sternal closure not reported 17.8% in treatment group refused to wear the vest

Continued

Table 1: (*Continued*)

Author, year, journal, study type	Population group	Outcome	Key results	Comments
	No significant risk differences between groups Follow-up: 90 days Exclusion criteria: <20 years old congenital heart defects or mechanical reanimation or irradiation or transplantation			

evaluated whether postoperative an external chest support device reduced the incidence of sternal wound complications in patients following cardiac surgery with sternotomy. Support devices assessed include Posthorax vest, Stern-E-Fix device, Cardibra and the elastic bandage.

Gorlitzer *et al.* [2] evaluated sternal wound complications in adult patients following cardiac surgery by randomizing 455 patients postoperatively to receive Posthorax external support or no support. In this study, 23.2% patients who were randomized to the external support group refused to wear the Posthorax vest due to the close fit and slipping of the vest. These patients were analysed as a separate third group. The patients were followed up for 90 days and the authors report a reduction in overall sternal wound complications (0.6 vs 4.9%; $P = 0.015$) in the vest group. A higher prevalence of diabetes was observed in the Posthorax vest and the refused vest groups compared with the non-vest group. A higher incidence of sternal wound complications (9.4%) was also observed in the refused vest group; however, the incidence of perfusion time exceeding 200 min was higher in this group compared with other groups.

Celik *et al.* [3] reported two studies in their paper. The first study was a retrospective cohort analysis of 842 patients who underwent elective cardiac surgery. The patients were stratified into two groups based on the presence or absence of COPD. Although the technique of sternal closure was similar in all patients, their analysis demonstrated that patients with COPD had higher incidence of sternal dehiscence and deep sternal wound complications (7.9 vs 1.2%, $P < 0.001$). The second study was an RCT with 221 adult patients with COPD who underwent cardiac surgery and were randomized to Posthorax vest postoperatively ($n = 100$) or no vest ($n = 121$). All patients were closed using the Robiscek lateral reinforced sternal closure and were followed up for 6 months postoperatively. They found a significant reduction of overall sternal wound complication (1 vs 11.5%, $P = 0.002$) and deep sternal wound complication (1 vs 9%, $P = 0.02$) in the Posthorax vest group. They analysed and concluded that 15 patients with moderate to severe COPD need to be treated to prevent one sternal wound complication (number needed to treat, NNT = 15).

Naismith and Street [4] performed an RCT involving 20 female patients with bra cup size greater than or equal to C cup and randomly allocated them into Cardibra ($n = 10$) or regular bra ($n = 10$) after cardiac surgery. The aim was to evaluate the effectiveness of Cardibra on sternal wound healing and postoperative pain. Wound was assessed on 7th, 14th and 42nd day using the Flanagan's wound assessment practical framework by measuring in millimetres, the length of non-approximated wound edges and the area of redness and swelling of the skin around the sternotomy wound. A Likert scale was used for pain scoring on the 1st, 3rd, 5th, 7th, 14th and 42nd day after surgery. They found no significant difference in pain relief or sternal wound complication between groups. However, the sample size in this study was extremely small.

Gorlitzer *et al.* [5] studied the effectiveness of Posthorax vest and the elastic bandage in reducing reoperations due to sternal wound complications. Patients who failed to use the vest were excluded (27.9%) from the final analyses. They observed that the reoperation rates due to sternal wound complications during the 90-day follow-up period were 0.6% in the Posthorax vest group and 3.9% in the elastic bandage group ($P = 0.05$). Total length of hospital stay was also shorter in the Posthorax vest group. They concluded that the need for additional surgical procedures was significantly reduced using the support vest. Unfortunately, some of the patients initially randomized were excluded from the final analysis, but it would have been interesting if this paper had published an analysis on 'intention to treat' basis as well.

Tewarie *et al.* [6] performed an RCT to determine the effect of Stern-E-Fix corset on prevention of sternal wound complications and mediastinitis in patients after cardiac surgery with sternotomy. They randomized 750 male patients to immediately receive either the Stern-E-Fix corset ($n = 380$) or an elastic bandage ($n = 370$) postoperatively. Patients received support devices for 6 weeks, given from first postoperative day, the mean follow-up was 8 weeks and 96% patients were pleased with the design. The sternal closure and antibiotic protocol were similar in all patients and female patients were not included in this study. They observed that only 1 patient in the corset group developed sternal complication requiring a reoperation as opposed to 22 patients in the elastic bandage group. They also found significant reduction in the mean length of hospital stay in the corset group (12.5 vs 18 days; $P = 0.002$). It is important to appreciate that the mean ventilation time was significantly higher in the elastic bandage group (2.5 vs 1.28 days, $P = 0.01$) which may have influenced the results.

Gorlitzer *et al.* [7] reported on a multicentre RCT with 2539 patients assessing the efficacy of Posthorax vest in comparison to elastic bandage in preventing sternal wound complications after cardiac surgery. The Posthorax vest was assigned to 1351 patients

and the elastic bandage to 1176 patients. The Posthorax vest was refused by 17.8% patients after randomization. The patients were followed up for 90 days, and the outcomes were analysed on intention-to-treat basis. They found significant decrease in deep sternal wound complication in the patients randomized to Posthorax group (1.04 vs 2.27%; $P = 0.017$). All complications in the vest group occurred among patients who did not receive or refused the vest.

In these studies, the Stern-E-Fix corset was not evaluated in female patients and a substantial population found the Posthorax vest uncomfortable and therefore refused to wear it.

CLINICAL BOTTOM LINE

Early post-sternotomy use of the available external non-elastic sternal support devices reduces sternal wound complications and may be associated with a shorter length of hospital stay.

Conflict of interest: none declared.

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