

# A Prospective Randomized Study of Sternal Closure: Comparison of Mersilene Tape versus Standard Wire Closure

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**Background:** To compare in a prospective randomized study Mersilene tape and standard metal wire for complications and pain upon sternal wound closure.

**Methods:** Sixty-four patients scheduled for cardiac surgery were prospectively randomized to undergo sternal closure using either Mersilene tape (n=30) or standard metal wire (n=34). The intensity of postoperative pain from the chest wound was assessed using a visual analogue scale (VAS) on the second and seventh postoperative days and one month after surgery. The examinations with chest X-ray and computed tomography (CT) one month after surgery were performed to evaluate the chest wound and sternum. Follow-up data on sternal and wound healing was assessed for up to one year.

**Results:** No deaths, sternal dehiscence or infection occurred in either group. No wound complications were observed in either group during the year following surgery. A review of data revealed that there was no difference in the intensity of postoperative pain according to the VAS between the two groups. Chest CT demonstrated that no patients in either group had cuts in the sternum.

**Conclusion:** This prospective randomized study showed Mersilene tape sternal closure not to be more closely associated with increased complications or patient discomfort due to sternal wound than the standard wire closure. (*Ann Thorac Cardiovasc Surg* 2004; 10: 362–6)

**Key words:** cardiac surgery, sternal closure, pain, visual analogue scale

## Introduction

Despite improvements in surgical techniques, anesthesia and antibiotic treatment, postoperative wound reopening still represents a significant and lethal complication after cardiac operations.<sup>1-3</sup> The origin of this condition has multiple causes and includes factors such as the use of internal mammary artery as a pedicled graft, longer stay in the intensive care unit, reexploration, diabetes mellitus and obesity.<sup>4</sup> In particular, the type of sternal closure

technique has been implicated in adversely affecting wound-related morbidity.<sup>5</sup>

Recently, there has been a revival of interest in performing sternal closure using Dacron tape.<sup>6,7</sup> There are, however, no data on the effects of type of sternal closure on wound healing or chest pain based on a prospectively randomized study of patients who underwent elective operations.

## Methods

### Patients

Sixty-four patients (45 men, 19 women, mean age 65±9 years) who were due to undergo first-time cardiac surgery from May to November 2002 were enrolled in the study. Patients were prospectively randomized into two groups: Group A, using Mersilene tape, and Group B,

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using metal wires. Exclusion criteria included emergent operation and previous cardiac surgery.

### **Surgical techniques**

A conventional cardiopulmonary bypass was used when the surgical procedure for a patient required cardiac arrest. The flow rate during bypass was 2.4 liter/m<sup>2</sup>/minute. Systemic temperature was maintained between 34°C and 36°C. Myocardial protection was achieved by using intermittent antegrade hyperkalemic warm blood cardioplegia. When a patient needed off-pump coronary artery bypass grafting (OPCABs), the operation was performed using the standard technique of exposure and stabilization used for anastomosis using an Octopus retractor (Medtronic, Cupertino, CA). An intra-coronary shunt (Anastoflo Intravascular Shunt, Research Medical Inc., Midvale, UT) was used in principle during the anastomosis.

### **Sternal closure**

Patients were prospectively randomized on the day before their operation into two groups by card allocation. Group A received sternotomy closure using 4 or 5 braided Dacron tapes (Mersilene tape, Ethicon, Inc., Somerville, N.J.), whereas Group B received conventional sternal closure with six metal wires (Metal wire, Matsuda, Tokyo, Japan). In patients in Group A, the manubrium of the sternum was united using one or two sutures with #2 braided polyester sutures (Ethibond, Ethicon Inc., Somerville, NJ).

In all patients, the wound over the sternotomy was closed in three layers. The deep layer was closed with 3-0 Dexon sutures and the middle layer with 4-0 Dexon sutures. The skin was approximated with subcuticular 3-0 nylon sutures, which were removed on the 5th postoperative day.

### **Antibiotic regimen**

Both groups of the patients received the same antibiotic regimen of cefazolin sodium 1 g every 8 hours for 72 hours. When the laboratory data showed WBC counts over 15,000/ $\mu$ l or CRP over 10 ng/ml on the third postoperative day, the patient started piperacillin sodium 1 g every 8 hours until their WBC count dropped to fewer than 8000/ $\mu$ l and CRP less than 5 ng/ml.

### **Pain assessment using a visual analog**

The degree of postoperative pain from the chest wound was assessed using a visual analogue scale (VAS) on the second and seventh postoperative days and one month

after surgery. Patients rated the pain experienced during treatment on a standard 100 mm VAS for pain, with 0 mm corresponding to no pain and 100 mm the worst pain possible.

### **Evaluation of the sternal healing**

Computed tomography (CT) of the chest was recorded to assess the healing of the sternum one month after surgery. Cuts and gaps in the sternum were checked using the CT images.

Follow-ups in the outpatient clinic were made over a period of at least one year to check sternal wound healing.

### **Statistical analysis**

Data are presented as mean  $\pm$  standard deviation. Comparisons between preoperative variables were made using  $\chi^2$  tests. Repeated measures of analysis of variance were used to assess the differences over time between groups, and the Bonferroni test was used to assess differences within each group. Analyses were performed using Stat View (SAS Institute Inc., Cary, NC).

### **Results**

Thirty patients (22 men, 8 women, mean age 66 $\pm$ 9 years) were assigned to Group A and thirty-four patients (23 men, 11 women, mean age 66 $\pm$ 8 years) to Group B. The randomization sequence was strictly adhered to, and no patients allocated to the wire group were crossed over to the Mersilene group.

The preoperative demographic and surgical data are shown in Table 1 and 2, respectively. The groups were similar with respect to age, gender, New York Heart Association functional class, number of patients with left ventricular ejection fraction of less than 40% and preoperative risk factors such as diabetes mellitus, as shown in Table 1.

Table 2 summarizes the surgical data of the 2 groups. Details of the surgical procedures are as follows. In Group A, sixteen CABGs were carried out, including 9 OPCABs, 9 surgeries for valvular heart disease, 4 operations on aortic aneurysms using selective cerebral perfusion (SCP) and 1 other operation. In Group B, twenty-one CABGs were carried out, including 13 OPCABs, 8 surgeries for valvular heart disease, 3 operations on aortic aneurysms using SCP, and 4 other operations. There were no differences in aortic cross-clamping time (Group A: 73 $\pm$ 43 vs. Group B: 79 $\pm$ 54) or extracorporeal circulation time

**Table 1. Preoperative demographic data**

Characteristic	Group A (n=30)	Group B (n=34)	P value
Age (years)	66±9	68±8	NS
Male / female	22/8	23/11	NS
BMI	22±4	20±5	NS
NYHA class III or IV	19 (17%)	10 (20%)	NS
EF <40%	9 (30%)	8 (24%)	NS
Risk Factors			
Diabetes mellitus	10 (33%)	11 (33%)	NS
Hypertension	13 (43%)	16 (47%)	NS
Hyperlipidemia	9 (30%)	12 (35%)	NS
COPD	3 (10%)	1 (3%)	NS

BMI = body mass index; NYHA = New York Heart Association; EF = ejection fraction; COPD = chronic obstructive pulmonary disease; NS = not significant

**Table 2. Surgical data**

Characteristic	Group A (n=30)	Group B (n=34)	P value
Operation			
CABG	16	21	NS
Valvular	9	8	NS
Aortic aneurysm with SCP	4	3	NS
Others	1	4	NS
AXC	73±43	79±54	NS
ECC	112±81	122±88	NS
Off-pump CABG	9	13	NS
Transfused patients	8 (27%)	8 (24%)	NS

AXC = aortic cross-clamping; ECC = extracorporeal circulation; CABG = coronary artery bypass grafting; SCP = selective cerebral perfusion; NS = not significant

(Group A: 112±81 vs. Group B: 122±88) in the two groups. The number of patients receiving aortic arch replacement using SCP, OPCAB or transfused patients showed no difference between the two groups.

Postoperative results are summarized in Table 3. No patients in either group showed sternal dehiscence or mediastinitis. The number of patients requiring piperacillin sodium was 5 in Group A and 6 in Group B, with no statistical difference. There were no instances of death or major morbidities in either group. Transient ischemic attack of the cerebellum was observed in one patient in Group A but there were no sequelae. There were no significant differences between the 2 groups with respect to length of ICU stay.

Pain levels according to the VAS on the second postoperative day (POD) were 46±22 in Group A and 52±17 in Group B; on the seventh POD they were 28±13 in Group A and 27±15 in Group B, and one month after the surgery were 22±11 in Group A and 21±12 in Group B,

respectively, as shown in Table 4. Patients' mean rating on the VAS showed no difference between the wire group and the Mersilene group in these three evaluations. In both Group A and B, pain intensities according to the VAS were statistically significantly higher ( $p < 0.05$ ) on the second POD compared to the seventh POD and one month after surgery.

## Discussion

Sternal dehiscence with or without infection was related to factors such as obesity, diabetes mellitus, chronic pulmonary disease, reexploration, length of stay in the intensive care unit, and type of sternal closure.<sup>4,8,9</sup> The incidence of this complication is rare; however, it is accompanied by a high mortality ranging from 16 to 26%.<sup>2,10</sup> This multi-factorial wound-related morbidity required prospective randomized assessment of the technique of sternal closure.

**Table 3. Postoperative data**

Characteristic	Group A (n=30)	Group B (n=34)	P value
Sternal dehiscence	0	0	NS
Mediastinitis	0	0	NS
Change of antibiotics	5	6	NS
Deaths	0	0	NS
Major morbidities	0	0	NS
Cardiac complications	0	0	NS
Cerebral complications	1	0	NS
ICU stay (days)	2.1±0.7	2.1±0.8	NS
Sternal wound complications during 1 year after surgery	0	0	NS

ICU = intensive care unit; NS = not significant

**Table 4. Pain intensity data**

	Group A (n=30)	Group B (n=34)	P value
PI on 2nd POD	46±22	52±17	NS
PI on 7th POD	28±13	27±15	NS
PI 1 month after surgery	22±11	21±12	NS

PI = pain intensity; POD = postoperative day; NS = not significant

The goal of wound care and closure is to have a resultant functional and cosmetically acceptable scar, with low morbidity combined with high patient satisfaction and comfort. These goals can be promoted by complete sternal closure. Few studies have evaluated, in a prospective and randomized fashion, the condition of wounds during the mid-postoperative period.

This is the randomized trial to determine whether the Mersilene tape technique produces clinical sternal healing similar to results seen with wire closure. No statistical difference was seen in the incidence of sternal wound complications, including sternal dehiscence and mediastinitis, in the early postoperative period and subsequent year.

The starting of administration of piperacillin sodium was assessed as a prolonged inflammatory response. Both WBC count and CRP are well-established indicators of the degree of infectious response. No difference was observed between the numbers of patients receiving piperacillin sodium as a result. Mersilene tape gives the same inflammatory response as the metal wires with respect to sternal closure.

The surgical results of cardiac surgery have improved markedly in the last 10 years. Some studies focus on postoperative QOL after cardiac surgery;<sup>11,12)</sup> however, few reports deal with wound pain and how it relates to the method of sternal closure. We also assessed the relation-

ship between the method of sternal closure and intensity of postoperative pain.

Pain intensity is somewhat individualized and actually a very difficult problem for objective assessment. Nevertheless, the use of a scoring system provides partial quantification of these otherwise subjective symptoms. Bucerius et al. has revealed the value of cryoablation in the lateral thoracotomy pain reduction by evaluating with the VAS.<sup>13)</sup> The pain intensity in this study was not high and showed no differences compared with former reports.<sup>14-16)</sup> Thoracic pain is assumed to be of tolerable intensity if the sternum remains in a stable condition postoperatively.

Our results demonstrated that Mersilene tape could provide sufficient quality in sternal healing. If sternal healing in the Mersilene tape group showed no difference compared with the conventional wire group despite having less biomechanical capacity,<sup>17)</sup> we believe it to have certain advantages, such as higher biocompatibility and feasibility of magnetic resonance imaging.

In summary, this randomized study showed that Mersilene tape showed no differences in comparison with standard wires, not only in the incidence of sternal wound complications but also in the intensity of postoperative chest pain. Mersilene tape provides the added benefit of enabling nuclear magnetic resonance imaging.

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