Prospective evaluation of a new sternal closure method with thermoreactive clips

A. Negri, J. Manfredi, A. Terrini, G. Rodella, G. Bisleri, S. El Quarra, C. Muneretto *

Department of Cardiac Surgery, School of Medicine, University of Brescia, Brescia, Italy

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Abstract

Objectives: The role of the sternal closure techniques on the incidence of sternal dehiscence and wound infection are well defined among a high number of other variables involved. In the various series, the incidence of wound complication in cardiac surgery varies from 2 to 8%. The aim of our study is to evaluate the role of thermal-dependent shape-memory Nitillium clips in reducing the incidence of sternal dehiscence following sternotomy.

Methods: We prospectively randomized 1000 consecutive patients requiring cardiac surgery to evaluate the incidence of sternal wound complications (SWC), sternal dehiscence and/or other related complications. We compared Group I (500 patients), in which sternal closure was achieved with standard sternal wires, with Group II (500 patients), in which sternal approximation was carried out by means of thermoreactive Nitillium clips. The two randomized groups were comparable in terms of age, gender, Euroscore and risk factors for sternal/wound complications.

Results: In our study the overall incidence of SWC was 4.7%. The incidence of SWC was considerably higher in Group I (6.8%) when compared to Group II (2.6%) (P = 0.003). Mechanical sternal dehiscence without infection occurred in 14 patients in Group I and in one patient in Group II (P = 0.002). Despite sternalotomy wound infection occurred similarly in both groups (15 patients in Group I vs. 12 patients in Group II, P = 0.001). Conclusion: Thermal shape-memory Nitillium clips provided superior results in sternal osteosynthesis following midline sternotomy, due to a considerable reduction of sternal dehiscence and related complications. The clinical benefit of Nitillium clips was demonstrated even in patients with several risk factors for SWC. © 2002 Elsevier Science B.V. All rights reserved.

Keywords: Cardiac surgery; Sternal wound infection; Sternal dehiscence; Thermoreactive clips

1. Introduction

Median sternotomy is the incision of choice for cardiac surgery [1,2] and it usually heals well, but the incidence of sternal dehiscence has been reported between 0.5 and 8% [3–5] as a consequence of mechanical breakdown and/or infection [6].

During the last decade an increasing number of pre-operative risk factors (e.g. age, diabetes, COPD) jeopardized sternal healing [7]. In addition, total arterial revascularization, bilateral ITA harvesting and more complex operations contributed to enhance the risk of wound complications.

Although several methods of sternal closure have been described in literature, none is entirely free from the risk of wound complications. Sternal approximation usually performed with steel wires, placed either parasternally or directly through the bone, can cause sternal bone cuts when excessive mechanical stress forces are applied, thus leading to dehiscence [8].

The aim of our study is to evaluate a new method of sternal closure based on the use of thermoreactive Nitillium clips (TRNC), specifically designed for sternal approximation.

2. Materials and methods

We enrolled 1000 consecutive patients requiring cardiac surgery for a perspective randomization in two groups. Standard sternal closure with six or more sternal wires was used in Group I (500 patients), while two to four Nitillium clips for bone approximation were used in Group II (500 patients). A picture of the TRNC devices is shown in Fig. 1.

The two randomized groups were homogeneous with
comparable distribution of age, gender, cardiac pathologies, cardiac surgery procedures, pre-operative risk stratification (Euroscore), risk factors for sternal/wound complications such as congestive heart failure, renal insufficiency, COPD, diabetes, obesity or bilateral ITA harvesting. Population characteristics are shown in Table 1.

Ten hours before the operation patients of both groups were shaved avoiding the sternal region, then they had a shower with Lifosan Soft® (B.Braun Medical Ag CH 6021, Emmenbuecke), Braunol H Plus® (B.Braun, Melsungen AG 34209, Germany) and with Hibiscrub® (Zeneca Pharma Reims, Cedex, France). Before entering the operating room, they were shaved in the sternal area, then they had another shower with the technique previously described. All patients received 2 g of Cefamandol pre-operatively in the OR, followed by 1 g every 6 h for 48 h.

The operative skin surface was prepared with Braunol 7.5% sol. (B-Braun, Melsungen A.G. 34209, Germany) and the skin was protected with a iodoform-impregnated adhesive plastic sheet (Ioban 2 6651, 3M Health Care, D-46325, Borken, Germany).

The skin and subcutaneous tissue were incised with a scalpel and electrocautery was used to open the presternal layers and the pericardium.

In CABG surgery left ITA was harvested as pedicled in situ graft, while right ITA was harvested as a pedicled or skeletonized free graft. Particular attention was paid in preserving the first intercostal branch and the diaphragmatic bifurcation of both ITAs. Operations were performed in both groups in standard fashion according to the type of disease. A single mediastinal drain was used and chest drainages were positioned when pleurae were entered. A small catheter for ‘mediastinum-clysis’ (normal saline with Tranexanic acid (Ugurol; Bayer AG Leverkusen, Germany) and Tobramicine (Nebicina Eli Lilly Spa, Sesto Fiorentino, Firenze, Italy)) was placed and the mediastinum was irrigated for 6 h at 100 ml/h.

2.1. Surgical technique for the sternal closure

Group I received a sternal closure in standard fashion by means of six or seven steel wires passed through the bone. In Group II a hole with electrocautery was performed in the second, third, fourth or fifth intercostal space bilaterally. Sternal approximation was achieved by placing two steel wires (at the top and the bottom). Then, the appropriate size of TRNC (Nitillium Research Srl, via Novi, 70-15060 Basaluzzo, Alessandria, Italy) was selected, ranging between 2.25 and 4 cm. Temperature of TRNC was instantly lowered with iced saline, thus resulting in full pliability of the device. Following the insertion of TRNC in the intercostal space bilaterally, the device was rewarmed with hot saline; its original shape was instantly restored and bone approximation achieved (Fig. 2).

The sternotomy wound was then closed in a standard fashion: the deep fascia with 0 sutures, the subcutaneous tissue with 2-0 sutures and the skin with 3-0 intradermal sutures.

Mediastinum-clysis was discontinued after 6 h and the mediastinal tube drainage was removed when bleeding was less than 200 ml over a 12 h period.

2.2. Statistical analysis

Fischer’s exact test, chi-square test and unpaired t-test were used to compare discrete and continuous variables of patients with and without sternal wound complications (SWC).

The statistical program used was ‘Statistics for bio-medical sciences’, Version 4.02i, by Stanton A. Glantz.

Table 1

<table>
<thead>
<tr>
<th>Group I</th>
<th>Group II</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>500</td>
<td>500</td>
</tr>
<tr>
<td>Age (years)</td>
<td>68 ± 8</td>
<td>67 ± 8</td>
</tr>
<tr>
<td>Cardiac pathologies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ischemic</td>
<td>325</td>
<td>347</td>
</tr>
<tr>
<td>Valvular</td>
<td>137</td>
<td>132</td>
</tr>
<tr>
<td>Ascending aorta</td>
<td>38</td>
<td>31</td>
</tr>
<tr>
<td>Bilateral ITA harvesting (%)</td>
<td>131 (26)</td>
<td>139 (27)</td>
</tr>
<tr>
<td>Congestive heart failure (%)</td>
<td>32 (6.4)</td>
<td>36 (7.2)</td>
</tr>
<tr>
<td>COPD (%)</td>
<td>33 (6.6)</td>
<td>28 (5.6)</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>93 (18)</td>
<td>102 (20)</td>
</tr>
<tr>
<td>Euroscore (mean value)</td>
<td>4.1</td>
<td>4.3</td>
</tr>
<tr>
<td>Obesity (%)</td>
<td>19 (3.8)</td>
<td>18 (3.6)</td>
</tr>
<tr>
<td>Renal insufficiency (%)</td>
<td>23 (4.6)</td>
<td>19 (3.8)</td>
</tr>
</tbody>
</table>

* Data for age are presented as mean ± standard deviation.
patients in Group I and in none in Group II

Wound infection occurred in 9 patients in Group I and in 12 patients in Group II without a favorable outcome.

Mechanical sternal dehiscence without wound infection occurred in 14 patients in Group I and in one patient in Group II \((P = 0.002)\). In patients with sternal dehiscence of Group I surgical revision demonstrated sternal cuts and fractures due to wires: 12 of these patients underwent sternal reconstruction by means of TRNC technique and they had uneventful sternal healing. The remaining ones as well as the patients of Group II had sternal healing as synchondrosis.

Aseptic sternal necrosis occurred in five patients in Group I and in none in Group II \((P = ns)\): all the patients in Group I underwent sternal reconstruction with Nitillium clips and had a favorable outcome.

Wound infection (superficial or deep) occurred in 15 patients in Group I and in 12 patients in Group II without differences between the two Groups \((P = ns)\). In patients with wound infection sternal dehiscence occurred in nine patients in Group I and in none in Group II \((P = 0.001)\).

All those patients (belonging only to Group I) required sternal debridement with antibiotic irrigation of the mediastinum and sternal closure with TRNC technique. One patient also required major pectoralis muscle flap interposition.

In Group I one patient had major sternal dehiscence and developed infective mediastinitis: he required surgical revision and developed severe sepsis which led to his death.

Wound infection without sternal dehiscence occurred in six patients in Group I and in 12 patients in Group II \((P = ns)\) (Table 2). Their management required prompt surgical local debridement followed by the use of a Vacuum-Assisted Closure Device (V.A.C.) (KCL, Medical Ltd, Wimborne Dorset, UK). Complete wound healing occurred in all these patients, including four patients with meticillin-resistant \textit{Staphilococcus aureus}.

In patients with infected sternal wound, positive bacterial cultures were obtained in 23 cases \((85\%)\): \textit{Staphilococcus aureus} was the most isolated bacterial species \((60\%)\), followed by \textit{Pseudomonas aeruginosa} \((13\%)\), \textit{Escherichia coli} and \textit{Staphilococcus epidermidis} \((8.7\%)\), \textit{Serratia marcescens} and \textit{Enterobacter} \((4.3\%)\).

In the overall group of patients with sternal wound complications, sternal revision was performed in 26 patients of Group I \((Group\ I = 26/34)\) but none in Group II \((Group\ II = 0/13)\). \((Group\ I\ vs.\ Group\ II: P < 0.001)\).

### 4. Discussion

Median sternotomy still remains the most common surgical approach in cardiac surgery. It provides excellent exposure of cardiovascular structures: it may be rapidly, easily and safely performed and it is well tolerated by most of the patients.

Great majority of sternotomy incisions heal without any complications, but relevant problems could develop in a small percentage of patients.

The incidence of sternotomy related complications is reported as ranging between 2 and 8\% [1,11–14]. These complications can be minor, such as prolonged sternal pain, sternochondritis or incomplete knitting, or can be very serious, such as sternal dehiscence and mediastinitis.

Sternal dehiscence, despite its low incidence, is a potentially serious complication because it may lead to mediastinitis, prolonged hospital stay and death [1,5,11–14].

In literature, pre-operative risk factors for sternotomy wound complications include: obesity, diabetes, COPD, renal insufficiency, congestive heart failure, advanced age, osteoporosis and smoking [11–13]. Other conditions that can increase the risk of sternal wound complications are intra and postoperative. Intraoperative factors include asymmetric sternal section, bilateral ITA harvesting, and improper sternal closure. Postoperative factors are mainly represented by respiratory failure, low cardiac output state and mediastinal re-exploration for bleeding [9,10].

In our study we evaluate the usefulness of TRNC to

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Sternotomy wound complications with and without infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>(N) patients (%)</td>
<td>(P) value</td>
</tr>
<tr>
<td></td>
<td>Group I</td>
</tr>
<tr>
<td>No wound infection</td>
<td>19</td>
</tr>
<tr>
<td>Mechanical sternal dehiscence</td>
<td>14 (2.8)</td>
</tr>
<tr>
<td>Aseptic sternal necrosis</td>
<td>5 (1)</td>
</tr>
<tr>
<td>Wound infection</td>
<td>15</td>
</tr>
<tr>
<td>With sternal dehiscence</td>
<td>9 (1.8)*</td>
</tr>
<tr>
<td>Without sternal dehiscence</td>
<td>6 (1.2)</td>
</tr>
<tr>
<td>*Death (mediastinitis)</td>
<td>1 (0.2)</td>
</tr>
</tbody>
</table>

Fig. 2. Sternal closure by means of Nitillium clips.
prevent wound complication following sternotomy. The rationale in using TRNC was based on their favorable characteristics, the most important one being the elasticity. The special Nitillium alloy allows 10–15% deformation in width in case of instantaneous increment of tension forces (vigorous coughing and straining). In laboratory, this fact alone was able to reduce peak stress at the bone level up to 70%. The geometry of the TRNC, a wide open ‘C-shape’, enhances the intrinsic elasticity of the Nitillium alloy.

The second favorable property of TRNC is the widely large contact surface with the sternum (5–7 times greater than the standard steel wires) with a better distribution of stress forces.

The third property of TRNC is the thermoreactivity that makes the implantation feasible without any trauma for the bone.

Additional properties of TRNC include: absence of bone or fibrous tissue incorporation (thus making the explantation easy) and finally the ideal compatibility with computed tomography (CT) scans and nuclear magnetic resonance (NMR).

The overall incidence of sternal wound complication in the entire population of our study (1000 patients) was 4.7%. This incidence was higher in Group I (Group I = 6.8% vs. Group II = 2.6%; \( P = 0.003 \)), thus demonstrating the usefulness of TRNC in reducing the overall number of wound complications following sternotomy.

TNRC were considerably effective in reducing sternal dehiscence in patients with wound infection (nine patients in Group I vs. none in Group II; \( P = 0.001 \)) as well as in patients without infection (14 patients of Group I vs. one patient of Group II; \( P = 0.002 \)).

In addition, in patients with SWC we observed a considerable number of sternal revisions in Group I when compared to Group II (Group I = 26/34 vs. Group II = 0/13; \( P < 0.001 \)).

On the contrary, the use of TRNC did not affect the incidence of superficial wound infection and/or sternal aseptic necrosis. These complications could be prevented by the use of sparing techniques for bilateral ITA harvesting, as the preservation of the first intercostal branches, distal diaphragmatic bifurcation and skeletonization.

Finally, sternal closure with Nitillium clips seems to dramatically improve the outcome of patients treated for sternal dehiscence, especially if related to wound infection. This resulted also in a considerable reduction of hospital stay and relative costs.

5. Conclusions

TRNC provided superior results in sternal osteosynthesis in cardiac surgery patients because of their favorable properties (elasticity, geometry and thermoreactivity) in reducing mechanical stress on the sternum. Mechanical sternal dehiscence and need for sternal reconstruction were both considerably reduced by the use of TRNC. Moreover, surgi-
cal reconstruction with TRNC proved to be effective for sternal healing even in patients with sternal dehiscence, who previously received sternal closure with steel wires. Finally, use of TRNC offered an improved outcome also in patients with several pre-operative risk factors for sternal wound complication (Tables 3 and 4).

References


Appendix A. Conference discussion

Dr J. Pirk (Prague, Czech Republic): I would like to ask you, who was closing the conventional group and who was applying these clips, or who was closing the experimental group? Was it the resident or staff surgeon?

Dr Muneretto: Residents in almost all cases, for both groups, of course. The technique is quite easy. The only caution that you have to apply is just to avoid any damage to the mammary artery in no coronary patients, you just put your finger down the sternum just to push the mammary out from your hole.

Dr R. de Vivie (Cologne, Germany): We know the patients with the osteoporosis, especially in the patients in which we prepare both mammaries, we have fractures of the sternum. How do you handle these patients with sternal fractures and their osteoporotic sternum? I think these are the real problems which we know go to mediastinitis. Don’t you think it is difficult to use these clips in these patients with a fractured sternum.

Dr Muneretto: First of all, we were not so interested from a scientific point of view in the developing of a new sternal closure method but by the fact that almost all of our coronary patients are operated by means of a bilateral IMA harvesting, so that we were prone to develop some more effective technique in preventing some sternal complication. This is the first thing that I can say. The technique could be easily applied in almost all patients. Only a few patients have some problem in creating the hole, and there are patients with a very hard osteochondritis. After all, they lost the intercostal space. So you could not be able to find the intercostal space. But this is the only problem in the use of this type of device.