Fewer reoperations and shorter stay in the cardiac surgical ward when stabilising the sternum with the Ley prosthesis in post-operative mediastinitis

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Abstract

Objective: Using the Ley prosthesis, a 0.5 mm thick titanium alloy plate for stabilising the sternum, is a new method in the treatment of mediastinitis after open-heart surgery. We report a retrospective analysis of our experience with this device. Methods: One hundred consecutive cases of post-operative mediastinitis in the period 1992–1997 were reviewed. The primary procedure at reoperation for infection was as follows: 52 patients were treated with the Ley prosthesis and 48 patients underwent other conventional procedures. The choice of the surgical technique depended on the attending surgeon. The prosthesis was used more frequently in patients with sternal dehiscence but otherwise patients’ characteristics were similar in the two groups. As a control population for outcome data, 100 uninfected patients were matched with regard to operative procedure, age, sex and date of surgery. Results: The median hospital stay was 48.5 days in the mediastinitis group vs. 14 days in the control group. The all-cause 90-day mortality in the mediastinitis group was 18% vs. 5% in the control group. The 52 patients treated with the Ley prosthesis had a median length of stay in the cardiac surgery ward for 29 days vs. 41.5 days in the mediastinitis group not treated with the prosthesis. However, when the total length of stay including hospitals outside the cardiac surgery ward was taken into account, the prosthesis did not reduce the length of stay. Only 8/52 patients treated with the prosthesis required further surgery vs. 23/48 patients who were not primarily treated with the prosthesis. The Ley prosthesis had no impact on mortality. Conclusion: The Ley prosthesis is a valuable adjunct to the treatment of mediastinitis after open-heart surgery. A shorter stay at the cardiac surgery ward and a reduced need for further surgical procedures were observed when using this prosthesis. © 2001 Elsevier Science B.V. All rights reserved.

Keywords: Heart surgery; Sternal dehiscence; Sternotomy; Mediastinitis; Hospital stay; Reoperations

1. Introduction

Median sternotomy is the standard approach in cardiac surgery. In general, it is a safe approach with few complications. However, sternal instability with dehiscence and mediastinitis are the major causes of morbidity and mortality [1–11]. Mediastinitis patients are usually subjected to multiple reoperations and prolonged hospital stay. A cost of SUS 60 000 has been calculated for the treatment of this complication [12]. Mortality ranges from 15 to 40%. The cornerstone in the surgical treatment of mediastinitis is prompt reoperation with the establishment of a closed irrigation–drainage system in the mediastinal space. Stabilisation of the sternum is often troublesome due to fractures and fragile necrotic bone. Leaving the sternum open, on the other hand, is often associated with secondary infections, problems with weaning off the ventilator and a prolonged stay in the intensive care unit.

We hypothesised that achieving a more stable mechanical fixation of the sternotomy once dehiscence and mediastinitis occurred might reduce complications and costs by promoting a faster healing of the wound. Consequently, the Ley prosthesis was developed by one of us (R.A.) for a rigid fixation of the sternum. It is a prosthesis made of titanium, shaped like a ladder to implant on the anterior side of the sternum. The present work is a retrospective analysis of our experience with mediastinitis since the start of using the Ley prosthesis.
prosthesis in order to assess its possible impact on the treatment of sternal dehiscence and mediastinitis.

2. Patients and methods

2.1. Study design

From January 1992 to December 1997, 6500 cases of open-heart surgery were performed at the Karolinska Hospital. During this time period, a total of 100 patients (1.5%) with post-operative mediastinitis were identified. The diagnosis was based on a positive bacterial culture from the mediastinum at the time of reexploration, a positive culture from pericardial effusion or obvious clinical signs of mediastinitis on reexploration. The records of these 100 patients were reviewed. The surgical technique used at reexploration, including whether the Ley prosthesis was used or not, depended on the experience and the preference of the attending surgeon. As a control population for outcome data, 100 non-infected patients were matched with regard to operative procedure, age, sex and date of surgery. As primary procedures at the first reoperation for infection, 52 patients received a Ley prosthesis while 48 patients were treated with conventional techniques.

2.2. Conventional surgical techniques without the Ley prosthesis

Simple rewiring was used in 37/48 patients. Resuturing was done with a larger number of sternal wires and in most cases, a parasternal reinforcement ad modum Robicsek was employed [13]. Six patients were laid open, three patients had transposition of the greater omentum, 1 patient had muscle flap transposition and one patient was treated by drainage via the left pleura. All patients were treated with post-operative, continuous mediastinal irrigation except for the six patients left with open sternum and the patient who was drained by a pleural drain.

2.3. The Ley prosthesis – its use and technique of implantation

The prosthesis is made out of 0.5 mm thick titanium alloy; it has the shape of a step-ladder and is malleable to conform to the sternal profile (Fig. 1). Implantation is carried out under general anaesthesia. We use double gloves due to the risk of glove tearing on the wires and possible sharp bone edges. First, the old wound margins are excised and the sternum is assessed in detail concerning fractures, solidity and infection. Any devitalised tissue (soft tissues and sternal bone) is aggressively debrided, excised and the wound is cleaned with 1.5% hydrogen peroxide solution. An advantage with the prosthesis is that it will provide a great degree of stability even in the cases with multiple sternal fractures or where substantial parts of the sternum have been removed. Next the muscular tissue adjacent to the sternum is mobilised bilaterally; lateral dissection is up to 5 cm subfascial to the pectoralis major muscle. Meticulous haemostasis with diathermy is necessary.

The size of the prosthesis should be selected so that it will cover at least 75–80% of the length of the sternum measured from the jugular notch to the basis of the xiphoid process. To aid correct placing of the sternal wires, the intended position of the prosthesis is marked with diathermy. Up to six wire sutures are introduced to firm the tissue, either the sternum, ribs or costal cartilages parallel to the sternotomy line in the shape of U’s on each side of the transverse fracture, when present, in the sternum. The U’s are introduced into the tissue so that when tightening the suture, the fracture will be compressed against the prosthesis. A minimum of five sutures should be used on each side. After these sutures have been introduced, but before the prosthesis is pulled down, three to four new wires, alternatively strong, absorbable monofilament sutures, are applied around the two sternal halves pulling them together in the right position. Next, the prosthesis is introduced into the field (Fig. 2). When attaching it to the steel wires, it is preferable that the superior and inferior wire holes on each side of the prosthesis are used. The wire sutures should be pulled as straight as possible directly into the proper hole in the prosthesis. The prosthesis is then slid down and the wires are twisted so that the wires cross each other equidistant from where they exit from the prosthesis. The slack in the wire is taken up and the wire is twisted carefully, avoiding building up tension that will cause metal fatigue fracture (Fig. 3). One thin (No. 14 or 18 Fr.) irrigating and two thick exit drains are placed retrosternally and thinner drains are placed submuscularly. The muscular fascia is closed over the drains with interrupted and absorbable monofilament sutures. Subsequently, the skin is closed with interrupted and non-absorbable monofilament suture.

Post-operatively, a regime of 6–12 l per day of continuous irrigation with Ringer lactate containing antibiotics was used. A moderate suction (10–15 cm H2O) is applied to the drainage tubes. The duration of irrigation–drainage depended on the amount of debris drained and the clinical progress of the patient, but rarely exceeded 7 days.

2.4. Statistical methods

Data were analysed using Statistica for Windows from StatSoft Inc. Statistical analyses of categorical data were done using Fisher’s exact test or the chi-square test. For
continuous variables, the Mann–Whitney U-test was used. Spearman rank correlation was used for correlation calculations. Two-sided analyses were done throughout.

3. Results

3.1. Patient characteristics, general results and number of reoperations

The patient characteristics and the primary operation, as well as the results of bacterial cultures for patients reoperated for mediastinitis using the Ley prosthesis compared with the patients reoperated with conventional techniques, are shown in Table 1.

All together 60/100 patients received the Ley prosthesis, 52 as a primary procedure at the time of the first reoperation due to infection, eight patients had another procedure performed at the first reoperation due to infection and then received a prosthesis at later reoperations. During the first year in our study (1992), the Ley prosthesis was implanted as a primary procedure in only 1 out of 17 patients with mediastinitis. During the subsequent years (1992–1997), the fraction of patients in which the prosthesis was used varied between 43 and 73% of the operations. Seventy-three percent of the patients with mediastinitis had coexisting sternal instability. The Ley prosthesis was used as a primary procedure in 46/73 (63%) of these but only in 6/27 (22%) of the patients with stable sternum ($P < 0.001$). Apart from this difference, the patients’ characteristics were similar for the 52 patients with a Ley prosthesis as first operative procedure for mediastinitis and those operated with conventional techniques (Table 1). In the groups with stable or unstable sternum, there was no difference in patients’ characteristics among the patients who were treated with the Ley prosthesis and those with a more conventional treatment.

Among the 52 patients who had a prosthesis implanted at the first reoperation, four patients died soon thereafter and 42 healed without further surgical exploration except for two cases of reoperation for bleeding. All the remaining six patients had the prosthesis removed due to continuous infection and non-healing. Two of these were treated with omental transfer to the mediastinum (one of whom died two days later), three patients had another prosthesis implanted and one had the prosthesis removed after 4 weeks due to

Fig. 2. Example of the sternum on reoperation for mediastinitis with multiple fractures when substantial parts of the sternum have been removed but yet a high degree of stabilisation can be achieved with the prosthesis. Wires are introduced through firm tissue, either the sternum, ribs or costal cartilages, parallel to the sternotomy, bridging the transverse fractures. Wires are threaded into the appropriate holes. In addition, three wires (alternatively heavy monofilament absorbable sutures) are used to pull the two sternal halves together.
continued infection. At this time, the sternum was stable and the infection healed without further surgery. Among the 52 patients with implantation of Ley prosthesis at the first reoperation, fewer patients underwent further reoperations due to mediastinitis (Table 2), only 8/52 vs. 23/48 \( P < 0.001 \). The total number of reoperations was also less in this group \( P = 0.007 \). The overall success rate in using the prosthesis as primary treatment of mediastinitis was 81% (42/52) when early deaths and removal of the prosthesis were counted as failures. The corresponding success rate when not using the prosthesis was 46% (22/48) \( P < 0.001 \).

For the patients with stable sternum, the use of the Ley prosthesis (6/21) had no effect on the number of reoperations. However, the number of patients is too low in this subgroup to give solid data. Among patients with unstable sternum at reoperation, 46/73 had implantation of the Ley prosthesis as the primary treatment. These patients had fewer reoperations \( P = 0.011 \).

The eight patients who received a prosthesis as secondary surgical treatment after conventional initial operation for mediastinitis had the following course: 4 patients had the sternum primarily resutured, but due to recurrent sternal instability had a secondary reoperation and received a prosthesis. Three of these healed without further surgery, but one prosthesis had to be removed and the patient underwent plastic surgery with transposition of a muscle flap. Four patients in this group had the sternum open for 2–4 days before another reoperation where a Ley prosthesis was implanted. They all healed without further surgery. Among the eight patients who received the prosthesis as a secondary procedure for infection, there was no mortality. For the 60 patients who received a Ley prosthesis either as a primary or secondary procedure in the treatment of mediastinitis, the overall success rate was 82% (49/60).

### 3.2. Mortality

The all-cause 90-day mortality in the mediastinitis group was 18% vs. 5% in the control group \( P = 0.002 \). Thus, the excess 90-day mortality attributable to mediastinitis was 13%. There was no significant difference in 90-day mortality whether mediastinitis was treated primarily with the Ley prosthesis or other surgical procedures: 8/52 (15%) and 10/48 (21%), respectively. In the subgroup with unstable sternum, there was no difference in mortality whether the patients were treated with (8/46 (17.4%)) or without (6/27 (22.2%)) the Ley prosthesis. Most of the excess mortality attributable to mediastinitis occurred within 90 days of the operation (Fig. 4).

### 3.3. Length of stay

The length of total hospital stay was evaluated as hospital stay during the first 90 days and was calculated as 90 days minus number of days out of hospital. Consequently, the length of stay for patients who died without leaving the hospital was regarded as 90 days.

Patients with mediastinitis had considerably longer hospital stay than controls (Table 3). In the mediastinitis group, there was no difference between treatment with the Ley prosthesis and those treated in other ways. However, length of stay in the cardiac surgery ward including intensive care was significantly shorter in the patients treated with Ley prosthesis (median 29 vs. 41.5 days, \( P = 0.013 \)). In the subgroup with unstable sternum, the patients with a Ley prosthesis implanted at first reoperation had shorter length of stay in the cardiac surgery ward (34.5 (mean) vs. 44.3 days) \( P = 0.02 \). However, total length of stay in an institution, including hospitalisation outside the cardiac surgery ward, was not influenced. In patients with stable sternum, no effect of the implantation of the Ley prosthesis on the length of stay was detected.

The length of stay increased in patients who had a reoperation (due to bleeding, sternal dehiscence, etc.) before the onset of mediastinitis \( P < 0.001 \). It also correlated with age \( P < 0.001 \), length of primary operation \( P = 0.009 \), and length of cardiopulmonary bypass \( P = 0.009 \).
4. Discussion

The patients presenting for cardiac surgery are more challenging now than in earlier years. They are older, overweight, often have chronic obstructive pulmonary disease and other severe comorbidities. All these factors may increase the risk for sternal dehiscence and mediastinitis [1,5,6,8,11,14]. Since 1992, we have been evaluating the Ley prosthesis as an alternative method for closing the sternotomy after reoperation for mediastinitis in our department. With a few important points taken into consideration, it is easy to use. It has been primarily used to treat sternal dehiscence, even in the presence of concomitant infection. Theoretically and traditionally, implanting a foreign body at a site of infection is strongly contraindicated. The reason why we started with the Ley prosthesis in spite of this potential problem, was the assumption that sternal instability is a primary cause both to start and to maintain infection after sternotomy. Thus achieving sternal stability may have advantages over-shadowing the theoretical drawbacks. The low acute failure rate of implanted devices suggests that the procedure is safe and that the infection can heal despite the presence of foreign material.

We have compared the results using the Ley prosthesis with conventional techniques in stabilising the sternum in mediastinitis. The study was not randomised and the choice of the operative technique was the decision of the individual surgeons. As can be expected, the prosthesis was favoured in cases with sternal instability on reoperation but apart

Table 1
Patients’ characteristics of 100 patients with post-operative mediastinitis

<table>
<thead>
<tr>
<th></th>
<th>Ley prosthesis as primary treatment for mediastinitis (n = 52)</th>
<th>Other procedure as primary treatment for mediastinitis (n = 48)</th>
<th>P-value(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean)</td>
<td>67 years</td>
<td>66 years</td>
<td>NS</td>
</tr>
<tr>
<td>Sex (male/female)</td>
<td>47/5</td>
<td>38/10</td>
<td>NS</td>
</tr>
<tr>
<td>COPD(^b)</td>
<td>13 (25%)</td>
<td>7 (15%)</td>
<td>NS</td>
</tr>
<tr>
<td>Diabetes</td>
<td>18 (35%)</td>
<td>19 (40%)</td>
<td>NS</td>
</tr>
<tr>
<td>BMI(^c)</td>
<td>29.0</td>
<td>27.7</td>
<td>NS</td>
</tr>
<tr>
<td>Operation time</td>
<td>225 min</td>
<td>240 min</td>
<td>NS</td>
</tr>
<tr>
<td>Time of cardiopulmonary bypass</td>
<td>115 min</td>
<td>114 min</td>
<td>NS</td>
</tr>
<tr>
<td>Sternal instability</td>
<td>46 (88%)</td>
<td>27 (56%)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Type of operation</td>
<td></td>
<td></td>
<td>NS</td>
</tr>
<tr>
<td>CABG(^d)</td>
<td>37</td>
<td>31</td>
<td>NS</td>
</tr>
<tr>
<td>VR(^e)</td>
<td>8</td>
<td>6</td>
<td>NS</td>
</tr>
<tr>
<td>CABG + VR</td>
<td>6</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Aortic operation</td>
<td>1</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Type of bacteria</td>
<td></td>
<td></td>
<td>NS</td>
</tr>
<tr>
<td>CNS</td>
<td>27</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>S aureus</td>
<td>10</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Other gram positive</td>
<td>4</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Gram negative</td>
<td>8</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Negative cultures</td>
<td>2</td>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>

\(^a\) NS, non-significant.
\(^b\) COPD, chronic obstructive pulmonary disease.
\(^c\) BMI, body mass index.
\(^d\) CABG, coronary artery bypass grafting.
\(^e\) VR, valve replacement.

Table 2
Number of additional reoperations after the first reoperation for mediastinitis using the Ley prosthesis or conventional surgical techniques\(^a\)

<table>
<thead>
<tr>
<th>Number of additional reoperations</th>
<th>Ley prosthesis as primary treatment in mediastinitis (number of patients)</th>
<th>Conventional technique as primary treatment in mediastinitis (number of patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>44</td>
<td>24</td>
</tr>
<tr>
<td>1</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>9</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

\(^a\) Late removal of the prosthesis (>90 days) is not included. One patient with mediastinitis was not reoperated at all but drained through the pleura.
from this, the two groups appeared comparable with regard to major risk factors for morbidity and mortality.

In the present evaluation, the Ley prosthesis had no impact on mortality. However, the group primarily treated with the Ley prosthesis required fewer additional reoperations. This is especially encouraging considering that the prosthesis was used preferably in patients with sternal instability on reoperation. In such situations, sternal closure may be complicated and further operations often are required after conventional resuturing of the sternum. The length of stay in the cardiac surgical ward was significantly reduced for patients receiving prosthesis, but not the total hospital stay. The reduced stay in the specialised, cardiothoracic surgical unit is an advantage. It reduces total costs because the patients can earlier be transferred to a less costly health care facility. It also improves the utilisation of the surgical resources as ward and theatre capacity is not occupied by repetitive surgery and also the long-term care of these patients.

The all-cause 90-day mortality in patients with mediastinitis was 18% and the mortality attributable to mediastinitis was 13%. Despite the matched control design, there is a distinct possibility that the patients with mediastinitis have more risk factors for a fatal outcome than the controls. The higher rate of mortality (days 90–365) in the mediastinitis group compared to the controls would support this observation. The 90-day excess mortality of 13% attributable to mediastinitis should be considered as a high estimate.

In the 11 recent publications comprising almost 60,000 operated patients, the crude mortality among 519 cases of post-operative mediastinitis was 20%, but with considerable variations [1–11]. Control group mortality in patients without mediastinitis was reported in some studies to be about 5% rendering the excess mortality attributable to mediastinitis about 15%, which is similar to our results. Some of the variations in morbidity and mortality are certainly due to variations in case definitions, surveillance and follow-up methods as well as selection of patients accepted for surgery. In two studies with long-term follow-up [1,2], a considerably higher mortality was reported (31%). It is obvious from our data that reporting 30-day mortality or hospital mortality will result in a substantial underestimation of mortality since the majority of deaths in mediastinitis occurred between 30 and 90 days after operation. A comparison of complication rates and outcome between centres will remain difficult until a consensus is reached on a common form for registration of surgical complications.

In conclusion, the Ley prosthesis provides a new method with several advantages for closing and stabilising the sternum in mediastinitis. It can be used even with multiple fractures and after aggressive debridement with removal of parts of the sternum. In our experience, we had a shorter stay in the cardiac surgical ward and a reduced need for further surgical procedures when using this prosthesis. We also postulate that the Ley prosthesis may be a valuable adjunct to be used prophylactically for closure of the sternum at risk for dehiscence.

Acknowledgements

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Appendix A. Conference discussion

Dr M. Botta (Milan, Italy): Do you have experience if you must redo a case operated with this prosthesis?

Dr Astudillo-Ley: Yes. Actually we have taken away the prosthesis in some patients, and the prosthesis is very easy to take away. It is exactly in the same way when you are taking the sternal wires, and there are no technical problems to do that. The prosthesis is still above the sternum and under the subcutis.

Dr R. Martinez (Tenerife, Spain): Are you randomizing the distribution of both groups of mediastinitis?

Dr Astudillo-Ley: No.

Dr Martinez: In other words, the distribution of the culture is the same in both groups?

Dr Astudillo-Ley: Yes. The patients were matched, as I told you, regarding age and date of surgery, surgical procedure and co-morbidity. Unfortunately they were not randomized, but, on the other hand, we were seven consultant surgeons at the Karolinska Hospital by that time and three of us used the prosthesis regularly.

Dr A. Schachner (Holon, Israel): I would like to make two comments. First, what you are reporting is a very high rate of mediastinitis with a 100 cases in 5 years. Second, I think most surgeons would use a muscle flap as the primary option in treating these patients – an option you exercised in only 7 patients.

Dr Astudillo-Ley: Yes. The choice of the procedure was done upon the experience and the preference of the surgeon when operating with either the prosthesis or doing the operation with a conventional procedure. Regarding the other question, yes, that is true, 6500 patients were operated on in this period, and that makes 1.5% the incidence of mediastinitis. We think it is a high incidence.

Dr R. Lorusso (Brescia, Italy): I wonder whether you can comment on the fact that your stabilizer should have been considered a way of treating mediastinitis, I mean, the infection. So how could you compare omental plasty with a stabilizer? I mean, how did you treat the infection in the patients where you used the stabilizer? Because we did the same study in 50 patients and we showed that using conventional treatment like lavage or muscle flap, you have a high rate of recurrence and then you have to use omental flap, which is very impressively effective in defeating the infection. So could you comment on what kind of treatment for the infection in the stabilizer group did you use?

Dr Astudillo-Ley: Yes. We introduced changes in the treatment of mediastinitis of the patients as soon as we started with this program. One of them is the post-operative irrigation. We have irrigated with up to 10, 12 l Ringer’s acetate per day and we have used the same antibiotics that the patients are receiving intravenously in the irrigation system but in a lower concentration. And I think that is, besides the proper fixation and the stabilization of the sternum, one of the most important factors in achieving the results that you have already seen.

Dr U. von Oppell (Cape Town, South Africa): The question that needs to be asked is, do you need the Ley prosthesis for stabilization? It is therefore incorrect to compare patients treated with the Ley prosthesis to patients who were treated by an open method. Did you use the same irrigation methods in your patients treated conventionally with normal rewiring? What were the results if you compared patients treated with the Ley prosthesis to only the conventional rewired group, excluding patients treated by the open method?

Dr Astudillo-Ley: The answer is yes, we used the same regimen for irrigation post-operatively, even in the cases which were resutured with wires, and the differences between the groups, these are very small groups, actually there were no differences between them that I have to mention.

Dr B. Schafmeister (Bad Rothenfelde, Germany): Do you use suction applied in your surgical wounds after implanting the Ley prosthesis, and the second question, what do you think are the limitations of your application? So in what case would you not use a Ley prosthesis?

Dr Astudillo-Ley: The answer is yes. We have an active suction of 10–15 cm of water. And the limitations for using the prosthesis are, I think, when you have already done sternectomy and there is no tissue left to fixate the prosthesis. But I have to mention to you that at the Sahlgrensk Hospital in Gothenburg, Dr Mogens Bugge has tried a prosthesis, it’s a little bit larger, and he is fixating the prosthesis in the ribs. Six patients have been treated in that way, and, as far as I know, it has been very successful.