Improved results of the vacuum assisted closure and Nitinol clips sternal closure after postoperative deep sternal wound infection

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Abstract

Objective: Postoperative deep sternal wound infection is a severe complication of cardiac surgery, with a high mortality rate and a high morbidity rate. The objective of this prospective study is to report our experience with the vacuum assisted closure (VAC) system for the management of deep wound infection. We also devised an innovative closure technique post VAC therapy using thermo reactive clips. The advantage of this technique is that the posterior face of the sternum does not have to be separated from the mediastinal structures thus minimising the risk of damage.

Methods: From October 2006 to October 2008, we prospectively evaluated 21 patients affected by mediastinitis after sternotomy. Nineteen patients had sternotomy for coronary artery bypass grafting (CABG), one patient for aortic valve replacement (AVR) and another one for ascending aortic replacement (AAR). All patients were treated with the VAC system at the time of infection diagnosis. When the wound tissue appeared viable and the microbiological cultures were negative, the chest was closed using the most suitable procedure for the patient in question; nine patients were closed using pectoralis flaps, nine patients using Nitinol clips, one patient with a combined technique (use of Nitinol clips and muscle flap), one patient with a direct wound closure and another patient, who needed AAR with a homograft performed in another institution, was closed using sternal wires. Results: We had no mortality; wound healing was successfully achieved in all patients. In more than 50% of the patients, the VAC therapy allowed direct sternal resynthesis. The average duration of the vacuum therapy was 26 days (range 14—37 days).

Conclusions: VAC is a safe and effective option in the treatment of post-sternotomy mediastinitis, with excellent survival and immediate improvement of local wound conditions; furthermore, the use of Nitinol clips after VAC therapy demonstrated to be a safe and non-invasive option for sternal resynthesis. After VAC therapy, a reduction in number of muscular flaps used and an increase of direct sternal resynthesis were observed.

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1. Introduction

Deep sternal wound infection, or mediastinitis, after open-heart surgery is a severe complication of cardiac surgery, with a high mortality rate, high morbidity, prolonged hospital stay, need for multiple surgical procedures and a high associated cost.

Mediastinitis is usually classified into four types based on the time of first presentation, the presence or absence of risk factors and the presence or absence of one or more failed therapeutic trials (El Oakley and Wright [1]) (Table 1).

The management of mediastinitis involves many procedures and the choice of the surgical strategies is usually based on the El Oakley and Wright classification. The most common conventional treatments involve surgical revision, open dressing, closed mediastinal irrigation, debridement, complete sternectomy, or reconstruction with omental or muscle flaps [1—3].

In the last years the vacuum assisted closure (VAC), an innovative system for the treatment of infected wound, was developed. The first description of a VAC was done by Morykwas and Argenta in 1997 and since then an ever increasing number of surgeons have adopted this method [4,5]. This extraordinary treatment for the management of infected wounds consists of a polyurethane sponge of different sizes, dressed into the wound cavity and covered by a transparent adhesive film. This sponge, through a small hole in the film, is connected by an evacuation tube to a
canister to collect excessive wound exudates located in a portable pump with an onscreen user interface. The pump generates a continuous negative pressure thus causing perfect wound drainage and arteriolar dilatation; this allows a decrease of bacteria levels and a faster tissue granulation [6—8].

In the last years the VAC has been successfully used in open-heart surgery, in the treatment of superficial or deep sternal wound infections, and as a bridge to chest closure with muscles flaps or direct sternal resynthesis [9].

After VAC therapy, rewiring can be difficult because the mediastinal structures are adherent to the posterior face of the sternum with a high bleeding risk. In the last decade a new sternal closure method using thermo reactive clips was developed. The clips can be inserted in the parasternal space without any preparation of the substernal tissue. This method allows easy clip insertion and fast clip removal [10—12].

2. Materials and methods

After appropriate experience was acquired with the VAC device in our division, we ran this prospective study from October 2006 through October 2008.

A total of 21 consecutive patients with post-sternotomy mediastinitis were treated with the VAC system: 19 patients showed deep sternal wound infection following coronary artery bypass grafting (CABG), one patient following aortic valve replacement (AVR) and one patient following ascending aortic replacement (AAR). Eighteen patients had open-heart operations in our institution whilst the other three patients came from other institutions (two of them after surgical treatment failures). The infection rate in our institution, based on a total of 750 open-heart surgeries carried out during our 2 year study, was 2.5%.

Patients with sterile dehiscence or superficial sternal wound infections were not included in this study. All the patients were classified according to the criteria proposed by El Oakley and Wright: type III A in 10 patients, type III B in nine and type IV B in the last two (all our patients had one or more risk factors).

Thirteen patients were male and eight were female with a mean age of 65 years (range 50—80 years).

3. Technique

All patients underwent initial surgical revision with removal of all sternal wires. Tissue cultures were sent for microbiological investigations. Bacterial culture samples were collected in the subcutaneous tissue, in the bone and in the deep wound tissue. Debridement was performed and all necrotic tissues and exposed cartilages were removed. All bone fragments and sharp sternal edges were eliminated to avoid a possible heart injury. Washing with H₂O₂, followed by irrigation with a diluted povidone-iodine solution, was performed in the entire wound. After protecting the heart with a special white non-adhesive foam, the polyurethane sponge was cut, shaped and inserted in the mediastinum between the sternal edges to give stabilisation to the sternum and to prevent ventricular rupture (Fig. 1). Then a second sponge was placed above the sternum and a drape sealed all of the wound area (Figs. 2 and 3).

The sponges were changed twice a week in the operating room, under general anaesthesia and the culture samples were always collected to assess the right antimicrobial therapy.

Once the cultures were negative, the C-reactive protein was at a normal level and the wound reduced and looking viable, the closure could be performed [13,14]. When the sternal bone was in good condition the closure of the chest was done using Nitinol clips. Seven patients presented multiple crushes in the sternum (usually in the left hemisternum), hence, a pectoralis flaps reconstruction was performed and the muscle flaps were used to obliterate the mediastinal dead space (Fig. 4). The status of the sternum was the only criteria used to determine which sternum closing technique to perform regardless of the mediastinitis classification or the depth of the wound. The use of flaps was only considered for cases where the sternum had several transversal fractures or when the debridement had been
particularly aggressive causing removal of bone fragments. One patient who underwent sternal resynthesis using two Nitinol clips, additionally needed obliteration of the superior mediastinal space due to an aggressive debridement in the left sternal manubrium.

The average duration of the vacuum therapy was 26 days (range 14–37 days).

4. Microbiologic methods

The tissue culture samples were promptly carried in the microbiology lab where they were processed on blood enriched media, inoculated in Thioglycollate medium and incubated at 37°C.

Enriched broth samples were plated after 48 h on blood enriched media and incubated in CO₂ as well as in anaerobic conditions at 37°C. Cultures were stopped after 5 days.

Identification and susceptibility tests were carried out with Bio-Mérieux Vitek²™. Positive cultures were immediately reported to the surgeon in order to adjust the antibiotic therapy.
5. Results

All patients were assessed as of wound exudation (the sample for microbiological investigation was always collected at that time), the presence of wound dehiscence and/or sternal instability. CT scan of the mediastinum was performed in all patients. The C-reactive protein was systematically tested as well as other inflammation indicators [13,14]. The plasma C-reactive protein level showed a progressive decline during the treatment. If an abnormal sudden increase in the level of the protein was noticed, it was either due to the presence of an infection or due to the failure of the antibiotic treatment. If this was the case, the antibiotic therapy was promptly corrected by increasing the dose or by establishing or combining two synergic antibiotics.

In the presence of temperature >38 °C, blood-cultures were always collected.

All patients underwent initial surgical revision and at that time a choice of the most suitable procedure was made.

The most common bacteria were Gram-positive (62% Staphylococci) [15,16]. Seven patients were affected by coagulase-negatives Staphylococci (CoNS) infection, two patients by methicillin resistant Staphylococcus aureus (MRSA) and four patients by methicillin susceptible Staphylococcus aureus (MSSA) (two associated with Gram-negative bacteria). Two patients, who needed prolonged mechanical ventilation and prolonged intensive care unit (ICU) stay, had MRSA infection in the blood. One of the two patients with MRSA infection (patient n.1), who underwent sternotomy for ascending aortic replacement, had a vascular prosthetic infection and needed, after 14 days of VAC therapy, prosthetic removal and homograft implantation (performed in another institution). The other patient with MRSA infection (patient n.2) previously operated for CABG, during the VAC therapy developed a Candida albicans infection in the blood and thus needed antifungal therapy with caspofungin after a 14 days fluconazole therapy failure. Moreover the patient developed a post-discharge fungal liver abscess due to the Candida albicans infection that needed surgical exploration followed by a 6-month antifungal therapy.

One patient with Klebsiella pneumoniae and Serratia marcescens infection, had a blood leak from sternal edges due to the debridement thus requiring daily sponge dressing changes for about 4 days. The VAC procedure was not

Table 2
Demographics.

<table>
<thead>
<tr>
<th>Patient number, sex and age</th>
<th>Primary procedure</th>
<th>Isolated germs</th>
<th>Antibiotical therapy</th>
<th>Blood culture</th>
<th>Type</th>
<th>Therapy and VAC duration</th>
<th>Closure procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>n.1, female, 50 years</td>
<td>AAR</td>
<td>MRSA</td>
<td>Telipoplanin, chinuprin–dalfopristin</td>
<td>Positive MRSA</td>
<td>III B</td>
<td>VAC, 14 days</td>
<td>Rewiring after homograft (performed in another institution)</td>
</tr>
<tr>
<td>n.2, male, 50 years</td>
<td>CABG</td>
<td>MRSA, Candida albicans</td>
<td>Teicoplanin, rifampicin, fluconazole</td>
<td>Positive MRSA</td>
<td>III B</td>
<td>VAC, 24 days</td>
<td>Pectoralis flaps</td>
</tr>
<tr>
<td>n.3, female, 77 years</td>
<td>CABG</td>
<td>E. cloace, MSSA</td>
<td>Oxacillin, minocillin, Meropenem levofloxacin fluconazole</td>
<td>Positive MSSA</td>
<td>III A</td>
<td>VAC, 34 days</td>
<td>Pectoralis flaps</td>
</tr>
<tr>
<td>n.4, female, 80 years</td>
<td>CABG</td>
<td>Proteus m., Enterobact., Candida albicans</td>
<td>Meropenem</td>
<td>Negative III B</td>
<td>VAC, 21 days</td>
<td>Pectoralis flaps</td>
<td></td>
</tr>
<tr>
<td>n.5, female, 65 years</td>
<td>AVR</td>
<td>MRSE, E. coli</td>
<td>Telipoplanin, Imipenem–cilastatin, gentamicin</td>
<td>Negative III B</td>
<td>VAC, 26 days</td>
<td>Pectoralis flaps</td>
<td></td>
</tr>
<tr>
<td>n.6, male, 68 years</td>
<td>CABG</td>
<td>MRSE, Candida albicans</td>
<td>Telipoplanin, fosfomycin, fluconazole</td>
<td>Negative III A</td>
<td>VAC, 31 days</td>
<td>Pectoralis flaps</td>
<td></td>
</tr>
<tr>
<td>n.7, male, 74 years</td>
<td>CABG</td>
<td>MRSE</td>
<td>Telipoplanin, rifampicin</td>
<td>Negative III B</td>
<td>VAC, 26 days</td>
<td>Pectoralis flaps</td>
<td></td>
</tr>
<tr>
<td>n.8, male, 76 years</td>
<td>CABG</td>
<td>MRSE</td>
<td>Oxacillin</td>
<td>Negative III B</td>
<td>VAC, 20 days</td>
<td>Pectoralis flaps</td>
<td></td>
</tr>
<tr>
<td>n.9, female, 61 years</td>
<td>CABG</td>
<td>MSSA</td>
<td>Meropenem</td>
<td>Negative III A</td>
<td>VAC, 25 days</td>
<td>Pectoralis flaps</td>
<td></td>
</tr>
<tr>
<td>n.10, male, 50 years</td>
<td>CABG</td>
<td>K. pneumoniae, S. marcescens</td>
<td>Vancomycin, chinuprin–dalfopristin</td>
<td>Negative III B</td>
<td>VAC, 28 days</td>
<td>Pectoralis flaps</td>
<td></td>
</tr>
<tr>
<td>n.11, male, 54 years</td>
<td>CABG</td>
<td>MRSE</td>
<td>Piperacillin–tazobactam, fluconazole</td>
<td>Negative IV B</td>
<td>VAC, 37 days</td>
<td>Pectoralis flaps</td>
<td></td>
</tr>
<tr>
<td>n.12, male, 67 years</td>
<td>CABG</td>
<td>Pseudomonas aeruginosa, Candida albicans</td>
<td>Meropenem</td>
<td>Negative III A</td>
<td>VAC, 22 days</td>
<td>Pectoralis flaps</td>
<td></td>
</tr>
<tr>
<td>n.13, male, 65 years</td>
<td>CABG</td>
<td>E. cloace</td>
<td>Meropenem</td>
<td>Negative III A</td>
<td>VAC, 21 days</td>
<td>Pectoralis flaps</td>
<td></td>
</tr>
<tr>
<td>n.14, male, 69 years</td>
<td>CABG</td>
<td>MRSE</td>
<td>Linezolid</td>
<td>Negative IV B</td>
<td>VAC, 26 days</td>
<td>Direct closure</td>
<td></td>
</tr>
<tr>
<td>n.15, female, 68 years</td>
<td>CABG</td>
<td>MDR Pseudomonas, Corynebacterium, Candida lusitaniae</td>
<td>Clarithromycin, linezolid, amikacin, imipenem</td>
<td>Negative III B</td>
<td>VAC, 36 days</td>
<td>Pectoralis flaps</td>
<td></td>
</tr>
<tr>
<td>n.16, female, 77 years</td>
<td>CABG</td>
<td>Nontuberculur Mycobacterium chelonae/abscess</td>
<td>Telipoplanin, piperacillin–tazobactam, imipenem</td>
<td>Negative III A</td>
<td>VAC, 23 days</td>
<td>Pectoralis flaps</td>
<td></td>
</tr>
<tr>
<td>n.17, female, 71 years</td>
<td>CABG</td>
<td>Pseudomonas aeruginosa, Entorococco faecalis</td>
<td>Oxacillin</td>
<td>Negative III A</td>
<td>VAC, 20 days</td>
<td>Pectoralis flaps</td>
<td></td>
</tr>
<tr>
<td>n.18, male, 67 years</td>
<td>CABG</td>
<td>MSSA</td>
<td>Vancomycin, ambisome</td>
<td>Negative III A</td>
<td>VAC, 30 days</td>
<td>Pectoralis flaps</td>
<td></td>
</tr>
<tr>
<td>n.19, male, 71 years</td>
<td>CABG</td>
<td>MRSE, Zygomycte</td>
<td>Oxacillin</td>
<td>Negative III A</td>
<td>VAC, 30 days</td>
<td>Pectoralis flaps</td>
<td></td>
</tr>
<tr>
<td>n.20, male, 55 years</td>
<td>CABG</td>
<td>Serratia marcescens</td>
<td>Imipenem</td>
<td>Negative III A</td>
<td>VAC, 17 days</td>
<td>Pectoralis flaps</td>
<td></td>
</tr>
<tr>
<td>n.21, male, 68 years</td>
<td>CABG</td>
<td>MSSA, K. pneumoniae</td>
<td>Oxacillin, meropenem</td>
<td>Negative III A</td>
<td>VAC, 30 days</td>
<td>Pectoralis flaps</td>
<td></td>
</tr>
</tbody>
</table>

AD: aortic dissection; CAD: coronary artery disease; AAR: ascending aorta replacement; MRSA: methicillin resistant S. aureus; CABG: coronary artery bypass grafting; MRSE methicillin resistant S. epidermidis; AVR: aortic valve replacement; and MSSA: methicillin susceptible S. aureus.
stopped. One patient, who suffered from MDR *Pseudomonas aeruginosa* infection following pectoralis flaps closure performed in another institution, needed antibiotic therapy with colistin followed by a complete bacterial eradication. Direct wound closure could then be carried out.

One patient suffered sternal infection by nontuberculous *Mycobacterium abscessus/chelon* and needed aggressive debridement followed by a long-term therapy with clary-tromycin, amikacin, imipenem and linezolid (28 days). The patient is still in follow-up after 3 months.

One patient had MRSE mediastinitis and zygomycete infection in the sternum and thus needed antifungal therapy with ambisome followed by a complete fungal eradication. The sternal closure was performed with two Nitinol clips but, because of the aggressive debridement in the left manubrium, an additional pectoral flap was needed to obliterate the superior dead mediastinal space. The serial microbiological cultures guided the antibiotic therapy.

Glycopeptides have been used for CoNS and MRSA, more specifically teicoplanin was used and the dosage was 6 mg/kg by intravenous route every 12 h until the discharge. Glycopeptides were used together with rifampicin (600 mg/day) or fosfomycin (2 g every 6 h) or chinupristin—dalfopristin (500 mg every 6 h). Post-discharge antimicrobial therapy was adjusted according to the last positive culture result and continued for 2/4 weeks, whilst monitoring the C-reactive protein levels.

Prior to the use of the VAC system, an aggressive debridement was performed, thus removing all of the exposed tissue and part of the sternum and cartilages. After the introduction of the VAC, this procedure was no longer needed. Thus, in most of the patients, direct chest closure was possible instead of more complex reconstructions using muscle flaps (Table 2).

We had no mortality. Wound healing was achieved in all patients. In more than 50% of patients VAC therapy allowed direct sternal resynthesis without using flaps.

6. Discussion

The VAC presents many advantages in the treatment of mediastinitis: sternal stability, perfect wound drainage, isolation of the wound and an increased blood perfusion in the wound tissues.

The constant negative pressure removes interstitial fluid, decreases localised oedema, increases blood flow with arteriolar dilatation and consequently improves antibiotic diffusion and decreases the tissue’s bacterial levels. Furthermore, the continuous negative pressure produces a mechanical deformation of cells that increases the proliferation. This stimulates tissue granulation, which in turn, accelerates wound healing. The recommended negative pressure is around 125 mmHg.

It is mandatory to protect the cardiac surface, or exposed vascular structures, with a special non-adhesive foam or other non-adhesive materials. The sponge dressing was changed twice a week in the operating room under general anaesthesia to control the sternal edge mobility during breathing. Sternal edge mobility has to be kept as low as possible as it can lead to ventricular rupture. Further debridement and washing with H$_2$O$_2$ and iodosopovidone was performed. No topical antibiotic was used, according to antibiotic therapy guidelines.

In the presence of prosthetic material, after wound debridement and VAC treatment, removal of infected vascular prosthetic and homograft replacement was performed.

When sternal resynthesis is feasible, it is preferred to use thermo reactive clips instead of steel wires. These staples have the advantage to be non-invasive because it is not necessary to free the posterior face of the sternum from mediastinal structures (Fig. 5). They are easy, safe and fast to implant and can also be easily removed. The clips are made of Nitinol, a material that contains a nearly equal mixture of nickel and titanium and are thermo reactive: cooling allows the transformation of Nitinol from austenite into martensite (a soft material) and heating allows the reverse cycle from martensite to austenite (a hard material).

Hence, before being implanted, these clips are cooled in order to allow a greater material deformation, which in turn, allows an easier insertion in the sternum sides. Once the clips are positioned, a warm gauze, placed above the clips, allows them to contract and to return to the initial shape thus pulling the sternum edges together.

The clips have different sizes. Each clip is measured and chosen to be 5 mm less than the sternal width and inserted through a hole close to the sternal rim, in the intercostal space, using electrocautery.

Three clips are generally sufficient to achieve good sternal stability (Fig. 6). Using VAC, there is a shorter hospital stay after closing the chest with pectoralis flaps or with Nitinol clips and no complications related to closure procedures have been observed.

In our experience, complete healing was achieved in all patients and no complications during VAC therapy were observed.

![Fig. 5. Nitinol clip.](image-url)
When feasible after VAC therapy the use of Nitinol clips is a safer and lesser invasive treatment for sternal resynthesis than any rewiring method.

References


Fig. 6. Sternal resynthesis with Nitinol clips.

7. Conclusions

VAC has been successfully used in post-sternotomy mediastinitis in the last years. It is a simple and safe solution in the treatment of this dreadful complication of open-heart surgery with excellent survival and immediate improvement of local conditions. As a conclusion, based on our acquired experience, we believe that the use of the operating room for dressing change, the short span of time between diagnosis and intervention and the accurate choice of the antibiotic therapy are key factors for the success of this treatment.

Prior to using the VAC therapy, a great number of reconstructions with muscle flaps, due to bone and exposed cartilage extensive demolition, were performed. After the advent of VAC, resynthesis was possible in more than 50% of cases and wound depth reduction allowed the use of the pectoralis major muscles without the need of harvesting other flaps such as the rectus abdominal muscle; furthermore, it was not necessary to obliterate the mediastinal dead space with an omental flap.