Vacuum-assisted closure of post-sternotomy mediastinitis as compared to open packing

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Abstract

Post-sternotomy mediastinitis is a rare but serious complication of cardiac surgery leading to prolonged hospital stay and higher mortality. In the last decades several treatment modalities have been described, of which vacuum-assisted closure (VAC) shows the most promising results. The aim of this study is to describe clinical outcomes of VAC as compared to open packing and to predict risk factors for mortality. We performed a retrospective analysis of 113 patients with mediastinitis undergoing VAC (n=89) or open packing (n=24) between January 2000 and July 2010. Patient characteristics, risk factors and procedure-related variables were analysed. C-reactive protein and leukocyte counts were determined on admission and at regular intervals during hospital stay. We compared length of treatment, treatment failure, hospital stay and mortality. We also analysed risk factors predicting mortality. In-hospital mortality in the VAC group was 12.4% compared to 41.7% in the conventional group (P=0.0032). Intensive care stay was 6.8 ± 14.4 days with VAC therapy compared to 18.5 ± 21.0 days with open packing (P=0.0081). Significant risk factors for mortality were pre-operative renal failure and obesity. Our findings indicate that VAC therapy is superior to open packing, resulting in shorter intensive care stay and improved survival.

Keywords: Vacuum-assisted closure • Mediastinitis • Infection • Sternotomy

INTRODUCTION

Median sternotomy is the most common approach for cardiac surgery. Despite the use of sterile technique, perioperative antibiotics and careful wound management, surgical site infections resulting in mediastinitis occur in up to 3% of patients [1]. Post-sternotomy mediastinitis is debilitating and often fatal, with high mortality rates of up to 30% [2]. Post-sternotomy mediastinitis can be managed by antibiotic therapy, wound incision and drainage, debridement, rewiring, closed irrigation, delayed closure and omental or myocutaneous flap reconstruction [3]. Over the last decades surgical therapy consisting of debridement followed by open packing has substantially evolved. Alternative techniques with primary or delayed mediastinal closure leading to higher success rates and lower mortality have been described [4]. Of considerable importance is the use of negative pressure to enhance wound granulation and closure as initially described by Davydov et al. in the early 1990s [5]. This technique known as vacuum-assisted closure (VAC) was later successfully adapted for surgical wound management by Morykwas et al. [6]. VAC is an alternative wound healing strategy in post-sternotomy mediastinitis and recent studies have reported promising results although studies comparing VAC with open packing are scarce [7].

In this study, the effectiveness of VAC was compared to open packing as either an adjunct to additional therapy (prior to vascular flap) or as sole therapy (delayed primary closure or secondary granulation). Risk factors for mortality were determined in patients treated with VAC.

MATERIALS AND METHODS

Study population and data collection

In our centre 19,254 patients were operated via median sternotomy between January 1, 2000 and July 1, 2010. Patients were included according to the criteria for mediastinitis as described by the Centers for Disease Control and Prevention [8]. A total of 161 patients (0.84%) were diagnosed to have mediastinitis. Eighty-nine patients were treated with VAC, 24 patients managed with open packing. The remaining patients were treated with other modalities and were therefore excluded. Variables included in the study are listed in Tables 1 and 2. Incubation period was defined as the period between primary surgery and reintervention for mediastinitis. Renal failure was defined as a creatinine blood level of ≥120 µmol/l. Obesity was defined as a body mass index >25 kg/m². Treatment failure was defined as
the need for re-intervention or as death of the patient as a consequence of mediastinal infection.

**Mediastinitis: classification and treatment**

Post-sternotomy mediastinitis was classified into five subtypes based on the presence or absence of risk factors, the duration of the incubation period and previous failed therapies according to Oakley and Wright [3]. The severity of mediastinitis was classified based on the level of tissue infiltration: the subcutaneous tissue (1), the sternum (2) or the pericardial sac (3).

All patients underwent surgical intervention on an urgent basis. The sternotomy was fully re-opened under general anaesthesia. Extensive debridement of the wound was performed. In the open-packaging group, wounds were irrigated with hydrogen peroxide, saline and diluted povidone–iodine solution, followed by packing with gauzes. This procedure was repeated on a daily basis.

In the VAC group a suction system was inserted in the wounds (KCI International, San Antonio, TX, USA). The technique for VAC application has been described by Obdeijn et al. [9]. VAC consists of polyurethane foam placed in the wound connected to a computer-controlled suction unit. In addition to this, we used a tailored polyvinyl alcohol dressing placed subternal to protect vital structures. The wounds were covered with a transparent sterile adhesive drape. The therapy unit delivered a continuous negative pressure of 75–125 mmHg. The VAC dressings were changed twice a week till the microbiological cultures were negative. Eight patients (9%) were able to go home with VAC and clinically healthy granulating wound. Sternal wounds were then allowed to close by secondary intention or closed surgically depending on their size. All patients received adequate antibiotic therapy.

**Outcome and evaluation**

Regular blood chemistry and cell counts were performed, at diagnosis of mediastinitis ($t_0$), at $t_1$ (3–7 days after $t_0$), at $t_2$ (8–13 days after $t_0$) and at $t_3$ (14–21 days after $t_0$).

Time interval between primary surgery and development of mediastinitis, in hospital stay, VAC and antibiotics therapy interval were registered. Completion of therapy was defined as the delayed primary closure of the sternum, until secondary wound healing was achieved, or use of a myocutaneous flap. Patients who were discharged home with VAC were reviewed weekly at our specialized outpatient wound clinic.

**Statistical analysis**

Standard descriptive statistics are given. Comparison of groups was performed by Student’s t-test, Mann–Whitney test or Chi-square test where appropriate. For time-related variables Kaplan–Meier estimates and log-rank test were computed. We used a mixed effect model with the square root transformed C-reactive protein (producing a near Gaussian distribution) to test the difference between groups and course in time by means of a likelihood ratio test. All statistical analyses were performed in R (R for windows version 2.13; www.r-project.org).

**RESULTS**

**Patient population and characteristics**

One hundred and thirteen patients with mediastinitis were included in this study of which 89 were treated with VAC and 24 with open packing. Patient characteristics and laboratory values are shown in Table 1. Statistically significant differences in age and preoperative haemoglobin value were seen. No differences were observed in variables related to the initial surgical procedure (Table 2). Time between primary operation and re-operation for...
mediastinitis in the VAC group ranged from 6 to 333 days (median 22) versus 6–92 days (median 17) in the conventional group.

**Pathogens of mediastinitis**

Type and severity of the mediastinitis are showed in Table 3. The majority of tissue cultures from mediastinitis patients showed *Staphylococcus aureus* (68 patients) or coagulase-negative *Staphylococcus* strains (11 patients). Three patients had positive cultures demonstrating *Staphylococcus epidermidis*, two patients had *Escherichia coli*, two patients had *Proteus mirabilis*, two patients had *Serratia marcescens* and one patient had *Klebsiella pneumoniae*. One patient had methicillin-resistant *S. aureus* in the tissue cultures. Other pathogens seen included *Pseudomonas aeruginosa*, *Enterococcus faecalis* and *Enterococcus faecium*. In 13 patients the tissue culture remained negative, most likely due to prior antibiotic treatment. In both groups *S. aureus* was detected in the majority of tissue cultures; 62.9% in the VAC group versus 62.5% in the conventional group.

**Outcome**

Intensive care stay was shorter in the VAC group compared to the open-packing group (6.8 ± 14.4 days versus 18.5 ± 21.0 days). Inhospital mortality was significantly lower in the VAC group (12.4%) compared to patients treated with open packing (41.7% P = 0.0032). The crude odds ratio (OR) of the VAC group compared to the open-packing group on in-hospital mortality was 0.20 (95% CI = [0.07–0.56]). Propensity adjustment was performed for gender, smoking, C-reactive protein count, year of start mediastinitis, prior surgery, left internal mammary artery usage, right internal mammary artery usage, type of mediastinitis and haemoglobin count. Propensity adjusted OR of the VAC group versus the open-packing group on in-hospital mortality was 0.18 (95% CI = [0.07–0.46]).

In both groups C-reactive protein levels and blood leucocyte counts declined significantly compared to their values at diagnosis of mediastinitis (Fig. 1a). Speed and extent of the decline were not significantly different in both groups.

Out of the 89 patients who received vacuum therapy 62 underwent a procedure for closure. These procedures were delayed wound closure (n = 23) including reconstruction with omentum or pectoral muscle flap, while the remaining (n = 39) had sternal re-fixation (delayed primary closure) without the use of additional procedure. In 27 patients, the wound was allowed to close by secondary intention.

**Risk factors for mortality**

Risk factors and laboratory values of patients treated with VAC therapy who died were compared to patients who survived (Table 4). Cause of death during VAC treatment was mostly sepsis, heart failure, respiratory insufficiency and bowel ischaemia. Incidence of obesity and renal failure was significantly different between groups. Mediastinitis was severe in all cases (3 on the severity scale) and patients had more polymicrobial infections in the mortality group compared to the surviving group.

Speed and extent of decline of C-reactive protein and leucocytes were less in the mortality group compared to the surviving group (Fig. 1b). The mixed effects modelling showed an overall statistical significant difference between groups of C-reactive protein values (P < 0.001) as well as a different course in time between both groups (P = 0.0275).

**Table 3:** Mediastinitis variables

<table>
<thead>
<tr>
<th>Category</th>
<th>VAC group</th>
<th>Conventional group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound classification</td>
<td>N=89</td>
<td>N=24</td>
<td></td>
</tr>
<tr>
<td>Type I</td>
<td>12 (13.6%)</td>
<td>5 (20.8%)</td>
<td>0.0389</td>
</tr>
<tr>
<td>Type II</td>
<td>32 (36.4%)</td>
<td>13 (54.2%)</td>
<td></td>
</tr>
<tr>
<td>Type III</td>
<td>35 (39.8%)</td>
<td>5 (20.8%)</td>
<td></td>
</tr>
<tr>
<td>Type IV</td>
<td>2 (2.3%)</td>
<td>1 (4.2%)</td>
<td></td>
</tr>
<tr>
<td>Type V</td>
<td>7 (8.0%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>Severity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild (1)</td>
<td>2 (2.3%)</td>
<td>1 (4.2%)</td>
<td>0.6116</td>
</tr>
<tr>
<td>Moderate (2)</td>
<td>9 (10.2%)</td>
<td>1 (4.2%)</td>
<td></td>
</tr>
<tr>
<td>Severe (3)</td>
<td>77 (87.5%)</td>
<td>22 (91.7%)</td>
<td></td>
</tr>
</tbody>
</table>

Figure 1: C-reactive protein levels and leucocyte course. A shows the decline in C-reactive protein level and leucocyte count in both the VAC-treated group and the open packing group. B shows the decline in C-reactive protein level of the surviving and mortality group in VAC-treated patients.
Table 4: Predicting factors for mortality in patient receiving VAC therapy

<table>
<thead>
<tr>
<th></th>
<th>Surviving group N = 78</th>
<th>Mortality group N = 11</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (male)</td>
<td>52 (67.5%)</td>
<td>8 (72.7%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Age (years)</td>
<td>67.3 ± 10.3</td>
<td>71.7 ± 9.3</td>
<td>0.1825</td>
</tr>
<tr>
<td>COPD</td>
<td>18 (23.7%)</td>
<td>5 (45.5%)</td>
<td>0.2442</td>
</tr>
<tr>
<td>Diabetes (any)</td>
<td>30 (39.0%)</td>
<td>5 (45.5%)</td>
<td>0.9344</td>
</tr>
<tr>
<td>Hypertension</td>
<td>32 (41.6%)</td>
<td>3 (27.3%)</td>
<td>0.5644</td>
</tr>
<tr>
<td>Renal failure</td>
<td>14 (18.2%)</td>
<td>8 (72.7%)</td>
<td>0.0004</td>
</tr>
<tr>
<td>BMI</td>
<td>27.0 ± 5.0</td>
<td>30.7 ± 3.7</td>
<td>0.0296</td>
</tr>
<tr>
<td>Severe mediastinitis*</td>
<td>66 (84.6%)</td>
<td>11 (100%)</td>
<td>0.3483</td>
</tr>
<tr>
<td>Staphylococcus aureus in tissue culture</td>
<td>51 (64.5%)</td>
<td>5 (45.5%)</td>
<td>0.3174</td>
</tr>
</tbody>
</table>

COPD, chronic obstructive pulmonary disease; BMI, body mass index. *3 on the seventy scale.

DISCUSSION

Post-sternotomy mediastinitis is a devastating complication with high mortality rates. Failure of open-packing therapy for mediastinitis aggravates an already complicated situation. VAC was introduced in the late 1990s as a therapeutic modality for the treatment of post-sternotomy mediastinitis [7]. Local application of uniform suction achieved with VAC therapy permits arteriolar dilatation promoting granulation tissue proliferation. This technique decreases excess fluids and oedema, reducing bacterial colonization of the wound and reducing the need for dressing changes [6]. We have been using VAC for the treatment of mediastinitis at our department since 1999. VAC has been compared several times with open packing during the last decade [10, 11].

Our study, however, includes the largest group of patients treated with VAC.

Our study demonstrates that VAC reduces intensive care stay and mortality. We were able to implement VAC therapy in a domiciliary setting, increasing mobilization, physical and emotional wellbeing of patients. Eight patients could leave the hospital with the VAC system in situ, visiting the outpatient clinic twice a week. The change of dressings was performed by specially trained nurse practitioners. This increases patient comfort and may lead to cost reduction [12].

Our mortality rates are similar to the earlier reported results, confirming the benefits of VAC therapy compared to open packing [13]. Sjögren et al. reported lower mortality rates in their VAC group compared to our results. A possible explanation for this observed difference could be the incidence of renal failure [10]. The incidence of pre-operative renal failure was higher in our group and we found this to be a strong predictor for mortality. Open packing was mostly used in the period between 2000 and 2002 while VAC was used from 2000 till 2010. Improved medical care during the last years could have positively affected mortality in the VAC group, although we do not see a decline of mortality in the VAC group over time.

Risk factors for mediastinitis have been previously reported [14]. We report for the first time risk factors for in-hospital mortality of VAC-treated patients. Karra et al. recently published several risk factors for 1-year mortality in patients with mediastinitis [15]. These results, however, were not specific for patients treated with VAC. Obesity and renal failure have been shown to be strong predictors for mortality in our VAC-treated patients. We have also shown that slow decline of C-reactive protein levels are indicative of treatment failure suggesting an increased risk of in-hospital mortality.

Our results are in accordance with previous studies showing that in-hospital stay was shorter, rewiring was earlier and survival tended to be better when VAC was used [10, 11].

VAC is an effective method to treat post-sternotomy mediastinitis. Possible drawbacks of VAC have recently been delineated in cases of right ventricle wall rupture due to the high negative pressure [13]. Despite protection of the vital structures by polyvinyl alcohol dressings, right ventricle rupture occurred in one patient in our study.

This study shows that VAC is superior to open packing in post-sternotomy mediastinitis. VAC reduces mortality, increases sternal stability, patient comfort and can be used in an outpatient setting. Pre-operative renal failure and obesity are risk factors for mortality in VAC-treated patients.

Conflict of interest: none declared.

REFERENCES

Vacuum-assisted closure therapy in cardiac surgery

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The retrospective study by Vos et al. has reported on the superiority of VAC-therapy compared to open packing in patients with post-sternotomy mediastinitis (PM) [1].

We have reviewed our experience regarding the management of deep sternal wound infections (also commonly called PM) in 85 patients over a period of 11 years (2000–2010) where the in-hospital mortality rate for this specific group was 7% vs. 3%. The higher logistic EuroSCORE for these patients (10.2% vs. 7.9%) indicates the higher rate of preoperative co-morbidities [2]. Our therapeutic approach is consistent with immediate application of VAC-therapy plus systemic antibiotics even when there is no clear distinction of whether there is an infective deep sternal wound or not [2]. This approach may improve the wound healing process through the early removal of the infective tissues and reduction of dead space. In case of sternal dehiscence, further surgical revision is required. Upon resolution of acute infection and confirmation of wound cultures as negative, a primary sternal closure technique is applied followed by insertion of closed irrigation - suction drains [2].

Bilateral myocutaneous pectoral flap reconstruction can be performed when necessary with particular emphasis on the preservation of its vascular supply. Six percent of these patients required a further plastic intervention [2].

In 2003, Luckraz et al. found that VAC-therapy combined with primary closure or myocutaneous flap is superior to VAC-therapy alone in patients with PM (VAC duration 13.5 days vs. 8 days, healed scar 77% vs. 64%, mortality rate 7.7% vs. 28.6%) [3]. The overall cost of the VAC-therapy per patient was regarded as nearly $4000 cheaper per patient than the single use of a closed irrigation system [3].

Pectoralis flaps can frequently be used for the definitive treatment of PM and the final sternal reconstruction. These flaps, as described by Jurkiewicz et al., allow early closure and healing of sternal wounds and are currently the conventional treatment for PM [4]. Alternatively, omental flaps can also be used for the treatment of PM specifically in the case of replacement of the ascending aorta with a prosthetic graft [4].

In 2007, Raja and Berg published their meta-analysis regarding the routine use of VAC-therapy in all patients with deep sternal wound infections post cardiac surgery. The authors identified 13 papers (out of 198) representing the best evidence in the use of VAC-therapy [5]. All the studies were retrospective or small cohort and the largest one was by Agarwal et al. with 103 patients (64% had the definitive diagnosis of PM) [5]. According to Agarwal et al., all the patients were treated with VAC-therapy (average period 11 days/patient) of whom 68% had definitive chest closure. The overall mortality rate was 28%, however, no deaths were related to VAC-therapy. Four deaths were due to PM sepsis [5].

This meta-analysis illustrates that VAC-therapy is a safe and effective additional method for the surgical management of PM. However, a prospective double-blinded randomized controlled trial is essential in order to validate the effectiveness, cost effectiveness and improvement of quality of life of patients undergoing VAC-therapy [5].

Conflict of interest: none declared.

References