Negative Pressure Wound Therapy Becomes the Treatment of Choice of Deep Sternal Wound Infection

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ABSTRACT

Background: Sternal wound infection, especially deep sternal wound infection, is a serious complication after open heart surgery. It leads to a marked increase in hospital stay, financial expenses, and mortality. Treatment is primarily surgical and may be divided into conventional treatment methods and negative pressure wound therapy.

Materials and methods: Between 2010 and 2021, 77 patients presenting back after cardiac surgery with deep sternal wound infection were treated surgically. Conventional treatment methods were utilized in 45 patients and included wound revision with primary closure, continuous wound irrigation, and open treatment with secondary closure. Negative-pressure wound therapy (NPWT) was applied in 32 patients. The two treatment arms were compared by two primary outcomes – rate of recurrent infection and hospital mortality. Predictors of mortality and infectious recurrence were identified using multivariate logistic regression.

Results: Recurrent infection occurred in 18.2% of cases and mortality was 13% in the whole group. NPWT was more successful in preventing recurrent infection OR: 5.4 (95% CI: 1.1-27.5; P = 0.044) than conventional treatment and more than moderate left ventricular systolic dysfunction (EF<40%) predisposed to infectious recurrence - OR: 4.7 (95% CI: 1.05-22.1; P = 0.049). Recurrent infection itself was the strongest predictor of mortality in the multivariate model OR: 0.14 (95% CI: 0.03 - 0.58; P = 0.007).

Conclusion: NPWT as an initial method of wound preconditioning followed by definitive wound closure effectively reduces the rate of infectious recurrence and patient mortality. It may become the modality of first choice when dealing with complicated incisional infections following heart surgery.

INTRODUCTION

Surgical site infection (SSI) after median sternotomy, also called sternal wound infection (SWI), has a prevalence of 4.1% in a recent large single-center study. Among them, 2.1% were superficial SWI without associated bloodstream infection and 2.0% were deep SWI (mediastinitis) involving the sternum and mediastinum often with associated blood infection [Lemaignen 2015].

Superficial sternal wound infection (SSWI) is limited to the skin, subcutaneous tissue and pectoral fascia, and involves localized abscess or phlegmon without bone and retrosternal tissue involvement. Deep sternal wound infection (DSWI) presents as osteomyelitis and mediastinitis. All tissues along the surgical incision are infected, including skin, subcutaneous layers, bone, metal wires, and pericardium. DSWI rapidly leads to sternal instability and destruction rendering vital intrathoracic organs vulnerable.

SWI, especially DSWI is a serious complication after open heart surgery. It leads to a marked increase in hospital stay, financial expenses, and mortality, as well as decrease in long-term survival, compared to patients without SWI [Sears 2016]. Increased mortality is due to prolonged septicemia and multiorgan failure. Repetitive surgical revision of the wound accumulates surgical trauma and stress. Patients who survive after surgical treatment of DSWI do not regain their quality of life [Jidéus 2009]. Thus, prompt diagnosis and implementation of effective surgical treatment are paramount.

Surgical treatment of SWI: The aim of surgical treatment of SWI after open heart surgery is control of the infectious process, achievement of sternal stability, and filling of tissue defects that create conditions for wound healing. At present, there are no established guidelines on the treatment of sternal wound complications. Traditional methods date back to the 1960s and consist of wound debridement, primary closure of the sternum, and catheter irrigation of the wound bed with antimicrobial or antiseptic solution [Shumacker 1963]. Later, new techniques developed, such as open treatment and secondary closure. A classic method is loose gauze packing of the wound bed, which absorbs exudate and permits aeration but retains moisture for its proper healing. Gauzes are changed every few days (1 to 5 days, depending on the degree of exudation) until a clean wound with granulations is achieved. Drawbacks of open treatment are risk of secondary infection, instability of the thoracic cage, need for mechanical

ventilation, and prolonged immobilization with their inherent consequences – muscular weakness, ventilator-associated pneumonia, and thromboembolic incidents. An alternative approach for wound preparation is the negative pressure wound therapy, also called vacuum therapy.

Negative pressure wound therapy (NPWT): NPWT, also known as vacuum therapy, or microdeformational therapy, is initially described in 1996 by Argenta [Argenta 1997]. During the first decade of our century NPWT gained widespread favor for treatment of various wounds including SWI [Fleck 2006]. NPWT is successfully applied to both superficial and deep poststernotomy infections. NPWT can be applied as a stand-alone method or in preparation of the wound for a plastic procedure.

MATERIALS AND METHODS

Between 2010 and 2021, 3724 median sternotomies were performed in the Department of Cardiac Surgery at St. Anna University Hospital, Sofia. All patient data was extracted from the electronic database and written records. The institutional ethics committee approved usage of personal patient records. Eligible candidates included all patients who had undergone surgical treatment for DSWI. Patients with a distant infectious process or any antibiotic treatment up to one month prior to the cardiac procedure were excluded. Diagnosis of DSWI was based on widely accepted and verified criteria [Horan 2008]. In cases with negative microbiologic results, SWI was established by clinical criteria in addition to typical changes in laboratory data. Our patient cohort was divided into two groups – conventional treatment and NPWT. We introduced NPWT in 2011 and over the years, it became our preferred method of treatment. Common patient characteristics, which would had impact on treatment outcome, were compared between groups. Effect of treatment was assessed by two outcome parameters - rate of recurrent infection and operative mortality.

Statistical analysis: Categorical variables were presented as number and percent, and metric variables with mean±standard deviation. Metric variables were tested for normal distribution with Kolmogorov-Smirnov or Shapiro-Wilk test. Metric variables without normal distribution were summarized as median and interquartile range. Differences in distributions of categorical variables were tested with the χ^2-test or Fisher's exact test, and metric continuous variables were compared with Student's t-test or the non-parametric Mann-Whitney test for not normally distributed data. Logistic regression analysis was used to define predictors of recurrent infection and mortality. All potential predictors were entered into the initial model. Using the backwards elimination method, the final model was created. Statistical significance was accepted if $P < 0.05$. Data analysis was performed with statistical software SPSS v.26.0.

Conventional surgical treatment: Conventional surgical treatment was performed in the operating room under general anesthesia. The patient was intubated and mechanically ventilated. The wound was opened entirely. All sternal wires were removed. Several microbiology samples were taken from different parts and layers of the wound. Thorough irrigation of the wound with saline or dilute povidone-iodine helped clear bacteria. Radical debridement of all nonviable tissue is paramount if success is anticipated. When this was achieved, the sternum and soft tissues were closed under drainage of mediastinal and subcutaneous spaces. If infection was advanced and primary closure was considered hazardous, debridement was done and the wound was left open loosely packed with gauze in preparation for secondary closure. The patients stayed sedated and mechanically ventilated. Gauze dressing changes were performed daily and sometimes as often as needed. Wound closure was performed on a well granulating wound, negative wound cultures, and subsiding of the infectious process.

Surgical technique of NPWT: The procedure was performed under general anesthesia in the operating suite. The wound was opened entirely. If the sternum was unstable or infection was evident, the sternal wires were removed. Tissue samples were taken from subcutaneous layer, bone, and retrosternal tissues, and sent for analysis. The wound was thoroughly irrigated with serum or antiseptic solution (dilute povidone-iodine). Adhesions between the heart and sternal halves were lysed to prevent traction on the right ventricle and rupture. All dead tissue was resected, including bone. Gdalevitch reports that inadequate debridement before NPWT risks relapsing bacteremia and recurrent infection [Gdalevitch 2010]. All bleeding points were controlled. Sharp bone edges that could injure the heart were resected. The wound bed was then filled with polyurethane sponge. The sponge was fitted in two layers – the lower one between the sternal halves and the upper one at the subcutaneous level. The sponge was modeled to match the wound shape and slightly larger in size to compensate for contracture when vacuum is applied. All spaces and channels should be filled with sponge material. Direct contact with wound surface greatly stimulates the granulation process. Direct contact of the sponge with large vascular structures should be prevented by a layer of non-adherent paraffin gauze beneath [Sjögren 2011]. Sterile transparent foil covered the sponge-filled wound. The system was connected to a portable vacuum source via a special tube. Vacuum mode may be continuous or intermittent and pressure is set at -50 mmHg to -125 mmHg. Wound reinspection and sponge changes were done every 2 to 4 days, preferably in the operating room. Further debridement was carried out, if necessary, and tissue samples were repeated. Negative wound culture, wide presence of viable granulations, normalization of laboratory parameters, and absence of fever allowed successful wound closure. The mediastinal space was always drained with 28 Fr drain. At this time, a decision was made as to the method of closure. If the sternum was relatively strong, standard replacement of sternal wires was possible. Most times, however, the sternum was fractured, in which case the Robicsek technique was appropriate. A subcutaneous flap was detached from the pectoral fascia to the level of the nipples as wound retraction and tissue deficit were common. The flaps were advanced toward the midline, and the subcutaneous space was closed with simple absorbable sutures over three Redon drains one middle along the sternum and two

lateral under the flaps. This advancement technique prevents tension on the suture line. We do not consider advancement of pectoral muscles necessary as we obtained excellent results with subcutaneous advancement only. Skin was similarly sutured with simple or vertical mattress sutures.

When bone deficit was significant and osteosynthesis unlikely, omental flap was used to fill the defect. The peritoneal cavity was entered through a 2 to 3 cm incision in pars sternalis of the diaphragm, the greater omentum was identified and inverted upward through the incision. The omentum was fixed to the pectoral fascia and muscles. Subcutaneous layer and skin were closed over the omentum.

Progress of treatment was followed up by regular testing of leukocytes and acute phase reactants (C-reactive protein), wound cultures, and blood cultures if fever recurred or persisted. It is argued whether negative microbiological result is necessary before wound closure. Some groups, including ours, undertake wound closure if no bacteria are recovered from the last wound sample. Others consider negative microbiological result non-essential as it does not affect the rate of recurrent infection [Biefer 2012].

RESULTS

Total number of patients with DSWI was 77, which represented 2.1% of all median sternotomies performed in that period. Thirty-eight females (49.4%) and 39 males (50.6%) comprised the group. Mean age was 66.9±7.6 for the whole group (65.0±7.5 for males and 68.8±7.2 for females). Mean body mass index was 28.7±6.0 kg/m2. Thirty-five (45.5%) had no proven diabetes mellitus or were not receiving antidiabetic treatment, 24 (31.2%) had non-insulin-dependent diabetes, and 18 (23.4%) had insulin-dependent diabetes type II. Mean group hemoglobin on presentation was 104.5±16.8 g/L. Median left ventricular ejection fraction was 52% (44-56). Thirty-seven (48.1%) patients had undergone isolated coronary bypass grafting, 21 (27.3%) – isolated valve surgery,

and 19 (24.7%) – combined surgery. There was no bilateral ITA harvesting in any patient. Forty-five patients underwent conventional surgical treatment and 32 – NPWT. (Figure 1) Median time from primary operation to DSWI diagnosis was 30 days (19-44). Median duration of NPWT from surgical revision to wound closure was seven days (4-9). Median hospital stay was 10.5 days (6-18). Fourteen patients (18.2%) underwent either secondary revision after definitive wound closure or continuous antibiotic treatment, due to recurrent infection. Hospital mortality was 13.0% (10 patients). Seven patients succumbed to overwhelming sepsis and multiorgan failure and three died of ischemic stroke. Tables 1 and 2 compare pre- and postoperative data of both groups, respectively. (Table 1) (Table 2)

Probable risk factors for the two primary outcome values included gender, age, BMI, diabetes, preoperative hemoglobin, EF<40%, type of primary operation, time to diagnosis, type of treatment (conventional vs. NPWT), and duration of treatment. The multivariable logistic regression model revealed two significant predictors of recurrent infection – NPWT was more successful than conventional treatment in preventing recurrent infection – OR: 5.4 (95% CI: 1.1-27.5; P = 0.044) and more than moderate left ventricular systolic dysfunction (EF<40%) predisposed to infectious recurrence - OR: 4.7 (95% CI: 1.05-22.1; P = 0.049). Recurrent infection itself was the strongest predictor of mortality in the multivariate model OR: 0.14 (95% CI: 0.03 - 0.58; P = 0.007). NPWT protective affect against death almost reached statistical significance in univariate regression OR: 7.6 (95% CI: 0.9-64.64.6; P = 0.058). However, in the final model type of treatment was evidently affected (OR: 5.4, P = 0.12) by the presence of recurrent infection.

The most common microorganisms recovered from tissue samples were coagulase-negative staphylococci (CoNS) - 22 (28.6%). Thirteen patients (16.9%) had negative wound cultures and one of them had a positive blood culture for Staphylococcus aureus. Distribution of microorganisms is shown in Figure 2. (Figure 2)

"Others" comprises predominantly Gram-negative bacteria – Enterobacter spp., Escherichia coli, Pseudomonas aeruginosa, Proteus vulgaris, as well as Gram-positive cocci – Enterococcus faecalis, Streptococcus spp. Within-group distributions of microorganisms, did not differ significantly. (Figure 3)

Table 1. Comparison of preoperative patient characteristics

N = 77	Conventional (N = 45)	Vacuum (N = 32)	P-value
Women	23 (51.1%)	15 (46.9%)	0.446
Age	68±8	66±7	0.364
BMI (kg/m²)	30.2	27.2	0.079
Diabetes			
No	22 (48.9%)	13 (40.6%)	
nIDDM	13 (28.9%)	11 (34.4%)	0.796
IDDM	10 (22.2%)	8 (25.0%)	
Hemoglobin (g/L)	104.5	104.6	0.976
EF <40%	6 (13.3%)	4 (12.5%)	0.60*

*Fisher's exact test

Table 2. Comparison of postoperative variables between both treatment arms.

N = 77	Conventional (N = 45)	Vacuum (N = 32)	P-value
Omental flap	3 (6.7%)	5 (15.6%)	0.186*
Hospital stay (days)	8 (5-14.5)	16 (8-25)	0.000**
Recurrent infection	12 (26.7%)	2 (6.3%)	0.034
Death	9 (20.0%)	1 (3.1%)	0.039*

*Fisher's exact test
**Mann-Whitney

DISCUSSION

SSI is a serious complication of open heart surgery, in particular DSWI, which leads to significant increase in mortality [Sears 2016]. SSIs result from perioperative wound inoculation in association with patient-related and technical factors for expansion of the process [El Oakley 1996]. Infection causes dehiscence of all wound layers from skin to bone. On the contrary, it is hypothesized that sterile sternal dehiscence is the basis of DSWI [Gottlieb 1994].

The NPWT exerts a variety of positive effects on the wound [Huang 2014]: 1. decreases tissue edema and improves blood flow [Morykwas 1997]; 2. evacuates exudate and proinflammatory cytokines; 3. inhibits bacterial growth; 4. causes microdeformations on the wound surface which stimulate angiogenesis, cell proliferation and migration, and granulation [Daigle 2013]; 5. retraction of the wound edges toward one another (macrodeformation); 6. isolation of the wound from the environment and retention of warmth and moisture. A recent experimental study proves that NPWT reduces bacterial load in the wound to 1/3 on the eighth day, whereas open treatment with gauze dressings actually increases bacterial burden [Li 2019]. NPWT suppresses bacterial multiplication, which is supported by low numbers of dividing cells on electron microscopy [Morykwas 1997; Li 2019]. NPWT ensures sternal stability and in general patients do not require mechanical ventilation. The sponge dressing is changed every 2 to 4 days, reducing the number of manipulations compared with open treatment. Maximal wound contracture is achieved experimentally at -75 mmHg, and maximal exudate drainage at -125 mmHg [Borgquist 2011]. Maximal blood flow enhancement of parasternal tissues is noted at -75 до -100 mmHg [Wackenfors 2005].

Outcome of treatment of SWI: The rate of recurrent infection after DSWI varies in different institutions in the range 3-6% for NPWT, and 18-20% for conventional treatment. Mortality varies widely – 3% to 12% for NPWT, and 7% to 40% for conventional treatment [Petzina 2010; Risnes 2014]. Multiple studies report superiority of NPWT in the treatment of DSWI with regard to early and late mortality [Petzina 2010; Risnes 2014] and recurrent infection [Petzina 2010; Risnes 2014]. Classical methods of primary wound closure with Redon drainage or continuous irrigation are summarized by Calvat et al., who report unsatisfactory results [Calvat 1996].

NPWT may cause additional harm if not appropriately applied. Contraindications to NPWT are: 1. presence of eschar; 2. fistulae; 3. malignancy in the wound; 4. exposed blood vessels and nerves; 5. exposed organs. Various
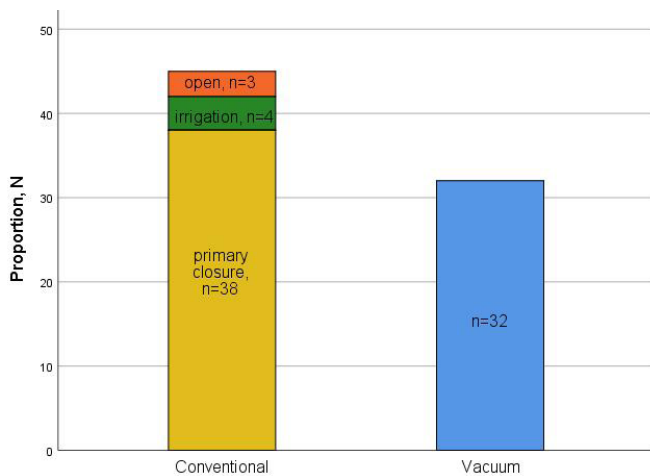

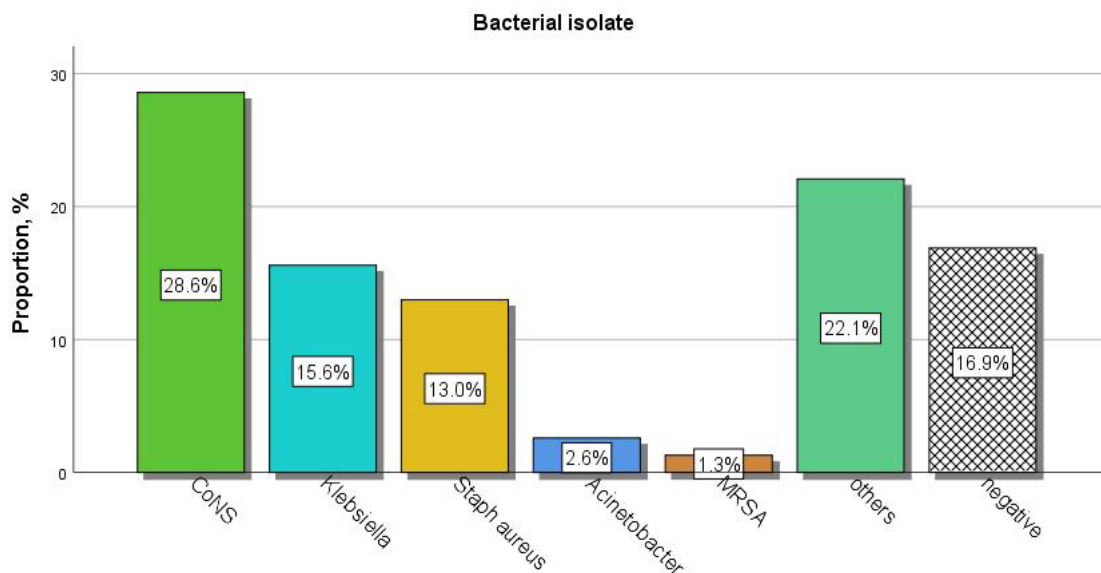Figure 1. Proportional distribution of different treatment methods

Figure 2. Relative distribution of bacterial isolates in all patients with DSWI

complications inherent to the method are described. Some of them are bleeding, rupture of the right ventricle, pain, sticking and retention of sponge in the wound, and omental herniation. NPWT has a potential for erosive damage and bleeding from underlying structures. This complication is not common but may be fatal if large vascular structures are affected – right ventricle, aorta, bypass grafts [Sjögren 2011]. Bleeding results from infectious erosion of underlying structures, as well as from the mechanical effects of vacuum. To prevent such a complication Petzina et al. recommend interposing a paraffin gauze between the sponge and heart [Petzina 2010]. Application of negative pressure directly on the heart decreases the filling of cardiac chambers and the cardiac output [Conquest 2003]. Some studies show that NPWT duration more than three weeks incurs unfavorable effects with recurrent osteomyelitis and sternal bone destruction [Bapat 2008]. NPWT is also not recommended in patients with elevated bleeding risk or taking antithrombotic drugs [Fleck 2006]. Hospital stay in surgical treatment of DSWI averages 25 days [Pericleous 2016].

Risk factors for treatment failure with NPWT are persistent bacteremia (positive blood cultures, septic episodes, fever), wound depth >4 cm, >50% bone exposure [Gdalevitch 2010]. Traditional risk factors for impaired wound healing (diabetes, COPD, cigarette smoking) do not affect treatment outcomes of NPWT [Gdalevitch 2010; Pericleous 2016].

Omental flap transposition has more than 90% survival [Parissis 2011]. The greater omentum fills dead spaces, has immunologic activity, is resistant to infection, and stimulates angiogenesis. Omentoplasty is especially useful in patients with resistant microorganisms or diabetes mellitus [Stump 2010]. Muscle flaps also demonstrate good results with regard to mortality (<10%) and risk of infection recurrence (6.5%) [Stump 2010]. The rate of complications of plastic procedures

when performed in collaboration with a plastic surgeon, is less than 10% in most studies, which justifies their involvement.

The present study encompasses a series of consecutive patients, which avoids selection bias. At present, our team employs both techniques for treating postoperative wound infection but a tendency exists toward NPWT. Decision to use either method is individual, based on surgeon preference and not on any particular clinical criteria. Conventional treatment consists of surgical revision followed by primary closure of the sternum and soft tissues. Four patients (2010-2016) were treated with continuous wound irrigation. Two of them suffered from recurrent infection. It is suggested that the low efficacy of this method is due to creation of irrigation channels within the wound as most of the wound bed is never perfused with solution. Open treatment with gauze dressings was utilized in three patients from the current group. Two of them succumbed – one due to continuing sepsis and another due to ventilator-associated pneumonia.

The rate of DSWI (2.1%) is fitting well within the ranges described in the literature [Lemaignen 2015; Ridderstolpe 2001]. There is no patient with upper ministernotomy (which we use as a standard approach for isolated aortic valve replacement) to develop DSWI. The male to female ratio in the group is practically 1:1 despite the proportion of women patients as a whole being 35.6% in our institution. Most authors report a smaller proportion of females within their SWI series in the range of 25-30% [Sjögren 2005]. This implies that female gender is a probable risk factor for DSWI in our group. More than half of patients (54.6%) have a history of diabetes mellitus. This correlates with the high prevalence of diabetes (30-40%) in the cardiac surgery population [Galindo 2018]. Also diabetes is proven to nearly double the risk SSI [Martin 2016]. In more than half of cases (66.2%), unilateral harvesting of internal thoracic artery was done. It is
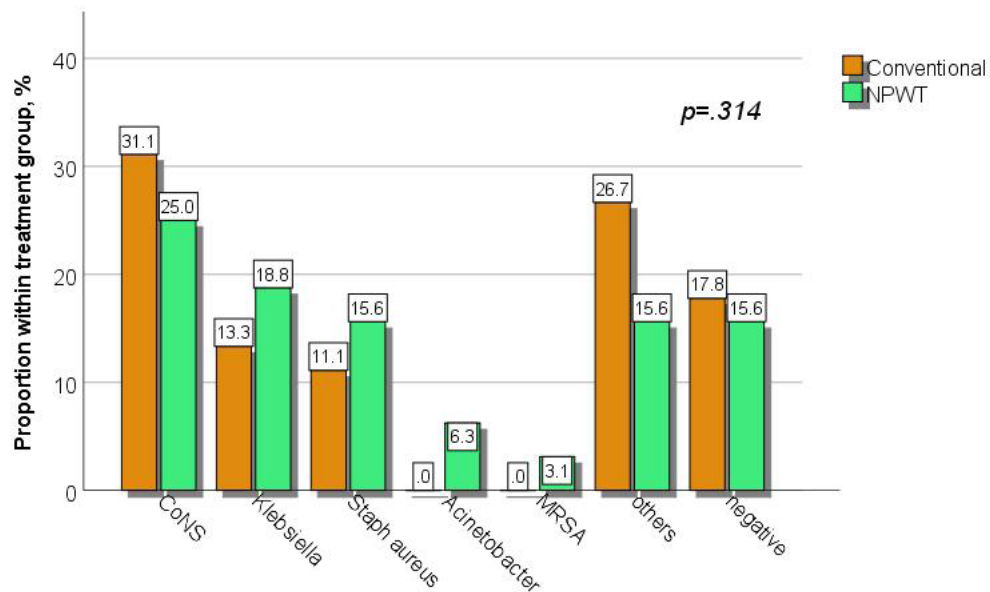

Figure 3. Relative distribution of bacterial isolates within each treatment arm

known that sternum devascularization is temporary and sternal blood supply is recovered within the first month. Nevertheless, sternal devascularization increases the risk of DSWI especially in cases of bilateral ITA grafting [Carrier 1992].

The rate of recurrent infection after surgical treatment of DSWI (18.2%) corresponds to that shared by other authors [Steingrimsson 2012]. The chi-squared analysis showed significant difference in the development of recurrent infection between both treatment arms (P = 0.034). The multivariate logistic regression model confirmed conventional therapy to be a significant independent predictor of infectious recurrence (P = 0.044) together with depressed left ventricular systolic function (P = 0.049). All other potential risk factors for relapse are insignificant in the present study possibly due the small number of patients. Other authors share similar observations [Petzina 2010; Steingrimsson 2012].

Fleck et al. analyze their experience with NPWT and summarized all potential causes of infectious recurrence [Fleck 2014]. Such causes can be an overlooked infection locus or osteomyelitis, no application of NPWT at first revision, bad surgical technique at sternal osteosynthesis, partial opening of the wound, and unknown allergy to sternal wires.

Overall mortality was 13.0% and it falls within the reported percentage in other studies [Fleck 2014]. Mortality was significantly higher in the conventional treatment arm (P = 0.039). Death also was markedly more common in cases with treatment failure (P = 0.015). However, when type of treatment and infectious recurrence are entered into multivariate logistic model, the former loses its predictor value (P = 0.126). Infectious recurrence remains the only true predictor of mortality (P = 0.045). Thus, we deduce that the choice of between conventional treatment and NPWT, which affects the incidence of recurrent infection, has indirect influence on mortality. All the other studied factors did not predict mortality in our group.

Hospital stay is significantly longer in NPWT arm (median 16 versus 8 days for conventional therapy, P = 0.000). The benefit of primary closure is no further need for wound manipulation, whereas NPWT takes a median of 7 days (4-9) of dressing changes before definitive closure. This explains the longer hospital stay. Other authors also report longer hospital stay with NPWT [Biefer 2012]. Considering the better outcomes of NPWT, prolongation of treatment is justified.

Complications directly related to NPWT were observed in two patients (6.3%). In both cases, active bleeding occurred, which necessitated operative revision. The source of bleeding was a branch of a non-harvested ITA, which was eroded by the negative pressure or the infectious process. No adverse consequences followed. Right ventricle laceration or hemodynamic disturbances were not registered.

Technical issues with the NPWT system are detachment of foil or loose connection along the vacuum line, which cause loss of hermeticity. Almost all cases are resolved by the patient's bed.

No pectoralis muscle flap reconstruction was performed in our group. Eight patients underwent omental flap transposition and in five, the wound was pretreated with NPWT. Two patients with omental reconstruction developed infectious recurrence; one died. No difference in outcome was conferred by the omental transposition (P = 0.41 for recurrent infection, P = 0.49 for death). However, omental flap is a last resort measure in patients with large chest wall defects who would otherwise die or experience significant morbidity.

Bearing in mind the significance of DSWI after cardiac surgery and its financial implications, it is reasonable to explore measures directed at prevention of this complication. Graf et al. state that implementation of interdisciplinary measures for infectious control can achieve a significant reduction in DSWI rates. They describe a series of measures that decrease DSWI rates two times [Graf 2009].

NPWT success with infected postoperative wounds raises interest in its use in clean postoperative wounds in patients with high risk of DSWI. Grauhan et al. report significant reduction in SSI rates after median sternotomy in obese patients whose wounds initially were treated with NPWT [Grauhan 2013].

This is a retrospective study, which is one of its major limitations. Open packing with serial dressing changes and continuous wound irrigation are applied in a minority of patients which may influence the interpretation of their effect on primary outcomes. The size of the sample is relatively small. The two treatment groups are compared by a small number of characteristics which are proven risk factors for SSIs. It is highly possible that other unstudied factors also affect the two primary outcomes – death and infectious recurrence. However, the evidence is strongly in favor of NPWT, which corresponds with results by other researchers [Petzina 2010; Steingrimsson 2012]. This was a single-center experience, and patients successively were recruited, ensuring uniformity in diagnostic algorithms, patient treatment, and reporting of results thus providing adequate information for analysis.

CONCLUSION

SWI, especially DSWI, is still a severe complication of open-heart surgery, linked to significant morbidity and mortality. NPWT is significantly associated with less infectious recurrence than conventional therapy and left ventricular systolic dysfunction predisposes to infectious recurrence after surgical treatment for DSWI. NPWT may reduce mortality but larger scale studies are needed to confirm this. Recurrent infection following DSWI is a strong predictor of hospital mortality. NPWT as an initial method of wound preconditioning, followed by wire osteosynthesis or a plastic procedure, is a main strategy for complicated postoperative infections. Our experience with NPWT demonstrates good functional and even cosmetic results and acceptable mortality rates.

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