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REVIEW

Abstract— Surgical site infections and complications (SSI, SSC) are relatively rare but potentially devastating events; particularly in cardiac surgery because of the importance of the structures involved.

In accordance with the main international guidelines, that recommend the use of negative pressure therapy in closed surgical wounds (ciNPWT) in high-risk patients, we selected a group of 112 patients at high risk of developing surgical site complications, presenting in the clinic from January 2018 to December 2019.

We applied 165 single-use negative pressure dressings in our cohort and kept them for seven days (± 1). All the wounds were closed by primary intention without edema or hematoma. Three cases of postoperative bleeding required us to pause the negative pressure therapy. After discharge, five patients at particularly high risk developed sternal wound dehiscence.

In conclusion, the use of ciNPWT, applied following a dedicated algorithm, gave good results in the prevention of SSI or SSC. Some limitations in the results are determined by the specific requirements of cardiac surgery.

Keywords—ciNPWT, cardiac surgery, DSWI, SSI, SSC,

INTRODUCTION

THE onset of complications and infections of the surgical site (SSC, SSI) are of great impact both in terms of therapy costs and fatality rate. It requires to revisit the use of resources, and evaluate patient's quality of life.

Surgical site infections occurs in up to 5% of patients following surgical procedures. Its occurrence increases average hospital length-of-stay by approximately 9.7 days, risk of mortality by 2 to 11-fold, and costs of hospitalization by more than \$20000 per admission.¹

Deep sternal wound infection (DSWI) remains a major concern in cardiac surgery. The impact of this complication is particularly related to the increasing proportion of patients at high risk of infection as well as to the many patient-related and surgery-related risk factors involved in their pathogenesis²

In 2016, the World Health Organization issued guidelines for the prevention of surgical site infections³ in which, it suggested, as a conditional recommendation, the use of prophylactic negative pressure on surgical wounds with a high risk

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of dehiscence or infection. A consensus document from the World Union of Wound Healing Societies (WUWHS) listed which were the main general and specific risk factors of the main surgeries for the appearance of wound complications.⁴ Meta-analysis and Randomized Controlled Trials showed the efficacy of PICO system (Smith&Nephew, Hull, UK) in preventing surgical site complications in general, obstetric and cardiac surgery.^{5,6} Afterwards, the NICE guidelines published in 2019 recommended the PICO device in case of surgical wounds at risk of dehiscence.⁷

There is an increasing body of evidence to suggest that negative pressure wound therapy (NPWT) could be effective in reducing the risk of postoperative wound complications including SSI.^{8,9}

In concordance with the position papers we tried to identify the most important risk factors and rate of SSI/SSC in cardiac surgery in our department.

MATERIALS AND METHODS

Inclusion criteria

Since January 2018, we have applied a single-use negative pressure dressing following sternal or safenectomy surgery to surgical wounds in patients who met the predefined risk criteria: obesity or cachexia, diabetes, kidney disease, age > 65, COPD, use of steroid or antiplatelet drugs, recent previous hospitalization, ongoing infection, heart failure, hypoalbuminemia, anemia) or the type of intervention the patient underwent (prolonged intervention, emergency procedure, need for deep hypothermia / circulatory arrest, harvesting of both mammary arteries, prolonged extracorporeal circulation, tensioned surgical suture, surgical revision of the wound).

A flowchart was created in which these parameters were divided into major and secondary after consultation with colleagues of various specialties, to facilitate the decision-making process. Major risk factors (only one sufficient) are a BMI greater than 35 or less than 18 kg/m², glycated hemoglobin greater than 9%, renal failure requiring dialysis, operation lasting longer than 360 minutes or performed in hypothermia or with circulatory arrest or in emergency conditions.

Secondary risk factors (at least 2 necessary) were: BMI between 30 and 35 kg/m², glycated hemoglobin between 7 and 9%, COPD in therapy, renal clearance lower than 30 mL / min, ongoing therapy with steroids or with combined

Table I
PATIENTS BASELINE CHARACTERISTICS

| No. patients | 112 |
|-----------------------------|------------------|
| Males (%) | 76 (67.8%) |
| Average age (years) | 70 (range 44-86) |
| Sternal dressings (n) | 111 |
| Left leg dressings (n) | 39 |
| Right leg dressing (n) | 15 |
| CABG (n) | 48 (42.9%) |
| CABG + valves (n) | 28 (25%) |
| Replace aortic valve (n) | 10 (8.9%) |
| Aortic vascular surgery (n) | 8 (7.1%) |
| Sternal resynthesis (n) | 7 (6.3%) |
| Mitral surgery (n) | 5 (4.5%) |
| Other (n) | 6 (5.4%) |

antiplatelet agents (DAPT), peripheral artery disease, repeated or recent hospitalization, an ongoing antibiotic therapy for a major infection, left ventricular ejection fraction less than 30%, hypoalbuminaemia (less than 2.5 g albumin/dL), anemia (Hb minor of 10 g/dL for women, 11 g/dL for males), both mammary arteries harvested, extracorporeal circulation > 180 minutes, a suture performed under tension, a surgical revision.

Procedure

The device consisted of an absorbent, breathable, multilayer, adhesive dressing connected to a battery-operated disposable pump that guarantees the delivery of negative pressure of -75 mmHg for the duration of about 7 days.

The silicone adhesive layer is atraumatic and comfortable for patients, the absorbent layer blocks the exudate away from the wound, the airlock technology allows a uniform distribution of negative pressure over the whole dressing, the external silicone layer protects the wound from external contaminants while allowing adequate perspiration.

Following this algorithm, 112 patients were selected and 165 negative pressure dressings applied from January 2018 to December 2019. The surgery that the majority of patients underwent was coronary artery bypass grafting (Tab. I).

As specified above, once one of the major risk factors or at least two of the secondary risk factors were met, the dressing was applied directly in the operating room at the end of the intervention after cleaning the site of the incision with saline solution.

A change of dressing was foreseen in the 2nd-3rd postoperative day if there was a detachment due to the removal of drainage or in case of excessive saturation of the pad (Fig. 1).

Usually, the dressing was removed at the end of the 7-day-period (unless the patient was discharged earlier: in this case the dressing was discontinued on the day of discharge as the management of the device was not planned at rehabilitation centers) (Fig. 2).

DISCUSSION

The identified risk factors were detected 352 times, 3.14 per patient; the most frequent ($\geq 12.5\%$) were: removal



Figure 1. Third postoperative day: medication change (no signs of seroma or hematoma, blood-clots, the wound edges are close together) Third postoperative day: dressing change (the dressing adsorbed a good amount of exudate)



Figure 2. Seventh postoperative day: dressing removal (the wound is closed in first intention). Seventh postoperative day: dressing removal (the dressing is quite clean)

Table II
RISK FACTORS AND THEIR FREQUENCY OF DETECTION; MAJOR RISK FACTORS ARE
INDICATED IN BOLD LETTER

| Risk factor | Number | % |
|--------------------------------|--------|--------|
| 18>BMI>35 | 15 | 13.39% |
| HbA1C>9 | 15 | 13.39% |
| Dialysis | 7 | 6.25% |
| Procedure>360 min | 6 | 5.36% |
| Emergency | 13 | 11.61% |
| Hypothermia/circulatory arrest | 7 | 6.25% |
| 30<BMI<35 | 25 | 22.32% |
| 7<HbA1C<9 | 31 | 27.68% |
| Age>75 | 38 | 33.93% |
| COBP | 7 | 6.25% |
| CrCl<30 | 14 | 12.50% |
| Steroids | 2 | 1.79% |
| PAD | 8 | 7.14% |
| DAPT | 11 | 9.82% |
| recent hospitalization | 24 | 21.43% |
| Infection under treatment | 6 | 5.36% |
| EF<30% | 18 | 10.07% |
| Albuminemia<2,5 | 1 | 0.89% |
| Anemia | 12 | 10.71% |
| BIMA harvested | 52 | 46.43% |
| ECC>180' | 7 | 6.25% |
| Suture under tension | 24 | 21.43% |
| Surgical revision | 9 | 8.06% |
| | 352 | |

of the double mammary artery 46.4%, senior age 33.9%, decompensated diabetes 27.7%, moderate obesity 22.3%, the tension on the suture and reoperation 21.4%, severe obesity, and diabetes severely decompensated 13.4%, moderate-to-severe renal failure 12.5% (Tab. II).

Of the 165 dressings applied 142 (86%) showed no complications, in 7 cases (4.2%) there was an early interruption of use (1 technical error at the beginning of this experience, 1 device malfunction, 1 pump loss (sic!), 4 early deaths).

The remaining 16 dressings (9.7%) presented minor problems, except in 3 cases (1.8%) in which, due to excessive bleeding, we decided to discontinue therapy (in a fourth case the soaked dressing has been replaced as per protocol and the problem has not re-occurred) (Tab. III).

RESULTS

In four cases it was not possible to evaluate the results as the patients died early (before the 24 hours post-op), in a fifth case the patient died from a multi-organ failure after removing the dressing with a good result limited to the conditions of the surgical wound.

The remaining cases had an immediate positive result with well-matched wound edges and the absence of perilesional edema or hematoma.

In five cases, however, the patients, after discharge, suffered from sternal dehiscence (1 patient with dialytic kidney insufficiency, 3 patients with decompensated diabetes, 1 patient with a significant tickling cough during the postoperative period). Only 3 of these patients required systemic antibiotic therapy for wound infection. All healed after surgical revision of the wound.

In 7 cases the dressing was used after a resynthesis of the wound dehiscence. In 3 of these cases the device wasn't applied even if the patient matched the criteria.

CONCLUSIONS

The mechanisms of action of traditional negative pressure medication have been well known for years. The prophylactic application in surgical wounds in patients at risk is a rather recent use of NPWT. The rationale for its use is based on the general principles and in particular on the prevention of the accumulation of liquids in layers underlying the incision and in the prevention of tensioning of the wound edges.

In our experience, the use of preventive negative pressure has given more than satisfactory results allowing, even in patients at high risk, for excellent wound healing. No seromas or hematomas nor skin changes were present throughout this study.

The adverse events related to the use of the dressing were episodic and of minimal intensity, however, no special measures have been taken except in three cases where the discontinuation of NPWT was necessary.

No superficial or deep wound dehiscence occurred during the same hospitalization of the intervention.

However, some peculiarities of our type of surgery probably partially reduce the effect of the ciNPWT: the dressings of predetermined dimensions do not always well adapt to the incision, since there is little space beyond the edges of the wound, between the jugule and the emergency of the drainages and this, in some circumstances, prevented its use, even if indicated.

In addition, our main surgical access is characterized by the presence below the soft tissues (muscle band, dermis, epidermis) of a bone structure, the sternum, which although re-synthesized at the end of the intervention, is often severely devascularized and subjected to continuous and sometimes improper stress of great intensity; this peculiarity means that the surface pressure exerted by the negative pressure dressing is not always able to contrast the traction forces exerted on the sternal stumps so that when a small diastasis occurs, the process can no longer be antagonized.

The use of a flowchart through which it is possible to identify the patients most at risk of wound dehiscence was a certainly useful tool for mitigating costs.

LIMITATIONS

There are several limitations of this observational study: the most important is the lack of a control group that can define the real effectiveness of ciNPWT.

In addition, the list of risk factors used to define the population on which to apply the negative pressure dressing, although it was created following the international literature available, would require a statistical analysis to define which of these factors are the most important in the increase the risk of adverse events. Lastly long-term follow-up is missing.

DISCLOSURES

The author declares no conflict of interest.

Table III
 COMPLICATIONS AROSE DURING USE STERNUM NOT VALUABLE: 1 EARLY REMOVAL, 1 MALFUNCTION, 4 DEATHS <12H LEFT LEG NOT VALUABLE: 1 PUMP LOSS

| Sede | Number | w/o compli- cation | Not valuable | Bleeding | Hematoma | Serosity | Detachment | Dehiscence | Blister |
|-----------|--------|-----------------------|--------------|----------|----------|----------|------------|------------|---------|
| Sternum | 111 | 94 | 6 | 2 | 1 | 3 | 3 | 2 | 0 |
| Left leg | 39 | 35 | 1 | 0 | 0 | 1 | 0 | 1 | 1 |
| Right leg | 15 | 13 | 0 | 2 | 0 | 0 | 0 | 0 | 0 |

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