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Prophylactic Negative Pressure Therapy in Reducing the Risk of Sternal Wound Infection after Cardiac Surgery

Salifu Timbilla[a], Ján Gofus[a], Petr Smolák[a], Eva Čermáková[b], Jiří Manďák[a], Jan Vojáček[a]

[a] *Department of Cardiac Surgery, Faculty of Medicine and University Hospital in Hradec Králové, Charles University, Hradec Králové, the Czech Republic*
[b] *Department of Medical Biophysics, Faculty of Medicine Hradec Králové, Charles University, Hradec Králové, Charles University, Faculty of Medicine in Hradec Králové, the Czech Republic*

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SOUHRN

Úvod: Pooperační infekce a dehiscence sternální rány jsou závažné komplikace kardiochirurgických operací, které prodlužují délku hospitalizace a zvyšují náklady na zdravotní péči. U vysoce rizikových pacientů je standardní péče o ránu pro prevenci této komplikace nedostatečná. Díky našim rozsáhlým zkušenostem s podtlakovou terapií rány (NPWT) při komplikacích po sternotomii předpokládáme, že okamžité ošetření rány touto technikou může snížit výskyt komplikací rány.
Metody: Provedli jsme prospektivní, randomizovanou, nezaslepenou studii srovnávající účinnost profylaktické NPWT (Prevena) aplikované na uzavřené sternotomii (n = 40) oproti standardnímu převazu rány (n = 40) u pacientů s vysokým rizikem infekce sternální rány po kardiochirurgickém výkonu. Primární výsledky zahrnovaly výskyt poruch hojení rány a délku hospitalizace. Komplikace rány jsme kontrolovali sedm dní po operaci a poté ve třech měsících.
Výsledky: Studie zahrnovala 80 pacientů (64 mužů, 16 žen; průměrný věk 65,4 roku), kteří byli do studie zařazeni od dubna 2023 do ledna 2024. Mezi komorbidity patřily diabetes mellitus (82,5 %), obezita (index tělesné hmotnosti [BMI] ≥ 30; 82,5 %), chronická obstrukční plicní nemoc (21,3 %), aktivní kouření (20 %), renální insuficience (12,5 %) a užívání kortikosteroidů (13,8 %). Oboustranný odběr vnitřní mamární tepny (BIMA) byl proveden v 18,8 % případů. Po sedmi dnech po operaci se vyskytly komplikace v ráně u čtyř pacientů ve skupině Prevena (10 %) a u sedmi v kontrolní skupině (17,5 %) (hodnota p = 0,52). Po třech měsících byla hluboká infekce rány přítomna u jednoho pacienta ve skupině Prevena (2,5 %) a u dvou pacientů v kontrolní skupině (5 %) (hodnota p = 1,00). Medián délky hospitalizace byl srovnatelný mezi skupinou Prevena (12 dní) a kontrolní skupinou (11 dní) (hodnota p = 0,75).
Závěr: Preventivní podtlaková léčba ran snižuje výskyt komplikací hojení ran u vysoce rizikových pacientů, i když ve studii nebyl statisticky významný. Ačkoli studie neprokázala významný vliv na délku hospitalizace, potenciální snížení výskytu komplikací rány si zaslouží další zkoumání. Ke zjištění účinnosti a nákladové efektivity této preventivní strategie jsou nutné rozsáhlejší studie.

Keywords:
Closed incisional negative pressure wound therapy
Negative pressure wound therapy
Poststernotomy
Prevena
Sternotomy

ABSTRACT

Background: Postoperative sternal wound infections and dehiscence are serious complications of cardiac surgery that increase the length of hospital stay and healthcare costs. Standard wound care may be insufficient for preventing these complications in high-risk patients.
Methods: We conducted a prospective, randomized study comparing the efficacy of closed incisional negative pressure wound therapy (ciNPWT) using Prevena (study group) versus standard wound dressing (control group) in patients at high risk of sternal wound infections following cardiac surgery. Primary outcomes included the incidence of sternal wound infection at seven days and three months postoperatively, and length of hospital stay.
Results: The study cohort comprised 80 patients (64 male, 16 female; mean age 65.4 years) randomized into two groups with 40 patients in each. At 7 days post-operation, there were four patients with sternal wound infection in the study group (10 %) and seven in the control group (17.5%) (*p*-value=0.52). At 3 months, deep wound infections were present in 1 patient in the study group (2.5%) and 2 in the control group (5%) (*p* = 1.00). Median length of hospital stay was comparable between the study (12 days) and control (11 days) groups (*p*-value = 0.75).
Conclusions: Preventive negative pressure wound treatment showed a trend towards reducing the incidence of wound healing complications in high-risk patients following cardiac surgery, although the differences were not statistically significant. Further large-scale studies are warranted to establish the efficacy and cost-effectiveness of this preventive strategy.

Address: MUDr. Salifu Timbilla, Department of Cardiac Surgery, Faculty of Medicine and University Hospital in Hradec Králové, Charles University, Sokolská, 500 05 Hradec Králové, the Czech Republic, e-mail: salifu.timbilla@fnhk.cz
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Introduction

Despite all the improvements in modern cardiac surgery, sternal wound infections remain a significant concern. These complications are associated with increased morbidity, mortality, length of hospital stay and cost.[1,2] They are particularly prevalent in high-risk patient groups, especially obese patients, those with diabetes, chronic obstructive pulmonary disease (COPD), and those undergoing bilateral internal mammary artery (BIMA) harvesting.[3–7]

Sternal wound infections (SWI) can be classified as superficial sternal wound infection (SSWI) or deep sternal wound infection (DSWI). SSWI involve the skin, subcutaneous tissue, and the pectoralis fascia. Sternal wounds with bony involvement and signs of infection in the mediastinum are classified as DSWI.[1] The prevalence of SSWI ranges from 0.5% to 8% with a combined morbidity and mortality of 0.5% to 9%.[1,3] DSWI prevalence ranges from 0.4% to 5% with mortality rates ranging from 19% to as high as 40%.[1,3,6]

Traditional strategies for preventing sternal wound complications have focused on optimizing patient risk factors, improving surgical technique, and implementing strict perioperative infection control measures.[1,7] These include preoperative skin preparation, appropriate antibiotic prophylaxis, meticulous surgical technique, and postoperative wound care.[1,7] Despite these measures, sternal wound infections remain a persistent problem, particularly in high-risk patients.

Negative pressure wound therapy (NPWT) has been widely studied and used for treating postoperative open wound complications. Its application as a prophylactic measure on closed surgical incisions, closed incision negative pressure wound therapy (ciNPWT), is relatively less utilized nor studied. The Prevena™ Incision Management System (KCI USA, Inc., San Antonio, TX) is one such ciNPWT device designed specifically for closed surgical incisions. It provides a sterile, closed environment, maintains wound edge approximation, and reduces tension on the incision, potentially decreasing the incidence of wound complications.[8] Studies have shown that ciNPWT can significantly reduce the incidence of SWIs in high-risk patients, particularly those with obesity, diabetes, and those undergoing BIMA harvesting.[3,4]

Given the significant morbidity and mortality associated with sternal wound complications, and the potential benefits suggested by early studies, there is a clear need for further investigation of ciNPWT in high-risk cardiac surgery patients. We hypothesized that immediate application of ciNPWT to closed sternal incisions could decrease the incidence of sternal wound infection in this population.

This study aims to contribute to the growing body of evidence regarding the use of ciNPWT in cardiac surgery and to inform clinical decision-making regarding its use in high-risk patients. By analyzing sternal wound healing outcomes in specific well-defined high-risk patient subgroups in the study, we hope to provide valuable insights into the potential benefits of ciNPWT for these specific patient groups.

Methods

Study design and patients

We conducted a prospective, randomized study from April 2023 to January 2024 at the Department of Cardiac Surgery, University Hospital in Hradec Králové, Czech Republic. The study protocol was approved by the institutional ethics committee, and all patients gave written informed consent.

Eligible patients were adults undergoing elective cardiac surgery via median sternotomy who had at least two of the following risk factors: diabetes mellitus, obesity (BMI ≥30 kg/m^2), COPD, active smoking, renal insufficiency, corticosteroid use, or planned BIMA harvesting. Exclusion criteria included emergency surgery, redo sternotomy, and known allergy to dressing materials. Eligible patients were randomly assigned in a 1 : 1 ratio to receive either prophylactic ciNPWT using the Prevena™ Incision Management System (study group) or standard wound dressing (control group). Randomization was performed using a computer-generated sequence. In the study group, the Prevena™ dressing was applied to the closed surgical incision immediately after skin closure in the operating room and left in place for 7 days. In the control group, standard sterile wound dressings were applied and changed as per our institution's protocol, usually every 2 to 3 days.

Our primary outcomes were the incidence of sternal wound infection at seven days and three months postoperatively, and length of hospital stay. Sternal wound infections were classified as superficial or deep wound infections based on the Centers for Disease Control and Prevention criteria.[9] We further compared the outcome of treatment using ciNPWT or standard dressings in specific high-risk patient sub-groups, stratified according to comorbidities.

Statistical analysis

Continuous variables are presented as mean ± standard deviation or median (interquartile range), and categorical variables as numbers and percentages. Between-group comparisons were performed using Student's t-test or Mann-Whitney U test for continuous variables and chi-square or Fisher's exact test for categorical variables. A *p-value* <0.05 was considered statistically significant. All analyses were performed using NCSS 2021 Statistical Software 2021 (NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/ncss).

Results

Baseline characteristics

Eighty patients were enrolled and randomized into two groups, 40 patients in each group. Baseline characteristics were generally well-balanced between the groups (**Table 1**). Eighty percent of the study population were male. Sixty-six patients had diabetes and 66 were obese with BMI ≥30. Patients in the study group were slightly older and had higher BMI. The study group had slightly more comorbidities compared to the control group. The use of BIMA grafting was similar between the groups.

Table 1 – Baseline characteristics of study participants

Characteristic	Study group (n = 40)	Control group (n = 40)	*p*-value
Age, years (mean ± SD)	66.4 ± 7.4	64.4 ± 10.5	0.58
Male sex, n (%)	31 (77.5)	33 (82.5)	0.58
BMI, kg/m² (mean ± SD) 32.9 (31–36.5)	34.0 ± 5.1	32.7 ± 3.8 32.5 (30.9–35.1)	0.35
Diabetes mellitus, n (%)	35 (87.5)	31 (77.5)	0.38
COPD, n (%)	12 (30)	5 (12.5)	0.06
Active smoking, n (%)	9 (22.5)	7 (17.5)	0.58
Renal insufficiency, n (%)	7 (17.5)	3 (7.5)	0.31
Corticosteroid use, n (%)	7 (17.5)	4 (10)	0.52
BIMA harvesting, n (%)	7 (17.5)	8 (20)	0.78
EuroSCORE II (mean ± SD)	2.7 ± 2.6	2.3 ± 1.5	0.77

Table 2 – Primary outcomes

Outcome	Study (n = 40)	Control (n = 40)	*p*-value
Wound defects at 7 days, n (%)	4 (10%)	7 (17.5%)	0.52
- Superficial wound infection	3 (7.5%)	5 (12.5%)	0.61
- Deep wound infection	1 (2.5%)	2 (5%)	
Deep wound infection at 3 months, n (%)	1 (2.5%)	2 (5%)	1.00
Length of hospital stay, days (mean ± SD) (IQR)	13.4 ± 6.3 12 (9–15)	13.7 ± 8.4 11 (9–16)	0.75

Primary outcomes

At 7 days post-surgery, 13.75% of the study population developed wound complications (11 patients) (**Table 2**). Three had deep wound infections and eight developed superficial wound infections. We observed fewer patients with wound complications in the study group (four patients, 10%) compared to the control group (seven patients, 17.5%). Three patients in the study group had superficial wound infection and one had deep wound infection compared to five superficial and two deep wound infections in the control group. This difference though did not reach statistical significance ($p = 0.52$).

At the 3-month follow-up, only deep wound complications were observed (3 patients). One patient had deep wound infections the study group (2.5%) compared to two patients in the control group (5%) (p-value = 1.00).

The median length of hospital stay was comparable between the study (12 days, IQR 9–15) and the control group (11 days, IQR 9–16) ($p = 0.75$).

Analyses of specific patient sub-groups

Our study included several predefined patient populations based on specific risk factors for sternal wound complications.

In the BIMA harvesting group (n = 15; 7 in the study group vs 8 in the control group), there was a notable trend towards fewer wound complications in the study group compared to the control group. At 7 days post-operation, there was 1 superficial wound infection in the study group (14.3%) and no deep wound infection whilst there were 4 superficial and 1 deep wound infection in the control group (62.5%) ($p = 0.184$). At 3 months, no deep infections were present in the study group, while 1 deep infection (12.5%) occurred in the control group (p-value = 1.00).

In obese patients (BMI ≥30; n = 66, 33 patients in each group), we observed a lower incidence of wound complications in the study group. In the study group, 3 patients had superficial wound infection (9.1%) and 1 patient had deep wound infection (3.0%) at 7 days compared to 4 patients with superficial wound infections (12.1%) and 2 deep wound infections (6.1%) in the control group (p-value = 0.78). At 3 months, both groups had 1 patient with deep wound infection.

Similar trends were observed in other high-risk patient populations, including patients with diabetes mellitus, renal insufficiency, corticosteroid use, active smoking, obesity and COPD. The differences however, did not reach statistical significance due to limited sample sizes.

Discussion

In this prospective, randomized study of high-risk patients undergoing cardiac surgery, we found that prophylactic ciNPWT using the Prevena™ system showed a trend towards reducing the incidence of sternal wound infections compared to standard wound dressing. Although the differences did not reach statistical significance, the potential clinical importance of these findings warrant further investigation.

Our results are consistent with previous studies that have suggested a benefit of ciNPWT in reducing surgical

site infections. A large multicentre propensity matched study by Suelo-Calanao et al. consisting of 1532 patients (766 per group) with high risk of sternal wound infection comparing ciNPWT and standard dressings found that ciNPWT reduced the incidence of sternal wound infection (6% vs 16%, *p*-value= 0.0001). However, length of hospital stay was not reduced.[10]

Grauhan et al. compared patients prospectively receiving ciNPWT with standard dressings retrospectively and reported lower infection rate in the group with ciNPWT compared to the control within 30 days (1.3% in the study group, 1 patient out of 237 vs 3.4% in the control group, 119 patients out of 3508, *p*-value = 0.05).[11] Witt-Majchrzak et al. reported a reduction in superficial sternal wound infections with the use of ciNPWT (PICO™) in a similar high-risk population undergoing cardiac surgery.[12] A retrospective study conducted by Jennings et al. demonstrated a statistically significant reduction in sternal wound infections in patients treated with ciNPWT compared to a predicted rate.[4] Similarly, Grauhan et al. found a significant reduction in wound infections in obese patients receiving ciNPWT after cardiac surgery.[3] A recent systematic review and meta-analysis of ten studies by Biancari et al. showed ciNPWT was associated with lower risk of developing sternal wound infection (both superficial and deep). However, the difference was not statistically significant for superficial sternal wound infection.[13]

The analysis of specific patient populations, while exploratory in nature and limited by small sample sizes, provide valuable insights into the potential benefits of ciNPWT in specific high-risk patient groups. The trend towards reduced wound complications in our BIMA harvesting subgroup is particularly noteworthy. Although these differences did not reach statistical significance, the magnitude of the effect is clinically relevant. This finding is particularly important given that BIMA harvesting is a known risk factor for sternal wound complications.[14,15] BIMA grafting has been associated with improved long-term outcomes in coronary artery bypass surgery but is often avoided due to concerns about sternal wound complications.[16] Should our findings be confirmed in a larger study focused on use of ciNPWT in patients after BIMA harvesting, it could potentially increase the utilization of BIMA grafting and improve long-term patient outcomes.

Even after developing deep sternal wound infection, Lo Torto et al. demonstrated the benefit of using ciNPWT (Prevena™) combined with monolateral pectoralis major muscle flap (MPMF) compared to a control group using standard dressings with MPMF in improving patient outcomes, with few patients in the study group developing wound complications compared to the control group.[17] A similar outcome was observed by Gabriel et al. who used ciNPWT to improve healing outcomes in patients who developed deep sternal wound infection.[18]

Length of hospital stay was comparable between the study and control group. This finding was unexpected, given the trend towards fewer wound complications in the ciNPWT group. Several factors may explain this result. With only a small number of wound complications in both groups, the impact on overall length of stay may have been limited. Our institution's standardized care protocols for postoperative cardiac surgery patients may have mitigated the impact of wound infections on discharge timing. Factors unrelated to wound healing, such as cardiac rehabilitation protocols or social factors affecting discharge planning, may have played a more significant role in determining length of stay.

Though cost-effectiveness was not analysed in our study, a study by Hawkins et al. found that ciNPWT was cost-effective for the prevention of deep but not superficial wound infection, and as such recommend using ciNPWT only in patients with a high risk of deep sternal wound infection.[19]

According to Hyldig et al.'s meta-analysis, ciNPWT is related with a considerable reduction in surgical site infections across various surgical specialities.[20] This implies that the benefits of ciNPWT may go beyond cardiac surgery and have broader uses in high-risk surgical groups.

What distinguishes this study from previous studies is its prospective and randomized design, which compared the use of ciNPWT and standard dressings on sternal wound healing outcomes in a well-defined high-risk patient cohort. While many prior studies on closed incisional negative pressure wound therapy (ciNPWT) have been retrospective or observational, this trial randomly assigned patients and monitored them for both early (7-day) and late (3-month) outcomes. This study design decreases bias and other confounding variables and as such makes the results more reliable. Furthermore, we analyzed specific high risk patient sub-groups providing a more granular insight into the effectiveness of ciNPWT in these patient groups. This helps determine which patient sub-groups might benefit the most from this therapy and aiding in providing patient tailored postoperative treatment strategies. The trend towards reduced wound infections in the BIMA harvesting sub-group suggests a potential clinical significance that could influence future surgical protocols and increase the use of BIMA grafts.

Although our findings were not statistically significant even in the sub-group analysis, the trend towards reduced sternal wound infections in high-risk cardiac surgery patients receiving ciNPWT merits larger studies to confirm these findings and assess its cost-effectiveness. These results if validated, could influence future clinical and surgical practices.

Conclusion

In conclusion, our findings indicate that ciNPWT may help minimize sternal wound complications in high-risk patients undergoing cardiac surgery, however, the differences were not statistically significant. Larger, multicenter trials are required to determine the efficacy and cost-effectiveness of this preventive method. Such studies should also seek to identify specific patient categories who may benefit the most from preventive ciNPWT, enabling for more tailored delivery of this resource-intensive strategy. Future study should include longer-term follow-up, economic evaluations, and patient-reported outcomes to gain a more complete picture of the impact of prophylactic ciNPWT in cardiac surgery.

Conflict of interest
None.

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Ethical statement
The study was approved by the Faculty of Medicine in Hradec Králové institutional ethics committee and complied with the Declaration of Helsinki.

Informed consent
All patients gave written informed consent for the conduction and publication of the study.

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