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SURGICAL MEDICAL SCIENCES / CERRAHİ TIP BİLİMLERİ

Prophylactic Application of Closed Incision Negative Pressure Therapy After High Risk Cardiothoracic Procedures: A Single Center Study

Yüksek Riskli Kardiyotorasik Cerrahi İşlemler Sonrası Kapalı İnsizyon Negatif Basınç Tedavisinin Profilaktik Uygulaması: Tek Merkezli Çalışma

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Abstract

Objectives: Sternal wound infections (SWIs) after cardiac surgery are devastating complications and cost loads for healthcare providers and vulnerable patients in the postoperative period after high-risk cardiothoracic operations. Although the prophylactic use of closed incision negative pressure therapy (ciNPT) is still controversial, recent studies report positive outcomes. Our study aims to identify the efficacy of ciNPT in ventricular assist device implantation procedures with focus on the hypothesis that the reduction rate of impaired healing and infection.

Materials and Methods: We performed a retrospective study with 18 advanced heart failure patients after ventricular assist devices implantations. Conventional sterile gauze dressings were applied in the control group (n=10), while ciNPT (Prevena™ system) was applied in the study group. Patients demographics, risk factors such as diabetes mellitus, obesity, smoking, chronic obstructive pulmonary disease, Euroscore II and Fowler Risk score were documented. Wounds were examined instantly after removal of Prevena™ system on postoperative 6 to 8 days and on follow-up 45 days. Signs of infections and healing problems, inflammatory biomarkers were noted.

Results: The number of ventricular assist device implantations were 18, with 10 in control and 8 in study group. Both groups were similar in all demographical characteristics. Driveline insertion site and superficial SWI rates were higher in control group than the study group (p=0.003 and p=0.018, respectively). One superficial SWI was noted in the control group. No deep wound infections requiring debridement was observed in both groups. Length of hospital stay was longer in control group (p=0.05).

Conclusion: We concluded that closed incision ciNPT has an impact on reducing driveline site infections, length of hospitalization and cost load for health care providers. This preliminary results appear to support the advantage of closed incision ciNPT application after ventricular assist device implantation procedures and serve as a basic information for more comprehensive studies.

Keywords: Closed incisional negative pressure therapy, sternal driveline site infections, wound infections, wound therapy

Öz

Amaç: Kalp cerrahisi sonrası sternal yara enfeksiyonları, özellikle yüksek riskli kardiyotorasik operasyonlardan sonraki postoperatif dönemde hastalar ve sağlık hizmeti sunucuları için önemli komplikasyonlara ve maliyet yüklerine neden olmaktadır. Profilaktik kapalı insizyon negatif basınç tedavisinin kullanımı halen tartışmalı olsa da, son yıllarda yapılan çalışmalarda olumlu sonuçlar bildirilmektedir. Çalışmamız, ventriküler destek sistemi implantasyonu prosedürleri sonrası kapalı insizyon negatif basınç tedavisinin etkinliğini, iyileşme sorunlarında ve enfeksiyon oranlarında azalma hipotezine odaklanarak sunmayı amaçlamaktadır.

Gereç ve Yöntem: Çalışmamız, ileri evre kalp yetmezliği olan ve ventriküler destek cihazı implantasyonu yapılan 18 hastanın takip verilerine retrospektif olarak ulaşılarak gerçekleştirilmiştir. Kontrol grubuna (n=10) geleneksel steril gazlı bez pansumanları uygulanırken, çalışma grubuna kapalı insizyon negatif basınç tedavisi (Prevena™ sistemi) uygulanmıştır. Hastaların demografik özellikleri, diabetes mellitus, obezite, sigara kullanımı, kronik obstrüktif akciğer hastalığı gibi risk faktörleri, Euroscore II ve Fowler risk skorları kaydedilmiştir. İnsizyonlar, Prevena™ sisteminin

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çıkarılmasından hemen sonra postoperatif 6 ila 8. günlerde ve 45. günde değerlendirilmiştir. Enfeksiyon belirtileri ve iyileşme sorunları, enflamatuvar biyobelirteçler kaydedilmiştir.

Bulgular: Ventriküler destek cihazı implantasyonu yapılan hasta sayısı 10'u kontrol, 8'i çalışma grubunda olmak üzere 18 idi. Her iki grup da tüm demografik özellikler açısından benzerdi. Driveline hattı ve yüzeysel sternal yara enfeksiyonu oranları kontrol grubunda, çalışma grubuna göre daha yüksek saptandı (sırasıyla p=0,003 ve p=0,018). Kontrol grubunda bir adet yüzeysel sternal yara yeri enfeksiyonu görüldü. Her iki grupta da debridman gerektiren derin yara yeri enfeksiyonu görülmedi. Hastanede kalış süresi kontrol grubunda daha uzundu (p=0,05).

Sonuç: Bu çalışma ile kapalı insizyon negatif basınç tedavisinin driveline hattı enfeksiyonlarını, hastanede kalış süresini ve sağlık hizmetlerindeki maliyet yükünü azaltmada etkisi olduğu sonucuna varılmıştır. Bu ön sonuçların, ventriküler destek cihazı implantasyonu prosedürleri sonrasında profilaktik kapalı insizyon negatif basınç tedavisi uygulamasının avantajını desteklediği ve daha kapsamlı çalışmalar için temel bilgi teşkil ettiği görülmektedir.

Anahtar Kelimeler: Kapalı insizyon negatif basınç tedavisi, driveline hattı enfeksiyonları, yara enfeksiyonları, yara tedavisi

Introduction

Sternal wound infections (SWIs) are not infrequent, still remain as a potential complication after high risk surgical cardiac procedures, range from 0.5-10% depending on the comorbidities of patients and SWI-associated mortality rates are 0.5 to 9%. In spite of the utilization of prophylactic antibiotics, postoperative SWI is still present and it lasts to be a devastating postoperative complication for any patient and for healthcare providers (1).

Recent studies have reported benefits of SWI after prophylactic usage of closed incision negative pressure therapy (ciNPT) (2). In our study, we report initial clinical results with the Prevena™ Incision Management System applications on closed sternal incisions after left ventricular assist device implantation procedures and aim to emphasize the effect of ciNPT for high risk cardiac surgeries and report the safety and efficacy of this system with focus on the reduction rate of infections and acceleration rate of wound healing.

Materials and Methods

This retrospective study is formed according to the ethical guidelines of the 1975 Declaration of Helsinki and approved by the Ankara University, Human Research Ethics Committee (approval no.: İ02-156-24, date: 06.03.2024). Informed consent was obtained from all participants in this study. This study includes 18 patients who underwent ventricular assist device implantation procedure between March 2018 and August 2020 under the care of the same surgical team. There were 10 patients in the control group prior to the introduction for the application of ciNPT dressing systems according to the state reimbursement rules' permission. For the latter eight study patients, we used the Prevena™ incision management system (Kinetic Concepts Inc, San Antonio, TX) for the wound closure. We used Fowler risk score to estimate the probability of infection (3). Demographics of the patients are documented at Table 1.

All patients were under the routine procedure. Standard procedures such as preoperative examination and preparation, sternal opening and closure, perioperative antibiotic prophylaxis were performed in the same way for all the patients in the study.

At the end of the surgical procedure and closure of the sternotomy incision, the control group patients received conventional dry sterile wound dressings and the study group received ciNPT [Prevena™ incision management system (Kinetic Concepts Inc, San Antonio, TX)]. In the study group, ciNPT was continued for six to eight days postoperatively. For all the patients we analysed C-reactive protein (CRP) preoperatively, on the first and fifth postoperative day. Evaluation parameters were inflammatory biomarkers, purulent drainage and gross morphological and anatomical signs of deep or superficial infections.

All patients' sternal incisions and ventricular assist device driveline insertion sites were followed up after postoperative 45 days.

Statistical Analysis

We analysed our study data using the SPSS for Mac OS X version 20.0 (IBM Corp., Armonk, New York). Demographics of patients were presented as percentage and mean ± standard deviation in the case of normal distribution. Comparisons of basic data were made by the chi-square test and Student's t-test. If the results were significant, Mann-Whitney U test was used. $P<0.05$ was considered statistically significant.

Results

There were no significant differences in the demographic characteristics of the two patients group. More detailed demographic informations about patients can be seen on Table 1. According to the Fowler estimated probability of infection risk scores, the average risk of infection for these eight patients in the ciNPT study group were 4.6%, and 3.78% in the control group (p=0.079).

At the end of the procedure, incisions were similarly closed with six stainless steel wires, for the muscular and subcutaneous

Table 1: Patients' characteristics of the ciNPT and control groups			
Baseline characteristics	**ciNPT group (n=8)**	**Control group (n=10)**	**p value**
Age (years, mean ± SD)	61.63±11	50.8±21.2	p=0.153
Gender (Male, %)	5 (62.5%)	5 (50%)	p=0.453
DM (%)	1 (12.5%)	5 (50%)	p=0.75
COPD (%)	2 (25%)	2 (20%)	p=0.64
Obesity (%) (BMI>30 kg/m^2, %)	2 (25%)	1 (10%)	p=0.11
Smoking (%)	3 (25%)	3 (30%)	p=0.65
Euroscore II	7.08±4.2	5.53±3.38	p=0.71
Resternotomy (%)	2 (25%)	1 (10%)	p<0.001
Operation time (minute, mean ± SD)	226±66.5	240±60.1	p=0.49
Intraoperative bleeding (%)	2 (25%)	0 (0%)	p<0.001
ciNPT: Closed incision negative pressure therapy, SD: Standard deviation, DM: Diabetes mellitus, COPD: Chronic obstructive pulmonary disease, BMI: Body mass index			

tissues double suture technique with a 1/0 monofilament absorbable suture and single intradermic suture with 3/0 absorbable suture. All procedures and dressings were handled by the same surgical team. The control group received dry sterile gauze dressings and changed daily on the routine postoperative period. For the study group, the Prevena™ incision management system was applied in the operating room instantly after dermal closure. The 24 cm long Prevena™ system was placed over the sternotomy incision and negative pressure was applied with -125 mmHg. For intact usage of the device, to make a perfect adhesion of the drape, hairy part of skin should be excluded from the Prevena™ system. The standard length of Prevena™ foam was limiting a complete treatment to surgical incisions no longer than 24 cm. Prevena™ was applied intraoperatively and removed six to eight days postoperatively. Patients were evaluated on each day for signs of infection. Wounds were inspected after removal of the Prevena™ system on 6-8 and 45 days after surgery (Figure 1). During the study period, there were no statistically significant variations of CRP levels between the groups.

No deep SWI and no wound healing problems significantly occured in both groups. One superficial wound infection was occured at the bottom of the sternotomy incision line in control group on the third day after surgery. Microbiological analyses were negative and treated by conventional dry steril gauze dressing. Driveline site infections occured in two patients in the control group on postoperative days 13 and 15 (Figure 2). Methicilin-resistant *Staphylococcus aureus* were positive in both patients' seropurulan drainage at the ventricular assist device driveline insertion site. By appropriate antibiotics treatment, surgical debridman and sterile gauze dressings, cultures became negative and visible markers of infection were resolved (Table 2).

Investigating the impact of risk factors of wound healing problems and infection, only diabetes mellitus seemed to have a significant role.

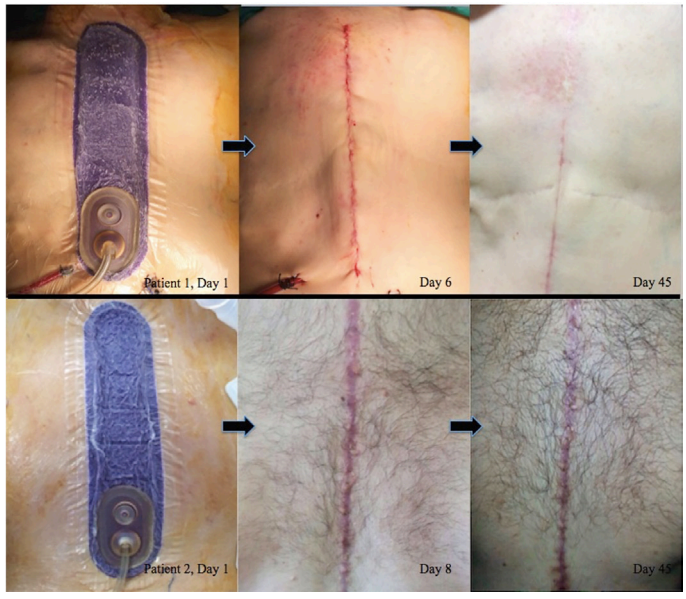

Figure 1: Sternal incisions and intraoperative application of Prevena™ system (Immediately after removal of ciNPT system on postoperative six to eight days and sternal incisions on follow-up 30 day)

ciNPT: Closed incision negative pressure therapy

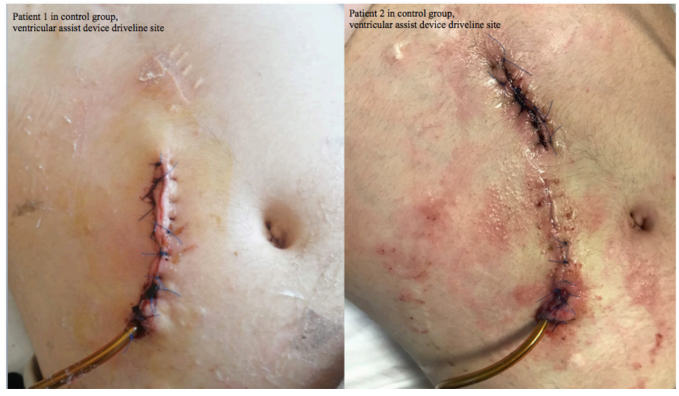

Figure 2: Driveline site infections and purulan drainage images of two patients in control group, on postoperative days 13 and 15, respectively

Table 2: Distribution of wound infections of patients receiving ciNPT and the control group			
	ciNPT (n=8)	**Control group (n=10)**	**p value**
No infection and impaired healing (n, %)	7 (87.5%)	8 (80%)	p=0.05
Superficial SWI (n, %)	1 (12.5%)	0 (0%)	p=0.018
Deep SWI requiring debridement (n, %)	0 (0%)	0 (0%)	p<0.001
Driveline site infection (n, %)	0 (0%)	2 (20%)	p=0.003
Purulan drainage (n, %)	0 (0%)	2 (20%)	p=0.003
Length of hospital stay (postoperative period) (days, mean ± SD)	22.63±6.2	34.8±21.9	p=0.05
ciNPT: Closed incision negative pressure therapy, SD: Standard deviation, SWI: Sternal wound infection			

Discussion

SWIs are not infrequent, with incidences between 1-10%. Approximetly 90% of SWIs are diagnosed after hospital discharge (4).

Asian Pacific Society of Interventional Cardiology guidelines for avoiding SWI advice aseptic technique when changing wound dressings. Type of dressings will depend on patient and wound necessities, different types of dressings such as negative pressure wound therapy, silver-based dressings and primary vacuum dressings have varied results and routine use for SWI is not recommended (5). For this reason, sternal wound management differs in each hospital and it is an individualized decision.

Primary closed incisions of high risk of surgical wound complications include several procedures such as cardiothoracic surgery, abdominal laparotomy, arthroplasty, and lower extremities bypass procedures (6,7). Those surgical procedures might be disposed by seroma and hematoma collection, because of the serum and blood in tissue space and this situation might cause surgical site infection, impaired healing and dehiscence.

Patients with comorbidities such as diabetes, obesity or malnutrition, smoking, radiation therapy, chemotherapy, use of steroids, harvesting of bilateral internal mammary arteries, poor vascular status, increasing number of grafts, renal failure, chronic pulmonary disease, prolonged duration of mechanical ventilation have increased risk of infectious complications (3,8-12).

Different studies have investigated different techniques or devices to decrease the incidence of SWI such as various methods of skin closure (intradermic closure), liquid skin adhesive, prophylactic gentamycin-collagen sponge, microbial sealant prior to surgery, skin staples, variable techniques of sternal closure (Robicsek technique), rigid-plate sternal fixation, nitinol clips, usage of autologous blood products, growth factors, hydrocolloids or such combinations of these mentioned above (13-17).

Prevena™ is a system that consists of a sponge dressing with non adherent layer and adhesive drape, a tube and a negative pressure suction with a 45 mL canister for excessive fluid collection. Prevena™ also has a bactericidal silver (0.0019% ionic silver) between sponge dressing and skin (to prevent possible bacterial growth), a pressure indicator manufactured into the drape that gives a visual sign about the air leak and a small case to carry easily on mobilisation (18).

In 2006, the application of closed incision negative pressure treatment was first reported by Stannard et al. (19). They described lower infection rates of negative pressure wound therapy over high-energy orthopedic injuries. Infection rates decreased from 16% to 8% with ciNPT, consistent with the results by Gomoll et al. (20). Similarly, Atkins et al. (21) reported the application of ciNPT in 57 patients with high risk of SWI after cardiac surgery and investigated wound outcomes associated with short-term prophylactic ciNPT use and advised routine application of ciNPT for high-risk patients. In their study, only one incision out of 213 (0.5%) had infection. This was lower than the authors' prediction of a 6.1±4% sternotomy infection complication rate for high-risk patients, based on estimated risk scores of Fowler et al. (3).

In 2020, Rashed et al. (22) reported the results about the magnitude of the scar analysed by 2D ultrasound imaging. Changes in wound contraction and organization of the scar tissue between the ciNPT and control groups were notable during the ultrasound evaluation. Wound contraction was reflected by shorter distances between the incised pectoral muscle edges and between the skin to the sternum, compared with preoperatively measured distance values (22).

The advantages of the ciNPT restrict conservation of a closed wound environment, removal of exudates, reducing oedema, increased perfusion at the site of incision. The tension decrease and normalization of strain around the skin incision may reduce the risk of dehiscence and may provide possible improvement in cosmetic results (23,24).

In our study, no infectious complications were occurred in the ciNPT study group. Mechanisms of preventing external contaminations may have relation with the high absorption property of the Prevena™, due to the bactericidal features of the silver-containing dressing material and to the closed system that avoids secondary colonisation (25).

Conclusion

In conclusion, 6-8 days of ciNPT using Prevena™ system under -125 mmHg reduced the incidence of superficial SWI and ventricular assist device driveline insertion site infections. This might be explained with supposed mechanisms such as the increase in lymph clearance originating from subcutaneous dead spaces of closed incisions, reduction of oedema and excessive fluids. Application of this system may improve wound healing of closed incisions with underlying dead spaces. The preliminary results observed in our center are motivating; nevertheless, our results are insufficient at this moment to advice a widespread use of this system for the patients undergoing ventricular assist device implantation procedures. Nevertheless, our data can serve as a basic information for more comprehensive studies to bring to a conclusion which patients and incision types could get more benefits from this treatment.

Ethics

Ethics Committee Approval: This retrospective study was approved by the Ankara University, Human Research Ethics Committee (approval no.: İ02-156-24, date: 06.03.2024).

Informed Consent: Informed consent was obtained from all participants in this study.

Authorship Contributions

Surgical and Medical Practices: N.D., E.Ö., Z.E., A.R.A., Concept: N.D., E.Ö., Z.E., A.R.A., Design: N.D., E.Ö., Data Collection and Processing: N.D., Analysis or Interpretation: N.D., E.Ö., Literature Search: N.D, Writing: N.D., E.Ö.

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