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Original Article

Negative pressure wound therapy versus conventional therapy for the treatment of post-coronary artery bypass graft mediastinitis

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Abstract

Background: Various treatments, such as negative pressure wound therapy or traditional therapy, can be employed to manage postoperative mediastinitis. The superiority of one approach over the other is still a subject of discussion. Our purpose was to compare the results of negative pressure wound therapy and conventional therapy for treating postcoronary artery bypass graft mediastinitis. Methods: This study included 50 individuals with mediastinitis after coronary artery bypass grafting. Patients were divided into Groups A and B according to whether the wound was treated with negative pressure wound therapy (n= 25) or conventional therapy (n= 25), respectively.

Results: The studied groups were comparable concerning age (P = 0.5), sex (P = 0.395), and body mass index (P = 0.556). No significant differences were detected among the studied groups concerning diabetes mellitus (P = 0.733), chronic obstructive pulmonary disease (P = 0.564), previous myocardial infarction (P = 0.370), isolated or combined surgery (P = 0.508), left main stenosis (P = 0.569), or emergency surgery (P = 0.508). Group A exhibited a significantly shorter hospital stay (26 ±4 days) than Group B (37 ±6) (P < 0.001). In contrast, no significant differences were observed among the studied groups concerning ventilation hours (P = 0.913) or ICU stay (P = 0.524). Group A demonstrated significantly lower reinfection than Group B (24% vs. 52%, respectively; P = 0.041). No significant differences were noted concerning reoperation for bleeding (P = 1.0) or mortality (P = 0.1). Group A demonstrated a significantly lower mean cost than Group B $(110\pm 23 \text{ vs. } 140\pm 37, \text{ respectively; P} = <0.001).$

Conclusion: Negative pressure wound therapy for postcoronary artery bypass graft mediastinitis could be more effective than the conventional treatment methods.

Introduction

Mediastinitis following coronary artery bypass graft surgery is a significant complication that is linked to considerable morbidity and expense [1]. Preliminary management for mediastinitis entails

surgical debridement of infected tissues, removal of sternal wires, and administration of antibiotics. Following debridement, the standard course of treatment includes sternal reclosure, which may or may not involve closed irrigation, as well as, if

KEYWORDS

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necessary, surgical correction of tissue defects via omentum or muscle graft. Recently, negative pressure wound therapy has gained prominence as a therapeutic approach for mediastinitis [2]. The superiority of one approach over the other is still a matter of ongoing research. Therefore, our goal in this research was to compare the results of negative pressure wound therapy versus conventional therapy to treat postcoronary artery bypass graft mediastinitis.

Patients and Methods

Design

A randomized controlled clinical trial was conducted on 50 individuals with mediastinitis after coronary artery bypass grafting who were receiving negative pressure wound therapy versus conventional therapy between June 2022 and October 2023. Fifty cases of mediastinitis were reported among the 1152 patients operated on during the period of study. The incidence of mediastinitis was 4.3%.

Patients

The study population was divided into two groups: Group A (n= 25), included patients who underwent negative pressure wound therapy to treat postcoronary artery bypass graft mediastinitis, and Group B (n= 25) included patients who underwent conventional therapy for the management of postcoronary artery bypass graft mediastinitis. We excluded patients with renal failure or any other form of organ failure before surgery and redo surgeries.

Surgical techniques Conservative treatment

Antibiotic therapy: The initial antimicrobial therapy was based on empirical evidence and consisted of antibiotics that target a variety of gram-negative organisms, such as aminoglycosides or cephalosporins, which have antipseudomonal effects. We started with intravenous combination therapy comprising vancomycin and imipenem until bacterial culture and sensitivity results came out. Then, a course of culture-dependent intravenous antibiotics was given, and the treatment was continued until the bacterial culture and sensitivity detected negative results, and the wound became clean with decreasing inflammatory parameters.

Open drainage with dressings: Patients were managed nonsurgically with antibiotic treatment, little drainage, or keeping the sternotomy incision open until it healed with the formation of granulation tissue. This entailed performing surgical debridement, reopening the sternum, and replacing dressings with moist compresses until granulation tissue and epithelialization occurred.

Negative pressure therapy

Before applying the negative pressure dressing, patients were transferred to the operating theatre. Wound debridement was performed under complete aseptic conditions. The infected wound was opened by exploring the affected area. Bacterial cultures were taken after careful assessment of the wound, sternum, and mediastinum. Subsequently, debridement with resection of all nonviable and infected tissue was carried out. From then on, meticulous hemostasis was performed. Finally, the wounds were irrigated with a normal saline solution, a povidone-iodine solution, or a hydrogen peroxide solution to ensure the wounds were cleaned before the application of the VAC foam.

After debridement of the wound, the implantation of foam was performed. To completely envelop the subcutaneous tissue of the wound and provide protection against superficial sternal wound infection, a sterile polyurethane foam dressing was used to fit the wound margins and the sternum. The polyurethane foam dressing was trimmed to a strip that was one and a half times broader than the wound size to allow for volume reduction when the VAC device was applied. Moreover, in a relaxed state, the polyurethane foam protruded one to two centimeters above the edge of the skin to allow for a decrease in the volume of the wound when the negative wound device was applied.

A constant suction created a vacuum within the polyurethane foam, resulting in a large contact area between the foam and the wound. This led to the establishment of a vacuum seal. If a deep infection occurred in the sternum with an open

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incision, a second piece of sterile polyurethane foam was cut to the appropriate size to be placed between the borders of the sternum. A rigid, noncollapsible perforated tube was inserted into the polyurethane foam dressing, and the distal end was connected to an exchangeable fluid canister that was present in the negative wound dressing device. The wound site included the foam and the proximal portion of the connecting tube. The five centimeters surrounding the wound margin were covered with a sterile, adhesive, transparent drape. This created a closed compartment where regulated negative pressure was achieved when the vacuum device was activated. In this step, we must ensure complete adherence of the adhesive drape to the wound site to ensure proper operation of the closed suction system. Finally, the tube was connected to the vacuum device, which created a negative pressure between 50 mmHg and 125 mmHg continuously or intermittently.

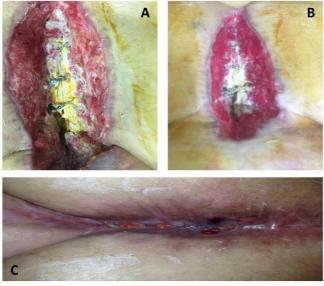


Figure 1: Female patient with a DSWI who was treated with negative pressure wound therapy. (A) Picture after the 1st dressing, (B) picture showing the wound and extent of granulation tissue, and (C) picture showing the wound after successful complete closure of the wound

The wound was followed up with every dressing change. This surgery took place whenever possible in the surgical ward. Following strict aseptic protocols, the vacuum dressing foam was replaced every forty-eight to seventy-two hours. After removing the vacuum unit, the foam was allowed to deflate by waiting for fifteen to thirty seconds. (Figure 1 and 2)

For both techniques, volumetric wound measurements were conducted utilizing a conventional ruler, while the extent of granulation was assessed as a percentage relative to the wound's surface area. The wound size was measured at the beginning, weekly during the therapy, and at the conclusion, using centimeters as the unit of measurement. The percentage of reduction in wound size was then calculated.

The extent of closure of sternal wounds depended on their size, type, depth, and presence of residual soft tissue defects. Patients with small superficial defects were allowed to close by secondary intention. Large defects were closed surgically by different methods, such as rewiring of the sternum, interrupted suturing to the subcutaneous space and skin, or reconstructive surgery with a pectoral or omental flap, based on defect size, viability of the sternum, and surgeon preference.



Figure 2: A male patient with deep sternal wound infection who was treated conservatively. (A) Before the start of treatment. (B) After rewiring the sternum with bilateral pectoral flaps

Study data

Clinical and demographic data were obtained prior to surgery. Intraoperative data included the type of surgery, cross-clamp and bypass timings, and surgical difficulties. Clinical data, hospital and intensive care unit (ICU) stays, surgical complications, and the length of postoperative ventilation constituted early postoperative information.

Statistical analysis

The statistical analysis was conducted utilizing SPSS version 28 (IBM, Armonk, New York, United

States). The normality of the quantitative data was evaluated by applying the Shapiro-Wilk test and direct data visualization techniques. Quantitative data were summarized using means and standard deviations, medians, and ranges in accordance with the principle of normality. Numerical and percentage summaries were compiled for the categorical data. The Mann-Whitney U test was used to compare quantitative data between the groups under study for nonnormally distributed variables, and the independent t-test was used for normally distributed variables. To compare categorical data, either Fisher's exact test or the chi-squared test was applied. Risk ratios with 95% confidence intervals (CIs) and numbers required for treatment were computed for various outcomes. Two-sided P values less than 0.05 were considered to indicate statistical significance.

Results

General characteristics

The studied groups were comparable concerning age (P = 0.5), sex (P = 0.395), and BMI (P = 0.556). No significant differences were detected among the studied groups concerning diabetes mellitus (P = 0.733), chronic obstructive pulmonary disease (COPD) (P = 0.564), previous myocardial infarction (P = 0.370), isolated or combined CABG (P = 0.508), left main stenosis (P = 0.569), or emergency surgery (P = 0.508) (Table 1).

Intraoperative findings

No significant differences were detected among the studied groups concerning graft types (P = 1.0), aortic cross-clamp (P = 0.556), or cardiopulmonary bypass times (P = 0.909) (Table 2).

Postoperative findings

The results of bacterial cultures were obtained during diagnosis of SWI as follows: As regarding blood culture, it shows Staph aureus in 6 patients (24%), CONS in 5 patients (20%), MRSA in 5 patients(20%), Pseudomonas aeruginosa in 3 patients (12%), Klebsiella in 2 patients (8%), E.coli in 2 patients (8%), Candida in 1 patient (4%) and combined organism in1 patient (4%) in Group A, while in group B it was Staph aureus in 5 patients (20%), coagulase-negative Staph (CONS) in 5 patients (20%), MRSA in 6 patients(24%), P.aeurginosa in 2 patients (8%), Klebsiella in 3 patients (12%), E.coli in one case (4%), Candida in 2 case (8%) and combined organism in one case (4%) with no significant difference between two groups.

Group A exhibited a significantly shorter hospital stay (26 ±4 days) than did Group B (37 ±6) (P < 0.001). In contrast, no significant differences were observed among the studied groups concerning ventilation hours (P = 0.913) or ICU stay (P = 0.524).

	Group A (n = 25)	Group B (n = 25)	P value
Age (years)	56 ±10	54 ±11	0.5
Sex			
Male	10 (40%)	13 (52%)	0.395
Female	15 (60%)	12 (48%)	
Body mass index > 30 Kg/m2	15 (60%)	17 (68%)	0.556
Diabetes mellites	20 (80)	19 (76)	0.733
COPD	9 (36)	11 (44)	0.564
Previous MI	7 (28)	10 (40)	0.370
Isolated or combined CABG			
Isolated	20 (80)	18 (72)	0.508
Combined	5 (20)	7 (28)	
Left main stenosis	10 (40)	12 (48)	0.569
Emergency surgery	5 (20)	7 (28)	0.508
MI: Myocardial infarction; COPD: Chr	onic obstructive pulmonary di	sease	

Table 1: Demographic and baseline characteristics of patients with negative wound therapy (Group A) vs. conventional therapy (Group B). Data are presented as numbers (%) or mean and SD

Table 2: Operative characteristics of patients with negative wound therapy (Group A) vs. conventional therapy (Group	
В)	

	Group A (n = 25)	Group B (n = 25)	P value		
Artery Graft Type			-		
LIMA	22 (88)	21 (84)	1.0		
BIMA	3 (12)	4 (16)			
Aortic cross-clamp (minutes)	50 ±9	51 ±8	0.556		
Cardiopulmonary bypass time (minutes)	79 ±13	79 ±12	0.909		
BIMA: bilateral internal mammary artery; LIMA: left internal mammary artery					

Group A demonstrated significantly lower reinfection than did group B (24% vs. 52%, respectively; P = 0.041). No significant differences were noted concerning reoperation for bleeding (P = 1.0) or mortality (P = 0.1). Group A demonstrated a significantly lower mean cost than Group B (110±23 vs. 140 ±37, respectively; P = <0.001). This is mainly due to Group B's longer hospital stay than Group A's (Table 3).

Discussion

Deep sternal wound infection (DSWI) is a significant surgical site infection (SSI) that has a detrimental impact on prognosis and is among the most common and catastrophic complications of cardiac surgery [3]. The treatment of mediastinitis after sternotomy often involves a mix of surgical debridement and antibiotic therapy. The most effective surgical approach for treating mediastinitis is still debated [4]. The present research sought to compare the outcomes of negative pressure wound therapy with those of conventional therapy for treating mediastinitis following coronary artery bypass graft surgery. Additionally, the aim was to determine the most effective method, whether negative pressure wound therapy or conventional therapy, for

treating mediastinitis after coronary artery bypass graft surgery.

The research was performed on 50 patients who underwent CABG surgery and had postoperative mediastinitis, 25 patients treated with vacuum-assisted closure therapy, and the other 25 patients treated with conservative treatment. In our study, Group A had a significantly shorter hospital stay (26 ±4 days) than did Group B (37 \pm 6) (P < 0.001). In contrast, no significant differences were observed among the studied groups concerning ventilation hours (P= 0.913) or ICU stay (P= 0.524).

There are three risk factors related to each other: prolonged CPB and prolonged ICU stay due to prolonged mechanical ventilation. These combinations do not increase the incidence of sternal wound infection or mediastinitis; rather, they increase mortality. These three factors are related to each other, as excessive CPB has many causes. The most important cause is weak myocardial contractility with inotropic support, prolonged mechanical ventilation, and prolonged ICU stay.

Table 3: Operative characteristics of patients with negative wound therapy (Group A) vs. conventional therapy (Group B)

	Group A (n = 25)	Group B (n = 25)	P value
Ventilation hours	12 (5 - 22)	11 (5 - 21)	0.913
ICU stay (days)	6 (3 - 10)	6 (3 - 12)	0.524
Hospital stay (days)	26 ±4	37 ±6	< 0.001
Reoperation for bleeding	5 (20)	4 (16)	1.0
Reinfection	6 (24)	13 (52)	0.041
Mortality	3 (12)	4 (16)	1.0
Mean cost (thousand pounds)	110±23	140 ±37	<0.001
ICU: Intensive Care unit			

Patients undergoing CPB were much more likely to become infected due to secondary immune system damage and the increased number of possible entry points for bacterial pathogens, which increased the likelihood of contamination [5]. The microbiological finding of our study is comparable to that of a study performed by Deniz and colleagues, in which culture-verified DSWI pathogens were identified as follows: S. aureus, 29.8%; EE coli, 8.5%; Klebsiella, 2.1%; CONS, 19.1%; MRSA, 25.5%; P. aeruginosa, 6.4%; A. baumannii, 4.3%; and combined infection (E. coli+ P. aeruginosa), 4.3%. [6]

All DSWI (mediastinitis) patients in our study were characterized by pain, purulent discharge from the sternotomy wound, fever, sternal instability (rocking), erythema, positive culture, and retrosternal collection on CT. Several studies also described this; therefore, clinical examination and follow-up are highly important for early detection of SWI, early management, and improved prognosis in patients who underwent cardiac surgery [7 - 9].

Six patients (24%) developed reinfection after mediastinitis treatment in Group A, whereas 13 (52%) developed reinfection in Group B. In this study, seven operative mortalities were recorded: 3 patients (12%) in Group A and four patients (16%) in Group B. Group A demonstrated significantly fewer reinfections than Group B (24% vs. 52%, respectively; P = 0.041). These findings align with the findings of Domkowski et al., who reported a 13% mortality rate because of overwhelming sepsis after undergoing vascular flap and multisystemic organ failure [6]. These findings are consistent with those of an investigation conducted by Simek et al., in which a patient with DSWI succumbed to multiple organ failure on the 24th postoperative day (7% mortality rate), notwithstanding the attainment of negative bacteriological cultures throughout the therapeutic process [10]. An analogous outcome was observed in a study conducted by Fleck et al., in which the overall mortality rate for this cohort was 3.6% (12/326). None of these deaths were attributed to the use of VACs; rather, the majority of the deaths occurred due to sepsis in four patients (because revision was not possible in time) or cardiac-related causes in the remaining patients [11].

Research has established that the DSWI, when considered separately, has an adverse impact on the long-term survival rate after coronary artery bypass graft surgery. Owing to the uncertainty of the cause of this unfavorable prognostic effect, sepsis episodes resulting from severe systemic infection can irreparably harm vital organs, including the heart, kidneys, and bypass grafts [12]. The VAC system has demonstrated encouraging outcomes in terms of both immediate and extended survival when contrasted with traditional methodologies [13].

A retrospective study conducted by Deniz et al. examined 90 patients diagnosed with DSWI. The investigation revealed that patients who received therapy via the VAC system had considerably lower rates of death and treatment failure within 90 days than those who received traditional treatment approaches. The underlying factor behind all fatalities was the simultaneous malfunction of many organs due to a severe systemic infection known as sepsis. Both trials also showed a higher rate of overall survival in the VAC group [6]. A further retrospective analysis conducted by Sjogren et al. showed that individuals who had DSWIs and underwent treatment with NPWT had comparable long-term survival rates to those without DSWIs following coronary artery bypass grafting [13].

The retrospective analysis of 157 patients by De Feo et al. supports the conclusion that VAC therapy was associated with a decreased mortality rate compared to conventional treatment. Additionally, VAC therapy was associated with a lower rate of reinfection. In a recent retrospective analysis, Risnes et al. reported no significant disparity in long-term survival between 130 patients who underwent confined drainage with irrigation and those treated with a VAC system [14]. Additionally, they documented a higher incidence of reinfection and failure to cure sternal wounds in the closed drainage group. Damiani et al. found no significant differences in mortality among patients who underwent negative pressure wound therapy or conventional therapy in a meta-analysis of 321 patients [15].

Group A had an average hospital stay of 26 days, whereas Group B had an average length of stay of 37 ±6 days. The findings presented here are similar to those of a retrospective investigation conducted by Fuchs et al., which contrasts the VAC technique with the conventional treatment of sternal infection established to date. The average length of hospitalization for patients in the VAC group was 25 days (18 to 35 days), which was considerably shorter than that of patients in the conventional therapy group (34 days; 24 to 55 days) [16]. Aydin et al. conducted an additional investigation in which they contrasted VAC therapy (Group A) with conventional therapy involving closed irrigation and antibiotics (Group B). The hospitalization duration in Group A was considerably shorter (median: 30.5 days; mean: 32.2 ± 11.3 days) than in Group B (median: 45 days; mean: 49.2 ± 19.3 days) [118]. These findings are consistent with a study conducted by Sjogren et al., which reported a mean hospital stay of 24.6 ± 16.4 days [13].

DSWI was initially managed through surgical revision, which may or may not involve multiple open dressing changes. These approaches have been linked to significant mortality rates and have substantial drawbacks, including sternal instability that necessitates mechanical ventilation as well as prolonged immobilization that heightens the risk of further complications, including pneumonia, thrombosis, and muscular atrophy [17]. After several unsatisfactory procedures, vascularized soft tissue flaps were adopted as an established technique. Since Jurkiewicz and colleagues published the first pectoral muscle flap, numerous studies have reported contradictory findings on pectoral muscle flaps for poststernotomy mediastinitis [18]. Additional research supports the use of omentum flaps initially proposed by Lee et al. to treat poststernotomy mediastinitis [19]. Several reports indicated that these soft tissue flaps have a comparatively low mortality rate; however, they may be linked to the morbidity associated with the flaps [20].

VAC therapy is an innovative approach to wound healing in which several beneficial effects are combined by administering negative pressure to a sternal incision. The VAC enhances pulmonary function by facilitating continuous active suction of wound drainage and exudates while simultaneously stabilizing the chest wall and mediastinal cavity. Additionally, vacuum isolation prevents incision contamination and reduces the bacterial count during vacuum therapy [20]. This promotes the production treatment of granulation tissue by creating а moist environment and increasing blood flow in the surrounding tissue. Moreover, VAC treatment achieves a close approximation to the wound borders and has a volumizing effect while minimizing surgical stress. Ultimately, due to sternal stability and wound isolation, patients can promptly be transported and undergo physiotherapy to reduce further problems [21].

The utilization of VAC treatment resulted in prompt eradication of sternal wound microbiological cultures, a reduced length of hospitalization, early achievement of sternal closure, and a tendency toward favorable longterm survival [21]. VAC treatment significantly decreases the need for surgical intervention and repeat surgeries in individuals with persistent infections, even those at high risk. The date of subsequent surgical closure is conventionally determined by visual assessment of the wound, the absence of harmful microorganisms in wound cultures, and the patient's overall health status [21].

Limitations

The research has several limitations. Several surgeons performed CABG, which could have affected the outcomes. Moreover, the outcomes were restricted to the short-term duration of the disease.

Conclusion

Negative pressure wound therapy for postcoronary artery bypass graft mediastinitis could be more effective than the conventional treatment methods. Our analysis recommends that negative wound therapy can be prioritized as the initial treatment for most patients with sternal wound infections.

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