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Nanocrystalline-Coated Silver Dressings for Patients with Type 2 Diabetes after Surgical Coronary Revascularization

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ABSTRACT

OBJECTIVE: To assess the suitability of nanocrystalline-coated silver dressings versus standard wound dressings in patients with type 2 diabetes after coronary revascularization.

METHODS: The study involved 194 patients who were divided into two homogeneous groups. The control group (n = 97) received a standard sterile dressing. The intervention group (n = 97) received silver dressings. Glycosylated hemoglobin, fructosamine, and creatinine were assessed in all patients. The emergence of superficial wound infection within 30 days was the primary endpoint of the study, and deep wound infections were a secondary endpoint.

MAIN RESULTS: Superficial wound infections were documented in 26 patients: 11 patients in the study group and 15 in the control group. There were no statistically significant differences between the analyzed groups regarding the occurrence of the primary endpoint. No deep wound infections were found in either the study or control group.

CONCLUSIONS: The frequency of sternotomy wound infection in patients with type 2 diabetes is comparable between patients treated with traditional dressings and those receiving silver dressings; therefore, to maximize cost savings, providers should consider using standard wound dressings in this patient population.

KEYWORDS: cardiac surgery, diabetes, nanocrystalline silver dressings, postoperative infection, sternotomy, surgical site infection, wound dressings

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INTRODUCTION

Postoperative surgical site infection (SSI) is one of the most serious and costly challenges of modern cardiac surgery.[1] The incidence of this complication, depending on the facility, ranges from 0.5% to 20%[2,3] and is associated with a significant increase in medical costs.[4] Epidemiologic studies conducted in the US in 2009 showed that, in patients with SSI, hospital stay was extended by an average of 9 days, increasing the cost of hospitalization by more than $20,000 for each patient, or nearly $1 billion a year. Similarly, at the authors' facility in Poland, in about 9% of patients with SSI, hospital stay was extended by an average of 5 days, increasing the cost of treatment by an average of 8,000 zł.[5–7]

Infections in sternotomy wounds are divided into superficial wound infections (SWIs), if the infection is limited to the skin and subcutaneous tissue, and deep wound infections (DWIs) when the inflammatory process includes the sternum and mediastinum.

Type 2 diabetes is, along with chronic obstructive pulmonary disease, the most common comorbidity of patients undergoing cardiac surgery. Its occurrence in patients undergoing cardiac surgery is estimated at 20% to 30%, of which almost three-quarters of cases are intensively treated with insulin.[8–10] Despite such treatment, because of frequent dietary errors or insufficient glycemic control and insulin supplementation, a significant percentage of patients (about 5%-10%) report for cardiac surgery with uncontrolled diabetes, in which their glycated hemoglobin levels exceed 8%. These patients, despite increased IV insulin therapy, remain at high risk of wound healing complications because of impaired collagen production. Further, chronic hyperglycemia reduces tissue resistance to infection, impairs peripheral blood supply to tissues, and induces neuropathy.

Treatment of SWI is a clinical challenge. It consists of intense IV antibiotic therapy, surgical debridement, and the use of vacuum wound closure methods.[2] A more recent treatment option is self-adhesive wound dressings containing nanocrystalline silver. They offer the bactericidal properties of silver enclosed in thin nanomesh fibers.[11] Clinical studies have confirmed their high

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effectiveness in the treatment of diabetic foot ulcers and wounds infected with multidrug-resistant bacteria.[12–14] The high efficacy of this dressing has also been demonstrated in the treatment of burns.[15]

The present study attempts to assess the efficacy of nanocrystalline silver-coated dressings in preventing SWI in patients with diabetes who have undergone cardiac sternotomy.

Declaration

This experimental study was approved by the Bioethical Committee of the Medical University of Silesia in Katowice, Poland (resolution no. KNW / 0022 / KB1 / 122/13). The datasets generated and/or analyzed during this study are available from the first author upon request.

METHODS

The study was designed as a pilot, single-center, prospective, open-label clinical trial. The research was carried out in the General Analytics Laboratory of the authors' hospital. It involved 194 patients who met the inclusion criteria and signed consent forms (Table 1).

Patients were randomized into two homogeneous groups. In all patients, blood draws were required to assess glycated hemoglobin, fructosamine, and creatinine levels. The dressings were administered in the OR after the cardiac surgery. The control group (n = 97) received a standard sterile dressing (Elastopor STERIL; ZARYS International Group, Zabrze, Poland). The study group (n = 97) received 10 × 10-cm silver dressings (Acticoat Flex 3 fitted with the Opsite Post Op Visible; Smith & Nephew, Fort Worth, Texas). After 3 days, a 10 × 25-cm silver dressing (Acticoat Surgical; Smith & Nephew) was applied.

In the control group, the frequency of dressing changes was consistent with the facility's normal treatment schedule (maintained up to 2 days after surgery and then changed daily). In the intervention group, the frequency of dressing changes was in accordance with the manufacturer's instructions (maintained up to 3 days after surgery and then changed every 3 days). Wounds were evaluated each time the dressing was changed. If no adverse outcomes were noted, the patient was discharged after 5 to 7 days for further treatment in outpatient settings. On postoperative day 14, the patient was invited to the authors' outpatient clinic to remove their stitches. On postoperative day 30, the patients were assessed based on a detailed telephone interview or a visit to the infirmary.

The appearance of any SWI within 30 days was treated as the primary endpoint. For SWI diagnosis, the patient had to meet the following criteria: (1) a red, swollen, and painful wound; (2) positive bacterial culture from the tissue or fluid removed from the wound; and (3) depth does not pass below the fascia of the pectoral muscle, and sternum bone fragments do not show pathological mobility. For DWI diagnosis, the patient had to meet at least one of the following criteria: (1) positive bacterial culture from the tissue or fluid removed from the wound; (2) evidence of infection of the wound during surgery such as purulent or serous leakage from the wound or mediastinum; (3) any of the following: chest pain, instability of the sternum, fever (>38° C), or positive culture from blood or a mediastinal drainage. When infection occurred, patients were to be treated according to established protocols.

Table 1.

INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria	Exclusion Criteria
• Age 18 y or older • Multivessel coronary disease qualifying for surgical treatment • Planned cardiac surgery, using full sternotomy as surgical access • Type 2 diabetes • Expected survival >1 y • Written consent for participation in the study and inspection visits	• Glucose intolerance • Coexisting heart defects requiring surgery • Any cardiac surgery that used median surgical access other than sternotomy • Pregnancy or planned pregnancy during the study and follow-up period • Comorbid condition reducing expected lifespan to <1 y after surgery • Immunomodulatory, immunosuppressant, or steroid therapy for 6 mo before cardiac surgery • Lung diseases that require treatment with inhaled immunomodulatory drugs • Chronic kidney disease requiring dialysis • A positive history of coagulopathy • Previous cardiac surgery • An active infection or sepsis • Participation in another clinical trial of a medical device and/or pharmaceutical • Cognitive impairment

Statistical Analysis

Statistical analysis was performed using the Microsoft Office Excel 2010 and Statistica 12.0 computer programs. To compare the values expressed in percentages, a significance test of the difference between two structure indices was used, including the χ^2 test and the Mann-Whitney *U* test. $P < .05$ was considered statistically significant.

RESULTS

The intervention and control groups were homogeneous in terms of baseline parameters (Table 2), differing only in glomerular filtration rate. The occurrence of the primary endpoint in both groups is described in Table 3. No DWI criteria were met in either the study or control group. However, SWI occurred in 26 patients (13.4%): 11 patients in the intervention group and 15 in the control group. This difference was not statistically significant (11.7% vs 16.67%, $P = .450$).

Table 2.

COMPARISON OF STUDY PARAMETERS BY GROUP

Parameter		Intervention n	Intervention Mean ± SD	Control n	Control Mean ± SD	*P*
Age, y		96	67.63 ± 8.11	92	65.46 ± 7.25	.06[a]
Glycated hemoglobin, %		95	7.15 ± 1.28	95	7.24 ± 1.33	.54[a]
Fructosamine, µmol/L		85	268.87 ± 36.20	89	275.96 ± 54.85	.79[a]
Body mass index, kg/m^2		93	29.78 ± 4.04	93	30.01 ± 4.52	.85[a]
Creatinine		97	87.66 ± 27.48	97	95.04 ± 36.93	.14[a]
EuroSCORE		94	4.05 ± 2.38	97	3.90 ± 2.19	.81[a]
Sex	Female	35	36.08	28	28.87	.36[b]
	Male	62	63.92	69	71.13	
Hypertension	No	9	9.28	2	2.06	.06[b]
	Yes	88	90.72	95	97.94	
Chronic obstructive pulmonary disease	No	95	97.94	92	94.85	.44[b]
	Yes	2	2.06	5	5.15	
Previous heart attack	No	49	50.52	52	53.61	.77[b]
	Yes	48	49.48	45	46.39	
Percutaneous coronary intervention in the last 12 mo	No	76	78.35	82	84.54	.36[b]
	Yes	21	21.65	15	15.46	
New York Heart Association III/IV	No	78	80.41	80	82.47	.85[b]
	Yes	19	19.59	17	17.53	
Cerebrovascular disease	No	75	77.32	80	82.47	.47[b]
	Yes	22	22.68	17	17.53	
Peripheral vascular disease	No	84	86.60	88	90.72	.50[b]
	Yes	13	13.40	9	9.28	
Glomerular filtration rate ≤60 mL/min	No	84	86.60	72	74.23	.04[b]
	Yes	13	13.40	25	25.77	

[a]Mann-Whitney *U* test.
[b]χ^2 Test.

Patients were divided by occurrence of SWI in search for determinants of wound infections (Table 4). However, none of the analyzed parameters appeared to be a significant factor of SWI.

DISCUSSION

Postoperative wound infections are one of the most serious complications of cardiosurgical procedures. In this study, 13.4% of patients (26 of 194) with type 2 diabetes had SWI after coronary artery bypass grafting, which is similar to a previously reported study.[16] Risk factors related to the patient include comorbidities (mainly diabetes and chronic obstructive pulmonary disease), and factors related to the procedure include time-consuming open-heart surgery with prolonged extracorporeal circulation, multiple blood transfusions or preparations, and reoperations because of bleeding or tamponade.[6] However, type 2 diabetes is the most common predisposing factor for SWI.[16] Issues attributable to chronic hyperglycemia are compounded by impaired blood supply to the sternum and adjacent tissues.

Treatment of SWI is still a clinical challenge. In addition to IV antibiotic therapy, surgical debridement, and the use of flow drainage, providers can use negative-pressure wound therapy (NPWT) to clean the wound and increase its blood supply. The effectiveness of NPWT has been repeatedly confirmed in numerous clinical trials,[17] and is now standard in the treatment of serious wounds after cardiac surgery. However, NPWT is associated with a need to hospitalize a patient and replace the suction system, on average, every 3 to 4 days.[17]

Nanocrystalline silver dressings have proven superiority to standard dressings in treating diabetic foot ulcerations.[18] They use the bactericidal properties of silver to create an antibacterial barrier that functions for up to 72 hours. Dressings of this type are effective against the pathogens most commonly found in SWI: *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and so on. However, this study showed that nanocrystalline-coated silver dressings have similar results to standard wound care in the

Table 3.

ENDPOINTS BY GROUP

Endpoint		Intervention n	Intervention %	Control n	Control %	*P*[a]
Superficial wound infection	No	83	88.30	75	83.33	.45
	Yes	11	11.70	15	16.67	
Saphenous vein graft	No	81	86.17	72	80.00	.36
	Yes	13	13.83	18	20.00	

[a]χ^2 Test.

Table 4.

COMPARISON OF PATIENTS WITH SURGICAL WOUND INFECTION BUT WITHOUT INFLAMMATION

Parameter		No		Yes		P^a
		n	%	n	%	
Sex	Female	45	28.48	12	46.15	.12
	Male	113	71.52	14	53.85	
Hypertension	No	9	5.70	2	7.69	.96
	Yes	149	94.30	24	92.31	
Chronic obstructive pulmonary disease	No	153	96.84	25	96.15	.68
	Yes	5	3.16	1	3.85	
Previous heart attack	No	85	53.80	11	42.31	.38
	Yes	73	46.00	15	57.69	
Percutaneous coronary intervention in the last 12 mo	No	130	82.28	20	76.92	.70
	Yes	28	17.72	6	23.08	
New York Heart Association III/IV	No	127	80.38	24	92.31	.23
	Yes	31	19.62	2	7.69	
Cerebrovascular disease	No	126	79.75	21	80.77	.89
	Yes	32	20.25	5	19.23	
Peripheral vascular disease	No	140	88.61	22	84.62	.80
	Yes	18	11.39	4	15.38	
Glomerular filtration rate ≤60 mL/min	No	127	80.38	20	76.92	.89
	Yes	31	19.62	6	23.08	
Test group	No	75	47.47	15	57.69	.45
	Yes	83	52.53	11	42.31	

[a]χ^2 Test.

prevention of sternal wound infections in patients with diabetes after coronary artery bypass grafting.

Limitations and Recommendations for Future Research

This study has several important limitations that warrant caution in clinical extrapolation of these results. Despite the advantages of a prospective randomized study, the sample size was relatively small, and larger-scale studies may be needed to support these findings. Further, on postoperative day 30, most patients were assessed based on a detailed telephone interview rather than during a visit to the hospital. If the patients who were contacted via telephone had been asked to send a picture of the wound or required to come in person, this could have potentially increased the detectability of the primary endpoint.

CONCLUSIONS

This study found that the frequency of sternotomy wound infection in patients with type 2 diabetes after surgical coronary revascularization is similar in patients treated with standard wound dressings versus nanocrystalline silver dressings. Because the silver dressings require replacement every day, standard wound care offers an inexpensive alternative that providers should consider. ●

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