Dialkylcarbamoyl chloride dressings in the prevention of surgical site infections after nonimplant vascular surgery

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Background: Dressings coated with dialkylcarbamoyl chloride (DACC) are highly hydrophobic and irreversibly bind multiple types of bacteria, trapping them in the dressing and reducing the number of organisms at the wound surface. We aimed to assess the impact of DACC-coated postoperative dressings on the incidence of surgical site infection (SSI) in nonimplant vascular surgery patients.

Methods: Two hundred patients undergoing nonimplant vascular surgery were prospectively recruited at a single vascular center. The initial 100 patients had their operative wounds dressed with conventional dressings followed by 100 patients who received DACC-coated postoperative dressings. Wounds were reviewed at day 5 and day 30 to determine the presence of SSI using the ASEPSIS scoring system. The variation in outcomes between groups was assessed using chi-squared test and logistic regression analysis to assess the effects of other variables, which may affect healing.

Results: Between 1 August 2015 and 29 February 2016, a total of 120 men and 80 women were recruited. The mean age was 63 (range 27–97) years, 92% were current or ex-smokers and 45.5% were diabetic. Rate of SSI at 5 days was significantly lower in the DACC group compared with standard dressings (1% vs 10%, $P < 0.05$). There was no difference in the rates of SSI at 30 days. Logistic regression suggested that the type of dressing used was the most prominent predictor variable for the presence of early SSI ($P = 0.028$, odds ratio = 0.09, 95% confidence interval: 0.01–0.77).

Conclusion: DACC-coated dressings were associated with a significant reduction in SSI rates in the early postoperative period.

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Introduction

Surgical site infections (SSIs) are infections occurring at the part of the body where surgery has taken place within 30 days of the procedure, or within 1 year of the procedure if a prosthetic surgical device was implanted (e.g., mesh, metalwork, vascular graft).[1] SSI accounts for up to 20% of all hospital acquired infection and occurs in at least 5% of all surgical procedures.[2] Morbidity and mortality due to SSI can be devastating and may be preventable with appropriate strategies and policies in preoperative, intraoperative, and postoperative patient and wound care.[2] One in 3 postoperative deaths are related at least in part to the presence of an SSI,[2] and mean additional costs incurred in managing a vascular SSI are estimated in the region of £8 500 per patient.[3]

The incidence of SSI following vascular surgery is 10–15%, rising to 30% in trials specifically monitoring SSI as an outcome.[4,5] This high incidence is thought to relate to the high rates of comorbidities, concurrent smoking, diabetes, and groin surgery in vascular patients. SSI in vascular surgery is potentially devastating for patients, with 30–40% of SSI in lower limb bypass graft infections resulting in a major amputation,[6] and over one-third of all postoperative deaths being attributable, at least in part, to an SSI.[2] Less severe SSI still impact on patients' wellbeing and quality of life.[7,8] The hospital costs of SSI are significant with estimates between £1 500 and £10 000 per patient episode in vascular surgery[3,9] (figures updated for 2016 equivalence[10]). Costs are attributable to extended hospital stays, need for readmissions and re-operations, drug treatments, increasingly complex wound management and dressing systems, and high demands on inpatient and community nursing staff. Any strategies to reduce SSI must be investigated for the benefit of patients and also to ensure the best use of limited surgical and health care resources.

Postoperative wound dressings act to absorb exudates and protect the wound from the external environment until epithelialisation occurs. A huge range of postoperative dressing options exist; however, a 2014 Cochrane review and meta-analysis, which examined data from 20 randomised controlled trials, found no evidence to suggest that any 1 dressing type was more effective at reducing SSI than any other.[11]

One newer technology not included in this review was the use of dialkylcarbamoyl chloride (DACC) as a coating on dressing surfaces. DACC is a highly hydrophobic fatty acid derivative which has recently been incorporated as a coating to the wound contact surface of dressings. Most

microorganisms responsible for SSIs have hydrophobic cell surfaces,[12,13] and when these organisms come into contact with DACC, they irreversibly bind via a hydrophobic interaction with the dressing and are then removed from the wound bed at the next dressing change. This removal of organisms reduces the bioburden at a wound surface,[14] thus theoretically preventing the ingress of organisms into the wound and reducing SSI rates.

The aim of this study was to undertake a prospective comparative evaluation of the impact of DACC coated postoperative dressings on the rate of SSI in patients undergoing open nonimplant vascular surgery, to inform the future design of a fully powered randomised controlled trial.

Methods

This was a prospective, nonrandomised comparative study in a single vascular surgery center. A total of 200 participants were recruited, with the initial 100 participants receiving a variety of inert, standard surgical dressings as per the routine clinical practice of the surgeons undertaking the procedure. The second group of 100 participants received DACC-coated dressings (Leukomed® Sorbact®; BSN Medical, Hull, UK).

Patients

All adult patients undergoing clean or clean contaminated nonimplant vascular surgical procedures were considered for inclusion into the study. Patients undergoing implant-containing vascular surgery were excluded due to the length of time needed for follow-up. Exclusion criteria included known allergy to the DACC dressing components and patients already undergoing treatment with antibiotics. Antibiotic prophylaxis was used as per standard operating procedures.

Table I: Participants demographics, ASA grades, and surgical procedure undertaken in standard and DACC-coated dressing groups

Demographic measure	DACC dressings group (*n* = 100)	Standard dressing group (*n* = 100)	*P* value
Age (range)	63 (29–94)	63 (27–97)	0.54
Male gender	54	66	0.11
Diabetic	39	52	0.08
Insulin use	24/39	21/52	0.07
Cardiac disease	42	39	0.66
Respiratory disease	25	47	0.01[a]
BMI (range)	28 (17–45)	27 (19–43)	0.81
Smoking status			
Ever smoked	92	92	1.0
Current smoker	58/92	50/92	0.38
Closure method			
Continuous	97	92	0.21
Interrupted	3	8	0.21
Grade of surgeon			
Consultant	52	54	0.88
Senior trainee (ST5–8)	43	38	0.56
Junior trainee (CT1–ST4)	5	8	0.56
Surgical procedure performed			
Limb revascularisation	27	13	< 0.05[a]
Major limb amputation	38	35	0.76
Minor amputation	0	19	< 0.001[a]
Carotid endarterectomy	4	8	0.37
Open varicose vein surgery	18	20	0.85
Dialysis fistula formation	8	3	0.21
Other	5	2	0.44
ASA grade			
ASA 1	8	7	0.78
ASA 2	24	29	0.52
ASA 3	54	51	0.77
ASA 4	14	11	0.66

Two-tailed *P* values were reported from Student's *t*-test and chi-square test with Yates correction. ASA – American Society of Anesthesiologists, BMI – body mass index.
[a]Signifies a significant difference between patient groups.

Table II: Results of ASEPSIS scores at assessments throughout study

Time	Wound score	DACC dressings group, *n* = 100 (*n* at risk)	Standard dressings group, *n* = 100 (*n* at risk)	*P* value
Day 5–7	SSI	1 (100)	10 (100)	0.01[a]
	Adequate healing	85 (100)	74 (100)	0.07
Day 30	SSI	9 (99)	9 (90)	0.83
	Adequate healing	88 (99)	75 (90)	0.37
Total	Incidence SSI	10%	19%	0.11

Two-tailed *P* values reported from chi-squared test with Yates correction.
[a]Signifies significant difference between patient groups.

Table III: Potential confounders to SSI included in logistic regression analysis

					95% CI	
Variable	Wald	df	Sig.	OR	Lower	Upper
Presence of diabetes	3.706	1	0.054	0.529	0.277	1.012
BMI	0.294	1	0.588	0.984	0.926	1.044
Current smoking	1.345	1	0.246	0.699	0.382	1.280
Grade of operating surgeon (consultant versus trainee)	0.141	1	0.707	0.891	0.488	1.627
Early SSI	4.840	1	0.028*	0.094	0.011	0.772
ASA grade ≥ 3	2.464	1	0.116	1.771	0.868	3.617
Type of surgery	0.035	1	0.851	1.070	0.529	2.163

Type of surgery is divided into treatment for critical limb ischemia versus other vascular surgery.
Df – degrees of freedom, Sig. – significance, BMI – body mass index, ASA – American Society of Anesthesiologists.
*$P < 0.05$.

Interventions

Procedures were undertaken by or under the supervision of 7 vascular consultants, and all other aspects of perioperative care remained unchanged between cohorts. All dressings were applied in a sterile fashion in theaters following wound closure and remained in situ until wound review was undertaken before discharge or earlier if required based on clinical need. Standard or DACC-coated dressings were continued for the duration of dressing use at that wound site. All patients were discharged home with extra wound dressings to ensure like-for-like dressing changes in the community.

Outcomes

To assess wound healing, we used the ASEPSIS scoring system, which utilises 7 clinical parameters to describe satisfactory wound healing (score ≤ 10), impaired wound healing (score 11–20), and SSI (score ≥ 21).[15] The primary outcome for this study was the presence of SSI (ASEPSIS wound score ≥ 21). Secondary outcomes included evidence of satisfactory heal-ing (ASEPSIS score ≤ 10). Wound assessments were performed on day 5–7 and on day 30. During the assessments, any dressings were removed, and a short patient interview and review of patient case notes and prescription chart were undertaken to allow comprehensive recording of all wound complications and ASEPSIS score.

Statistical analysis

Data were collated into IBM SPSS (IBM SPSS Corporation, version 22; Rochester, USA) to facilitate statistical analysis. Data were presented descriptively using mean (SD) or *n* (%) for each group. The groups were compared using chi-squared tests or Fisher's exact tests for categorical data and *t*-tests for continuous data (e.g., age). The primary outcome, SSI, was dichotomised into presence or absence of infection, and statistical differences between groups were compared using chi-squared tests. To measure the association level, crude odds ratio (OR) and the 95% corresponding test-based confidence interval (CI) were calculated. A logistic regression analysis was undertaken to control the effects of other variables, which might be expected to influence healing. A *P* value of < 0.05 was considered statistically significant.

Results

Two hundred patients were recruited from 1 August 2015 to 29 February 2016, of which 120 were men and 80 were women, with mean age of 63 (range 27–97) years. Each group had 100 patients. Comparative data for the 2 groups are summarised in Table I.

Less patients had SSI in the DACC-coated group than the standard group at 5–7 days (1/100 and 10/100, respectively; OR = 0.09 [95% CI: 0.01–0.072, $P = 0.005$]). In those remaining at risk, there was no difference in SSI at the 30-day wound assessment (9/99 and 9/90, $P = 0.832$). There was no

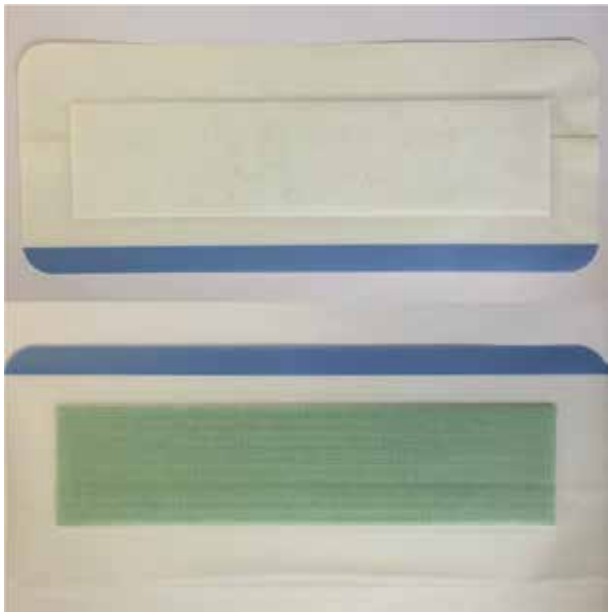

Figure 1: Photographs of Leukomed Sorbact, the DACC-coated dressing used in the trial, against a white background. The colored nature of the wound contact layer is demonstrated.

difference in adequate wound healing at any time. ASEPSIS scores recorded for all wounds are summarised in Table II.

For SSI at day 5–7, the single incident of SSI in the DACC dressing group required 7 days of intravenous antibiotics. In the non-DACC group, all 10 patients with SSI at day 5–7 were treated with antibiotics. Two of these required intravenous antibiotics, one for 21 days in total. The other 8 patients were treated with oral antibiotics, with 5/8 treated for 14 days total. At 30 days, there was no significant difference in readmission rates due to SSI between the 2 groups (7/99 and 9/90, $P = 470$).

Logistic regression analysis was performed to control the effects of recorded variables, which would be expected to impact on the risk of SSI as listed in Table III. Seven potential confounding variables were included in the model.[16] After regression analysis, the type of dressing used remained the most prominent predictor in early SSI ($P = 0.028$) with an odds ratio of 0.09 (95% CI: 0.01–0.77).

Discussion

This small prospective comparative trial suggests that DACC coating may reduce the rate of SSI in nonimplant vascular surgery patients. Prior in vitro evidence strongly supports the proposed mechanism of action by which DACC might be expected to limit ingress of bacteria into incision wounds.[12,13,17] DACC-coated dressings act by trapping and physically removing bacteria, rather than being bactericidal, which in the context of wider societal concerns regarding antibiotic resistance make this action particularly attractive as a novel intervention as the development of bacterial resistance is less likely. They have been shown to bind to organisms that are antibiotic resistant in vitro.[17] Results of in vivo application of DACC-coated dressings in chronically infected wounds have also been promising both in terms of bioburden reduction and enhanced clinical evidence of healing.[18-21]

Equally, no absorption of DACC into the wound surface is known to occur, and no evidence to date has reported any adverse effects to its use, allowing its potential application to all patient groups.

This study was intended as a pilot study to examine the possible effectiveness of DACC impregnated dressings as a prophylactic measure in reducing SSI rate and was able to show a significant reduction in incidence of SSI in a cohort of clean and clean contaminated nonimplant vascular surgery with their use. These results are in keeping with recently published evidence supporting the use of DACC-coated dressings as prophylaxis against SSI in fit and well patients undergoing caesarean section.[22] The maximal protective effect appears to be in the early post perioperative period, before the 5- to 7-day assessments. The timing of the apparent action reported in these results appears logical because the mechanism of action of DACC would be prevention of ingress of bacteria into freshly incised wounds, which are yet to re-epithelialise. Logistic regression analysis suggested a significant impact of the dressings for all instances of SSI when controlling for potential confounding variables expected to impact healing, such as smoking and diabetes.

Limitations of the study

There were several potential sources of bias within this study. The nature of the study design was as an exploratory proof of concept study before an intended randomised trial. Although patients were not randomised, groups were well matched for most variables. There is the possibility that introducing a study, or a study dressing, reduces the rate of measured SSI through observer bias or through bias of the study participant (the so-called Hawthorne effect[23,24]). However, although the subjective aspects of the ASEPSIS scoring system were undertaken by a study clinician, treatment for infection, antibiotic use, and infection recorded in the patient case notes were contemporaneous and were recorded by the patients' main care team. Patient reported outcomes were not included in the final analysis. Study follow-up, at 5–7 days and 30 days, was standardised across both cohorts; therefore, any Hawthorne effect should be seen in both groups.

A further source of bias was the lack of blinding. Leukomed Sorbact, the DACC-coated dressing in the study, contains a green coloring to the wound contact layer to identify it has a DACC-coated dressing (shown in Figure 1). Because of this, blinding is difficult, although not impossible to achieve in any trial studying its effects, leading to the open label nature of this study. Future randomised studies into DACC-coated dressings should make use of a wound assessor that is blind

to the dressing type used, after removing and disposing of dressings in opaque bags.

Conclusion

SSI is a significant problem, which is likely to rise as increasing numbers of surgical procedures are performed in an aging and comorbid population. Results reported from this study support a growing body of evidence, including a recent systematic review[25] that DACC-coated hydrophobic dressings have effects in preventing SSI in a number of different patient groups and may have a significant role in future surgical wound management. However, an adequately powered randomised controlled trial comparing DACC-coated and conventional dressings is warranted and is now in preparation to provide the robust evidence essential before this technology being adopted into routine practice.

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