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ORIGINAL ARTICLE

The use of a surgical incision management system on vascular surgery incisions: a pilot study

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Key words
SIM; Surgical incision management; Surgical site infection; Vascular surgery

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Abstract

Health care-associated infections in hospitals, including surgical site infections, contribute significantly to morbidity as well as mortality. Surgical incision management (SIM) using negative pressure wound therapy (Prevena™ Incision Management System, Kinetic Concepts, Inc., San Antonio, TX, USA) is designed to cover and protect closed surgical incisions from external factors including infectious sources and local trauma, while negative pressure removes fluid and infectious material from the surgical incision. A prospective case-control study assessed wound complications in patients undergoing vascular bypass procedures, where both femoral areas were incised to gain access to the femoral arteries. SIM was placed on one femoral area while a standard postoperative wound dressing was placed on the contralateral femoral area. Eight patients were included in this pilot study. All of them required bilateral femoral artery access. During the follow-up period patients were monitored for wound complications. All wound complications requiring surgical intervention were considered significant. No significant wound complications occurred in wounds treated with SIM, compared with three significant complications in control wounds. These preliminary data would suggest a potential reduction in wound complications and no observed increase in haemorrhage in high-risk patients with severe co-morbidities undergoing vascular surgery.

Introduction

Health care-associated infections in hospitals contribute significantly to morbidity as well as mortality. In American hospitals alone, the Centers for Disease Control and Prevention (CDC) estimates that health care-associated infections account for an estimated 1·7 million infections and 99 000 associated deaths each year. Of these infections, 17–22% are surgical site infections (SSIs) (1–4).

Surgical incision management (SIM; Prevena™ Incision Management System, Kinetic Concepts, Inc., San Antonio, TX, USA) was introduced to the South African market in 2010. This topical negative pressure system showed potential for use in the context of patients and procedures where an increased risk of complications exists.

A prospective case-control pilot study was designed to evaluate wound complications in patients undergoing vascular bypass procedures, where both femoral areas were incised to gain access to the femoral arteries. The intent was to establish whether SIM would be effective in preventing wound complications and whether it was safe to use in this patient population.

Key Messages

- this prospective case-control study assessed wound complications in patients undergoing vascular bypass procedures, in which both femoral areas were incised to gain access to the femoral arteries
- no significant wound complications (i.e. those requiring surgery) occurred in wounds treated with surgical incision management, compared with three significant complications in control wounds
- these preliminary data would suggest a potential reduction in wound complications and no observed increase in haemorrhage in high-risk patients with severe co-morbidities undergoing vascular surgery

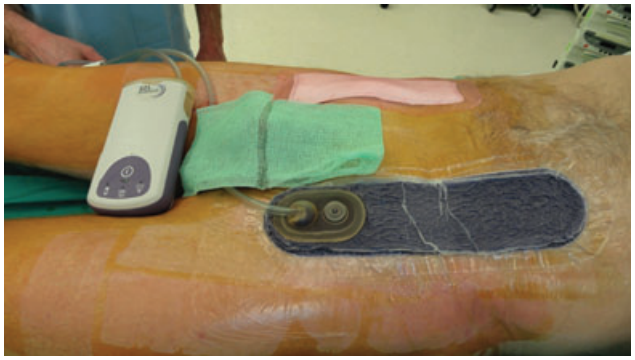

Figure 1 Surgical incision management dressing on left femoral area and highly absorbent postoperative dressing on right femoral area after femoro-femoral bypass.

Methods

Surgical incision management

SIM covers and protects the surgical incision from external factors including infectious sources and local trauma, while negative pressure removes fluid and infectious material from the surgical incision. The manufacturer designed this topical negative pressure system to:

- Create an environment that helps to hold the incision edges together.
- Protect the incision site from external infectious sources.
- Remove fluids and infectious materials from the surgical site.

The resulting system is a battery-powered, lightweight, portable device for single-patient use (Figure 1). The system is preset to −125 mmHg and has a canister with a maximum volume of 45 ml.

The dressing was designed to be a self-adhesive, peel-and-place dressing (Figure 1). This integrated one-piece dressing was designed for use over the surgical incision and surrounding intact skin and conforms to patient contours.

Study design

This prospective case-control study was designed to assess the outcome of wound complications in patients undergoing vascular bypass procedures, where both femoral areas were incised to gain access to the femoral arteries. SIM was placed on one femoral area, while a standard postoperative wound dressing was placed on the contralateral femoral area (Figure 1). In an attempt to avoid selection bias, SIM was placed on the side considered to have had increased haemorrhage during the procedure.

All patients undergoing procedures in which bilateral femoral artery access was created were included concurrently in this single-center, single-surgeon pilot study. All patients gave informed consent prior to the study.

All patients were exposed to the same pre-operative preparation, including prophylactic antibiotics (Cefazolin 1 g before surgery as well as 8 and 16 hours after the procedure). All of these procedures were done under general anaesthesia with the same prophylactic measures. Intravenous unfractionated heparin was given to all patients at a dose of 100 U/kg. All of the patients received protamine after completion of the anastomoses, to partially reverse the effect of the heparin. The incisions were all longitudinal, to allow adequate arterial access as per the surgeon's preference.

Table 1 Patient co-morbidities

Co-morbidities	Number (%)
Diabetes	2 (37·5%)
Smoking within 6 weeks prior to surgery	6 (75·0%)
Obesity	4 (50%)
HIV/AIDS	1 (12·5%)
Hypertension	6 (75·0%)
Hypercholesterolaemia	6 (75·0%)

AIDS, acquired immunodeficiency syndrome; HIV, human immunodeficiency virus.

Table 2 Surgical procedures performed

Surgical procedure	Number (%)
Femoro-femoral bypass	4 (50%)
Femoro-femoral bypass plus femoro-popliteal bypass	1 (12·5%)
Aorta-uni-iliac endovascular abdominal aortic aneurysm repair plus femoro-femoral bypass	3 (37·5%)

Results

The results are only preliminary findings of an on-going pilot study and should be interpreted as such. At the time of writing, eight patients were included in this study. None of the patients were excluded or refused inclusion. Table 1 summarises patient co-morbidities. The average patient age was 71 years (range: 51–80 years). One female and seven males were included. The average postoperative follow-up was 8 months (range: 3–11 months). Surgical procedures (Table 2) included femoro-femoral bypasses as well as aorta-uni-iliac endovascular abdominal aortic aneurysm repairs, with femoro-femoral bypasses. The median theatre time was 112 minutes.

Seven of the eight patients were placed on anticoagulation in the form of warfarin during the postoperative period. The warfarin dose was prescribed to maintain an international normalized ratio (INR) between 2·0 and 3·0. One patient was continued on clopidogrel (Plavix®, Sanofi Aventis, Bridgewater, NJ) 75 mg because of a drug-eluting coronary stent that was placed 4 months earlier. In this study, risk factors for wound complications included obesity, active smoking and diabetes. At least one of these factors was found in all the patients included in the study. The number and types of wound complications by treatment group are listed in Table 3. Initial concerns regarding the increased risk of haemorrhage in this subset of patients undergoing vascular surgery with intra-operative heparin and postoperative anticoagulation were not clinically justified.

Table 3 Wound complications

Complication	Standard post-op dressing	SIM
None	5	6
Small haematoma managed conservatively	0	1
Supericial wound necrosis managed conservatively	0	1
Seroma requiring surgery	2	0
Deep wound necrosis requiring surgery	1	0

SIM, surgical incision management (Prevena™ Incision Management System).

Discussion

Wound complications, especially SSIs, continue to be a significant cause of morbidity and mortality. Various attempts have been made to reduce the incidence of SSIs but, in spite of these measures, no major advances have been made.

As mentioned in the introduction, the CDC estimates that health care-associated infections account for an estimated 1·7 million infections and 99 000 associated deaths each year in the USA. Of these infections, 17–22% are SSIs. Certain surgical procedures and patient conditions can create difficulties in optimal incision healing, which could lead to postoperative wound infection, dehiscence, seromas, haematomas and/or additional surgeries. High-risk surgical procedure incision types include sternotomies, caesarean sections, open hysterectomies, hip and knee arthroplasties, traumatic wounds such as tibia fractures and lower extremity bypasses.

Patients with multiple co-morbidities, such as diabetes, obesity, smoking and ischaemia, are at higher risk of surgical site complications, including SSI, dehiscence and seroma or haematoma formation. SSIs and dehiscences can lead to delayed healing rates, increased direct medical costs such as longer hospital stays and additional surgeries, increased indirect costs such as loss of productivity by the patient and family members, and decreased patient satisfaction and quality of life.

The preliminary results of this case-control study demonstrated a potential advantage in those wounds where SIM was applied. None of the studied wounds, on which SIM was applied, required secondary surgery. One wound developed a small haematoma and another developed superficial wound necrosis a week after the SIM system was removed. Three of the control wounds required surgical intervention. This is admittedly higher than the expected incidence of wound complications in the average patient population undergoing procedures of this nature; however, a formal study would require more patients and multiple surgeons in multiple centres.

This study did not attempt to assess the cost-effectiveness of topical negative pressure in vascular surgery wounds. Further analysis of wound complications in this specific subgroup of patients in our socio-economic setting will be done.

The author would like to stress that this article reflects only the preliminary results of an on-going study and should be interpreted as such. More intensive investigation is required before one can unequivocally state that SIM reduces the incidence of SSIs. These preliminary data suggest a potential reduction in wound complications and no observed increase in haemorrhage in high-risk patients undergoing vascular surgery.

Conflicts of Interest

Dr. GW presented as a faculty member during the 2013 International Surgical Wound Forum (ISWF), an annual educational event sponsored by Kinetic Concepts, Inc. (KCI). His article is part of a KCI-funded educational supplement based on 2013 ISWF faculty presentations about wound care strategies using negative pressure wound therapy (V.A.C.® Therapy and Prevena™ Incision Management System) over closed surgical incisions and negative pressure therapy (V.A.C.® Abdominal Dressing System and ABThera™ Open Abdomen Negative Pressure Therapy) to treat the open abdomen. KCI assisted with editorial review of the manuscript. The study reported in this article was made possible by an unrestricted grant by KCI Medical South Africa. The study design and results were not influenced by the sponsors. The author received no funding for this study other than the materials provided by KCI. A donation was made to the Wound Healing Association of Southern Africa (www.whasa.org), a registered non-profit organisation, by KCI International.

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