Experience with a new negative pressure incision management system in prevention of groin wound infection in vascular surgery patients

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Objective: Groin wound infection is an important cause of postoperative morbidity in vascular surgery patients, especially when prosthetic grafts are involved. The objective of this study was to investigate if Prevena (Kinetic Concepts, Inc, San Antonio, Tex), a negative pressure incision management system, could reduce the risk of groin wound infection in patients after vascular surgery.

Methods: Ninety patients (115 groin incisions) underwent longitudinal or transverse femoral cutdown for vascular procedures. A retrospective chart review was performed on 63 consecutive incisions in patients in the non-Prevena group from December 2009 to November 2010 and on 52 consecutive incisions in patients in the Prevena group from January 2011 to December 2011. Prevena was applied intraoperatively and removed 5 to 7 days postoperatively. The non-Prevena group received either a skin adhesive or absorbent dressing. Groin incisions were assessed, and infection was graded based on Szilagyi classifications. Student t-test and two-sample proportion z test were used for statistical analyses. A P value < .05 was considered statistically significant.

Results: Comorbidities and known risk factors for infection were compared; there were no statistically significant differences between the two groups. Prosthetic material was used in 54 (65%) incisions in the Prevena group and 29 (46%) incisions in the non-Prevena group. Fifty (96%) incisions within the Prevena group and 60 (96%) in the non-Prevena group were classified as clean surgical wounds. Wounds were evaluated at 7 days and 30 days postoperatively. Of 63 groin incisions in 49 patients in the non-Prevena group, 19 (30%) incisions had groin wound infections. Wound infections were classified into Szilagyi grade I (10; 16%), Szilagyi grade II (7; 11%), and Szilagyi grade III (2; 3%). Of 52 groin incisions in 41 patients in the Prevena group, three (6%) incisions had Szilagyi grade I wound infections. No grade II or III infections occurred in this group. Overall incidence of infection between the two groups was statistically significant (P = .0011).

Conclusions: In this clinical study, Prevena negative pressure dressing significantly decreased the incidence of groin wound infection in patients after vascular surgery. (J Vasc Surg 2013;57:791-5.)

The incidence of surgical site infections (SSIs) at the groin after vascular procedures is 3% to 44%.1,8 This reported incidence is up to five times higher than the expected incidence of infection in clean cases as predicted by the U.S. Centers for Disease Control and Prevention National Nosocomial Infections Surveillance System.9 Factors contributing to increased incidence of SSIs in this subset of patients include disruption of lymphatics, proximity of the groin to the perineum, and prosthetic graft placement.1,10 Morbidity associated with infection includes limb loss, sepsis, prolonged hospital stay, and increased mortality. There is no “gold standard” for treatment of these infections. Multiple treatment modalities have been attempted with limited success and increased health care costs, including rotational flaps, wound vacuum-assisted closure, and excision of prostheses with extra-anatomic bypass. Standard infection prevention measures such as preoperative antibiotics have significantly decreased SSIs. However, even when combined with other preventive techniques, such as oblique incisions, use of antibiotic-impregnated grafts, meticulous wound closure, and closed suction drain placement, wound infection rates in this subset of patients remain substantially higher than the accepted norm for clean cases.7,11 Because most bacterial infections occur from direct spread of bacteria from the wound, prevention must be given just as much importance as treatment.11 The aim of this study was to investigate if a new negative pressure incision management system, Prevena (Kinetic Concepts, Inc, San Antonio, Tex), could reduce the incidence of groin wound infections after vascular surgery.

METHODS

This study was approved by institutional review committee at Louisiana State University Health Sciences Center.
Center—Shreveport, and informed consent was waived. We retrospectively studied the charts of 90 consecutive patients (115 groin incisions) who underwent femoral cutdown for vascular procedures. The patient population was divided into a “Prevena group” and a “non-Prevena group.” From December 2009 to November 2010, 63 consecutive incisions in the non-Prevena group were reviewed, and 52 consecutive incisions were reviewed in the Prevena group from January 2011 to December 2011. In the non-Prevena group, skin was covered using Primapore (Smith & Nephew UK, London, UK), which was removed 3 days postoperatively, or Dermabond Adhesive (Ethicon Inc, Somerville, NJ). In the Prevena group, Prevena was applied intraoperatively under sterile conditions (Fig) and removed 5 to 7 days postoperatively. Patients underwent preoperative hair clipping and were prepared with iodophor (DuraPrep; 3M, St. Paul, Minn) or povidone-iodine (Betadine; Purdue Products L.P., Stamford, Conn) for pre-existing open wounds or chlorhexidine in iodine-allergic patients. Patients received cefazolin, or clindamycin if allergic to penicillin, 30 minutes before incisions. In the patients who had been receiving antibiotics for lower extremity open wound infection or sepsis at the time of the vascular procedure, therapeutic antibiotic doses were given again within 1 hour of skin incision. The orientation of the incision was based on the site of vascular access. All incisions were reaproximated in three layers of running polyglactin 910 suture (Vicryl; Ethicon Inc, Somerville, NJ) for subcutaneous tissue, and skin was closed in a subcuticular fashion with poliglecaprone 25 (Monocryl; Ethicon Inc). After closure, incisions and surrounding skin were clean and dried with sterile gauzes. The Prevena dressing was placed by covering the incision with the foam bolster in the center and then surrounding adhesive dressing to intact skin. Negative pressure was applied, and a complete seal was confirmed.

Attending physicians evaluated wound appearance on postoperative day 5 to 7 and at 1-month follow-up or sooner if patients presented with symptoms or signs of wound infection (mean follow-up was 7 days and 33 days in the Prevena group and 10 days and 40 days in the non-Prevena group). Groin wound infection in both groups was graded according to the Szilagyi grading system. Incidences of infection with different grades were recorded and analyzed.

All patients who underwent longitudinal or transverse incisions for groin cutdown were eligible for inclusion in this study. Patients who could not have Prevena placed because of the inability to obtain a seal were excluded. Two morbidly obese patients were excluded because a complete seal with Prevena dressing could not be achieved owing to the patients’ giant pannus.

Szilagyi classification was used to describe SSIs.12 Grade I infections had only dermal involvement. Grade II infections extended to the subcutaneous region but did not involve the arterial graft. Infection that involved the arterial graft was grade III. If a patient presented initially with a lower grade of infection but then developed a higher grade because of failure of medical or surgical treatment, the patient was placed into the higher category. Localized infection was defined as acute or chronic ipsilateral lower extremity infection occurring before vascular surgery. Renal insufficiency was defined as glomerular filtration rate <50, and anemia was defined as hemoglobin <12 g/dL.

Student t-test and two-sample proportion z test were used for statistical analyses. A P value <.05 was considered statistically significant.

RESULTS

Comorbidities such as diabetes and coronary artery disease and other known risk factors for infection such as cigarette smoking and body mass index were compared between the two groups, and there was no statistically significant difference (Table I). No patients required hemodialysis or peritoneal dialysis. Prosthetic material was used in 34 incisions (65%) in the Prevena group and 29 incisions (46%) in the non-Prevena group. Prosthetic material was subdivided further into polytetrafluoroethylene or polyethylene terephthalate (Dacron) (Table II). In the Prevena group, 40 incisions (77%) were longitudinal, and 12 incisions (23%) were transverse. In the non-Prevena group, 47 incisions (75%) were longitudinal, and 16 incisions (25%) were transverse. There was no statistically significant difference in the incision types of longitudinal vs transverse between the two groups. Of the 22 infected incisions in both groups, 16 incisions were longitudinal and six were transverse.

Groin exposure was performed for revascularization, endovascular, or other vascular procedures (Table II). The number of patients with a history of revascularization or amputation was greater in the Prevena group (17; 41%) compared with the non-Prevena group (12; 24%), but this was not statistically significant (P = .0844). The presence of a localized or systemic infection at the time of operation was not statistically significant between the two groups. Perioperative risk factors were compared as well.
(Table II). In the Prevena group, the mean time for first and second wound evaluation was 7 days and 33 days postoperatively vs 10 days and 40 days postoperatively in the non-Prevena group. In the non-Prevena group, seven incisions healed without evidence of infection at 1-week follow-up. These patients reported no problem with healing and did not return to the clinic for the second wound evaluation. In the non-Prevena group, wound infection was diagnosed 3 to 20 days (mean, 11.8 days) postoperatively. In the Prevena group, timing of infection was 5 to 12 days (mean, 9 days) postoperatively.

Total infection rates were 30% (19/63) in the non-Prevena group and 6% (3/52) in the Prevena group (Table III). Of the 19 (30%) patients with infected incisions in the non-Prevena group, 10 (16%) developed Szilagyi grade I infection, seven (11%) developed grade II infection, and two (3%) developed grade III infection. Patients with grade III infection subsequently underwent excision of the infected graft with extra-anatomic bypass. One of those patients eventually required an amputation.

In the non-Prevena group, eight incisions were redo incisions with previous ipsilateral femoral cutdown. Two patients developed grade I infection, one developed grade II infection, and one developed grade III infection. Among seven redo incisions in the Prevena group, one patient developed grade I infection; there were no grade II or III infections.

In the Prevena group, 3 to 10 mL of fluid was recovered in the tubing and canisters from 37 (71%) of the incisions. In the remaining 15 (29%) incisions, no fluid was drained out, and three of these patients developed Szilagyi grade I infection. All three patients were successfully treated with a 7-day course of oral antibiotics. No grade II or III infections occurred in this group. The Prevena group had a statistically significantly lower incidence of groin wound infection ($P = .001$). The incidence of grade I and III infections was lower in the Prevena group, although this was not statistically significant (Table III); this may be due to type II statistical error from relatively small samples. No deaths occurred in either group.

**DISCUSSION**

An SSI at the groin in a patient after a vascular procedure can have a disastrous outcome leading to limb loss and death. Groin incisions are prone to complications...
including infection, wound dehiscence, lymphatic leaks, and hematomas. Prevention of SSIs is just as important as and much more cost-effective than treatment. On average, SSIs increase hospital stay by 9.7 days and increase cost by approximately $20,842 per admission. A single Prevena unit cost is $495; although this is significantly greater than other dressings, the use of Provena may potentially save on in-hospital stay cost and treatment of infection. In this study, total cost of 52 Prevena units was $25,740. However, no patient needed an extended hospital stay, and only three patients received oral antibiotics for 1 week. In the non-Prevena group, two patients with Szilagyi grade III wound infections required long hospitalization with a cost >$45,000. This figure does not include the cost of seven grade II and 10 grade I SSIs.

Many authors have studied vascular groin site infection and how to prevent them. Stewart et al performed a meta-analysis of 34 randomized controlled trials to determine the effectiveness of perioperative strategies in preventing infection in patients undergoing peripheral arterial reconstruction. These investigators concluded that although there was clear evidence supporting prophylactic antibiotics for vascular reconstruction, their data did not support the effectiveness of other preventive techniques, such as rifampin-bonded grafts, preoperative skin antisepsis, suction wound drainage, minimally invasive in situ bypass techniques, intraoperative glove change, and different wound closure techniques. Our study patients routinely received perioperative antibiotics. Aside from an increased incidence of renal insufficiency in the Prevena group, there were no significant differences between the two patient groups, and we found that placement of a negative pressure wound management system resulted in a statistically significantly lower incidence of infection overall.

Easterlin et al reported that a drawback of sutures and staples is that they are tensioning devices, which concentrate the spreading force to small points along the incision. These tension points may result in ischemia and possibly necrosis of the tissue. The rationale of a negative pressure dressing includes holding incision edges together, protecting the incision from external infectious sources, and removing fluid and infectious materials from the surgical site. Prevena application adds approximately 10 minutes of intraoperative time, which was not statistically significant in this study. Although there are other negative pressure wound management systems currently in use, Prevena differs from these because the interface layer is a polyester knit fabric that performs the same functions as a nonadhering dressing in that it protects the skin from contact with the foam bolster, while allowing delivery of negative pressure and fluid removal. Current negative pressure wound management systems do not have this barrier between the wound and the foam bolster.

We believe that the lower incidence of wound infection with Prevena is multifactorial. Not only does Prevena decrease lateral tension on the wound and act as a dressing to provide a sterile environment for wound healing, but also the negative pressure may decrease lymphocele formation (as lymphatics are often transected during this type of incision), which prevents skin edges from becoming macerated, promoting epithelialization. Patients were noted to have 0 to 10 mL of fluid in the Prevena tubing and canister at the time of removal. In our three patients in the Prevena group who presented with Szilagyi I infections, all had 0 mL output in the Prevena canister. Prevena dressings in these patients were functioning properly. Absence of fluid in the tubing or canister may be due to tight wound closure. In addition, the presence of fluid in the foam bolster was difficult to quantify, but we knew that it was present because fluid droplets accumulated throughout the polyurethane shell encapsulating the foam bolster. Simple placement of an occlusive dressing may contribute to decreased groin wound infection. However, most of the incisions (71%) in the Prevena group had 3 to 10 mL of collectable fluid sucked out. Removing even a small amount of proinflammatory fluid and decreasing wound edema may prove to be beneficial. Based on our limited data, it cannot be suggested that absence of fluid in the tubing or canisters of Prevena is associated with incision infection. Further investigation is needed to draw this conclusion. A randomized prospective clinical trial comparing simple occlusive dressing with the Prevena negative pressure wound management system would be valuable.

CONCLUSIONS

Overall, Prevena negative pressure dressing combined with standard perioperative infection prevention significantly decreases the incidence of groin SSIs in patients undergoing vascular procedures.

AUTHOR CONTRIBUTIONS

Conception and design: KR, TM, WZ
Analysis and interpretation: KR, TM, LD, CZ, WZ
Data collection: KR, TM, LD, WZ
Writing the article: KR, TM, WZ
Critical revision of the article: KR, TM, WZ
Final approval of the article: WZ
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