Closed-incision negative-pressure therapy in high-risk general surgery patients following laparotomy: a retrospective study

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Abstract

Aim Surgical site infection (SSI) and wound dehiscence are dreaded complications following laparotomy in general surgical patients, and can potentially occur more often in various comorbid states. Negative-pressure wound therapy (NPWT) has a positive effect of on open and complicated wounds and so has been used for at-risk surgical incisions with the aim of redistributing lateral tension and holding incision edges together. The aim of the present study was to compare the rate of wound complications following laparotomy in high-risk general surgical patients with a clean incision treated with closed-incision negative-pressure therapy (ciNPT) with those receiving conventional care.

Method A retrospective review was performed of the hospital medical records of patients who underwent laparotomy between 1 October 2010 and 31 March 2012. Records of 69 patients who received ciNPT and 112 who were managed by adherent gauze dressings were included in the final analysis.

Results Two (2.9%) patients in the ciNPT group and 23 (20.5%) in the non-NPWT group developed a wound complication following laparotomy ($P < 0.0009$). The relative risk (RR) was 0.14 (0.03–0.58), suggesting that infection is less likely to occur in ciNPT-treated incisions, compared with gauze dressings.

Conclusion ciNPT was associated with a positive clinical outcome and was a safe and effective method of postsurgical management in our general surgery patients considered to have risk of developing wound complications following laparotomy.

Keywords Closed incision, negative-pressure therapy, general surgery, laparotomy, high risk

Introduction

Wound complications after laparotomy in general surgical patients are common and are of particular concern in patients undergoing colorectal surgery owing to the high incidence of surgical site infection (SSI), reported to be as much as 45% [1,2]. Even following elective colorectal surgery, the average rate of SSI is approximately 10%, ranging from 3% to 30% [3]. In a review of the commercial health insurance records of more than 10,000 colorectal surgery patients, Wick et al. [4] reported readmission rates of 11.4% at 30 days and 23.3% at 90 days with a 30-day SSI rate of 18.8%. The mean length of stay of the readmission was 8 days, and the median cost per SSI readmission was $12,835 [4]. Interventions that reduce rates of SSI are therefore likely to reduce length of stay and cost.

Certain comorbid conditions are known to potentially increase the risk of surgical wound complications, including obesity, malignancy, immunosuppression, emergency surgery, malnutrition, tobacco use and diffuse atherosclerosis [5]. Management of complicated wounds not only increases hospital stay and cost but can also cause psychological trauma to the patient and surgeon. The use of negative-pressure wound therapy (NPWT) has increased greatly since its introduction in 1996. NPWT has mostly been used to manage acute or...
chronic open wounds through such mechanisms as protection of the wound bed, splinting of soft tissues, reduction of oedema, increased perfusion and enhanced formation of granulation tissue [6,7].

The application of NPWT to clean, closed incisions is a newer concept. An elongated dressing, via a dedicated closed-incision negative-pressure therapy (ciNPT) system (PREVENA™ Incisional Management System; KCI, an ACELITY company, San Antonio, Texas, USA), is applied to the closed incision with several aims, including holding the incision edges together, redistributing lateral tension, reducing oedema and protecting the surgical site from external sources of infection [8]. A growing body of literature has reported the benefits of NPWT over closed incisions to help reduce complications in high-risk groups [9–11], but there is little comparative evidence for the use of ciNPT in acute incisions of general or colorectal surgical patients considered to be at high risk of wound complications secondary to comorbidity. The aim of the present study was to compare the rate of wound complications, including wound dehiscence or deep infection requiring intervention, following laparotomy in high-risk general surgical patients with clean, closed incisions treated with ciNPT or with conventional care.

Method

The medical records of adult patients over 18 years who underwent a midline laparotomy in a general surgical ward between 1 October 2010 and 31 March 2012 were retrospectively reviewed. Patients were included if they had a body mass index (BMI) greater than 35 kg/m² or two or more of the following risk factors: malignancy, history of smoking, immunosuppression, malnutrition, emergency surgery and diffuse atherosclerotic disease. Patients who did not meet the inclusion criteria were excluded from analysis.

A closed-incision negative-pressure therapy (NPT) system (PREVENA™ Incision Management System) was applied in the operating room, immediately after skin closure. A ‘peel and place’ dressing (PREVENA™ PEEL & PLACE™ Dressing, KCI) was used for a standard laparotomy incision (Fig. 1) and a ‘customizable’ dressing (PREVENA™ CUSTOMIZABLE™ Dressing, KCI) was used for more complex incisions (Fig. 2). Pressure was applied continuously at –125 mmHg for 7 days in hospital. The dressing was removed on the seventh postoperative day, the condition of the incision line was noted and, if indicated, the patient was discharged. All patients were followed for 30 days after surgery.

Deep incisional wound infection or dehiscence seen on clinical examination was recorded during a 30-day follow-up period. Any wound infection requiring intervention was noted, such as removal of sutures or clips, drainage of deep pus, packing or standard NPWT (V.A.C.® Negative Pressure Wound Therapy, KCI). Skin dehiscence or separation of the wound edges was also recorded. All ciNPT systems were applied and followed by one surgeon. The complication rate after ciNPT was compared with that of high-risk patients with a closed incision managed conventionally by adherent gauze dressings during the same period of time, controlling for the following covariates: age, BMI, smoking, diabetes, malignancy, emergency surgery and atherosclerosis.

Statistical analysis

Baseline demographics and complication results are all binary variables and are reported as count and percent-age. Statistical analysis was performed using MedCalc® version 15.10 (Medcalc Software bvba, Ostend, Belgium). Proportions of the two groups were compared using the chi-square test. The relative risk (RR) and 95% confidence interval (CI) were calculated according to Altman [12]. A P-value of less than 0.05 was considered significant.
Results

During the study period, 317 patients underwent emergency and elective general and colorectal surgery. Of these, 136 were excluded because they were considered to be at low risk of wound complications. All 136 excluded patients received adherent gauze dressings and none received ciNPT. Of the remaining 181 patients included in the analysis, 69 received ciNPT and 112 adherent gauze dressings. All the 69 who received ciNPT were treated by one surgeon, and the other 112 were treated by two other surgeons in the same department. Most patients in both groups were admitted for a major open colorectal resection. The wounds were clean-contaminated or contaminated in all patients, as they underwent colorectal elective or emergency surgery. The number of patients in each grade was not analysed.

There were no significant differences in patient demographics between the two groups (Table 1). Two (2.9%) patients in the ciNPT group developed a wound complication (one skin dehiscence and one deep infection requiring standard NPWT), compared with 23 (20.5%) in the control group ($P < 0.0009$) (Table 2). One ciNPT patient with Crohn’s disease who was on immunosuppressive medication developed wound dehiscence after removal of the skin staples at 7 days postoperatively and required re-suturing. The second complication occurred in a ciNPT patient with a high BMI who underwent Hartmann’s procedure to treat generalized peritonitis secondary to perforated diverticulitis. The patient subsequently developed a deep incisional infection that required standard NPWT for 2 weeks followed by the insertion of secondary sutures. All the wound complications in the control group were in the form of deep infection. The RR of a wound complication in the ciNPT group was 0.14 (95% CI 0.03–0.58) compared with the controls. The odds ratio (OR) was 0.12 (95% CI 0.03–0.51).

Discussion

Retrospective analysis of patients at risk of a postoperative wound complication showed that the incidence of dehiscence or deep infection was significantly lower in ciNPT-treated incisions than conventionally treated

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Table 1 Patient demographics.

| Risk factors         | ciNPT ($n = 69$) | Control ($n = 112$) | $P$-value |
|----------------------|------------------|---------------------|-----------|
| BMI $>$ 35 kg/m², n (%) | 29 (42.0)        | 37 (33.0)           | 0.1442    |
| Malignancy, n (%)    | 28 (40.6)        | 41 (36.6)           | 0.3522    |
| Emergency surgery, n (%) | 21 (30.4)        | 30 (26.8)           | 0.3576    |
| Atherosclerosis, n (%) | 18 (26.1)        | 20 (17.9)           | 0.1290    |
| Smoker, n (%)        | 6 (8.7)          | 18 (16.1)           | 0.3710    |
| Diabetes mellitus, n (%) | 5 (7.2)         | 12 (10.7)           | 0.3086    |

ciNPT, closed-incision negative-pressure therapy; BMI, body mass index.

Table 2 Study results.

|                      | ciNPT ($n = 69$) | Control ($n = 112$) | $P$-value | Relative risk (95% CI) |
|----------------------|------------------|---------------------|-----------|------------------------|
| Skin wound dehiscence, n (%) | 1 (1.4)         | 0 (0)               | <0.2105   | 4.84 (0.20–117.24)     |
| Deep Incisional Infection, n (%) | 1 (1.4)        | 23 (20.5)          | <0.0002   | 0.07 (0.0097–0.51)     |
| Total complications, n (%)       | 2 (2.9)         | 23 (20.5)         | <0.0009   | 0.14 (0.03–0.58)       |

ciNPT, closed-incision negative-pressure therapy.
incisions. In the study, patients were considered to be at high risk based on well-known patient-related risk factors for SSI. Other recognized risk factors including blood transfusion, stoma formation, type of operation, use of drainage, male gender and performance of the surgeon [13] were not considered in this study.

The results support the findings of Bonds et al, who recently evaluated the effect of known risk factors and the use of ciNPT on SSI rates in patients having an open colectomy [14]. SSI was reported in 4 (12.5%) of 32 patients and 65 (29.3%) of 222 managed by a standard occlusive dressing. The authors concluded that the use of incisional NPWT significantly decreased the chance of SSI [odds ratio (OR) 0.32, \( P < 0.05 \)] whereas the respective ORs for SSI in diabetes mellitus and obesity were 1.98 (\( P < 0.05 \)) and 1.64 (\( P = 0.10 \)), respectively [14].

Colorectal resection has unusually high rates of SSI owing to the inherently contaminated intraluminal environment [15]. ciNPT may diminish the risk of external wound contamination, since the dressing is sealed and applied in a sterile environment. It is also well known that a reduced rate of SSI is one of the benefits of laparoscopic compared with open colorectal surgery, but, since ciNPT was used only in patients with a high-risk laparotomy wound incision it was not possible to study its effects in laparoscopic cases.

Typically, ciNPT dressings do not need to be changed throughout the 7-day duration of therapy; Gomoll and colleagues reported that the decreased frequency of dressing change is especially advantageous in obese patients or in patients with difficult-to-access incisions [16]. A patient’s closed incision line during ciNPT and 7 days later at dressing removal following total colectomy with ileostomy is shown in Fig. 3.

Application of ciNPT has generally been associated with safe administration and a low risk of side effects for patients with cardiothoracic, vascular, gynaecological, general, traumatic, plastic, oncological and orthopaedic incisions [11,17–24]. There is consensus that intact skin should not be exposed to polyurethane foam because the foam can excoriate and blister the tissue [21]. A nonadherent layer is recommended between the foam and the incision [16]. The authors know of no other complications that have been reported with ciNPT.

Reduced rates of complications observed in our patient population with use of ciNPT would appear to translate to overall cost savings at our institution, but controlled research is required to determine real cost savings. Based on anecdotal experience, the authors believe that the cost of ciNPT is more justified for high-risk laparotomy patients, and the therapy is not used in patients at low risk for SSI. However, future controlled cost analyses are needed to determine the actual cost effectiveness of ciNPT in low- and high-risk laparotomy patients.

To the authors’ knowledge, this study comprises the highest number of high-risk general surgery patients treated with ciNPT to be evaluated in a comparative study to date. Our results are encouraging, but controlled prospective data are needed to determine the patient and wound characteristics that would most benefit from this therapy. Weaknesses of this study include inherent limitations of a retrospective analysis, such as patient selection bias, differences in surgical technique between surgeons and potential flaws in record keeping. Despite these limitations, this study demonstrates safety and potentially beneficial effects of ciNPT in limiting

![Figure 3](image_url) (a) Closed-incision negative-pressure therapy (ciNPT) applied after total colectomy with ileostomy. (b) Closed incision after 7 days of ciNPT.
complications of surgical incision following laparotomy in high-risk surgical patients. Based on our analyses, ciNPT appeared to be a low-risk intervention that may significantly help decrease the morbidity and costs associated with the development of a SSI in high-risk patients. Large, randomized controlled studies appear to be under way [15,25] and are needed to validate the efficacy of ciNPT in this subset of patients.

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