Phase II Randomized Trial of Negative-Pressure Wound Therapy to Decrease Surgical Site Infection in Patients Undergoing Laparotomy for Gastrointestinal, Pancreatic, and Peritoneal Surface Malignancies

Perry Shen, MD, FACS, Aaron U Blackham, MD, Stacey Lewis, RN, BSN, Clancy J Clark, MD, FACS, Russell Howerton, MD, FACS, Harveshp D Mogal, MD, Rebecca M Dodson, MD, Gregory B Russell, MS, Edward A Levine, MD, FACS

BACKGROUND: Surgical site infections (SSIs) remain a major source of morbidity and cost after resection of intra-abdominal malignancies. Negative-pressure wound therapy (NPWT) has been reported to significantly reduce SSIs when applied to the closed laparotomy incision. This article reports the results of a randomized clinical trial examining the effect of NPWT on SSI rates in surgical oncology patients with increased risk for infectious complications.

STUDY DESIGN: From 2012 to 2016, two hundred and sixty-five patients who underwent open resection of intra-abdominal neoplasms were stratified into 3 groups: gastrointestinal (n = 57), pancreas (n = 73), or peritoneal surface (n = 135) malignancy. They were randomized to receive NPWT or standard surgical dressing (SSD) applied to the incision from postoperative days 1 through 4. Primary outcomes of combined incisional (superficial and deep) SSI rates were assessed up to 30 days after surgery.

RESULTS: There were no significant differences in superficial SSIs (12.8% vs 12.9%; $p > 0.99$) or deep SSI (3.0% vs 3.0%; $p > 0.99$) rates between the SSD and NPWT groups, respectively. When stratified by type of surgery, there were still no differences in combined incisional SSI rates for gastrointestinal (25% vs 24%; $p > 0.99$), pancreas (22% vs 22%; $p > 0.99$), and peritoneal surface malignancy (9% vs 9%; $p > 0.99$) patients. When performing univariate and multivariate logistic regression analysis of demographic and operative factors for the development of combined incisional SSI, the only independent predictors were preoperative albumin ($p = 0.0031$) and type of operation ($p = 0.018$).

CONCLUSIONS: Use of NPWT did not significantly reduce incisional SSI rates in patients having open resection of gastrointestinal, pancreatic, or peritoneal surface malignancies. Based on these results, at this time NPWT cannot be recommended as a therapeutic intervention to decrease infectious complications in these patient populations. (J Am Coll Surg 2017;224:726–737. © 2017 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

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From the Department of General Surgery, Section of Surgical Oncology (Shen, Blackham, Clark, Howerton, Mogal, Dodson, Levine), Department of Biostatistical Sciences (Russell), Wake Forest School of Medicine, and Wake Forest Baptist Comprehensive Cancer Center, Wake Forest Baptist Medical Center (Lewis), Winston-Salem, NC.

Correspondence address: Perry Shen, MD, FACS, Department of General Surgery, Section of Surgical Oncology, Wake Forest School of Medicine, Watlington Hall, 5th Floor, Winston-Salem, NC 27157. email: pshen@wakehealth.edu

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Abbreviations and Acronyms

CRS/HIPEC = cytoreductive surgery/hyperthermic intraperitoneal chemotherapy
NPWT = negative-pressure wound therapy
SSD = standard surgical dressing
SSI = surgical site infection

Surgical site infections (SSIs) are the most common cause of nosocomial infection, accounting for 38% of all hospital-acquired infections. Although the overall incidence of SSI is low, developing in 2% to 5% of the more than 30 million patients undergoing surgical procedures each year,[1-3] the highest rates occur after abdominal surgery. Patients undergoing gastrointestinal and hepatopancreatobiliary surgery are reported to have SSI rates ranging from 8% to 15%.[4,5] In addition, patients with cancer who are undergoing surgical procedures have an increased risk of SSIs.[6] The impact of SSIs on the healthcare system is considerable, resulting in increased morbidity and mortality, prolonged hospital stay, and greater financial costs.[7-9] Among patients who die in the postoperative period, death is related directly to SSIs in >75% of cases. Another study found that compared with patients who did not have a postoperative infection, those with SSIs were more than twice as likely to die, 60% more likely to spend time in an ICU, and more than 5 times as likely to be readmitted to the hospital.[10]

Several approaches to decreasing SSI in patients undergoing gastrointestinal surgery have been advocated in the recent literature. Laparoscopic surgery has been reported to reduce SSIs substantially compared with open surgery, based on an analysis of a large administrative database[11] and a systemic review and meta-analysis.[12] Also SSI bundles have been reported to decrease SSI rates in gastrointestinal surgery.[4,13,14] By implementing a set of interventions across the entire surgical episode of care in a multidisciplinary fashion, the rate of superficial SSIs was reduced significantly. Some authors have advocated the inclusion of negative-pressure wound therapy (NPWT) to SSI bundles, based on preliminary evidence of its efficacy in the prevention of SSIs on closed laparotomy incisions.[15]

Negative-pressure wound therapy has traditionally been used for complex open wounds in both acute and chronic care settings.[16] The device consists of an open-pore polyurethane foam that is placed in the wound, covered by a semi-occlusive dressing, and connected by a tube to a vacuum source. Originally developed by Argenta and Morykwas in the 1990s,[17,18] NPWT has revolutionized the treatment of complex wounds, and is currently used not only in the acute care hospital setting, but also increasingly in nursing facilities, home care settings, and internationally.[16] There is a growing body of literature reporting the use of NPWT for closed primary incisions to decrease wound complications[19-23] and specifically closed abdominal laparotomy incisions in general surgery patients,[24-27] including a retrospective case-control series from our own institution.[28] All of these reports suggest NPWT can substantially reduce wound complications and SSIs compared with standard surgical dressing (SSD).

Due to the results of published studies and our own preliminary experience with NPWT for closed laparotomy incisions in high-risk surgical oncology patients, we conducted a phase II randomized clinical trial comparing NPWT with SSD in patients undergoing open resection of gastrointestinal, pancreatic, and peritoneal surface malignancies. Our hypothesis was that NPWT would significantly decrease the incidence of superficial and deep SSIs compared with SSD in surgical oncology patients having abdominal surgery.

METHODS

This study was approved by the Protocol Review Committee of the Wake Forest Baptist Comprehensive Cancer Center and the Wake Forest University Health Sciences IRB. Additional details about the trial can be found at ClinicalTrials.gov (ID: NCT01656044).

Trial design

This was a prospective phase II randomized controlled intervention study assessing differences in SSI rates after using an incisional NPWT dressing compared with a standard postoperative surgical dressing. Patients were stratified by type of surgery (gastrointestinal, pancreatic, or cytoreductive surgery with hyperthermic intraperitoneal chemotherapy [CRS/HIPEC]). Demographic, perioperative, and outcomes data were prospectively collected. Three hundred and seventy-five patients were consented to the study with 265 patients evaluable for analysis. Patients were enrolled on the study from June 2012 to June 2016.

Participants

Eligibility criteria were as follows: age 18 years or older; scheduled for open surgical procedure, which included laparoscopic-assisted cases (consisting of a hand port resulting in an incision of at least 7.5 cm); surgery for bowel resection (esophagus to rectum), pancreatectomy, or CRS/HIPEC for peritoneal surface malignancy; procedure performed via midline laparotomy; clean-contaminated (class II) case; and ability to understand and willingness to sign written informed consent.