ORIGINAL CONTRIBUTION

Barrier Wound Protection Decreases Surgical Site Infection in Open Elective Colorectal Surgery: A Randomized Clinical Trial

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PURPOSE: Surgical site infection following colorectal surgery is a frequent and costly problem. Barrier protection at the time of this form of surgery has been used with varying results. The aim of this randomized study was to examine the efficacy of barrier retractional wound protection in the prevention of surgical site infections in open, elective colorectal surgery.

METHODS: One hundred thirty consecutive patients undergoing open elective colorectal resectional surgery were randomly assigned to have either barrier retractional wound protection or standard wound retraction. Patients were then followed up for a minimum of 30 days postoperatively. The primary end point was surgical site infection as defined by the Centers for Disease Control and Prevention. The secondary end point was performance of the wound protector as assessed by operating surgeons.

RESULTS: There was a significant reduction in the incidence of incisional surgical site infections when the wound protector was used: 3 of 64 (4.7%) vs 15 of 66 (22.7%); $P = .004$. Most surgical site infections were diagnosed after discharge from the hospital (78%), and there was no difference in the rates of reoperation, readmission, or formal wound drainage between the 2 groups. Surgeons found the wound protector to be helpful with retraction during surgery, with 88% (7/8) adopting it as part of their standard setup.

CONCLUSIONS: In this study the use of barrier wound protection in elective open colorectal resectional surgery resulted in a clinically significant reduction in incisional surgical site infections. Barrier wound protection of this nature should be considered routine in this type of surgery.

KEY WORDS: Colectomy; Colorectal surgery; Laparotomy; Surgical wound infection; Wound protector.

Surgical site infection (SSI) is a common and costly complication of colorectal surgery. The incidence of SSI in colorectal surgery is reported to be between 11%[1] and 27%.[2] This figure increases when an independent surgeon–trained observer is used,[3] and where outpatient follow-up is conducted, with as many as 32%[4] to 72%[5] of SSIs being diagnosed after discharge from the hospital.[6] The cost of SSI can be quantified either in terms of increased morbidity and mortality, or as a monetary cost to the health care system. Patients who develop an SSI are likely to spend additional days in the hospital[7] and are more likely to be readmitted to the hospital within 30 days of discharge.[8] The additional cost to the hospital system of an "incisional superficial" SSI following colorectal surgery is approximately UK£2267.[7] There are further additional costs to the patient and the community in terms of loss of productivity, the cost of care, and lost income. These costs are much more difficult to quantify.[9]

The development of an SSI depends on a number of factors best summarized by Altemeier,[10] who proposed

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that the risk of infection can be expressed as: (Dose of bacterial contamination × virulence)/resistance of host. Virulence and host defenses are factors that are difficult to control for and the "dose of bacterial contamination" is the factor over which surgeons have the most control.

The concept of using a physical barrier between surgical work and the wound edges (wound protector) to decrease potential exposure to bacterial contaminants has existed for some time. The results of studies on early "wound protectors" were contradictory,[11–13] regarding their ability to decrease the rate of SSI, as well as their "ease of use."

The Alexis (Applied Medical, Rancho Santa Margarita, CA) wound protector was developed in 2000, with a design that acted as a form of barrier protection, while also retracting wound edges. This wound protector is made up of 2 stiff rings with a cylinder of impervious plastic between the 2 rings. The inner ring is placed in the peritoneal cavity, and the outer ring is placed outside of the abdomen. The outer ring is then rolled over the cylinder of impervious plastic until the plastic becomes taut circumferentially around the wound. The key differences between this protector and previous wound protectors is its ability to reliably provide protection to the whole wound and its ability to be removed easily without spillage into the wound.

At the time of the design of this study there had been no clinical trial to our knowledge to assess the efficacy of this form of retraction in open colorectal surgery. The primary objective of this study was to determine whether this form of barrier protection resulted in a decrease in SSI when used at the time of open colorectal surgery. The secondary objective was to determine the wound protector's ability to assist with retraction.

METHODS

All 8 gastrointestinal surgeons with an appointment at the John Hunter Hospital participated in the study. Consecutive patients were recruited from 4 hospital sites where the participating surgeons worked. All patients older than 18 years scheduled for an elective colorectal resection were eligible to participate in the study. Patients who were cognitively impaired or otherwise unable to give informed consent were excluded from the study. Patients undergoing a laparoscopic colorectal resection were also excluded because of the concern about possible extraction site metastases in the absence of wound protection. The study was conducted over 18 months from January 2007 until June 2008.

The study protocol was approved by the local ethics committee (Hunter New England Human Research Ethics Committee: 06/11/22/5.04) in November 2006. The trial was registered with the Australian New Zealand Clinical Trials Registry: ACTRN12609000020280. The trial was performed by members of the Division of Surgery, John Hunter Hospital, Newcastle, NSW, Australia.

Randomization

Randomization was performed after consent had been obtained and after the patient was anesthetized. Allocation was performed in blocks of 20 by computer-generated sequence allocation and concealment was achieved by use of opaque envelopes opened at surgery by a third party.

Interventions

The demographic details of the participants were collected, and information on comorbidities was recorded. Mechanical bowel preparation was used at the discretion of the treating surgeon and its use was recorded.

All patients received a single dose of intravenous prophylactic antibiotics according to Australian Therapeutic Guidelines[14] (cephazolin 2 g and metronidazole 500 mg) after being anesthetized and before skin incision. A repeat dose of cephazolin was given to patients at 3 hours if their procedure had not been completed. All patients had skin preparation with Betadine, which was left to dry before skin incision.

Ventilation was maintained intraoperatively with 80% oxygen and no nitrous oxide was used. Oxygen was also continually administered for 24 hours postoperatively by nasal prongs. Patient warming devices were used intraoperatively and in the recovery ward (Bair Hugger, Arizant, MN).

In the control group wound retraction was achieved by retractors routinely used by the treating surgeon. Patients in the intervention group had the wound protector placed once the peritoneum was opened and adhesions to the anterior abdominal wall were cleared. Treating surgeons then used extra retraction where required by the retractors of their choice. All patients underwent colorectal resection and anastomoses as per the technique of the treating surgeon.

Wound closure was standardized with mass fascial closure using 1 PDS (Ethicon) followed by a wound washout using warm normal saline and subcuticular skin closure with 3/0 Caprosyn (Covidien). Wounds were dressed with a transparent hydrocolloid dressing (COM feel) that remained in place for 5 days.

All patients were mobilized and given a full fluid diet on day 1 with progression to a selective diet once the fluid diet was tolerated. They were discharged from the hospital when they were mobile, independent in the activities of daily living, and medically fit.

The principal outcome measure was the incidence of superficial or deep SSI occurring within 30 days of surgery, as defined by the Centers for Disease Control and Prevention (CDC).[15] Definition of a surgical site infection as defined by the CDC is as follows: "Any infection of the superficial or deep tissues or the organ/space affected by surgery,

and which occurs within 30 days of surgery when no prosthesis has been implanted."

An infection is defined by the CDC as being the presence of at least one of the following:

1. Purulent drainage, with or without laboratory conformation, from the superficial incision.
2. Organisms isolated from an aseptically obtained culture of fluid from the superficial incision.
3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness *and* superficial incision is deliberately opened by surgeon, *unless* incision is culture-negative.
4. Diagnosis of superficial incisional SSI by the surgeon or attending physician.

All postoperative assessment was performed by one trained observer (KR) who was blind to the allocation and was not a practicing clinician at the institution involved. Wounds were reviewed on day 3, day 5, the day of discharge, and at postsurgery outpatient follow-up by the observer. In addition, antibiotic usage was assessed in the hospital and at outpatient follow-up. Antibiotics were prescribed for SSIs only if there was evidence of systemic sepsis or surrounding cellulitis and the wound was adequately drained or draining. The general practitioners for all of the patients were also notified to determine whether any antibiotics had been prescribed within 30 days of surgery.

Operating surgeons were surveyed about their experiences with the devices at the completion of the study. Surgeons were asked specifically whether they would use the wound protector routinely in the absence of any proven reduction in SSI. They were also asked to clarify the ability of the protector to assist with retraction using a 5-point score as: very unhelpful, unhelpful, no change, helpful, very helpful. A Visual Analog Scale was also filled out by participating surgeons assessing the general assistance in retraction that the wound protector provided (0–10, with 0 representing no assistance and 10 representing best possible assistance).

Statistical Analysis

Before commencement of recruitment for this trial Horiuchi et al[16] published a randomized clinical trial examining the use of the Alexis wound protector in patients undergoing general surgery. A subgroup analysis of colorectal operations within this trial identified a reduction in SSI from 13.4% to 0% when the wound protector was used. On the basis of these data a power calculation was performed; to identify a reduction from 13% to 0% (80% test power and α level of 0.05), 56 patients were required in each arm. Allowing for a loss to follow-up of approximately 15%, a total sample size of 132 patients was chosen.

Patients were evaluated according to intention-to-treat principles. Fisher exact probability test was used for categorical baseline data, whereas the comparison between noncategorical baseline data was with the Student *t* test. Comparison was made between SSIs using the Fisher exact probability test. Statistical analysis was performed using Minitab 14 Statistical software and the analyst was blinded as to which group was control or intervention (groups were designated A or B by a third party for analysis).

RESULTS

At the conclusion date 135 patients were enrolled of a total of 137 eligible patients. Two patients refused consent and 5 were excluded from analysis (2 deaths and 3 protocol violations). The protocol violations consisted of 2 patients who had their wounds closed with surgical skin staples rather than the prescribed subcuticular suture and one patient who was too obese for the extra large wound protector that fell out of the wound.

The study population therefore comprised 130 patients randomly assigned to either the control group (66) or the wound protection group (64). No patient in this group of 130 was lost to follow-up (Fig. 1). The cohort of 130 consisted of 76 men and 54 women with a mean age of 63 (range, 21–95) years and a mean body mass index (BMI) of 28. The 2 groups were well matched with regard to demographic data and characteristics (Table 1). There were no differences between the 2 groups with regard to the procedures performed. Both groups were equally represented in the 4 hospitals involved in the study. One of 8 surgeons had an unequal distribution of groups (7 wound protector vs 1 control), but the remaining 7 had equivalent distributions. There was no difference between the 2 groups with regard to the other operative details outlined in Table 2. No adverse events occurred as a result of use of the wound protector.

Eighteen wound-related SSIs were diagnosed in the entire cohort. The majority of infections (78%) were diagnosed after discharge from hospital. Seventeen of these infections were superficial SSIs, whereas one deep SSI occurred in the control group, necessitating operative drainage. One organ space infection developed in each group, both requiring percutaneous drainage, whereas 2 postoperative anastomotic leaks occurred in the wound protector group requiring reoperations.

Incisional related surgical site infections occurred in 15 of 66 (22.73%) patients in the control group compared with 3 of 64 (4.69%) patients in the wound protector group (15/66 vs 3/64; $P = .004$) (see results in Table 3). This represented an absolute risk reduction of 18.04% reduction in SSI when the Alexis wound protector was used, and a numbers needed to treat to prevent one SSI of 6 (95% CI 3.4–15.0). There was no difference in the rate of surgical interventions or readmissions for SSI between the 2 groups (Table 3).

Surgeons participating in the trial found the wound

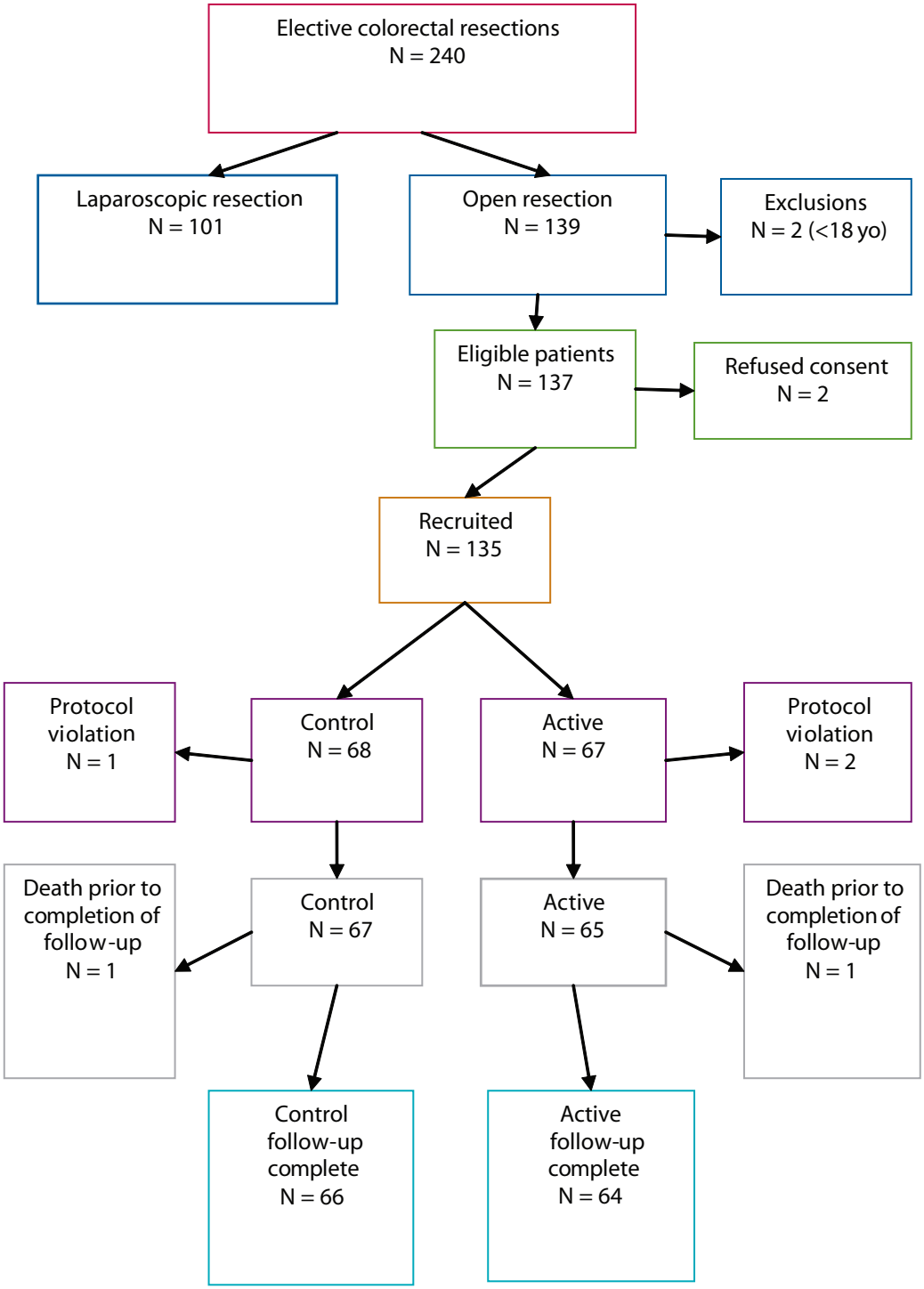

FIGURE 1. Consort diagram.

protector to be useful as a retractor, with 7 of 8 (88%) rating it as helpful or very helpful and adopting it as standard for their laparotomy setup. The mean Visual Analog Scale for its value as a retractor as rated by the surgeons involved was 7 (range, 5–10).

DISCUSSION

This randomized clinical trial comparing the use of the wound protector with standard retraction in elective colorectal resectional surgery revealed a significant reduction

TABLE 1. Patient demographic data

Variable	*Control (n = 66)*	*Intervention (n = 64)*	*P*
Age: mean (SD)	63.1 (13.1)	64.2 (14.8)	.654
Sex M/F	41/25	37/27	.721
BMI: mean (SD)	28 (6.9)	27 (6.4)	.394
Mechanical bowel preparation (Y/N)	21/45	17/47	.566
Immunosuppression (current use of corticosteroids or other immune suppressant)	4	5	.742
Preoperative chemoradiotherapy	6	12	.132
Diabetes	8	12	.338
Anemia (Hb <115 for women, <130 for men)	5	2	.441
Malnutrition (BMI <18 or albumin <32)	3	2	1.000
Alcohol abuse (>14 standard drinks/wk)[a]	9	4	.242
Smoking history	26	19	.273
Skin disease	1	4	.204
Hypertension (BP >140/90 on 3 occasions, requiring medical treatment)	25	21	.586
ASA 1, 2, 3, 4	9, 33, 22, 2	8, 33, 22, 1	.948
Cancer vs benign indication	52:14	53:11	.658

BMI = body mass index; Hb = hemoglobin; BP = blood pressure.
[a]A standard drink refers to one standard glass of wine, one 30-ml shot of spirits, or 325 ml of 5% beer.

in SSI in patients in the intervention arm. The reduction in SSI in the patients randomly assigned to the wound protector group was not only highly significant but clinically relevant.

To our knowledge this is the first trial to assess the ability of this form of wound protection to decrease SSI in resectional colorectal surgery. It mirrors the findings of the subgroup analysis of colorectal patients in the study by Horiuchi et al[16] and reinforces the value of impervious wound protection for this group of patients.

Maxwell et al[11] describes the theory behind wound protection with impervious plastic as an attempt to protect the sides of the wound from inevitable contamination from skin and enteric bacteria and to protect it from trauma during the operation. Prior studies assessing this form of protection have produced conflicting results,[12,13] possibly as a result of the "cumbersome" properties of older styles of wound protectors.

The wound protector used in this study differs from earlier styles of wound protectors in its ability to afford full wound protection as a result of the firm and retractable nature of the inner and outer rings. The design of this protector enables the impervious cylinder of plastic between the 2 rings to lie firmly in contact with the wound once the outer ring has been "wound," regardless of the wound depth. In contrast to previous designs it provides consistent protection of the entire wound for the duration of the procedure and can also be removed without spillage of fluid onto the wound before closure. Our trial sought to determine whether this property resulted in a

TABLE 2. Operative details

Variable	*Control (n = 66)*	*Intervention (n = 64)*	*P*
Right-sided colectomy	10	16	.191
Left-sided colectomy	9	8	1.000
Rectal resections	37	34	.860
Subtotal colectomy	3	1	.620
Total proctocolectomy	7	5	.764
Colostomy takedown procedures	4	3	1.000
Procedures involving stoma creation	28	29	.860
Duration of operation: mean minutes (SD)	173.4 (76.5)	158.4 (60.9)	.219
Blood loss: mean mL (SD)	162 (306)	128 (206)	.460
Public vs private hospital	37/29	38/26	.726
Hospital distribution, JHH/NPH/CMH/Ling.	34/28/3/0/1	34/26/3/1/0	NS
Surgeon distribution, 1/2/3/4/5/6/7/8	37/17/11/1/0/0/0/0	33/16/4/7/1/1/1/1	.032 (surgeon 4)
Incision midline vs transverse	64/2	56/8	.053
Drains	40	29	.113
Perioperative blood transfusion	4	2	.680

JHH = John Hunter Hospital; NPH = Newcastle Private Hospital; CMH = Calvary Mater Hospital; Ling. = Lingard Private Hospital; NS = not significant.

TABLE 3. Results

	Control (n = 66)	*Intervention (n = 64)*	*P*
SSI: as per CDC guidelines, n (%)	15 (22.73)	3 (4.69)	.004
Reoperation for SSI	1	0	1.000
Readmissions for SSI	3	2	1.000
Formal wound drainage for SSI	3	1	.619
Purulent wound drainage	12	2	.009
Intravenous antibiotic (no. of courses used to treat SSI)	10	3	.077
Oral antibiotics (no. of courses used to treat SSI)	10	3	.077
Total length of stay: mean days (SD)	12.3 (6.2)	13.7 (14.1)	.463

SSI = surgical site infection; CDC = Centers for Disease Control and Prevention.

more effective form of protection and retraction. It stands to reason that surgery with a potentially higher rate of wound contamination would benefit more from this form of wound protection and it is with this in mind that we chose to test its properties on colorectal resectional surgery. Horiuchi et al[16] performed a study of a wide range of general surgical procedures and found that the wound protector appeared most effective for colorectal operations, with a reduction in SSI from 13.4% to 0%. Our study designed purely for colorectal surgery revealed a similar rate of reduction, albeit from a higher baseline with the similar proportional reduction validating this wound protector's ability.

Although both groups in this study were well matched, representation of the groups was unequally matched for one surgeon. It is difficult to see how this chance occurrence could be prevented, with stratification for 8 surgeons being impractical. It is also difficult to see how this occurrence could have affected outcome: this surgeon had 7 wound protector vs one control patients and no postoperative SSIs.

The potential weakness of this study is the high SSI rate in the control group. It is unlikely that this represented any form of bias because the observer, patients, and analyst were blinded as to the form of intervention. Interventions such as antibiotic prophylaxis,[1] perioperative hyperoxygenation,[17,18] and maintenance of normothermia[19,20] were all used to minimize the baseline SSI. the main factor accounting for the high SSI in the control arm of this study could possibly be the high mean BMI of the cohort (28 compared with 22 in Horiuchi's cohort).[16] Tanner et al[2] identified high BMI as being the most significant risk factor for the development of SSI, with rates as high as 27% in their study when strict CDC criteria were used with 30 days follow-up by experienced observers. This finding compares favorably with the results in this trial and further validates the comparative findings with Horiuchi's trial.

In this study we also used a follow-up method that involved a blinded, unbiased, surgeon-trained observer. This method has been shown to increase the detected infection rate, indeed sometimes doubling the detected rate.[3] The use of a 30-day postsurgical follow-up, also used in this study, ensures that out-of-hospital or postdischarge SSIs are also detected, and other studies have shown that this at least doubles the detected infection rate.[4–6] Indeed, 78% of SSIs in this study were diagnosed after discharge from the hospital. The overall SSI incidence in this study was 13.85%, whereas the inhospital SSI rate was 3.18%. The exclusion of postdischarge infections gives surgeons a false impression about the risk of SSI. As the length of hospital stays decreases, the impact of SSI may appear to have been substantially reduced to those working in the hospital system, but, in reality, the problem has not been solved, but merely shifted into the community. Our study highlights this previously described phenomenon.

The ability of this wound protector to assist with retraction is a result of the stiff nature of the 2 rings, which, when rolled with the inner ring in the peritoneal cavity and the outer ring on the skin, provide circumferential wound retraction. Furthermore, directed wound retraction is usually required, but the wide view afforded is why surgeons in our study felt that the protector was useful purely on the basis of its retractional ability.

This randomized clinical trial of the use of retractional wound protection in open colorectal resectional surgery has demonstrated a statistically significant decrease in the rate of SSI. The large and clinically relevant reduction in SSI between the 2 study groups along with the retraction afforded by this form of wound protector suggests that barrier protection of this nature should be considered standard practice in open colorectal surgery.

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