Original article

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ALEXIS O-Ring wound retractor *vs* conventional wound protection for the prevention of surgical site infections in colorectal resections[1]

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Abstract

Aim Surgical site infection (SSI) remains a common postoperative morbidity, particularly in colorectal resections, and poses a significant financial burden to the healthcare system. The omission of mechanical bowel preparation, as is performed in enhanced recovery after surgery programmes, appears to further increase the incidence. Various wound protection methods have been devised to reduce the incidence of SSIs. However, there are few randomized controlled trials assessing their efficacy. The aim of this study is to investigate whether ALEXIS wound retractors with reinforced O-rings are superior to conventional wound protection methods in preventing SSIs in colorectal resections.

Methodology Patients undergoing elective open colorectal resections via a standardized midline laparotomy were prospectively randomized to either ALEXIS or conventional wound protection in a double-blinded manner. A sample size of 30 in each arm was determined to detect a reduction of SSI from 20% to 1% with a power of 80%. Secondary outcomes included postoperative pain. The operative wound was inspected daily by a specialist wound nurse during admission, and again 30 days postoperatively. Statistical analysis was performed using SPSS version 13 with $P < 0.05$ considered significant.

Results Seventy-two patients were recruited into the study but eight were excluded. There were no SSIs in the ALEXIS study arm ($n = 34$) but six superficial incisional SSIs (20%) were diagnosed in the control arm ($P = 0.006$). Postoperative pain score analysis did not demonstrate any difference between the two groups ($P = 0.664$).

Conclusion The ALEXIS wound retractor is more effective in preventing SSI in elective colorectal resections compared with conventional methods.

Keywords Alexis, retractor, prevention, surgical site infection, colorectal

What is new in this paper?

This paper investigates the effectiveness of the updated ALEXIS wound retractors with reinforced O-rings in preventing surgical site infection in colorectal resections only. The control arm was standardized to abdominal packs wound protection and Balfour retraction which was not done in preceding studies.

Introduction

Surgical site infection (SSI) is a serious complication to abdominal surgery, causing increased morbidity. SSI can have a devastating impact on the patient's course of treatment and is associated with increased treatment intensity, increased antibiotic usage, prolonged length of stay, higher costs and decreased quality of life. The SSI burden may be disproportionately high in countries with limited resources [1].

In spite of modern standards of preoperative preparation, antibiotic prophylaxis and refinements in anaesthetic and operative techniques, postoperative wound infection remains a serious problem. More than 20% of hospital acquired infections are attributed to infection of a surgical site, only second to urinary tract infection, and are typically defined according to procedure and location of infection [2].

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Colorectal procedures are known to have higher risk of developing SSI compared with other operations, and therefore preventive measures are especially needed [3,4]. Wound protectors are designed to protect the abdominal wall from desiccation, contamination and mechanical trauma during abdominal procedures. Theoretically, these devices minimize bacterial contamination of the wound by shielding it from potential contaminants.

The Alexis O-Ring (Applied Medical, Rancho Santa Margarita, California, USA) wound retractor is a revised and updated version of the retractor originally developed in 2000, with a design that functions both as barrier protection and also wound edge retraction. It is made up of two stiff rings with a cylinder of reinforced polyurethane between the two rings. The inner ring is placed in the peritoneal cavity, and the outer ring is placed outside the abdomen. The outer ring is then rolled over until it becomes taut circumferentially around the wound. The main difference between this ALEXIS O-Ring retractor and the preceding protector is that it reliably provides atraumatic retraction and all-round wound protection. It can be removed easily without spillage into the wound.

At the time of the design of this study there had, to our knowledge, been no clinical trial 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 with an ALEXIS O-Ring wound retractor 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 reduce postoperative pain.

Methods

Approval was obtained from the University Malaya Medical Centre (UMMC) Medical Ethics Committee before the commencement of subject recruitment. A short-term research grant FS322/2008C was obtained through the University of Malaya Institute of Research Management and Monitoring. This study has been registered with the National Medical Research Register NMRR-11-341-8072.

This study was a double-blind prospective randomized controlled study. The patients, nurses and doctors who were not involved in the intra-operative care were blinded to the type of wound protection used. Adult patients undergoing elective colorectal resections via a standardized midline incision were enrolled in this study.

Exclusion criteria included a laparoscopic approach, requirement for an emergency re-laparotomy or any contraindication to patient-controlled analgesia (PCA) with morphine. Written informed consent was obtained from each study patient. Patients were randomized by the investigator using sealed envelopes. The incisions of study group patients were protected with the ALEXIS O-Ring retractor during the operation whereas incisions of the control group were protected via a conventional method which comprised four abdominal packs and Balfour retraction.

Intravenous cefoperazone 2 g and metronidazole 500 mg were given for antibiotic prophylaxis. Incisions were standardized to 17 cm, the maximum length recommended by the ALEXIS manufacturer for a snug fit. This was to enable a more accurate comparison of postoperative pain between the two study groups. Incisions were closed with absorbable subcuticular Vicryl and infiltrated with 20 ml of local lignocaine 1%. Six colorectal consultants/fellows were involved in the resections in this study.

Postoperative analgesia was standardized to PCA morphine for 3 days and then subsequently converted to oral tramadol and paracetamol. None of the patients received epidural analgesia. Although this contravenes enhanced recovery after surgery (ERAS) principles, it allows calculation and comparison of postoperative analgesic requirement. Pain scores were charted with a numerical scale every 4 h during this period.

Incisions were inspected on a daily basis from the second postoperative day onwards by one accredited wound, ostomy and continence specialist nurse until the day of discharge. Diagnosis of SSI was confirmed by surgeons not involved in this study. Patients were followed up in clinic on day 30 to assess the wound and general well-being. SSIs were diagnosed according to the Centers for Disease Control and Prevention (CDC) criteria within 30 days of the operation [5]. 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 deliberately opened by the surgeon, unless incision is culture-negative.

4 Diagnosis of superficial incisional SSI by the surgeon or attending physician.

Assuming that the rate of SSI in the control group and ALEXIS O-Ring retractor group is 20% (average incidence in colorectal resections) and 1% (average incidence in clean operations), respectively, the sample size required to detect this difference with a power of 80% is 30 patients in each arm. SPSS for Windows (version 13.0, SPSS Inc., Chicago, Illinois, USA) was used for statistical analysis. Confounding factors for SSI were compared

between the two study groups and a simple calculation of cost effectiveness of ALEXIS retractors to prevent SSI was done.

The Mann–Whitney *U*-test was used for nonnormally distributed data. For categorical data, percentages were calculated and the chi-square test was used. *P*-values were calculated and $P < 0.05$ was considered statistically significant.

Results

A total of 72 patients undergoing elective colorectal resections were recruited from November 2008 to November 2010. Eight patients (11%) were excluded from the study for various reasons (Fig. 1). The majority of patients were excluded due to re-laparotomy (50%, $n = 4$). The remaining subjects were excluded for contraindications to PCA morphine (25%, $n = 2$), cancellation due to inadequate operating theatre time (12.5%, $n = 1$) and incision extension due to inadequate exposure (12.5%, $n = 1$).

Study patients underwent various colorectal procedures as shown in Table 1. The surgery performed involved handling of the large bowel. Mechanical bowel preparation (MBP) was only given to patients planned for ultra-low anterior resection (ULAR) with covering ileostomy. The remaining surgeries noted above were done without bowel preparation as part of the protocol for enhanced recovery after surgery. There was no difference between the two groups in terms of procedures performed ($P = 0.663$). All procedures were clean-contaminated with no gross faecal spillage.

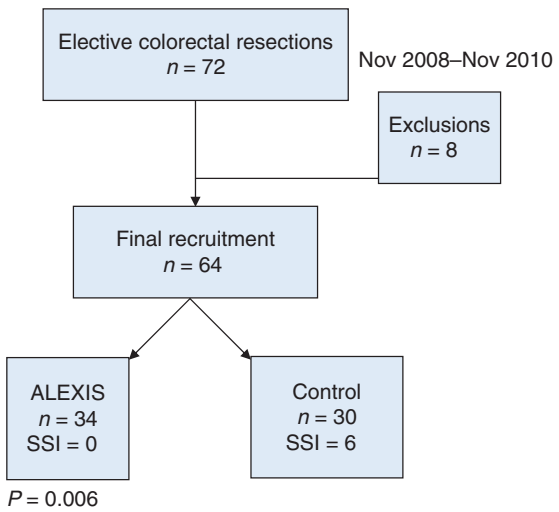

Figure 1 Consort diagram.

Table 1 Type of surgery.

Type of surgery	Alexis (*n*)	Abdominal pack (*n*)	Total (%)
En bloc tumour resection	1	1	3.1
Right hemicolectomy	2	6	12.5
Extended right hemicolectomy	5	3	12.5
Left hemicolectomy	2	1	4.7
Sigmoid colectomy	4	3	10.9
Anterior resection	3	5	12.5
ULAR + loop ileostomy	6	2	12.5
Abdominoperineal resection	4	2	9.4
Completion colectomy	3	1	6.2
Panproctocolectomy	1	0	1.6
Hartmann's procedure	1	2	4.7
Reversal of Hartmann's	2	3	7.8
Open polypectomy	0	1	1.6
Total	34	30	100

ULAR, ultra-low anterior resection.

Confounding factors

Patient characteristics between study and control group such as age, sex, blood parameters, immune status, prophylaxis, duration of surgery and length of hospital stay were analysed (Table 2). These confounding factors for SSI were compared between both arms with a nonparametric Mann–Whitney *U*-test for the variable data and a chi-square test for the categorical data. Tabulated variables were represented by the median.

Comparison between patients in the study and control groups revealed that there was no significant difference in terms of age, duration of surgery, albumin and length of hospital stay. The number of patients with diabetes, immunocompromised status and recipients of prior antibiotic treatment was not significantly different. However, the median bilirubin level between both arms was statistically different ($P = 0.022$). The median bilirubin level in the ALEXIS group was on average 3 μM higher than the control group. The median bilirubin level for the ALEXIS and abdominal pack group was 8.0 and 5.0 μM, respectively, which were still within the normal physiological range.

Further analysis of the median bilirubin level among patients in the abdominal pack group only did not show any difference between those who developed superficial incisional SSI (9.0 μM) and those that did not (5.0 μM) ($P = 0.432$).

There was one renal transplant patient in the abdominal pack group receiving maintenance immunosuppressant medication, which rendered her immunocompromised. She did not develop SSI. There was also one patient in the control arm who received antibiotic

Table 2 Confounding factors for surgical site infection.

Characteristics	ALEXIS	Abdominal packs	*P*-value
Age (years)			
Median (range)	65 (22–83)	58.5 (39–86)	0.187
Duration of surgery (min)			
Median (range)	207.5 (90–480)	195 (80–435)	0.946
Albumin (g/l)			
Median (range)	35 (17–46)	31 (22–41)	0.203
Bilirubin (μM)			
Median (range)	8 (3–20)	5 (1–22)	**0.022***
Length of hospital stay (days)			
Median (range)	7 (4–30)	7 (4–30)	0.957
Diabetes	3	6	0.199
Immunocompromised	0	1	0.283
Prior antibiotic treatment	0	1	0.283
Bowel preparation	6	2	0.157
ASA classification			
1	10	8	0.555
2	24	21	
3	0	1	
Sex			
Male	20	13	0.216
Female	14	17	
Race			
Chinese	18	15	0.408
Malay	9	8	
Indian	6	3	
Other	1	4	

ASA, American Society of Anesthesiologists.
*Statistically significant.

treatment 2 days prior to surgery for suspected sigmoid volvulus. He did not develop SSI either.

Endpoints

Surgical site infection

There was no incidence of SSI in the ALEXIS study group whereas six superficial incisional SSIs were recorded in the control arm (Table 3). Statistical analysis with categorical a chi-square test proved significant ($P < 0.05$). All six superficial incisional SSIs in the control arm had frank purulent discharge. Superficial incisional SSI was significantly diminished in the ALEXIS wound retractor group ($P = 0.006$).

Table 3 Rate of surgical site infection (SSI).

	ALEXIS		Abdominal packs			
SSI	Number	%	Number	%	Total	*P*-value
No	34	59	24	41	58	0.006
Yes	0	0	6	100	6	

Pain assessment

Given the small sample size of the study, pain scores and the amount of postoperative PCA morphine analgesia were analysed with the nonparametric Mann–Whitney *U*-test. The result of statistical analysis did not show any difference in pain score nor the amount of analgesia per

Table 4 Pain score and PCA morphine.

	ALEXIS	Abdominal packs	*P*-value
Number	34	30	
Pain score			
Median (range)	3 (1–7)	3 (2–6)	0.664
Total PCA (mg/kg)			
Median (range)	0.92 (0.02–2.62)	0.76 (0.23–5.17)	0.830

PCA, patient controlled analgesia.

body weight between the two study groups ($P > 0.05$) (Table 4).

Discussion

Surgical site infection is the most frequent complication in colorectal surgery, and the occurrence of SSI leads to sepsis, prolonged hospitalization, increased healthcare costs and patient dissatisfaction. It prolongs hospitalization by, on average, 7–10 days [6,7].

Laparotomies in our centre are routinely performed with Balfour retractors and wound protection with abdominal packs. The use of an impervious wound-edge protector has been shown to reduce postoperative wound infections; however, it is possible that the porosity and migration of abdominal packs might not reduce the risk of SSI as effectively [8]. The ALEXIS wound protection system should be able to overcome the shortcomings of the aforementioned protection methods as it is impervious, pliable and requires less retraction force. The advantage of such retractors would be lower incidence of SSI and less postoperative pain given the fact that it requires less mechanical and vigorous retraction.

This randomized prospective double-blinded ALEXIS study revealed that SSI rates with conventional retraction methods for colorectal procedures in UMMC were 20%. This was expected, as recent publications investigating the outcomes of patients with preoperative MBP had SSI rates of between 16 and 19% [3,4]. The SSI rate in patients without preoperative MBP in these two studies was, in fact, as high as 35%. Both the referenced studies were relevant benchmarks for SSI rates in this ALEXIS study because only colorectal procedures were recruited. The SSI rate for colorectal procedures only in these studies was clearly higher than the clean-contaminated surgery SSI rate that has long been accepted to be approximately 10%.

The six superficial incisional SSIs diagnosed in this study were laparotomy incisions with frank purulent discharge not involving the deep fascia or muscle, therefore eliminating the possibility of over-diagnosis. All culture isolates from the SSIs in this study revealed gut commensals such as *Escherichia coli*, *Enterococcus*, *Enterobacteria cloacae* and *Morganella morganii*, corresponding to the nature of surgery these patients underwent. Isolates demonstrated scanty to moderate growth in the laboratory.

This study has demonstrated that there was no difference in patient characteristics between study and control arms; hence patients were concluded to have been randomized properly. The statistical analysis of preoperative bilirubin levels noted a difference between the two study groups ($P = 0.022$). This was due to the statistical method used to analyse the nonparametric data, as the median rather than the mean was used in the comparison. The other reason for a significant difference in bilirubin levels was due to the fact of a small sample size. Nevertheless, the median levels in both arms were still in the normal physiological range and did not render any particular group at any higher risk of developing SSI (<12 μM). In addition, had the difference impacted on the outcomes, the ALEXIS arm would be expected to have included some SSI.

There were six diabetic patients in the control group and two developed SSI. Both the diabetic patients with superficial incisional SSI had poorly controlled mean sugar levels of 10.0 and 12.3 mM, respectively. A further analysis did not show any significant difference in mean sugar levels among diabetic patients in the control group ($P = 0.355$). Comparison of mean sugar levels of diabetics between both arms also did not reveal any difference ($P = 0.439$). Therefore, diabetes was not a surrogate marker for SSI and this reflected the true effect of retraction methods in preventing SSI.

Albumin levels were not statistically significant between both groups and the proportion of patients with levels of more than 25 g/l were equal in both arms, approximating 90%. It can be concluded that albumin levels did not contribute to SSI.

Pain analysis did not reveal any significant difference between patients with the ALEXIS and patients with the Balfour retractor. This could be attributed to the fact that this study was not powered to detect any difference in postoperative pain. The duration of hospital stay was also not significantly different between the two groups. Based on this observation, the conclusion can be drawn that although superficial incisional SSIs only developed in the control arm, they did not require prolonged hospitalization. There were also no hospital readmissions to treat the SSIs.

Absolute risk reduction of SSI with the ALEXIS wound retractor was 20% as there was zero incidence of SSI in the ALEXIS arm compared with a 20% rate SSI in the control arm. The number needed to treat (the inverse of the absolute risk reduction) was five. This meant that the ALEXIS wound retractor would have to be used in five patients to prevent one probable SSI compared with conventional abdominal pack protection.

An estimation of an additional cost of £97 was incurred in the inpatient healthcare cost to treat an event of superficial incisional SSI in this study. Such charges encompassed the use of antibiotics, wound cultures, dressings, disposables and staffing over the average postoperative length of hospitalization of 7 days calculated from the control group.

Five ALEXIS O-Ring retractors cost £70 × 5 = £350. One superficial incisional SSI for every five patients undergoing surgery using abdominal packs and sterilized Balfour retractor cost £97 + (£4 × 5) = £117. This means that £350 is required to prevent one probable superficial incisional SSI that cost £117 to treat (£1 = RM5.0 based on the exchange rate on 21 November 2011). However, the cost to treat one probable superficial incisional SSI might be underestimated by not taking into account regular outpatient consultation with medication, repeated travel to the hospital for dressing and absenteeism from work. 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].

Some of the merits of the ALEXIS wound retractor were noticed during the course of this study. Its ease of use and constant, uniform and atraumatic retractile forces around the laparotomy wound margin would provide good exposure during surgery. It is made of reinforced polyurethane and therefore is hypoallergenic. No allergic reactions have been reported before [10].

However, the length of incision is limited by the use of the ALEXIS wound retractor, as a larger incision exceeding the recommended length would render the retractor loose fitting and unable to provide an appropriate seal on the wound. Therefore, problems would arise if surgical exposure needed to be extended due to unforeseen circumstances. Feedback from the surgeons involved was that the exposure and mobilization of the splenic flexure proved challenging in low and ultra-low anterior resection.

In conclusion, the ALEXIS wound retractor is more effective in preventing SSI than conventional methods during elective colorectal surgery. Rates of SSI in colorectal patients with the ALEXIS wound retractor were comparable to rates of SSI in clean surgery, therefore its use is strongly recommended for patients undergoing colorectal procedures under ERAS protocols.

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None reported.

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