Does Alexis Wound Protector/Retractor Reduce the Risk of Surgical Site Infections After Open Radical Cystectomy for Bladder Cancer? Results From a Single Center, Comparative Study

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OBJECTIVE To assess if Alexis dual-ring wound protector/retractor reduced the incidence of superficial and deep incisional infection following open radical cystectomy (ORC).

METHODS Since January 2020, all procedures were performed using the Alexis retractor. We retrospectively reviewed our ORC database and compared patients who were operated on with Alexis with the same number of consecutive patients operated with a stainless steel retractor in the previous period. Data are presented as median and (interquartile range).

RESULTS Seventy-four patients underwent RC with Alexis (group 1) and 74 with stainless steel retractor (group 2). Median age was 73.0(13) in group 1, 73.5(14) in group 2 ($P = .338$). There were 59(79.7%) men in both groups. The groups were comparable in terms of comorbidities, body mass index, American Society of Anesthesiology score, and neoadjuvant chemotherapy rate. There was no statistically significant difference in type of lymph node dissection and urinary diversion, total surgical time. Postoperative stay was shorter in group 1 [8(4) days vs 9(4) in group 2, $P = .012$]. Group 2 had a significantly higher rate of both superficial (8.1% vs 18.9%, $P = .045$) and deep incisional infection (2.7% vs 14.9%, $P = .009$). At multivariable analysis, body mass index (OR 1.129 95% CI 1.162-1.283, $P = .043$) was significantly associated with higher odds of superficial incisional infection. The use of Alexis was significantly associated with lower odds of having both superficial (OR 0.274 95%CI 0.033-0.781, $P = .023$) and deep incisional infection (OR 0.159 95% CI 0.034-0.745, $P = .020$).

CONCLUSION The use of Alexis significantly reduces the rate of superficial and deep incisional infection following ORC. UROLOGY 184: 162–168, 2024.

Open radical cystectomy (ORC) with lymph node dissection can still be considered the gold standard treatment for muscle-invasive bladder cancer since it has demonstrated favorable long-term oncological outcomes, even extending beyond a decade.[1] ORC also exhibited no difference in 90-day minor and major complications, progression-free survival and overall survival as compared with robotic-assisted RC.[2]

Infections are the most common complications following RC with incidence varying according to the type of urinary diversion (10.4%),[3] and inclusion (25.0%)[4] and definition criteria (67.4%).[5] Surgical site infections (SSI) remain an important infectious complication affecting 7.4% of patients undergoing RC[3] and lead to reoperation, increased morbidity and readmission, prolonged hospitalization, increased antibiotic usage, and higher costs.[6] Several strategies have been demonstrated to reduce the risk of SSI including smoking cessation, prophylactic antibiotics, chlorhexidine-based skin antisepsis, and maintenance of normothermia throughout the perioperative period.[7]

Wound protection devices are becoming more commonly utilized as a strategy to decrease SSI. In randomized

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trials of gastrointestinal surgery, wound protection devices showed a significant decrease in the odds of developing SSI, and this difference was associated only with the application of dual-ring wound protectors.[8] Data regarding the use of dual-ring wound protectors in ORC are limited to a single series.[9]

In the present study, we aimed to assess if a dual-ring wound protector reduced the incidence of superficial and deep incisional infections following ORC as compared to a self-retaining, stainless steel retractor. The secondary aims were evaluating differences in postoperative outcomes between the two groups and assessing risk factors associated with superficial and deep incisional infections.

MATERIALS AND METHODS

A retrospective analysis of our prospective collected database of bladder cancer patients who had RC between October 2018 and September 2022 was performed. The inclusion criterion was adult patients with bladder cancer who underwent RC for localized bladder cancer. Exclusion criteria were cystectomy done for other diseases, previous pelvic radiotherapy, salvage cystectomy for metastatic bladder cancer with intractable hematuria, and age < 18 years. The following variables were collected: age, gender, body mass index (BMI), comorbidity, American Society of Anesthesiology (ASA) score, systemic neoadjuvant chemotherapy, preoperative hemoglobin, and serum creatinine. Intraoperative and perioperative data were also gathered: total surgical time, type of urinary diversion, concomitant nephroureterectomy or urethrectomy, lymph node dissection, time to first flatus, 24-hour hemoglobin value, postoperative stay, and readmission within 30 days. Complications were considered as any adverse event occurring within the first 30 days following surgery and were graded according to the Clavien classification system.

Patients were divided into two groups according to the type of abdominal retractor applied. Group 1 included patients who had RC using Alexis dual-ring wound protector/retractor (Applied Medical, Rancho Santa Margarita, CA), whilst group 2 patients who were operated on with a self-retaining, stainless steel abdominal retractor (Bracci retractor, Berto Guarducci, Florence, Italy). Since January 2020, all procedures were performed using the Alexis retractor (Fig. 1). Therefore, the same number of consecutive patients operated on with the stainless steel retractor in the earlier period were included in group 2 (since December 2019 back in time until we reached 74 patients). Formal ethics committee approval was not required for this type of study in our institution according to the local Ethics because the study was conducted retrospectively following the 1964 Helsinki declaration and its later amendments. Data collection was obtained for clinical purposes, and all the procedures were performed as part of routine care.

Surgical Procedure

No patient had perioperative care following the enhanced recovery after surgery pathway. Bowel preparation was performed using Rifaximin 400 mg twice a day and lactulose 12 g twice a day starting 3 days before surgery. All patients received antibiotic prophylaxis with intravenous cefazolin 2 g and metronidazole 500 mg 30 minutes before induction of anesthesia, and antibiotics were continued for at least 48 hours after surgery. Skin hair clipping was performed in all patients outside the theater (in the recovery room), using a designated surgical electric shaver. The skin was always carefully disinfected immediately before the incision using the 10% povidone-iodine solution and diathermy was never used for the surgical incision. Transperitoneal ORC was performed according to Skinner's technique.[10] All patients in both groups were operated by one experienced urologist. Laparotomy was performed with a sagittal, midline incision along the linea alba starting below the umbilicus. In the case of nephroureterectomy, the skin incision was extended above the umbilicus for about 5 cm. Alexis was placed immediately after entering the peritoneum or after lysis of peritoneal adhesions if present and was the main device for retraction throughout the whole case. As a standard of care, the surgical team and scrub nurse changed their gloves after urinary diversion. Uretero-ileal and cutaneous ureterostomies were stented in all cases. The fascial incision was closed with a running loop 0-Maxon suture (Covidien, Dublin, Ireland) reinforced with interrupted Vicryl 0 suture (Ethicon Inc, Raritan, NJ). The subcutaneous space was always sutured with interrupted Vicryl 2/0 suture. The skin was disinfected again with a povidone-iodine solution at the end of the procedure and sutured with metal clips in all cases.

Statistical Analysis

Continuous variables were assessed for their normal distribution with the Shapiro-Wilk test and are reported as median and interquartile range. Categorical variables were reported as absolute frequency and percentage. The Mann-Whitney U-test was used to assess the difference between the two groups for continuous variables, whereas the Chi-square test for categorical variables. Two univariable logistic regression analyses were performed to assess factors associated with higher odds of superficial and deep incisional infection. Potentially prognostic variables in univariable analysis were entered into a multivariable model to assess their significance as predictors. Superficial incisional infection was defined as infection within 30 days after RC that involves only skin or subcutaneous tissue of the incision and at least one of the following: (i) purulent drainage from the superficial incision; (ii) pathogens isolated from an aseptically obtained culture of fluid/tissue from the superficial incision; (iii) any sign/symptom of infection (ie, redness or heat, pain/tenderness, localized swelling, and superficial incision deliberately opened by

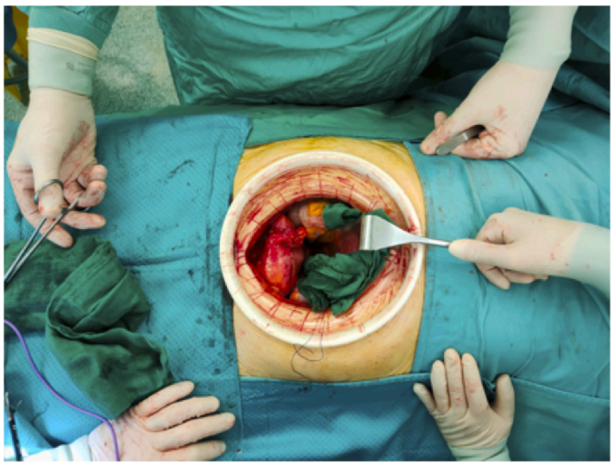

Figure 1. Alexis wound protector/retractor applied for open radical cystectomy. (Color version available online.)

surgeon).[11] Deep incisional infection was defined as infection within 30 days after RC that involves deep soft tissues (eg, fascial and muscle layers) of the incision and at least one of the following: (i) purulent drainage from the deep incision but not from the abdomen; (ii) a deep incision spontaneously dehisces or is deliberately opened by surgeon when the patient has at least localized pain/tenderness, fever >38 °C; (iii) an abscess or other evidence of infection involving the deep incision found on direct examination or during reoperation.[11]

Data are presented as odds ratio (OR) and 95% confidence interval (CI). Statistical significance was set at a 2-tailed *P*-value < .05. All statistical tests were conducted using SPSS software package version 25.0 (IBM Corp, Armonk, NY).

RESULTS

During the study period, 74 patients meeting the inclusion criterion underwent RC with the Alexis wound protector/retractor and were compared with 74 consecutive patients operated on in the previous period with stainless steel abdominal retractor. Table 1 shows patients' baseline characteristics and intraoperative/postoperative outcomes. Median age was 73.0 (13) in group 1 and 73.5 (14) in group 2 ($P = .338$). There were 59 (79.7%) men in both groups. The two groups were comparable in terms of BMI, comorbidities, ASA score, and preoperative serum creatinine and hemoglobin. The rate of neoadjuvant chemotherapy was also similar (25.7% in group 1 vs 14.9% in group 2, $P = .120$). There was no statistically significant difference in type of lymph node dissection and urinary diversion, concomitant surgery, total surgical time, and time to first flatus (Table 1). Postoperative stay was significantly shorter in group 1 [8 (4) days] than in group 2 [9 (4), $P = .012$]. Regarding 30-day complications, groups had a similar rate of blood transfusion (71.6% in group 1 vs 64.9% in group 2, $P = .377$), fever >38 °C (9.5% in group 1 vs 18.9% in group 2, $P = .099$), sepsis (1.4% in group 1 vs 2.8% in group 2, $P = .649$), 30-day readmission (14.9% in group 1 vs 18.9% in group 2, $P = .419$) and 90-day death (4.1% in group 1 vs 4.1% in group 2, $P = .215$). Group 2 had a significantly higher rate of both superficial (8.1% vs 18.9%, $P = .045$) and deep incisional infections (2.7% vs 14.9%, $P = .009$) which required reoperation in all cases. Three patients in group 2 were readmitted for a deep incisional infections, whilst the rest of incisional infections were diagnosed during the same hospitalization. No patients had allergic reactions to the Alexis device.

At univariable analysis (Table 2) BMI was a factor significantly associated with a higher odds of superficial incisional infection, whilst the use of Alexis wound protector/retractor was significantly associated with lower odds. At multivariable analysis BMI confirmed to be significantly associated with a higher odds (OR 1.129 95% CI 1.162-1.283, $P = .043$) and Alexis wound protector/retractor with a lower odds (OR 0.274 95%CI 0.033-0.781, $P = .023$) of superficial incisional infection (Table 2). There was no factor associated with a higher odds of deep incisional infection at univariable analysis (Table 3), while the use of Alexis wound protector/retractor was the only factor significantly associated with lower odds of having deep incisional infection (OR 0.159 95% CI 0.034-0.745, $P = .020$).

DISCUSSION

Wound protection devices are becoming more commonly utilized as a strategy to decrease SSI rates in surgical procedures. In particular, the Alexis device integrates the functions of a wound retractor and a wound barrier protection system and consists of two plastic rings connected by a plastic sleeve. During surgery, the inner ring is positioned beneath the body wall, while the outer ring is placed on top of the skin. The plastic sleeve is then rolled over the outer ring, exerting equal force throughout the wound and causing the body wall to be retracted outward in a circumferential manner with a constant, uniform, and atraumatic retractile force.

In this study, we assessed the incidence of superficial and deep incisional infections following ORC for bladder cancer, comparing patients operated with a dual-ring wound protector/retractor vs those operated with the traditional self-retaining, stainless steel abdominal retractor. Our study pointed out 3 important findings. Firstly, we found that patients who had surgery with the use of Alexis wound protector had a significantly lower incidence of both superficial and deep incisional infections as compared with those operated with the traditional abdominal retractor. In our series, all patients suffering from SSI required a reoperation and this can partially explain why patients in group 2 had a significantly longer postoperative stay. Dual-ring wound protector devices are designed to create a barrier between the surgical incision site and the surrounding

Table 1. Patients' baseline characteristics and intraoperative and postoperative outcomes.

	Group 1 Alexis (n = 74)	Group 2 Stainless Steel Retractor (n = 74)	*P*-Value
Age, median (IQR)	73.0 (13)	73.5 (14)	.338
Males, n (%)	59 (79.7)	59 (79.7)	.596
Comorbidity, n (%)			
Chronic ischemic heart disease	21 (28.4)	24 (32.4)	.630
Diabetes	17 (23)	16 (21.6)	.809
Blood hypertension	42 (56.8)	47 (63.5)	.458
CKD	11 (14.9)	11 (14.9)	.972
COPD	26 (35.1)	21 (28.4)	.347
BMI, median (IQR)	25.8 (4.91)	26.1 (5.88)	.361
ASA score, n (%)			
1	5 (6.7)	5 (6.7)	.180
2	40 (54.1)	32 (43.6)	
3	26 (35.1)	36 (48.6)	
4	3 (4.1)	1 (1.4)	
Neo-adjuvant chemotherapy, n (%)	19 (25.7)	11 (14.9)	.120
Hemoglobin, g/dL, median (IQR)	12.9 (2.6)	12.9 (1.4)	.963
Serum creatinine, mg/dL, median (IQR)	1.03 (0.42)	1.12 (0.54)	.815
Total surgical time, min, median (IQR)	290 (70)	310 (73)	.815
Time to first flatus, d, median (IQR)	3 (2)	3 (2)	.517
Urinary diversion, n (%)			.301
Ileal conduit	47 (63.5)	53 (71.6)	
Orthotopic neobladder	12 (16.3)	13 (17.6)	
Bilateral cutaneous ureterostomy	15 (20.2)	8 (10.8)	
Nephroureterectomy, n (%)	0	1 (1.4)	.316
Urethrectomy, n (%)	8 (10.8)	5 (6.8)	.384
Lymph node dissection, n (%)			.161
Not performed	1 (1.4)	1 (1.4)	
Standard	7 (9.4)	10 (13.5)	
Extended	66 (89.2)	63 (85.1)	
Postoperative stay, d, median (IQR)	8 (4)	9 (4)	**.012**
24-h hemoglobin, g/dL, median (IQR)	10.1 (1.75)	10.0 (1.2)	.504
Blood transfusion (Clavien 2), n (%)	53 (71.6)	48 (64.9)	.377
Fever ≥38 °C (Clavien 2), n (%)	7 (9.5)	14 (18.9)	.099
Pneumonia (Clavien 2)	2 (2.7)	3 (4.1)	.723
Atrial fibrillation (Clavien 2)	2 (2.7)	1 (1.4)	.829
Sepsis (Clavien 4), n (%)	1 (1.4)	2 (2.8)	.649
Superficial incisional infection (Clavien 3a), n (%)	6 (8.1)	14 (18.9)	**.045**
Deep incisional infection (Clavien 3b), n (%)	2 (2.7)	11 (14.9)	**.009**
30-d readmission for any reason, n (%)	11 (14.9)	14 (18.9)	.419
Death within 90 d, n (%)	3 (4.1)	3 (4.1)	.215

ASA, American Society of Anesthesiology; BMI, body mass index; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; IQR, interquartile range.
Bold value stands for significant *P*-values.

environment to minimize the risk of wound contamination and infection and to promote optimal wound healing maintaining moisture.[12,13] Indeed, this wound protector has been demonstrated to shield incision sites from bacterial invasion.[13] However, it is also important to note that the effectiveness of wound protection devices may vary depending on the specific procedure, patient characteristics, and adherence to proper application and care protocols. In our series, preoperative care and antibiotics prophylaxis were standardized, patients' baseline and intraoperative characteristics were similar and surgery was performed by the same surgeon in a standard fashion, ensuring no significant difference between the two groups despite the patients were not randomized. Conversely, Sidhu et al in their study on 168 patients who had ORC showed a trend of lower incidence of 60-day SSI in patients operated on Alexis device (4%) vs Bookwalter retractor (12%) but this difference did not reach statistical significance. However, the authors did not differentiate between superficial and deep infections and did not report if patients required reoperation for infections.

Secondly, logistic regression analysis confirmed that the use of the Alexis device conferred a change of 73% and 84% in the odds of superficial and deep incisional infection, respectively. This reinforces the concept that Alexis wound protector was an independent factor of lower odds of SSI. The benefit of this device was also demonstrated in a study published by Huynh et al.[14] The authors showed no wound cellulitis or hernia on progress

Table 2. Univariable and multivariable logistic regression analysis of factors affecting superficial incisional infection.

	Univariable Analysis		Multivariable Analysis	
	OR (95% CI)	*P*-Value	OR (95% CI)	*P*-Value
Age	0.997 (0.948-1.049)	.920	—	—
Female gender	1.81 (0.56-5.687)	.432	—	—
Body mass index	1.144 (1.011-1.294)	**.033**	1.129 (1.163-1.283)	**.043**
Alexis retractor (ref. stainless steel retractor)	0.282 (0.079-0.889)	**.031**	0.274 (0.033-0.781)	**.023**
Surgical time	1.002 (0.993-1.011)	.691	—	—
ASA score (ref. 1)				
2	1.552 (0.650-3.683)	.421	—	—
3	2.454 (0.775-6.004)	.561	—	—
4	2.787 (0.86-10.983)	.065	—	—
Urinary diversion (ref. cutaneous ureterostomy)				
Ileal conduit	0.983 (0.498-1.992)	.965	—	—
Neobladder	1.94 (0.244-3.001)	.072	—	—

ASA, American Society of Anesthesiology.

Table 3. Univariable logistic regression analysis of factors affecting deep incisional infection.

	OR (95% CI)	*P*-Value
Age	1.006 (0.945-1.070)	.861
Female gender	1.213 (0.977-1.943)	.10
Body mass index	1.097 (0.910-1.284)	.134
Alexis retractor (ref. Stainless steel retractor)	0.159 (0.034-0.745)	**.020**
Surgical time	1.006 (0.995-1.017)	.257
ASA score (ref. 1)		
2	1.238 (0.462-3.546)	.565
3	2.8016 (0.783-9.852)	.241
4	3.349 (0.970-11.101)	.070
Urinary diversion (ref. cutaneous ureterostomy)		
Ileal conduit	1.022 (0.454-2.298)	.958
Neobladder	3.11 (0.821-7.361)	.061

ASA, American Society of Anesthesiology.

or follow-up in 15 patients who had ileal conduit formation through the wound protector during robotic-assisted RC. Indeed, the involvement of the bowel for urinary diversion is part of RC that induces the major bacteria colonization of the surgical incision.

Thirdly, we found that BMI was associated with higher odds of superficial incisional infection at logistic regression analysis. This finding is in line with a study by Kaczmarek et al that showed that obesity was a predictor associated with all types of postoperative infections after RC.[3] Indeed, it has been postulated a close correlation between adipose tissue, inflammatory responses, the immune system, and infections.[15] The hypothesis behind this relationship could be the same embryonic origin shared by proliferating preadipocytes with immune cells. As a consequence, adipose tissue can expand during infections, similar to the expansion of cells of the immune system. For this reason, obese patients may experience exacerbation of infections.[15] In addition, adipose tissue produces several proinflammatory factors and cytokines which play important roles in wound healing.[16] The higher incidence of SSI in obese patients may be further explained by the increased local tissue trauma related to prolonged operative time, retraction[17] and reduction of oxygenation of subcutaneous tissue.[18]

The present study has some limitations starting from its retrospective nature which has inherent bias. However, baseline and intraoperative characteristics were comparable between the groups minimizing selection bias. Yet, standardized preoperative patients care and the involvement of a single surgeon ensured a uniform approach in the whole series despite the lack of randomization. In addition, we could have missed minor complications but we were able to capture infectious complications, particularly SSI, which were the aim of our study. Finally, this study relies on a small sample size, and studies with larger populations may have different findings.

CONCLUSION

This study demonstrated that the Alexis wound retractor was more efficient in preventing SSI than our conventional stainless steel abdominal retractor in bladder cancer patients undergoing ORC. This protective effect was seen in both superficial and deep incisional infections. Therefore, we advocate the use of Alexis wound retractor to reduce the risk of SSI following ORC but further larger, multicenter studies are required to confirm our results.

Declaration of Competing Interest

The authors have no conflict of interest to declare.

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Editorial Comment: Does Alexis Wound Protector/Retractor Reduce the Risk of Surgical Site Infections After Open Radical Cystectomy for Bladder Cancer? Results From a Single Center, Comparative Study

In this well-presented study, the authors describe their experience using the Alexis self-retaining retractor to reduce surgical site infections (SSI) during open radical cystectomy. A retrospective analysis detailed a single surgeon's outcomes over 4 years. 74 consecutive cystectomies were performed using a self-retaining Bracci retractor followed by 74 consecutive cystectomies using an Alexis retractor. The Alexis retractor was associated with significantly lower rates of superficial SSI (8.1% vs 18.9%, $P = .045$) and deep SSI (2.7% vs 14.9%, $P = .0009$).

The Alexis retractor, a dual-ring wound protector/retractor, has shown promise in general surgery and gynecology to reduce SSI. The Alexis provides retraction in a circumferential manner with a plastic wound protection system. This may increase protection of wound edges and decrease traumatic retraction, leading to lower SSI incidence.[1] Reduction of SSI is particularly important following open radical cystectomy. SSI is the most common hospital-acquired adverse event following radical cystectomy; each infectious event correlates with a five-fold increase in in-hospital mortality. Each SSI also increases hospitalization costs from $28,271 to $64,725.[2]

The authors provide compelling data for reducing SSI using the Alexis retractor. However, we also note some limitations to the study's generalizability. The authors did not specify use of enhanced recovery after surgery (ERAS) protocols, commonly utilized for radical cystectomy patients in high-volume centers. ERAS protocols have routinely decreased hospital length of stay, an independent predictor of SSI, to 4-5 days.[3,4] However, length of stay in this cohort was 8-9 days. Furthermore, as surgeons consider adjusting their operative technique, they must also consider the ability of the Alexis to provide adequate exposure. For example, limitations in exposing the deep pelvis or in obese patients may increase operating time and surgeon fatigue.[1]

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Despite these limitations, we commend the authors for modifying their surgical technique to limit SSI. The marked decrease in SSI may inform the construction of prospective studies, which can provide critical evidence to reduce cystectomy-related morbidity. In the interim, evidence-based modifications, particularly at the patient and surgeon level, to reduce SSI should be utilized. These include patient-related factors such as blood sugar control, preoperative fitness, and smoking cessation. Operative modifications include minimizing operative time, ensuring sterile technique, and limiting perioperative hypothermia.[5] As these authors demonstrate, critical evaluation of these individual factors remains an essential tool to improve cystectomy outcomes and reduce surgical morbidity.

Declaration of Competing Interest

No conflict.

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