Cost-effectiveness analysis of O-Ring wound retractor in elective laparoscopic colorectal surgery

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INTRODUCTION: *Surgical site infections (SSIs) are a feared complication following colorectal surgery and have a sizeable economic impact on the healthcare system. The aim of this study is to assess the clinical effectiveness and cost-effectiveness of O-Ring wound protector/retractor in elective laparoscopic colorectal surgery.*
METHODS: *Data were analyzed from a retrospective colorectal database from January 2015 to June 2018. SSI was defined according to the criteria published by the European Centre for Disease Prevention and Control (ECDC). An economic evaluation was conducted comparing the group in which Alexis® device was used during surgery (Group A) with a control group (Group B) in which Alexis® device was not used.*
RESULTS: *Two hundred fifty-eight consecutive patients were enrolled in our study. Among them, the intervention group (Group A, 154 patients) was compared with the control group (Group B, 94 patients). A total of 8 (5.2%) and 14 (15%) patients with SSIs were identified in groups A and B, respectively (p = 0.008). The economic evaluation showed that there was no difference in terms of costs and returns on comparing both groups.*
CONCLUSION: *The final costs and profit are similar in both groups, but the use of O-Ring protector reduces SSI rates and may significantly improve patient's quality of life.*

KEY WORDS: Colorectal surgery, Cost-effectiveness, Surgical site infection, Length of stay, Wound protector/retractor

Introduction

Surgical site infections (SSIs) are among the most common healthcare-associated infections occurring in up 5%-15% patients undergoing abdominal surgery [1]. Even when a minimally invasive treatment is performed, they represent a feared complication of colorectal surgery.
The European Centre for Disease Prevention and Control (ECDC) defines SSI as superficial, deep, and organ/space SSIs occurring within 30 days of a surgical procedure (or within one year for permanent implants) [2]. SSIs can have a devastating effect on the patient's quality of life due to increased patient morbidity and mortality; the protract use of antibiotics, dressings, analgesic drugs, prolonged hospitalization, and readmissions cause a significant financial impact on the healthcare system. The negative impact on national health system is probably due to the increase in running costs related to SSIs and loss of profit during patient's recovery.
Compared to other surgical specialties, colorectal surgery is associated with higher SSI rates, ranging from 2% to 45%. As the colonic lumen hosts a wide range of bacteria, colorectal surgery involves greater bacterial exposure, which is responsible for wound tissue contamination during surgical procedures [3,4].
Wound healing is a dynamic and complex process that requires active participation from both physicians and nurses. Several preventive measures to avoid SSIs have

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been routinely adopted, e.g., oral antibiotic prophylaxis, the change of sterile gloves closing laparotomy, and mechanical bowel preparation [4]. Moreover, the use of wound protectors to avoid or reduce SSI incidence has been widely employed in colorectal surgery. Laparoscopic surgery is associated with a reduced incidence of wound infections than open surgery: wound protectors have been developed to facilitate the retraction of the wound margins during surgery and to protect the surgical area from bacterial contamination, including contamination both from outside and inside the peritoneal cavity [5]. However, their real benefits and cost-effectiveness are still debated and controversial in literature.

Our team already published a clinical analysis of the effect of a specific wound protector/retractor device available in the market (Alexis®, Applied Medical, Rancho Santa Margarita, CA) on the incidence of SSI in elective laparoscopic colorectal surgery[6].

In this study we analize the cost-effectiveness and the economic impact of the use of the same device.

Material and Method

We analyzed a retrospective chart review of patients undergoing laparoscopic elective colorectal surgery between 2015 and 2018. Exclusion criteria were patients aged <18 years old, surgical laparotomic approach, emergency surgery, and trans-anal extraction of the specimen. Patients requiring laparotomic conversion were excluded from the analysis.

Group A comprised consecutive patients who underwent elective laparoscopic colorectal resections in which Alexis® retractor was intraoperatively used; this group was compared with a control group (Group B) which included randomly chosen patients from our hospital database in whom no such device was used. All epidemiological data were collected from the hospital information system and a colorectal database was created. SSI was defined according to criteria published by the European Centre for Disease Prevention and Control (ECDC) and was recognized within 30 days postoperatively [2].

In all patients, the surgical specimen was extracted through a Pfannenstiel incision. In Group A, the O-Ring retractor was immediately inserted after opening the peritoneum and maintained during the extraction of the surgical specimen. In Group B, the surgical specimen was extracted without the use of any retractor or wound protector.

Institutional review board approval was obtained from our university hospital, and we received permission to access the data from electronic patient medical records. Patient confidentiality was maintained by coding the patients' names and all personal information; patient files were reviewed at the hospital. All patients included in the study were contacted, and their consent to access their medical records was obtained.

An economic evaluation was conducted comparing groups A and B. The detailed bifurcation of the in-hospital costs and revenues linked with each case was obtained from the hospital information system. Variables were tested for normal distribution using the Kolmogorov–Smirnov test. Median values of total costs, cost for hospital stay, and costs for materials, economic gain, contribution revenue, and length of stay (LOS) were compared using the non-parametric Mann–Whitney's test. Post-surgical infection prevalence between the two study groups were compared using the χ^2 test for proportion. A p-value < 0.05 was considered statistically significant. Data were analyzed using Med-Calc 11.6.1.0 statistical package (MedCalc Software, Mariakerke, Belgium).

Results

Group A included all the consecutive patients fulfilling the inclusion criteria who were operated in the study period of January 2015-December 2018. These were the patients in whom the device was used (248 cases). Group B included 94 patients fulfilling inclusion criteria who were operated in the same period without the use of the device.

TABLE I - *Cost, Gain and patient outcome in case of Alexis use compared to the routine management.*

Variable	Median value (Alexis)	Median value (No Alexis)	Mann-Whitney comparison
	COST		
Cost for hospital stay (euro)	-1386.00	-1386.00	p = 0.083
Cost for materials (euro)	-2162.93	-2334.02	p = 0.003
Total cost (euro)	-5841.31	-5860.42	p = 0.422
Contribution revenue (euro)	8296.18	10378.17	p = 0.980
Economic Gain (euro)	2894.20	2616.88	p = 0.890
	Patient outcome		
LOS (days)	6.0	6.0	p = 0.086
SSIs (%)	8/154 (5.2)	14/94 (15)	p= 0.008

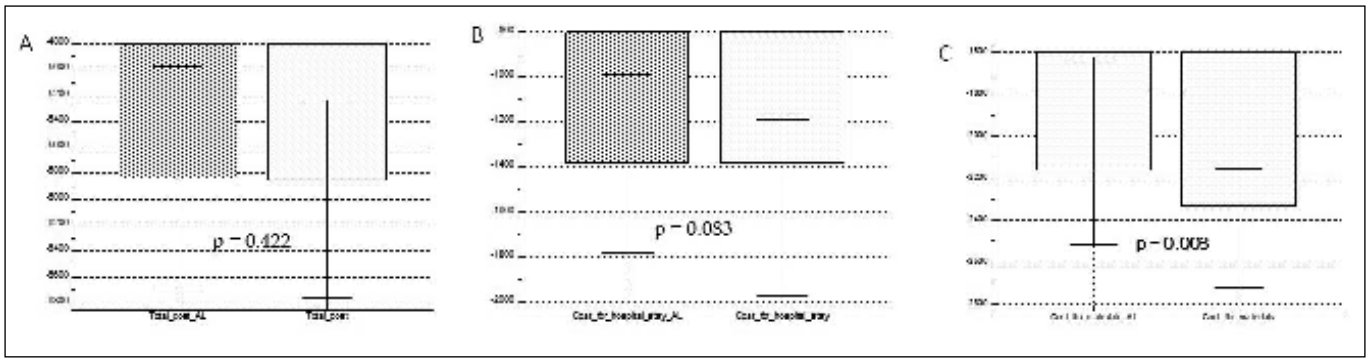

Fig. 1: A) Mann Whitney comparison of total cost, B) cost for hospital stay, C) cost for materials between Alexis Group (AL) and no Alexis. p<0.05 was considered significant.

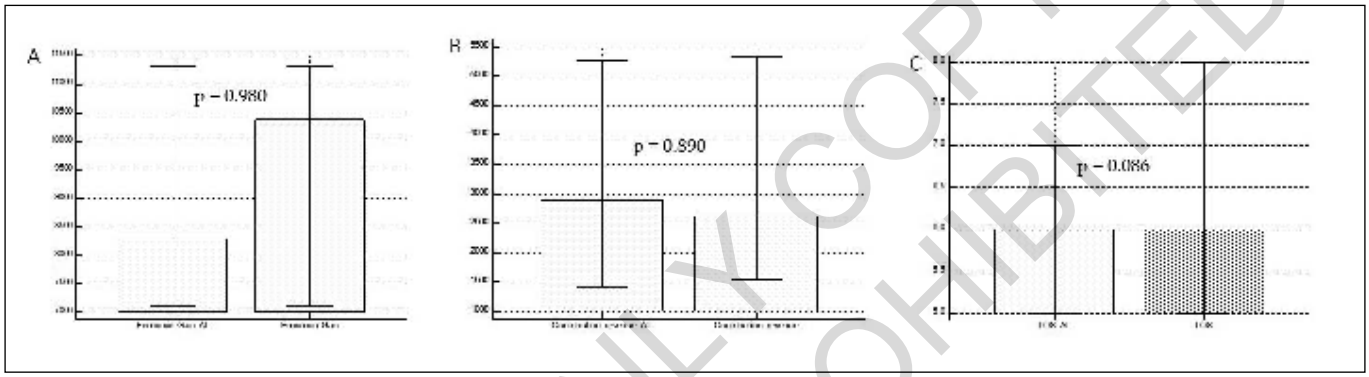

Fig. 2: A) Mann Whitney comparison of economic gain, B) contribution revenue, C) LOS between Alexis Group (AL) and no Alexis. p<0.05 was considered significant.

Eight patients (5.2%) and 14 (15%) were identified to have developed SSI within 30 days of surgery in groups A and B, respectively. All the infections detected in the group A were identified as superficial according to the criteria published by the ECDC; in group B, deep and superficial SSIs were found in 2 and 12 patients, respectively. The SSI rate showed a threefold increase in group B. This difference was statistically significant (p = 0.008; Table I). All the patients were administered more than one dressing to obtain complete wound healing.

Variables analyzed in the economic analysis did not follow normal distribution. Median values of cost and gain evaluated in the study were compared by the Mann–Whitney test, and the results are reported in Table I. No statistically significant difference was found on comparing the total cost and cost related to hospital stay between the two groups. However, the cost for material was significantly lower in the Alexis® group (p = 0.003) (Fig. 1 A, B, C). Economic gain and the LOS were not significantly different between the two groups (Fig. 2 A, B, C).

Discussion

Surgical site infections (SSIs) remain a devastating complication following colorectal surgery and are the second most common cause of hospital-acquired infection [6]. Morbidity and mortality rates associated with postoperative SSIs are substantial. The healing of damaged tissue can be also compromised by multiple factors including patient characteristics (obesity, diabetes, smoking, vascular disease , malnutrition, renal failure) and postoperative complications such as anastomotic leakage which is well known to be the most feared complication following colorectal surgery [7]. The development of SSIs has a sizeable economic impact to the healthcare system due to the increased direct costs incurred by prolonged hospitalization of the patient, protract use of antibiotics, laboratory tests, and treatments. In addition, increased pain or discomfort around the affected area in the postoperative period may significantly affect patient's quality of life. When an SSI is detected, some patients may also require re-admission for surgical or therapeutic reintervention, which is associated with additional hospital costs.

A systematic review was conducted by Badia et al. to assess and evaluate the impact of SSI on healthcare costs across various surgical specialties in six European countries. The review revealed that the financial burden of surgery and the length of hospitalization were consistently higher in patients who develop SSIs compared with those who do not [7]. A review conducted by Broex et al., which included sixteen articles, showed that European hospitalized patients who develop an SSI

account for a substantial increase in healthcare-related costs, which are two times higher than those of patients who do not develop an SSI [8].

Several studies have shown that LOS is higher in patients affected by SSIs following surgery compared to uninfected patients [9-17]. However, our data showed that LOS was similar in both groups; a statistically significant difference was not found.

The reduction of SSIs through prevention and improved diagnosis and management of SSIs are challenges facing colorectal surgeons. Several measures, such as oral antibiotic prophylaxis, the change of sterile gloves closing laparotomy, and mechanical bowel preparation have been adopted to minimize the risk of SSI. The use of wound protectors has been widely reported, and their role in preventing SSI has been long discussed [18]. The plastic wound protectors were originally designed to be useful in preventing SSIs, reducing the contact between bacteria and incisions, and protecting the wound edge from pathogen contamination. The study conducted by Arenal et al. found that SSIs were significantly reduced by wound protectors in colorectal surgery [19].

However, an economic evaluation conducted alongside the Rossini TRIAL to assess the relative cost-effectiveness of wound-edge protection devices compared to standard care revealed no clear evidence of the former being more beneficial in terms of SSI reduction (OR 0.97;95% CI 0.69 to 1.36), health-related quality of life, or hospital length of stay [20]. Although the authors concluded that their use is not recommended, they patients included in the analysis underwent open abdominal surgery which is well known to be more susceptible to develop SSI compared to a minimally invasive approach [21-23].

Despite the fact that minimally invasive treatment was adopted in all patients enrolled in our research, SSI rates were significantly higher in the group where the O-Ring retractor was not used.

Our results reflected that the Alexis® device was effective in reducing the incidence of surgical site infections in patients who underwent laparoscopic colorectal surgery. However, the economic implications of these findings are not obvious. The total cost for devices is significantly lower in Group A ($p = 0.033$). The higher costs incurred in Group B could be related to the higher incidence of SSIs and the consequent use of many devices and techniques required for treating SSIs. However, the impact of this finding on total costs was very small and did not reach a statistically significance difference due to the very high number of confounders. The economic gain is higher in patients in whom the device was used (2894.20 vs. 2616.88 Euros); however, a statistically significant difference was not found.

There are some limitations of this study that need to be acknowledged. A weakness of the present study is the relatively small sample size; this could be attributed to the study design and restricted adopted inclusion criteria. Furthermore, only one variant of all available wound protectors/retractors was investigated in our study. Moreover, this is a single-institution study.

However, this is the first study analyzing the cost effectiveness of Alexis® wound protector/retractor in elective colorectal laparoscopic surgery patients.

Conclusions

O-ring wound protector is a safe and useful tool in preventing SSI following colorectal surgery. We reported that patients in whom Alexis® was not used had a 3-fold higher risk of SSIs compared with those in whom it was used. Our data show that the use of O-Ring wound protector/retractor during elective laparoscopic colorectal surgery significantly reduces postoperative wound infection rates. However, the use of the device failed to translate into a significant benefit in terms of costs and revenues when compared with not using the device. Our analysis shows that the use of Alexis® is associated with a lower cost for materials and does not increase overall costs.

Riassunto

Introduzione: Le infezioni del sito chirurgico (ISC) rappresentano ad oggi una temibile complicanza dopo chirurgia colorettale, costituendo un fenomeno dal notevole impatto economico sul sistema sanitario nazionale. Lo scopo di questo studio è quello di valutare l'efficacia clinica ed i costi relativi all'utilizzo del protettore/retrattore di ferita Alexis® in chirurgia elettiva colorettale laparoscopica

Metodi: I dati relativi ad ogni paziente sono stati raccolti in un database di chirurgia colorettale ed analizzati retrospettivamente, valutando l'arco temporale da Gennaio 2015 a Giugno 2018. L'infezione del sito chirurgico è stata definita in accordo ai criteri pubblicati dal Centro Europeo per la prevenzione e il controllo delle malattie (ECDC). In primo luogo, è stata condotta un'analisi costi-efficacia comparando il Gruppo in cui l'anello di protezione/retrazione della ferita è stato utilizzato intraoperatoriamente (Gruppo A), con un gruppo di controllo (Gruppo B) in cui il dispositivo in esame non è stato utilizzato.

Risultati: Duecentocinquantotto pazienti consecutivi sottoposti a chirurgia elettiva colorettale laparoscopica da Gennaio 2015 a Giugno 2018 sono stati arruolati nel nostro studio. Di questi, il gruppo di intervento (Gruppo A con 154 pazienti) è stato comparato con il gruppo di controllo (Gruppo B, 94 pazienti). Le infezioni del sito chirurgico sono state del 5.2% e del 15%, nel gruppo A e B rispettivamente ($p = 0.008$). L'analisi economica ha mostrato che non ci sono differenze in termini di costi totali e ricavi totali comparando i due gruppi.

Conclusione: I costi totali ed il profitto totale sono

simili in entrambi i gruppi oggetto del nostro studio. Non sono state osservate differenze statisticamente significative. Tuttavia, l'utilizzo del dispositivo Alexis® ha mostrato ridurre significativamente i tassi di infezione del sito chirurgico potendo quindi considerevolmente migliorare la qualità di vita del paziente.

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