



EFFECT OF A SURGICAL CARE BUNDLE ON THE INCIDENCE OF SURGICAL SITE INFECTION IN COLORECTAL SURGERY: A QUASI-EXPERIMENTAL INTERVENTION

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ABSTRACT

Background: Surgical site infections (SSI) have an important impact on morbidity and mortality. **Objective:** This study, therefore, sought to assess the effect of a surgical care bundle on the incidence of SSI in colorectal surgery. **Methods:** We conducted a quasi-experimental intervention study with reference to the introduction of a surgical care bundle in 2011. Our study population, made up of patients who underwent colorectal surgery, was divided into the following two periods: 2007-2011 (pre-intervention) and 2012-2017 (post-intervention). The intervention's effect on SSI incidence was analyzed using adjusted odds ratios (OR). **Results:** A total of 1,727 patients were included in the study. SSI incidence was 13.0% before versus 11.6% after implementation of the care bundle (OR: 0.88, 95% confidence interval: 0.66-1.17, $p = 0.37$). Multivariate analysis showed that cancer, chronic obstructive pulmonary disease, neutropenia, and emergency surgery were independently associated with SSI. In contrast, laparoscopic surgery proved to be a protective factor against SSI. **Conclusions:** Care bundles have proven to be very important in reducing SSI incidence since the measures that constitute these protocols are mutually reinforcing. In our study, the implementation of a care bundle reduced SSI incidence from 13% to 11.6%, though the reduction was not statistically significant. (REV INVEST CLIN. [AHEAD OF PRINT])

Key words: Surgical site infection. Incidence. Care bundle. Colorectal surgery.

INTRODUCTION

Surgical site infections (SSIs) are an important problem in public healthcare, giving rise to high morbidity, mortality, prolonged hospital stays, and an ensuing

financial impact. These factors are especially relevant in the case of colon surgery since SSI incidence is higher in this field than in other surgical subspecialties¹⁻⁴. SSIs are defined as infections related to a surgical procedure, which affect the surgical incision or

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surrounding tissues during the surveillance period, set at 30 days after surgery if no implant is used, or up to 3 months if a prosthetic implant has been placed *in situ*⁵⁻⁷. SSIs are one of the main causes of nosocomial infections, accounting for more than 20% of all hospital-acquired infections, and currently rank as the most frequent nosocomial infection in patients who have undergone surgery⁸⁻¹⁰.

Taking into account the National Research Council classification of surgical procedures by reference to the risk of infection¹¹, there are three types of SSIs that can be distinguished according to their localization¹², that is, superficial, deep, and organ-space SSIs. Somewhere between 2% and 5% of all patients who undergo surgery will develop an SSI¹³, with the risk of SSIs being even greater in the case of colorectal surgery¹⁴.

According to different guidelines, up to 60% of infections are preventable by implementing evidence-based recommendations¹⁵. As a result, different initiatives have been introduced in recent years to reduce the incidence of SSIs^{16,17}. What all of these have in common is the implementation of care bundles, consisting of a series of three or more interventions to be applied in all patients by means of checklists¹⁸. Indeed, the success of these measures depends on the systematic application of all rather than one or two selective interventions, as each intervention enhances the others¹⁹. In light of this evidence, in 2011, we implemented a surgical care bundle consisting of a series of measures aimed at reducing the incidence of SSIs. Accordingly, the aim of this study was to evaluate the effect of this surgical care bundle on the incidence of SSIs in colorectal surgery.

METHODS

Patients and Study Design

We conducted a quasi-experimental intervention study with a before-and-after analysis, with reference to the introduction of a surgical care bundle made up of four items with scientific evidence of proven effect, recommended by the Spanish Ministry of Health²⁰, and analyzed its effect on the incidence of SSI. Our study population comprised patients who had undergone colorectal surgery, as per the National Nosocomial

Table 1. COLO surgical procedures

| ICD-9_MC Code | Colon surgical procedure description |
|---------------|--|
| 45.03 | Incision of large intestine |
| 45.26 | Open biopsy of large intestine |
| 45.41 | Excision of lesion or tissue of large intestine |
| 45.49 | Other destruction of lesion of large intestine |
| 45.52 | Isolation of segment of large intestine |
| 45.71 | Open and other multiple segmental resection of large intestine |
| 45.72 | Open and other cecectomy |
| 45.73 | Open and other right hemicolectomies |
| 45.74 | Open and other resection of transverse colon |
| 45.75 | Open and other left hemicolectomies |
| 45.76 | Open and other sigmoidectomies |
| 45.79 | Other and unspecified partial excision of large intestine |
| 45.80 | Total intra-abdominal colectomy |
| 45.92 | Anastomosis of small intestine to rectal stump |
| 45.93 | Other small-to-large intestinal anastomosis |
| 46.03 | Exteriorization of large intestine |
| 46.04 | Resection of exteriorized segment of large intestine |
| 46.10 | Colostomy, not otherwise specified |
| 46.11 | Temporary colostomy |
| 46.13 | Permanent colostomy |
| 46.14 | Delayed opening of colostomy |
| 46.43 | Other revision of stoma of large intestine |
| 46.75 | Suture of laceration of large intestine |
| 46.76 | Closure of fistula of large intestine |
| 46.94 | Revision of anastomosis of large intestine |

Infections Surveillance/National Healthcare Safety Network (NNIS) COLO category (Table 1), at the Alcorcón Foundation University Teaching Hospital. All patients received a low-residue diet before surgery, oral prophylaxis with neomycin 1 g, and an oral cathartic (Bohm® solution) administered the day before surgery for mechanical bowel preparation. In 2017, the oral cathartic was changed to CitraFleet®. Patients received antibiotic prophylaxis with amoxicillin-clavulanic 2 g 30-60 min before surgery and 4 h afterward. Allergic patients received metronidazole 500 mg and gentamicin 3-5 mg/kg. Patients undergoing colorectal surgery were divided into the following two periods: 2007-2011 (pre-intervention); and

Table 2. Surgical preventive measures care bundle implemented in 2011

| |
|---|
| Replacement of hygienic and surgical handwashing with chlorhexidine by washing and disinfection with hydroalcoholic solutions |
| Replacement of surgical field shaving with a razor blade by removal of hair from the surgical field with an electric razor |
| Antisepsis of the surgical field with 2% alcoholic chlorhexidine instead of povidone-iodine as was previously used |
| Prospective surveillance, update, and assessment of surgical antibiotic prophylaxis |

2012-2017 (post-intervention). Patients were selected and included consecutively from the surgical schedule listings of the General and Digestive Surgery Department.

Sample size was estimated on the basis of a 95% confidence level, a statistical power of 80%, an incidence of SSI of 15% in the non-intervention group and 10% in the intervention group, and a 5% loss to follow-up. A sample of at least 1528 patients was thus deemed necessary. The EPIINFO v7 software suite was used to calculate the sample size.

Since an SSI is defined as an infection established within the first 30 days after surgery, patients' progress was recorded from the time of surgery to the end of the maximum incubation period (30 days). The association between risk factors and SSI and the effect of the surgical care bundle on the incidence of infection were assessed by reference to the odds ratio (OR). The component measures of the surgical care bundle developed and drawn up in 2011 are shown in Table 2.

Study Variables

The variables studied included sex, age, comorbidities (renal failure, diabetes mellitus, cancer, chronic obstructive pulmonary disease (COPD), liver cirrhosis, obesity, and neutropenia), hospital stay, study group ("pre-intervention group" and "post-intervention group"), urgency and duration of surgery, type of surgery (laparoscopic or open), surgical contamination, administration of antibiotic prophylaxis (antibiotic administered, route, dose, start time, and duration)

according to the hospital protocol, pre-operative preparation-related aspects (pre-operative antiseptic shower and mouthwash), presence or absence of infection according to the diagnostic criteria of the CDC⁶, and the microorganisms involved.

Statistical Analysis

A descriptive analysis of the sample was performed. Quantitative variables were described using either the mean and standard deviation (SD) or the median and interquartile range if they did not meet the conditions of normality. Quantitative variables were compared by means of the Student's t-test or in cases where they did not follow a normal distribution by means of the Mann-Whitney U test. Qualitative variables were described with their frequency distribution and compared with Pearson's Chi-square test or with Fisher's exact test if they did not meet the application criteria.

Antibiotic prophylaxis was defined as correctly used when all the items were administered according to the hospital protocol and inappropriate when any of them were not used correctly.

The cumulative incidence of infection was assessed, both overall and stratified by the NNIS risk index, for the pre-intervention and post-intervention group periods of implementation of the surgical care bundle. The effect of the intervention on SSI incidence was evaluated using the OR and its 95% confidence interval (CI) and adjusted for the different covariates with a backward stepwise logistic regression model. Covariates with $p < 0.2$ in the univariate analysis or proving clinically relevant were included in the study. All statistical analyses were performed using the SPSS v.24 software package, with values being deemed statistically significant at $p < 0.05$.

RESULTS

The study covered a total of 1727 patients who underwent colorectal surgery, 899 in the period 2007-2011 and 828 in the period 2012-2017. The characteristics of the patients are shown in Table 3. Patients' mean age was 67.3 years (SD: 14.4) in the pre-intervention group and 67.9 years (SD: 13.3) in the post-intervention group ($p = 0.345$). In terms of gender,

Table 3. Patient characteristics

| Variable | Pre-intervention n (%) | Post-intervention n (%) | p |
|----------------------------|------------------------|-------------------------|--------|
| Gender | | | |
| Male | 559 (62.2) | 484 (58.5) | 0.114 |
| Female | 340 (37.8) | 344 (41.5) | 0.114 |
| Mean age (SD) | 67.31 (14.4) | 67.94 (13.3) | 0.345 |
| Comorbidities | | | |
| Diabetes mellitus | 162 (18) | 112 (13.5) | 0.011 |
| Obesity | 58 (6.5) | 61 (7.4) | 0.453 |
| COPD | 59 (6.6) | 39 (4.7) | 0.096 |
| Neutropenia | 8 (0.9) | 7 (0.8) | 0.921 |
| Cancer | 420 (46.7) | 441 (53.3) | 0.001 |
| NNIS | | | |
| 1 | 291 (32.4) | 334 (40.3) | <0.001 |
| 2 | 476 (52.9) | 392 (47.3) | <0.001 |
| 3 | 132 (14.7) | 102 (12.3) | <0.001 |
| Surgical approach | | | |
| Open | 702 (78.1) | 528 (63.8) | <0.001 |
| Laparoscopic | 197 (21.9) | 300 (36.2) | <0.001 |
| Average hospital stay (SD) | 3.05 (13.7) | 2.69 (6.9) | 0.505 |

SD: standard deviation; COPD: Chronic Obstructive Pulmonary Disease; NNIS: National Nosocomial Infections Surveillance risk index.

559 patients were male and 340 were female in the pre-intervention group versus 484 and 344, respectively, in the post-intervention group.

The most frequent comorbidities among the patients were cancer (49.8%), diabetes mellitus (15.9%), obesity (6.9%), and COPD (5.7%). The average hospital stay was 3.1 days during the first period and 2.65 days during the second period, with a non-significant decrease in the average hospital stay after implementation of the care bundle ($p = 0.505$). With respect to the moment of surgery, 83.8% of the interventions were scheduled, while 16.2% were emergency surgeries.

Pre-surgical preparation of the skin consists of three main items: body hygiene, hair removal, and surgical field antisepsis. Hair removal decreased from 17% to 9.1%, and 76.9% of the patients were correctly prepared. Only 10.8% of the patients with adequate preparation developed an SSI, while the percentage of SSIs among patients with inadequate preparation rose to 17.3% ($p = 0.001$). Antibiotic prophylaxis was correctly administered in 93.5% of patients and increased

from 89.7% to 97.6% ($p < 0.05$), while 11.5% of patients who received proper antibiotic prophylaxis developed an SSI, 20.5% in whom antibiotic prophylaxis was inappropriate became infected.

In terms of surgical approach, 28.8% of the interventions were performed by laparoscopy (21.9% during the pre-intervention period and 36.2% during the post-intervention period).

The types of surgery performed were as follows: right hemicolectomies (29.7%); sigmoidectomies (21.9%); total intra-abdominal colectomies (14.7%); right hemicolectomies (12.3%); colostomies (10.6%); stoma closure (9.6%); and resections of transverse colon (1.2%). A breakdown of the type of surgical intervention performed by the risk of contamination showed that 88.8% were contaminated and 11.2% were dirty. With respect to the localization of SSIs, 71.4% were superficial, 13.6% were deep, and 14.1% were organ-space. The percentage of SSIs was as follows: 9.3% among patients with NISS 0; 11.5% among patients with NISS 1; 12.6% among patients with NISS 2; and 14.1% among patients with NISS 3.

Figure 1. Etiology of infections.

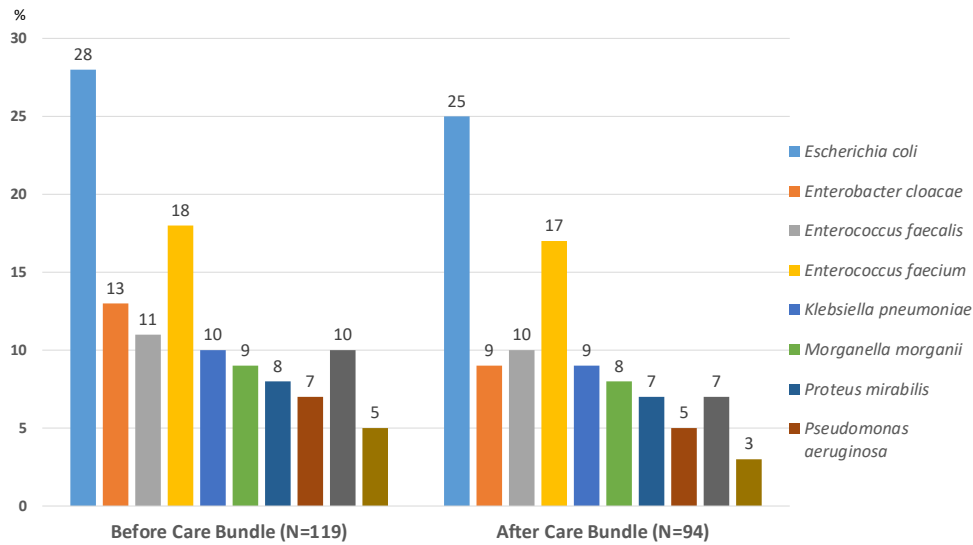
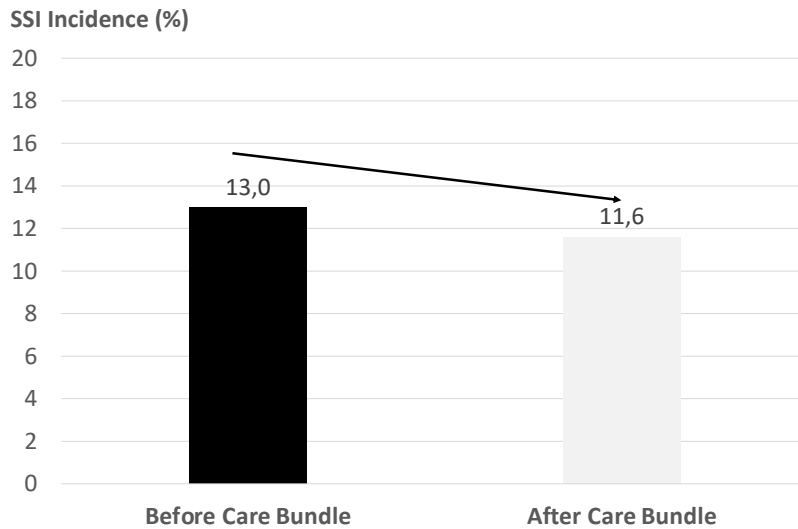


Figure 2. Effect of the surgical care bundle on surgical site infection incidence.



In the period 2006 through 2017, 213 patients who underwent colorectal surgery developed SSIs, with an overall incidence of 12.3%. (95% CI: 10.9-14). The most frequent pathogenic microorganisms identified were *Escherichia coli* (26.3%), *Enterococcus faecium* (12.7%), *Enterococcus faecalis* (9.9%), and *Enterobacter cloacae* (8.9%). Microorganisms causing infection in both periods are shown in figure 1. Analysis of the results by reference to the two periods of the study indicated an SSI incidence of 13.0% before implementation of the care bundle; after

implementation, SSI incidence decreased by some 1.4-11.6% (OR: 0.88, 95% CI: 0.66-1.17, p = 0.37) (Fig. 2).

The univariate and multivariate analyses are shown in Table 4. The multivariate analysis showed the following risk factors to be independently associated with SSI: COPD (OR: 2.10, 95% CI: 1.26-3.49, p = 0.004); immunodeficiency (OR: 3.59, 95% CI: 1.19-10.83, p = 0.024); and emergency surgery (OR: 1.86, 95% CI: 1.32-2.63, p < 0.001). In contrast, endoscopic

Table 4. Univariate and multivariate analyses

| Univariate analysis | | | | |
|------------------------------------|--------|-------|------------|--------|
| Risk factors | | OR | 95% CI | p |
| Emergency surgery | | 2.05 | 1.47-2.88 | 0.001 |
| Incorrect pre-surgical preparation | | 1.72 | 1.26-2.35 | 0.001 |
| Inadequate antibiotic prophylaxis | | 1.98 | 1.30-3.01 | 0.001 |
| COPD ^a | | 2.18 | 1.33-3.59 | 0.002 |
| Neutropenia | | 3.62 | 1.22-10.7 | 0.013 |
| Obesity | | 1.68 | 1.03-2.74 | 0,034 |
| Laparoscopic surgery | | 0.42 | 0.28-0.61 | 0.001 |
| Cancer | | 1.51 | 1.11-2.23 | 0.012 |
| Multivariate analysis | | | | |
| Risk factors | Coef | OR | 95%CI | p |
| COPD | 0.741 | 2.10 | 1.26-3.49 | 0.004 |
| Neutropenia | 1.278 | 3.59 | 1.19-10.83 | 0.024 |
| Laparoscopic surgery | -0.72 | 0.49 | 0.33-0.72 | 0.0001 |
| Emergency surgery | 0.621 | 1.86 | 1.32-2.63 | 0.0001 |
| Period (after) | -0.049 | 0.95 | 0.71-1.28 | 0.75 |
| Cancer | 0.712 | 1.489 | 1.18-2.01 | 0.02 |

COPD: Chronic Obstructive Pulmonary Disease. OR: odds ratio.

surgery, as shown by the univariate analysis, again proved to be a protective factor against SSI (OR: 0.49, 95% CI 0.33-0.72, $p < 0.001$).

DISCUSSION

Colorectal surgery is a surgical procedure with a high risk of SSI²¹, which registers a higher infection rate than other digestive system surgeries. In our study, the incidence of SSI after colorectal surgery was 12.3%, a figure in line with recent data²²⁻²⁴. SSI incidence is a good indicator of improvement in health-care quality and safety and accounts for the fact that actions grouped into preventive care bundles and targeted at preventing SSI have not only achieved a significant decrease in incidence but have also proved to be cost-effective^{8,25,26}.

In Spain, previous experiences have provided evidence of a 10.9-1.9% ($p < 0.05$) decrease in risk of SSI after application of a preventive care bundle in pediatric

patients for heart surgery²⁷, as well as a 27.5-16.9% ($p = 0.03$) drop in SSI recorded by a similar study on colorectal surgery². Furthermore, other international reviews have reported favorable results similar to those described^{18,28-31}. Our study observed a reduction in SSI from 13.0% to 11.6%, amounting to a reduction in risk of 1.4% (OR: 0.88, 95% CI: 0.66-1.17).

In this respect, reductions of almost 84% in the risk of SSI in colon surgery have been described after implementation of different preventive care bundles, findings much higher than those reported by our study³². The components of our care bundle included measures to optimize antibiotic prophylaxis, appropriateness of patients' pre-operative preparation, reinforcement of hand hygiene promotion, shaving with electric razor, and the participation of members of the multidisciplinary group to ensure prolonged maintenance over time of the measures implemented. These measures are recommended by the Spanish Ministry of Health. No significant improvement

($p = 0.75$) was seen in SSI incidence after implementation of the care bundle.

Appropriateness of antibiotic prophylaxis went from 89.7% to 97.6%, with timing of administration being the most frequent cause of inappropriateness, a finding in line with those of other SSI studies conducted in Spain^{33,34}. There was a 17-9.1% reduction in hair removal, indicating heightened awareness of the need to remove hair only where this is essential³⁵. Appropriateness of pre-operative preparation rose from 88.1% to 96.6%. The recent study by Bagga et al.³⁶ showed how implementation of a similar care bundle, including pre-operative bathing with chlorhexidine, hair removal with electric clippers, monitoring of antibiotic use, optimization of hand hygiene compliance, and intraoperative glycemic control, achieved reductions of 3.4% through 1.2% in SSI.

In addition, our study evaluated other possible risk factors, both intrinsic and extrinsic to the patient. In the univariate analysis, the following proved significant: cancer, emergency surgery, incorrect pre-surgical preparation, inappropriate antibiotic prophylaxis, COPD, neutropenia, and obesity. Obesity was considered of interest, given its clinical significance and prognosis as a risk factor for SSI, but neither obesity nor incorrect pre-surgical preparation nor inappropriate antibiotic prophylaxis was kept as risk factors in the multivariate analysis. Rather than diabetes *per se*, this may be more closely connected to the fact that what really predisposes patients to suffer infections is poor glycemic control of the disease; however, on not having access to the blood glucose levels of these patients, we have no way of confirming their baseline status for the purpose of establishing such an association^{37,38}. Laparoscopic surgery happened to be a protective factor against SSI, as described in the literature^{39,40}.

During the study period, some changes were introduced along with the implementation of the care bundle. Thus, antibiotic prophylaxis changed according to the continuous updating of the antibiotic prophylaxis protocol, the oral cathartic also changed, and the percentage of use of laparoscopic surgery grew. The fact that the effect of the care bundle was not statistically significant may be due to the confounding effect of the improvement in antibiotic prophylaxis, the change of the oral cathartic, and increased use laparoscopy.

The most frequent pathogenic microorganisms identified were *Enterobacteriaceae*, in line with the data published in the literature⁴¹.

In conclusion, care bundles have shown themselves to be vital in reducing the incidence of SSI since the measures that constitute these protocols are mutually reinforcing. To compare different cohorts across time is the best way to conduct such quasi-experimental protocols. Nowadays, it is not considered ethical to conduct a blinded study in which part of the patients is included in one arm with the care bundle and part is included in another arm without proper measures. In our study, the implementation of a care bundle reduced the incidence of infection from 13% to 11.6%, though there was no statistically significant difference between the pre-intervention period and after its implementation.

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