ORIGINAL ARTICLE

# Incidence of surgical infection and risk factors in colorectal surgery – A prospective cohort study

## *Incidencia de infección quirúrgica y factores de riesgo en cirugía colorrectal. Estudio de cohorte prospectivo*

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## Abstract

**Objective:** *The objective was to measure the incidence of surgical site infection (SSI) and identify risk factors, in patients undergoing elective surgery of the colon and rectum.* **Materials and methods:** *A prospective cohort study was performed from January 2017 to December 2018.* **Results:** *A total of 130 patients were studied. The cumulative incidence of SSI was 12.3%. The 56.25% were superficial wound infections and the 31.25%, organ-space infection. The risk factors significantly associated with SSI were the non-administration of pre-operative oral nutrition, diabetes mellitus, heart disease, symptomatic state at the diagnosis of colorectal cancer (CRC), and ≥ 2 altered nutritional biochemical parameters at diagnosis. After multivariate , risk factors associated with SSI were: non-administration of preoperative enteral nutrition (odds ratio [OR] = 0.27; 95% confidence interval [CI]: 0.07-1.0), DM (OR = 3.0; 95% CI: 0.9-9.9), the heart disease (OR = 4.6; 95% CI: 1.1-18.6), and laparoscopic surgery (OR = 0.28; 95% CI: 0.08-0.97). The average stay was higher in patients with a diagnosis of SSI (11.9 vs. 9.2 days).* **Conclusions:** *Independent risk factors for SSI in CRC were the non-administration of pre-operative enteral nutrition, the existence of heart disease, and open surgery.*

***Key words:*** *Surgical site infection. Colorectal surgery. Surgical wound infection. Incidence. Risk factors. Cohort study.*

## Resumen

**Objetivo:** *Estudiar la incidencia de infección del sitio quirúrgico y evaluar sus factores de riesgo en pacientes intervenidos de cirugía colorrectal electiva.* **Método:** *Se realizó un estudio de cohortes prospectivo desde enero de 2017 hasta diciembre de 2018.* **Resultados:** *Se incluyeron 130 pacientes. La incidencia acumulada de infección del sitio quirúrgico fue del 12,3% (n = 16), siendo el 56,25% infecciones de herida y el 31,25% infecciones órgano-espacio. Los factores de riesgo asociados a infección del sitio quirúrgico con significación estadística fueron la no administración de nutrición oral preoperatoria, la diabetes mellitus, la enfermedad cardiaca, la presencia de síntomas en el momento del diagnóstico de cáncer colorrectal y tener al menos dos parámetros bioquímicos nutricionales alterados. Tras el análisis multivariante se asociaron la no administración de nutrición*

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Date of reception: 20-03-2020
Date of acceptance: 25-04-2020
DOI: 10.24875/CIRU.20000205

Cir Cir. 2021;89(2):156-162
Contents available at PubMed
www.cirugiaycirujanos.com

*enteral preoperatoria (odds ratio [OR] = 0,27; intervalo de confianza del 95% [IC95%]: 0,07-1,0), la diabetes mellitus (OR = 3,0; IC95%: 0,9-9,9), la enfermedad cardiaca (OR = 4,6; IC95%: 1,1-18,6) y la cirugía laparoscópica (OR = 0,28; IC95%: 0,08-0,97). La estancia media fue mayor en los pacientes con diagnóstico de infección del sitio quirúrgico (11,9 frente a 9,2 días).* **Conclusiones:** *Los factores de riesgo independientes para el desarrollo de infección del sitio quirúrgico en los pacientes con cáncer colorrectal fueron la no administración de nutrición oral preoperatoria, la enfermedad cardiaca y la cirugía abierta.*

***Palabras clave:*** *Infección del sitio quirúrgico. Cirugía colorrectal. Infección de herida quirúrgica. Incidencia. Factores de riesgo. Estudio de cohortes.*

## Introduction

A healthcare-associated infection (HCAI) is an infection occurring in a patient during the process of care in a hospital or other health-care facility[1]. These infections first appear 3 days or more after admission, considered day 1. Any infections the patient already had at the time of admission are excluded, except when a change in pathogen or symptoms suggests the acquisition of a new infection[2].

HCAI is a primary public health concern, which falls within the lines of monitoring and control defined by the European Commission and the European Centre for Disease Control (ECDC), urging countries to adopt and implement strategies for the prevention and control of HCAI[3]. According to the ECDC, the prevalence of HCAI is 6.5% in European hospitals[4]. Surgical site infection (SSI) has a significant impact on HCAIs. According to the EPINE study, SSI is the main cause of HCAI (21.6%), ahead of respiratory and urinary tract infections[5]. SSIs are usually caused by an imbalance between bacteria and the body's defenses, and their development is, therefore, related to many endogenous and exogenous factors[6-10]. The most important related factors include type of surgery, degree of contamination, duration of surgery, comorbidities, age, American Society of Anaesthesiologists (ASA) classification, nutritional status, and obesity[11,12]. An estimated 60% of SSIs are preventable[6]. The Indicators of Continuous Quality Improvement (INCLIMECC) program of continuous surveillance of hospital infection[7] has observed CSI rates of 17.1% in colon surgery and 21.36% in rectal surgery[8].

Knowledge of the factors that influence the development of SSI in colorectal surgery can encourage the adoption of corrective measures to prevent its occurrence[9]. The aim of this paper was to study the incidence of infection in surgical sites and to evaluate risk factors in patients undergoing elective colon and rectal surgery.

## Materials and Methods

A prospective cohort study was conducted at the Hospital Universitario de Móstoles (Madrid, Spain). The study included patients undergoing colon and/or rectal surgery in the general and digestive surgery department from January 2017 to December 2018. The study was approved by the Hospital Universitario de Móstoles Clinical Research Ethics Committee. Patients with suspected infection at the time of surgery or undergoing antibiotic treatment, those receiving neoadjuvant therapy, and patients with no primary anastomosis and emergency surgery were excluded from the study. An estimate of the sample size was made according to a 95% confidence, an accuracy of 4.5%, an estimate of infection rate of 10%, and predicting a 5% loss. Based on these premises, a study sample of 130 patients was considered necessary. Patients were selected from the surgical schedule and were included by consecutive inclusion from the beginning until the end of the study period. The evolution of the patients from the moment of surgery to the end of the maximum incubation period of 30 days was studied. The criteria of the Centers for Disease and Prevention Control (CDC) were used for the diagnosis of SSI and the Clavien-Dindo classification for the rest of the surgical complications.

The variables included in the study were age, sex, body mass index (BMI), ASA classification, high blood pressure (HBP), diabetes mellitus (DM), chronic obstructive pulmonary disease (COPD), heart disease, taking antiplatelet agents, taking oral anticoagulants, hypothyroidism, taking anticoagulants, weight loss related to diagnosis, nutritional risk according to the MUST tool, analytical parameters and degree of alteration thereof, duration of surgery, blood transfusion, type of surgical intervention, symptomatic status at diagnosis, and adequacy of preoperative prophylactic measures. The dependent variable in our work was the diagnosis of SSI.

A specific database was designed for data collection and a relational database and standardized with the Microsoft Access® program for recording them. A descriptive study of the sample was carried out. Quantitative variables were described with the mean and standard deviation (SD) or median and interquartile range (IRQ) if they did not follow a normal distribution. They were compared with the Student's t-test and if they did not follow normal distribution, the Mann–Whitney U-test was used. Quantitative variables with more than 2 categories were compared with the analysis of variance (ANOVA) and if their application conditions were not met, the non-parametric Kruskal–Wallis test was used. Qualitative variables were described with their frequency distribution and compared with Pearson's Chi-square test or Fisher's exact test if the application criteria were not met. The cumulative incidence of SSI and the influence on its appearance as risk factors of the different variables under study were evaluated. The statistical and epidemiological analysis was performed with the SPSS v.22 and Epidat v.4.2 programs. Statistically significant differences were considered to be those with $p < 0.05$ and all estimates were described with their 95% confidence interval (CI).

## Results

Most patients were classified as ASA II (60%) and ASA III (34.6%). The most frequent comorbidities of the patients were HBP (55.4%), dyslipidemia (DL) (40%), and DM type I (17.7%). A total of 13.1% of the patients had heart disease (heart failure, atrial fibrillation, or coronary disease) and 13.8% had COPD. The BMI in the total population studied had an average of 27.5 (SD = 4). The characteristics of the patients are described in table 1.

According to the symptoms of the patients at the time of diagnosis, a distinction was made between those patients who had a clinical history related to the disease and those who came from the Prevecolon screening campaign and were, therefore, asymptomatic. Overall, 29% of patients (n = 37) came from the screening campaign and were asymptomatic, while 71% (n = 93) were symptomatic. A total of 51.5% were overweight and 24.6% were obese. In the group, it was found that 33% (n = 43) of the patients had no weight loss, 18.5% (n = 24) lost < 5 kg, 25.4% (n = 33) lost between 5 and 10 kg, and 2.3% (n = 3) lost ≥ 10 kg. Weight loss was higher in the group of patients not from the screening campaign (p = 0.016).

The pathological study in the first consultation was as follows: adenocarcinoma in 71.5% (n = 93), tubular adenoma with unresectable dysplasia in 14.6% (n = 19), and tubulovillous adenoma with unresectable dysplasia in 13.8% (n = 18). In the general population studied, 36.2% (n = 47) had the neoplasm located in the right colon, 33.8% (n = 44) in the left colon, 20.8% (n = 27) in sigma, 6.9% (n = 9) in the rectum, and 2.3% (n = 3) with location in the transverse colon. About 93% (121) of patients underwent surgery for colon neoplasia and 7%9 underwent rectal surgery. Despite the small number of rectal procedures, we have not found differences in the distribution by population group.

Open surgery was used in 36.2% (n = 47) of the operations, laparoscopic surgery in 53.1% (n = 69), and the procedure could not be completed by laparoscopy in 10.8% (n = 14) and had to be reconverted to laparotomy. The mean surgery time was 227.9 min (SD = 63) and the median was 217.5.

The alteration of analytical parameters was also assessed as a possible risk factor associated with SSIs. The mean and frequency distribution of these groups is detailed in table 2.

There were a total of 9 patients (6.9%) with superficial and/or deep incision infection, 5 (3.8%) with organ/space infection, and 2 (1.5%) with combined wound and organ/space infection. This resulted in an overall incidence of SSI of 12.3%. When studying the average hospital stay of patients (in days) as they developed SSIs, we found that the average stay is 9.2 days (SD = 6.8) for the group of patients with no infection, slightly lower than that of patients with SSI, which is 11.9 days (SD = 6.1), although with p = 0.6. The results are not statistically significant.

In the univariate analysis, the risk factors associated with SSIs were the absence of pre-operative oral enteral nutrition administration, DM, heart disease, diagnosis with symptoms secondary to the neoplastic disease, and having more than 2 altered biochemical nutritional parameters.

In the multivariate analysis, we studied the independent risk factors of SSI, statistically significant after the univariate analysis, and those with significance ≤ 0.2 that were considered relevant because of their clinical and prognostic significance (age, sex, application of the plan, DM, ATH, heart disease, chronic lung disease, BMI, weight loss, surgical technique, symptomatic state at diagnosis, albumin deficit, total protein deficit, and degree of alteration of analytical parameters). After the multivariate analysis, the following were statistically significant: the administration of preoperative enteral nutrition (OR = 0.27; IC 95%: 0.07-1.0), DM (OR = 3.0; IC 95%: 0.9-9.9), previous heart disease (OR = 4.6; IC 95%: 1.1-18.6), and

**Table 1. Description and characteristics of patients**

| | |
|---|---|
| Gender, n (%) | |
| Male | 85 (65) |
| Female | 45 (35) |
| Age ± SD (años) | 70,9 ± 8 |
| Comorbidities, n (%) | |
| HBP | 72 (55,4) |
| Diabetes mellitus | 23 (17,7) |
| Dyslipidemia | 52 (40) |
| Cardiac disease | 17 (13,1) |
| COPD | 18 (13,8) |
| Thyroid disease | 14 (10,8) |
| Toxic habits, n (%) | |
| Active smoker | 16 (12,3) |
| Former Smoker | 65 (50) |
| Non-smoker | 49 (37,7) |
| No alcohol consumption | |
| Alcohol occasional | 26 (20) |
| Alcohol moderate | 31 (23,8) |
| Alcohol abuse | 2 (1,5) |
| ASA, n (%) | |
| ASA Iw | 5 (3,8) |
| ASA II | 78 (60) |
| ASA III | 45 (34,6) |
| ASA IV | 2 (1,5) |
| BMI ± SD | 27,5 ± 4 |
| Weight loss, n (%) | |
| No weight loss | 43 (33) |
| Weight loss ≤ 5 kg | 24 (18,5) |
| Weight loss 5-10 kg | 33 (25,4) |
| Weight loss ≥ 10 kg | 3 (2,3) |
| Not asked | 27 (20,7) |
| Symptomatic status at diagnosis, n (%) | |
| Asymptomatic (screening) | 37 (29) |
| Symptomatic | 93 (71) |
| Neoplasm location | |
| Right colon neoplasm | 47 (36,2) |
| Left colon neoplasm | 44 (33,8) |
| Sigma neoplasm | 27 (20,8) |
| Rectum neoplasm | 9 (6,9) |
| Transverse colon neoplasm | 3 (2,3) |
| Surgical technique, n (%) | |
| Open | 47 (36,2) |
| Laparoscopy | 69 (53,1) |
| Reconverted laparoscopy | 14 (10,8) |
| Duration of surgery ± SD | 227,9 ± 63 |

**Table 2. Analytical parameters**

| | |
|---|---|
| Analytical parameters ± SD | |
| Hemoglobin (g/dl) | 13,2 ± 2.2 |
| Lymphocytes | 2,53 ± 2,16 |
| Albumin (g/dl) | 4,2 ± 0,6 |
| Pre-albumin (mg/dl) | 26,2 ± 18,5 |
| Total proteins (g/dl) | 6,7 ± 0,73 |
| Retinol bound protein (mg/dl) | 4,3 ± 0,98 |
| Cholesterol (mg/dl) | 168 ± 39 |
| Transferrin | 256,5 ± 61 |
| Total number of altered analytical parameters, n (%) | |
| Non altered parameters | 28 (21,5) |
| 1-2 altered parameters | 80 (61,5) |
| > 2 altered parameters | 22 (17) |

**Table 3. Univariate and multivariate analysis of ISQ risk factors**

| **Univariate analysis** | **SSI** | **No SSI** | **p-value** |
|---|---|---|---|
| Pre-operative oral nutrition | 12 (18,5%) | 53 (81,5%) | 0,033 |
| DM | 8 (24,2%) | 25 (75,8%) | 0,16 |
| Cardiac disease | 5 (29,4%) | 12 (70,6%) | 0,02 |
| Albumin deficit | 2 (28,6%) | 5 (71,4%) | 0,21 |
| Pre-albumin deficit | 1 (8,3%) | 11 (91,7%) | 0,90 |
| Total proteins deficit | 6 (20%) | 24 (80%) | 0,18 |
| ≥ 2 altered analytical parameters* | 16 (12,3%) | 114 (87,7%) | 0,04 |
| Symptomatic patients | 16 (17,2%) | 77 (82,8%) | 0,007 |
| Age ≥ 70 years | 11 (16,2%) | 57 (83,8%) | 0,16 |
| Male gender | 9 (10,9%) | 76 (89,1%) | 0,4 |
| HBP | 10 (13,9%) | 62 (86,1%) | 0,54 |
| COPD | 2 (11,1%) | 16 (88,9%) | 0,87 |
| Weight loss | 13 (14,8%) | 75 (85,2%) | 0,22 |
| ASA ≥ III | 7 (14,9%) | 40 (85,1%) | 0,5 |
| BMI ≥ 30 | 13 (12,4%) | 22 (88%) | 0,96 |
| Open surgery | 5 (7,2%) | 64 (92,8%) | 0,06 |
| Surgical duration ≥ 150 min | 15 (12,8%) | 102 (87,2%) | 0,28 |
| **Multivariate analysis** | **OR** | **IC 95%** | **p-value** |
| Pre-operative oral nutrition | 0,27 | 0,07-1,01 | 0,05 |
| DM | 2,99 | 0,91-9,87 | 0,07 |
| Cardiac disease | 4,57 | 1,12-18,64 | 0,03 |
| Laparoscopic surgery | 0,28 | 0,08-0,97 | 0,04 |

*Analytical parameters studied are albumin, transferrin, pre-albumin, retinol binding protein, cholesterol, total proteins y lymphocytes

laparoscopic surgery (OR = 0.28; IC95%: 0.08-0.97). Table 3 details the univariate and multivariate analysis for the various risk factors for SSI.

## Discussion

There is scientific evidence of the influence that several modifiable and non-modifiable risk factors have on the development of post-operative complications, including SSI, after colon and rectal surgery[13].

An overall rate of SSI of 12.3% was observed in our study.

Patients were monitored during the 30 days post-operative period. Some studies limit SSI monitoring to the period of hospitalization rather than 30 days after surgery, which may underestimate its incidence[14,15].

The rate of SSIs recorded in our study is low when compared with other studies, such as the Community of Madrid's multicenter INCLIMECC Task Force study, which observed overall SSI rates of 17.1% in colon surgery and 21% in rectum surgery. The VINCat study observed an incidence of 20.8% in colorectal surgery. In international literature, several studies such as Poon et al. describe lower rates of SSI (6.5%)[16]. Gianotti et al. observed an incidence of 13.4%[17]. Howard et al. reported a 7% incidence of SSI for laparoscopic surgery and 25% for open surgery[18].

A total of 6.9% presented superficial and/or deep incisional SSI, 3.8% organ/space infection, and 1.5% presented SSI in both spaces.

There is a high level of variability of significant risk factors for SSI in the studies analyzed. Most of the risk factors acknowledged in the literature were evaluated in our study. In the univariate study, we found statistical significance for the incorrect administration of nutritional support protocol, DM, heart disease, diagnosis with symptoms, and having more than 2 altered nutritional biochemical parameters. After the multivariate study, only the incorrect application of the nutritional assessment program, the surgical approach, and heart disease were found.

In our study, we observed a SSI rate of 21.3% (n = 10) in open surgery, 7.2% (n = 5) in laparoscopic surgery, and 7.1% (n = 1) in the group with reconverted surgery, with no statistically significant difference between the groups with p = 0.064. However, in the multivariate study, laparoscopic surgery is a protective factor for the development of SSI with an OR = 0.28, IC 95% 0.08-0.97, p = 0.04. A Japanese retrospective cohort study of 9655 patients observed that laparoscopic surgery is a protective factor against SSI compared to open surgery[19]. These findings are consistent with those of Poon et al. (2009) and Kiran et al. (2010)[16,20].

A decrease in the incidence of SSIs was found in those patients given pre-operative oral nutrition (OR = 0.29, CI95%: 0.09-0.95) (p = 0.033). However, and following the multivariate study, we observed that this fact protects against SSI with an OR of 0.27 and a 95% CI of 0.07-1.01 and value of p = 0.05. Therefore, the result requires a non-categorical interpretation. We believe that other factors may have influenced the decrease in the risk of SSIs. After reviewing scientific studies, we found Spanish papers that refer to these findings. The study by Barreiro et al. shows a reduction in SSI from 1.9% to 0.8%[21] and Manzanares et al. reported a reduction in SSI from 40% to 33%[22].

There is a widespread perception that DM is associated with increased tissue and organ susceptibility to the development of certain infections[23]. Several, the majority retrospective observational studies, identified DM as an independent factor for the development of SSIs in univariate and multivariate studies[24,25]. Other studies have not found such a relationship[26-30]. In our database, we identified that 17% (n = 23) suffer from type I DM and 8% (n = 10) from type II DM. Overall, 25% of the population studied was diagnosed with DM. These figures are slightly higher than those published by the Diabetes Foundation, which establishes a prevalence of DM for those over 18 years of age at 13.8%[31]. This considerable difference may be conditioned by the fact that the range of patients diagnosed with colorectal neoplasia is greater than the general population when studying the general prevalence of disease. In our multivariate study, we observed an OR 2.99 (95% CI 0.91-9.87, p = 0.07) when studying DM as a risk factor for the development of SSI.

We found heart disease to be a risk factor for the development of SSIs with an OR = 4.57, 95% CI 1.12-18.64 and a p = 0.03 in the univariate and multivariate studies. Patients previously diagnosed with heart disease (coronary heart disease or heart failure), COPD, or other comorbidities have a worse immediate post-operative evolution and also, in general terms, their clinical condition may lead to a limited therapeutic approach to their oncological disease and consequently a worse survival rate[32]. In a systematic review by Boakye et al., heart disease was associated with an increased risk of mortality for patients with moderate or severe comorbidity before surgery, with an OR = 1.71, 95% CI = 1.26-2.31 and OR = 2.62, 95% CI = 1.97-3.47, respectively[33]. In our case, after the multivariate study for heart disease, although statistically significant, we observed a wide CI. This may be secondary to the sample size and the fact that the prevalence of disease in our study population was 13% (n = 17). Perhaps, an enlargement of the sample size would have helped to reduce this interval.

In the univariate study, we found that the risk of having SSI with previous diagnosis of nutritional analytical parameters deficit of ≥ 2 is 12.3% with p = 0.04. These findings have not been demonstrated in multivariate analysis, so we are unable confirm that, in isolation, the degree of analytical alteration increases the risk of SSI.

## Conclusions

The incidence of SSI in colorectal surgery in our study was low (12.3%). The risk factors associated with a higher probability of developing SSIs were as follows: the administration of a pre-operative nutritional assessment and support protocol and the existence of heart disease. We found the laparoscopic surgery as a protective factor for the development of SSI. The average hospital stay was higher in patients diagnosed with SSI (11.9 vs. 9.2 days), which was not statistically significant. It is important to evaluate risk factors for the development of pre-operative SSIs and to adopt preventive measures in those factors that are potentially modifiable to minimize their incidence and impact.

## Acknowledgments

The authors thank to their colleagues at “Hospital Universitario de Móstoles” for always offering quality and humanity in their patient care.

## Conflicts of interest

The authors declare have no conflicts of interest.

## Ethical disclosures

**Protection of human and animal subjects.** The authors declare that no experiments were performed on humans or animals for this study.

**Confidentiality of data.** The authors declare that they have followed the protocols of their work center on the publication of patient data.

**Right to privacy and informed consent.** The authors declare that no patient data appear in this article.

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