

Risk factors analysis for surgical site infection following elective colorectal resection: a retrospective regression analysis

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Abstract

Background: A surgical site infection (SSI) is a major post-operative complication from elective colorectal surgery; however, few studies have focused on evaluating the risk factors for SSI. This study aimed to analyze the relative correlation of medical and environmental factors as well as patient-related factors that contribute to the incidence of all types of SSI.

Methods: A retrospective search for eligible patients was conducted using the patient database of the Gastrointestinal Surgery Center of the Third Affiliated Hospital of Sun Yat-sen University from January 2011 to August 2017. Pre-operative demographic and surgical data were extracted and recoded according to the study protocol. Univariate and multivariate analyses were performed to clarify factors affecting the incidence of SSI. Propensity analysis was conducted to minimize bias in the demographic characteristics to explore the prophylactic effect of pre-operative administration of oral antibiotics.

Results: Univariate analysis of the baseline characteristics revealed that younger age (odds ratio [OR]: 0.378; 95% confidence interval [CI]: 0.218–0.657) and pre-operative oral antibiotic use (OR: 0.465; 95% CI: 0.255–0.850) were protective factors, while pre-operative anemia (OR: 4.591; 95% CI: 2.567–8.211), neoadjuvant chemotherapy history (OR: 2.398; 95% CI: 1.094–5.256), and longer surgical duration (OR: 2.393; 95% CI: 1.349–4.246; $P = 0.002$) were identified as risk factors for SSI. Multivariate analysis indicated that age ($P = 0.003$), surgical duration ($P = 0.001$), and pre-operative oral antibiotic use ($P < 0.001$) were independent factors that affect the incidence of SSI. Furthermore, a propensity-matched analysis confirmed the protective effect of oral antibiotic use, with a 1-day course of oral antibiotic producing a similar effect to a 3-day course.

Conclusions: Age, surgical duration, and pre-operative oral antibiotic use were associated with the incidence of SSI. However, pre-operative oral antibiotic use was the only controllable factor. From the results of our study, pre-operative oral antibiotic use is recommended before elective colorectal surgery and a 1-day course is enough to provide the protective effect.

Keywords: Surgical site infection; Colorectal cancer; Antibiotic

A surgical site infection (SSI) is a major post-operative complication after abdominal surgery, especially in the colorectal field.^[1] According to the Centers for Disease Control and Prevention,^[2] SSI can be classified into three distinct types: superficial incisional SSI (SSSI), involving only the skin and subcutaneous tissue of the incision; deep incisional SSI (DSSI), involving deep soft tissues such as the fascia and muscle layers, and organ space infection (OSI), involving any part of the anatomy that was opened or manipulated during an operation, other than the incision.^[3,4] The majority of SSIs occur within 30 days post-operatively. The overall incidence of SSI is around 20% and is strongly associated with increasing the length of stay (LOS), readmission rate, expense, and mortality.^[5,6]

Therefore, identification of effective methods to reduce the incidence of SSI is critically important. The main objective of our study was to analyze the relative correlation of medical and environmental factors as well as patient-related factors that contribute to the incidence of all types of SSI.

Methods

Ethical approval

After approval by the Ethics Committee of the Third Affiliated Hospital of Sun Yat-sen University (No. [2019] 02-008-01), retrospective search for eligible patients was

Access this article online

Quick Response Code:



Website:
www.cmj.org

DOI:
10.1097/CM9.0000000000000670

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Chinese Medical Journal 2020;133(5)

Received: 08-05-2019 Edited by: Yuan-Yuan Ji

conducted using the patient database of the Gastrointestinal Surgery Center of the Third Affiliated Hospital of Sun Yat-sen University from January 2011 to August 2017. Written informed consent was obtained from all patients before their enrollment in this study.

Patients' data

Only patients who underwent elective laparoscopic or laparotomic colorectal resection due to malignancy could be enrolled. Each SSI was sub-classified as SSSI, DSSI, and/or OSI.^[2] Surgical, environmental, and demographic data were extracted after the review of the database. The following data were extracted: age, sex, smoking status, nutritional status as evaluated by body mass index (BMI; with the range of 18.5–24.0 kg/m² defined as the standard healthy BMI for a Chinese population), comorbidities as classified by the American Society of Anesthesiologists (ASA) score, surgical approach, tumor and resection region, pre-operative bowel preparation modes (oral antibiotics plus mechanical bowel preparation [MBP] or MBP alone), pre-operative levels of serum albumin (cut-off level: 3.5 g/dL, according to the standard reference range), pre-operative levels of hemoglobin (cut-off level: 110 g/L, according to the standard reference range), pre-operative diagnosis of diabetes, surgical duration, post-operative intravenous antibiotic use and duration, and pathological tumor stage according to 7th American Joint Committee on Cancer Tumor Node Metastasis (TNM) staging.^[7]

All patients received MBP according to local protocols; either polyethylene glycol or magnesium sulfate was administered as a laxative 1 day before the surgery. Clyster was administered on the morning of the surgery. Streptomycin (1 g) plus metronidazole (0.2 g) was administered 3 times per day from 1 day or 3 days pre-operatively for some of the patients.

Intravenous antibiotic prophylaxis was based on local guidelines and resistance profiles with most patients receiving cefmetazole (2 g) pre-operatively via an intravenous drip 30 min before the initial incision and post-operatively every 12 h until 48 h after the surgery. Patients with penicillin or cephalosporin allergies were given clindamycin (0.6 g) twice a day. If the surgical procedure lasted more than 180 min, a booster dose of an additional application of antibiotic was administered.

Statistical analysis

Extracted data were recorded using a spreadsheet (Excel 2010; Microsoft Corp., Redmond, WA, USA) while all statistical analyses were performed using IBM SPSS Statistics software (version 22; IBM Corp., Armonk, NY, USA). Frequency was presented for categorical variables, while continuous variables were presented as mean \pm standard deviation. Pearson χ^2 or Fisher exact tests were used to analyze categorical variables. Student's *t* tests or Mann-Whitney *U* tests were used to compare continuous variables. Univariate logistic regression was conducted to identify potential risk factors significantly associated with SSI. A multivariate logistic regression model to explore risk factors of SSI was performed. The

stepwise forward method was used for variable selection. Propensity score matching was performed for minimizing confounding factors based on: TNM stage, laparoscopic or laparotomy approach, ASA score, gender, BMI, and neoadjuvant chemotherapy history with 1:1 ratio. Stratification etiology analysis for SSSI and OSI was conducted by logistic regression model. The level of significance was established as indicated by *P*-values < 0.05.

Results

Patients' features

Between January 2011 and August 2017, the data of a total of 806 patients were reviewed retrospectively from the patient database of The Third Affiliated Hospital of Sun Yat-sen University. In the final review, 581 patients who underwent elective surgeries were enrolled in our data analysis. SSIs developed in 57 patients over the entire period, representing an overall rate of 9.81%. Overall, there were 37 cases of SSSI, 12 cases of DSSI, 31 cases of OSI, and nine patients with more than one type of SSI. The overall mean post-operative LOS in the SSI group was 16.1 \pm 9.3 days, which was significantly longer (*P* = 0.0001) than the LOS in the no SSI group at 8.9 \pm 3.8 days. The total hospitalization expense was also higher in the SSI group (81,704.26 \pm 46,920.38 RMB [CNY] *vs.* 60,404.29 \pm 16,815.52 RMB [CNY]; *P* = 0.001).

Univariate analysis

Univariate analysis of the baseline characteristics revealed that age < 65 years (odds ratio [OR]: 0.378; 95% confidence interval [CI]: 0.218–0.657) was a protective factor for SSI, while pre-operative anemia (OR: 4.591; 95% CI: 2.567–8.211) and neoadjuvant chemotherapy (OR: 2.398; 95% CI: 1.094–5.256) were risk factors for SSI.

However, gender (*P* = 0.287), smoking status, BMI, diabetes (*P* = 0.496), hypertension (*P* = 0.084), and low albumin (*P* = 0.067) failed to show any significant association with the contraction of an SSI [Table 1].

For surgical and pathological factors, the univariate analysis indicated that only the combination of pre-operative oral antibiotic use plus MBP (OR: 0.465; 95% CI: 0.255–0.850; *P* = 0.011) and surgical duration longer than 4 h (OR: 2.393; 95% CI: 1.349–4.246; *P* = 0.002) were factors that were associated with SSI. The surgical approach, surgical region, pathological stage, and individual TNM stage were not associated with SSI [Table 2].

Multivariate and stratification analysis

The multivariate analysis indicated that surgical duration > 4 h was associated with a significantly increased SSI risk (*P* = 0.003), while age < 65 years old (*P* < 0.001) and oral antibiotic use plus MBP (*P* = 0.001) could reduce SSI incidence, as shown in Table 3. A Hosmer-Lemeshow test confirmed the efficiency of the logistic regression: *P* = 0.285, indicating no evidence of a poor fit and that the model is correctly specified.

Table 1: Univariate analysis of the baseline characteristics with incidence of SSI among patients who underwent elective colorectal resection.

Variables	SSIs (N= 57)	No SSIs (N= 524)	OR [95% CI]	P
Age				
<65 years	27	369	0.378 (0.218, 0.657)	0.0001
≥65 years	30	155		
Gender				
Male	30	314	0.743 (0.429, 1.286)	0.287
Female	27	210		
Smoking				
Yes	24	224	0.917 (0.262, 3.267)	0.893
No	30	273	1	
Ex-smoker	3	27	0.967 (0.273, 3.425)	0.959
ASA Grade				
1	36	286	1	
2	15	185	1.128 (0.453, 2.809)	0.796
3	6	53	0.716 (0.265, 1.937)	0.511
Diabetes				
Yes	4	57	0.618 (0.216, 1.772)	0.496
No	53	467		
Hypertension				
Yes	7	116	0.492 (0.217, 1.115)	0.084
No	50	408		
Albumin level				
≥3.5 g/dL	45	459	0.531 (0.267, 1.056)	0.067
<3.5 g/dL	12	65		
Pre-operative HGB				
<110 g/L	38	159	4.591 (2.567, 8.211)	<0.001
≥110 g/L	19	365		
BMI				
≤18.5 kg/m ²	6	47	1.019 (0.569, 1.826)	0.949
18.5 < BMI ≤ 24 kg/m ²	29	269	1	
>24 kg/m ²	22	208	1.207 (0.464, 3.141)	0.700
Neoadjuvant chemotherapy				
Yes	9	38	2.398 (1.094, 5.256)	0.025
No	48	486		

Values were shown as *n*. SSI: Surgical site infection; OR: Odds ratio; CI: Confidence interval; ASA Grade: American Society of Anesthesiologists (Grade1: Healthy individual with no systemic disease; Grade 2: Mild systemic disease not limiting activity; Grade3: Severe systemic disease that limits activity but is not incapacitating); HGB: Hemoglobin; BMI: Body mass index.

Furthermore, patients with a simple SSSI or OSI were enrolled in a stratification analysis (A simple DSSI analysis was not feasible due to the limited sample size). Surgical duration >4 h ($P=0.002$) were associated with an increased risk of SSSI, age <65 years ($P=0.004$) and oral antibiotic use were still identified as a protective factor for SSSI ($P=0.021$). However, age <65 years ($P=0.044$) was identified as the only protective factor for OSI in the logistic analysis.

Propensity and dosage analysis

To further explore the prophylactic effect of the pre-operative application of oral antibiotics, patients were propensity-matched and analyzed according to age, sex, BMI, tumor stage, neoadjuvant chemotherapy, ASA grade, smoking status, surgical site, surgical approach, and surgical duration. A total of 110 patients were enrolled, with 55 patients in each group. The baseline characteristics were equivalent between the groups. The effect of reducing the incidence of SSI through pre-operative oral antibiotic use combined with MBP was shown to be significant (OR:

0.024; 95% CI: 0.009–0.096). Furthermore, a 1-day and 3-day course of antibiotics had similar protective function [Table 4].

Discussion

SSI strongly affects patient morbidity and expense and is one of the most common post-operative complications.^[1,5,6] Due to the bacterial load and the potential for intra-operative contamination, patients who undergo colorectal surgery incur a high risk of SSI.^[8] Therefore, the identification of factors associated with SSI is critically important. Previous studies have investigated the causes and risk factors of SSI.^[9-12] The majority of these trials identified patient age, length of surgical duration, BMI, ASA stage, pre-operative anemia, smoking, and other comorbidities as being associated with the incidence of post-operative SSI.

In the univariate analysis, the overall mean age was 65.4 years, thus we defined the cut-off point as 65 years of age,

Table 2: Univariate analysis of the surgical and pathological characteristics with incidence of SSI among patients who underwent elective colorectal resection.

Variables	SSIs (N= 57)	No SSIs (N= 524)	OR [95% CI]	P
Surgical approach				
Laparoscopy	48	462	0.716 (0.335, 1.530)	0.386
Laparotomy	9	62		
Bowel preparation				
OA + MBP	16	239	0.465 (0.255, 0.850)	0.011
MBP	41	285		
Surgical region				
Right	14	187	1	
Transverse	1	14	1.048 (0.128, 8.591)	0.965
Left	7	57	1.719 (0.195, 15.138)	0.625
Sigmoid	20	176	1.591 (0.199, 12.745)	0.662
Rectal	15	90	2.333 (0.285, 19.075)	0.429
Surgical duration				
>4 h	22	109	2.393 (1.349, 4.246)	0.002
≤4 h	35	415		
Stage				
≤2	28	289	0.792 (0.458, 1.368)	0.402
>2	29	235		
T stage				
1	4	42	1	
2	6	51	0.804 (0.273, 2.373)	0.693
3	11	127	0.993 (0.398, 2.477)	0.989
4	36	304	0.731 (0.361, 1.482)	0.385
N stage				
0	30	301	1	
1	15	137	1.136 (0.590, 2.188)	0.702
2	12	86	1.587 (0.791, 3.187)	0.194
M stage				
0	44	442	0.628 (0.324, 1.217)	0.165
1	13	82		

Values were shown as *n*. SSI: Surgical site infection; OR: Odds ratio; CI: Confidence interval; OA: Oral antibiotics; MBP: Mechanical bowel preparation; T: Tumor; N: Node; M: Metastasis.

Table 3: Multivariate analysis of incidence of SSI among patients who underwent elective colorectal resection.

Variables	OR	95% CI	P
Surgical time >4 h	2.654	1.399–5.034	0.003
OA + MBP mode	0.260	0.123–0.549	0.001
Age <65 years	0.274	0.147–0.510	<0.001

SSI: Surgical site infection; OR: Odds ratio; CI: Confidence interval; OA: Oral antibiotics; MBP: Mechanical bowel preparation.

Table 4: Odds ratio of oral antibiotics and dosage with SSIs after propensity matching among patients who underwent elective colorectal resection.

Categories	OR	95% CI	P
Application of OA			
Univariate analysis	0.465	0.255–0.850	0.011
Multivariate analysis	0.260	0.123–0.549	0.001
Propensity analysis	0.024	0.009–0.096	0.0001
Dosage			
1-day dosage	0.418	0.189–0.926	0.030
3-days or more	0.017	0.002–0.129	0.0001

SSI: Surgical site infection; OR: Odds ratio; CI: Confidence interval; OA: Oral antibiotics; MBP: Mechanical bowel preparation.

and we similarly determined the optimal cut-off for surgical duration as 230.64 min averagely. The results demonstrated that age <65 years and pre-operative oral antibiotic use were protective factors for SSI, while the surgical duration >4 h, pre-operative anemia, and neo-adjuvant chemotherapy were risk factors for SSI. In the multivariate analysis, only surgical duration >4 h, pre-operative oral antibiotic use, and age <65 years correlated with the incidence of SSI. Furthermore, in the stratification analysis, age <65 years was a significant protective factor for both SSSI and OSI. Older people often suffer from concomitant comorbidities, such as hypertension, coronary heart disease, and kidney disease. In addition, immunity degeneration can also fail to prevent bacterial proliferation. Once the surgical area is contaminated, infection can easily occur. Longer duration of the surgery may owe to the difficulty of the surgical procedure and this may lead to extensive tissue stripping and prolonged exposure of the incision site to colonic bacterial flora. Furthermore, a complicated surgery is often accompanied by more peri-operative morbidities such as anastomotic leakage and peripheral organ injury, which can also affect the incidence of SSI.

However, the factors outlined above were either demographic intrinsic factors (age) or unpredictable surgical

factors (length of surgical duration). Therefore, an actionable method to reduce incidence of SSI is in great demand. Pre-operative oral antibiotic administration seems to be the ideal method for minimizing the risk of SSI.

Colonic bacterial flora is the major cause of SSI. Pre-operative MBP was initially developed to decrease the bacterial load within the surgical field. However, subsequent study challenged the efficacy of this approach.^[5,13] Pre-operative oral antibiotic use combined with MBP was introduced in 1930s.^[5] MBP can reduce fecal bulk, helping the function of the oral antibiotic to decrease the bacteria load, thus reducing the potential for surgical site contamination, at least in theory.^[14]

To further analyze the prophylactic effect of oral antibiotic use, a propensity-matched analysis was performed in the current study. Patients were matched according to multiple variables mentioned above. The protective correlation of oral antibiotic use remained stable (OR: 0.024; 95% CI: 0.009–0.096; $P = 0.0001$). In addition, the effect of the dosage was investigated in our study. Oral antibiotics were administered in various dosages in previous studies, usually as a 3-day course. The amount of antibiotics administered over a 3-day course is of concern as it may contribute to drug-related morbidities such as diarrhea, antibiotic resistance, and an increase in the financial burden on the patient. The current analysis indicated that a 1-day course could have a significant effect (OR: 0.418; 95% CI: 0.189–0.926; $P = 0.03$).

Multiple trials have been performed to explore the best bowel preparation strategies, but their results remain controversial.^[19–21] Since 2005, several randomized controlled trials and meta-analyses have demonstrated that MBP alone was not associated with a reduced incidence of SSI compared to patients that did not undergo MBP, whereas patients who underwent MBP exhibited paradoxical increases in post-operative ileus, anastomotic leakage, and other complications.^[15–18,22] Recently, the merit of combining oral antibiotic use and MBP has been rediscovered in several studies. A meta-analysis^[23] of 7 randomized controlled trials including 1769 patients identified that the total incidence of SSI was significantly reduced in patients who received a combination of pre-operative oral antibiotics and MBP compared with those who received MBP alone (7.2% vs. 16.0%; $P < 0.001$). Bellows *et al*^[24] also reported that non-absorbable antibiotics administered pre-operatively reduced the risk of superficial wound infection (relative risk: 0.57; 95% CI: 0.43–0.76; $P = 0.0002$). Kiran *et al*^[25] evaluated the effects of bowel preparation using the 2012 Colectomy-Targeted American College of Surgeons National Surgical Quality Improvement Program database, finding the dual preparation method resulted in lower rates of SSI, anastomotic leak, and post-operative ileus. However, this study included patients with diverting stomas which have the potential to account for a reduction in infectious complications and anastomotic leak rates. All of these analyses were conducted using data from western countries, where dietary structure, BMI, colon bacteria composition, and tumor type are different from Chinese patients. An investigation and analysis using a Chinese population is needed. Furthermore,

in the previous study, the oral antibiotics were administered usually over a 3-day course. A 3-day course of antibiotics may contribute to drug-related morbidities such as diarrhea, antibiotic resistance, *Clostridioides difficile* infection, and an increase in the financial burden on the patient, sometimes compromising compliance. In the current analysis, we were delighted to demonstrate that a simple 1-day course could effectively reduce the incidence of SSI and avoid the morbidities mentioned above.

The relationships between age, surgical duration, and administration of pre-operative oral antibiotics and SSI were evaluated in the current study. Surgeons should be aware of the SSI risk when specific patients undergo colorectal surgery. However, there are some limitations in our study. First, while all data were tracked through the database, the compliance and quality of bowel preparation could not be evaluated. Second, although a propensity-matched analysis helped to minimize bias in the baseline characteristics of enrolled patients thus enhancing the generalizability of our findings, we still lack external validity due to the nature of our single institution source of data. Third, as a retrospective analysis, historical and other bias may still exist and interfere with the results. Fourth, it is still unknown what the ideal mechanical bowel preparation and oral antibiotic agents are. The author is now conducting a randomized controlled trial on the prophylactic function of pre-operative oral antibiotic use (Clinicaltrials.gov, NCT03856671) to support our findings.

In conclusion, age <65 years and oral antibiotic use combined with mechanical bowel preparation were independent protective factors, while surgical duration >4 h was an independent risk factor for SSI. Among them, the combination of pre-operative use of oral antibiotics and MBP was the only actionable method worthy of recommendation. A 1-day course of oral antibiotics would significantly reduce the incidence of SSI.

Funding

This study was supported by a grant of the Sun Yat-sen University Clinical Research 5010 Program (No. 2018023).

Conflicts of interest

None.

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How to cite this article: Lei PR, Liao JW, Ruan Y, Yang XF, Hu KP, Liu JP, Chen TF. Risk factors analysis for surgical site infection following elective colorectal resection: a retrospective regression analysis. *Chin Med J* 2020;133:571–576. doi: 10.1097/CM9.0000000000000670