

# Incidence and Risk Factors of Surgical Site Infections after Elective Gastrointestinal Surgery: A Prospective Cohort Study

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## ABSTRACT

**Introduction:** Surgical Site Infection (SSI) is defined as an infection that occurs within an incisional wound within 30 days following the procedure. SSI continues to be a significant contributor to extended hospital stays and elevated morbidity, with significant mortality even with well-equipped operation theaters with modern sterilisation techniques, surgical equipment, proper antibiotic cover, and newer surgical methods. Proper identification of the risk factors and modification, if possible, is the only way to optimise surgical outcomes and reduce SSI.

**Aim:** To assess the incidence of SSI and analyse the risk factors associated with SSI.

**Materials and Methods:** A prospective cohort study was conducted from March 2020 to March 2022 at a rural medical college in the coastal area of Alappuzha district of Kerala, India. Patients over 18 years of age admitted for elective Gastrointestinal (GI) surgery for various indications were included. Those presenting

with pre-existing infections other than the indication for surgery and those undergoing laparoscopic surgeries were excluded. Operations were performed on the third day after admission for all patients. The incidence of SSI and its relation with age, gender, smoking, diabetes, preoperative serum albumin, White Blood Cell (WBC) count, type and duration of surgery, American Society of Anaesthesiologists (ASA) physical status, and surgical wound were analysed using the Chi-square test and Fisher's exact test.

**Results:** On analysis of 216 patients, variables such as smoking, diabetes, preoperative low serum albumin, higher ASA physical status, contaminated and dirty wound, and prolonged duration of surgery were strongly associated with the development of SSI.

**Conclusion:** Patients with risk factors such as smoking, diabetes, preoperative low serum albumin, higher ASA physical status, contaminated and dirty wound, and prolonged duration of surgery should receive special attention to optimise surgical outcomes and mitigate the risk of infection.

**Keywords:** Contaminated wound, Duration of surgery, Serum albumin, Smoking

## INTRODUCTION

Postoperative wound infection has long been one of the most serious complications in surgical practice. SSI is defined as an infection that occurs within an incisional wound within 30 days following the procedure [1]. SSI, the most common postoperative complication, leads to pain and suffering [2,3] and ranks among the most frequent healthcare-associated infections, occurring after 1-3% of all surgical procedures [4]. Despite advances in operating room ventilation, sterilisation methods, surgical techniques, and antibiotic prophylaxis, SSI continues to be a major cause of prolonged hospital stays, increased morbidity, and mortality, with a mortality rate of upto 3% [5]. Patients with SSI are twice as likely to die, more likely to spend time in an Intensive Care Unit (ICU), and more than five times more likely to be readmitted to the hospital [6]. Most studies indicate that SSIs are more common with abdominal surgery than other types of surgery [4,7-9].

When SSI develops, management becomes more difficult due to costly antibiotics, prolonged hospital stays, and ICU admission, especially in patients in low socio-economic groups. Although many reports are available in the literature, studies among the population from coastal areas, attending rural medical colleges, are lacking. Hence, the study was conducted to assess the incidence of SSI and analyse the risk factors associated with SSI.

## MATERIALS AND METHODS

A prospective cohort study was conducted from March 2020 to March 2022 at a rural medical college in the coastal area of Alappuzha district in Kerala, India. Institutional Ethical Committee (IEC) (EC/32/2020) approval was obtained. Patients were informed

about the study in their native language, and written consent was obtained. The study included 216 patients.

**Inclusion criteria:** Patients over 18 years of age admitted for elective GI surgery for various indications and patients classified as ASA physical status Classes I to IV were included in the study.

**Exclusion criteria:** Those presenting with pre-existing infections unrelated to the indication for surgery and those who underwent laparoscopic surgeries were excluded. Patients with prior abdominal surgery and those on immunosuppressive therapy, patients of Class V ASA was excluded from the study.

All consecutive patients meeting the inclusion criteria were included. Selected patients underwent preoperative investigations, preanaesthesia check-ups, and consultations with other departments before admission. Medications for other ailments, such as diabetes and hypertension, were initiated before admission. Study details were entered in a prestructured performa. The preoperative details included age, gender, smoking history, diabetes, preoperative serum albumin, preoperative WBC, ASA physical status (I to IV). The immediate postoperative details included the type of surgery (Upper GI/Lower GI), surgical wound class (clean/clean contaminated/contaminated), duration of surgery ( $\leq 120$  minutes and  $>120$  minutes). Data was collected until day 30. The duration of surgery was calculated using a timer set-up in the theatre, from the beginning of incision to the completion of surgery. The surgical wound class was assessed by the operating surgeon according to standard guidelines.

Operations were performed on the third day after admission. The night before surgery, the operative area was shaved, and on the day of surgery, patients were advised to shower in the morning. An intravenous injection of ceftriaxone (1 g) was administered to all patients one hour before the first incision.

Aseptic precautions were observed, including the use of autoclaved gowns, drapes, sterile gloves, and instruments. A standard surgical scrub was performed for six minutes before surgery for all patients. The operation area was painted with 5% povidone iodine, followed by methylated spirit. Basic surgical principles, such as minimal tissue handling and adequate hemostasis, were followed in all cases. Normal core temperature, oxygen saturation, and glycaemic control were maintained for all patients during surgery and the postoperative period, as per Centers for Disease Control and prevention (CDC) guidelines for the prevention of SSI [10]. Drains were used as necessary, and skin staples were used for skin closure. Povidone iodine was applied locally, and the wounds were covered with adhesive dressings.

Postoperatively, injections of ceftriaxone and metronidazole were administered. The wounds were inspected for signs of infection starting 48 hours after surgery until the eighth postoperative day. Daily inspections of the surgical site were conducted for swelling, erythema, local temperature changes, induration, purulent discharge, wound gaping, pain, and increased body temperature during this period. Patients were followed-up until the 30<sup>th</sup> postoperative day in the ward, outpatient clinic, or by telephone. Patient data were collected using a structured proforma. After surgery, patients were classified into clean, clean-contaminated, contaminated, and dirty categories. The criteria for SSI were based on the definitions provided by the United States Centers for Disease Control and Prevention [11]. The incidence and risk factors for SSI were analysed, considering variables such as age, gender, smoking history, diabetes, preoperative albumin levels, WBC counts, ASA score, type of surgery, surgical wound class, and duration of surgery.

### STATISTICAL ANALYSIS

Categorical variables were evaluated in terms of frequencies and percentages, while quantitative variables were assessed as means ± standard deviations. The prevalence of SSI was determined using a 95% Confidence Interval (CI). To identify associations between categorical variables, the Chi-square test was employed, and odds ratios with 95% CI were used to explain the occurrence of SSI with selected variables. A p-value <0.05 was considered statistically significant. Data were entered into Excel (Microsoft Corp., Redmond, WA, USA) spreadsheets, and statistical analyses were conducted using Statistical Package for the Social Sciences (SPSS) Statistics for Windows, version 20.0 (IBM Corp., Armonk, NY, USA).

### RESULTS

Total 216 patients were included, among them, 37 patients (17.1%) developed SSIs. Out of the total, 186 patients (86.1%) were below 75 years of age, while 30 patients (13.9%) were 75 years or older [Table/Fig-1,2].

Background characteristic	n (%)	
Age, years	<75	186 (86.1)
	≥75	30 (13.9)
Sex	Male	117 (54.2)
	Female	99 (45.8)
Smoking	No	165 (76.4)
	Yes	51 (23.6)
Diabetes	No	171 (79.2)
	Yes	45 (20.8)
Preoperative serum albumin, g/dL	≥3.5	138 (63.9)
	<3.5	78 (36.1)

Preoperative WBC count, cells/μL	≤10,000	180 (83.3)
	>10,000	36 (16.7)
ASA physical status class	I	45 (20.8)
	II	126 (58.3)
	III	39 (18.1)
	IV	6 (2.8)
Type of surgery	Upper GI surgery	81 (37.5)
	Lower GI surgery	135 (62.5)
Surgical wound class	Clean	18 (8.3)
	Clean contaminated	192 (88.9)
	Contaminated	6 (2.8)
Duration of surgery, min	≤120	96 (44.4)
	>120	120 (55.6)

[Table/Fig-1]: Percentage distribution of the sample according to background characteristics (N=216).

SSI	n (%)	95% CI
No	179 (82.9)	12.1-22.1
Yes	37 (17.1)	

[Table/Fig-2]: Percentage distribution of the sample according to SSI status (N=216).

There were 165 non smokers and 51 smokers. Among the non smokers, 17 (10.3%) developed SSIs, whereas among the smokers, 20 (39.2%) developed SSIs. A significant association was found between smoking and SSIs. Among the 138 participants with serum albumin levels ≥3.5 g/dL, 18 (13%) developed SSIs, while among the 78 participants with levels <3.5 g/dL, 19 (24.4%) developed SSIs [Table/Fig-3].

Risk factor	SSI		χ <sup>2</sup>	p-value	95% CI	
	No	Yes				
	n (%)	n (%)				
ASA physical status class	I	45 (100.0)	0	12.84**	0.002	1
	II	101 (80.2)	25 (19.8)			2456.5 (0-0)
	III/IV	33 (73.3)	12 (26.7)			3608.81 (0-0)
Diabetes	No	151 (88.3)	20 (11.7)	17.07	p<0.01	1
	Yes	28 (62.2)	17 (37.8)			4.58 (2.14-9.82)
Duration of surgery, min	≤120	88 (91.7)	8 (8.3)	9.42**	0.002	1
	>120	91 (75.8)	29 (24.2)			3.5 (1.52-8.09)
Smoking	No	148 (89.7)	17 (10.3)	22.94	p<0.01	1
	Yes	31 (60.8)	20 (39.2)			5.62 (2.64-11.93)
Preoperative serum albumin, g/dL	≥3.5	120 (87.0)	18 (13.0)	4.49*	0.034	1
	<3.5	59 (75.6)	19 (24.4)			2.15 (1.05-4.39)

[Table/Fig-3]: Comparison of risk factors according to Surgical Site Infection (SSI) status (N=216).

\*\*Significant at 0.01 level, \*Significant at 0.05 level

Among the 81 patients who underwent upper GI surgery, 17 (21%) developed SSIs, and among the 135 who underwent lower GI surgery, 20 (14.8%) developed SSIs. This difference was not statistically significant, and no association was found between SSI and the site of surgery [Table/Fig-4].

Risk factor	SSI		χ <sup>2</sup>	p-value	
	No	Yes			
	n (%)	n (%)			
Age, years	<75	156 (83.9)	30 (16.1)	0.94	0.331
	≥75	23 (76.7)	7 (23.3)		
Sex	Male	97 (82.9)	20 (17.1)	0	0.988
	Female	82 (82.8)	17 (17.2)		

Preoperative WBC count, cells/ $\mu$ L	$\leq 10,000$	150 (83.3)	30 (16.7)	0.16	0.686
	$> 10,000$	29 (80.6)	7 (19.4)		
Type of surgery	Upper GI surgery	64 (79.0)	17 (21.0)	1.36	0.244
	Lower GI surgery	115 (85.2)	20 (14.8)		
Surgical wound class	Clean	16 (88.9)	2 (11.1)	0.5	0.479
	Clean contaminated/ Contaminated	163 (82.3)	35 (17.7)		

**[Table/Fig-4]:** Comparison of risk factors according to Surgical Site Infection (SSI) status (N=216).

Eighteen (8.3%) wounds were categorised as clean, 192 (88.9%) as clean-contaminated, and 6 (2.8%) as contaminated. Among the clean category of 18 patients, 2 (11.1%) patients developed SSI. Among the clean-contaminated category of 192 patients, 29 (15.1%) patients developed SSI. Among the contaminated category of six patients, all 6 (100%) developed SSI. The rate of SSI among clean, clean-contaminated, and contaminated wounds was 11.1%, 15.1%, and 100%, respectively. Present study analysis of clean cases alone, along with clean-contaminated and contaminated cases together, revealed a significant association with SSI [Table/Fig-5].

Surgical wound class	SSI		p-value*
	No	Yes	
	n (%)	n (%)	
Clean	179 (85.2)	31 (14.8)	p<0.01
Contaminated	0	6 (100.0)	

**[Table/Fig-5]:** Comparison of surgical wound class based on Surgical Site Infection (SSI) (N=216).

\*Fisher's-exact test

## DISCUSSION

In the present study, 37 out of 216 patients (17.1%) developed SSI, which was consistent with previously reported SSI rates. A multicentre cohort study conducted by the Global Surg Collaborative, investigating SSI after GI surgery across different income countries, found that SSIs affected 12.3% of patients globally, with the incidence increasing across income groups. In low-income countries, the incidence reached 39.8% among patients undergoing dirty surgery [12]. In India, the reported incidence of SSI has varied between 5% and 24% in studies from different regions [13,14].

Regarding age in present study, the statistical analysis revealed no significant association between the age groups and SSI. Present study findings align with other studies that concluded older age is not an independent risk factor for SSI [15-18]. Some studies have even shown that increasing age is associated with a decreased risk of SSI [19-21]. A study by Kaye KS et al., revealed an increase in SSI up to the age of 65 years, followed by a decrease in the rate among older patients [22].

Present study found no statistically significant association between gender and SSI. Other studies have shown varying results. For example, Langelotz C et al., analysed data from the German Nosocomial Infections Surveillance System (KISS) and found that women had a lower rate of SSI after abdominal procedures compared to men [23]. In contrast, a study by Lindsjö C et al., in a rural hospital in Ujjain, India, identified female gender as a risk factor for SSI [24].

Statistical analysis revealed a significant association between serum albumin levels and SSI (p-value <0.05). This finding was consistent with a study by Hennesey DB et al., where preoperative hypoalbuminemia was identified as an independent risk factor for

SSI following GI surgery, leading to prolonged inpatient stays [25]. Numerous studies have associated poor patient outcomes with hypoalbuminemia [26,27].

No statistically significant association was found between preoperative WBC count and the risk of developing SSI, which aligns with the results of other studies. For example, Mahmood E et al., found no significant difference in the development of superficial and deep SSI based on preoperative WBC count [28]. Tffaly MA et al., also demonstrated no relationship between preoperative WBC count and superficial and deep SSI [29].

In present study, a significant association was observed between diabetes and SSI. This was consistent with a systematic review and meta-analysis by Martin ET et al., which showed a pooled odds ratio of 1.61 for gynaecology, 1.16 for colorectal, and 1.58 for breast surgeries [30]. A study conducted by Lindsjö C et al., in Ujjain, India, found that among 1.8% of diabetic patients in their cohort, seven individuals developed SSI with an odds ratio of 4.43 and a p-value of 0.005 [24].

Present study did not find a statistically significant association between the type of surgery and SSI. However, a slight increase in SSI following upper GI surgery was observed. The lower incidence of SSI associated with lower GI cases may be attributed to proper planned bowel preparation, targeted antibiotics against colonic bacteria, and the use of systemic antibiotics.

There was a statistically significant association between prolonged surgical duration and SSI. The duration of surgery is often considered an independent risk factor for SSI. Similar results were seen in a systematic review by Cheng H et al., which included 81 studies of variable duration. Three studies in their review had durations similar to our study ( $\leq 120$  and  $> 120$  minutes) [31]. One of the studies included was by Biscione FM et al., which had 6,892 patients. They reported a relative risk of 2.8 for long-duration surgery with a p-value of <0.001 [32]. Another study by Anaya DA et al., included 503 patients, of which 263 underwent long-duration surgery. They found a significant association with SSI with a p-value of 0.001 [33]. Davis GB et al., also reported similar findings in their study with 38,739 patients, where 891 patients developed SSI (2.3%), and long-duration surgery was identified as a significant risk factor [34]. The pooled adjusted odds ratio for SSI among these three studies was 1.65 with a p-value of <0.00001.

There was also a statistically significant association between surgical wound class and SSI. Higher wound class was identified as a major risk factor, which was consistent with previous studies. For example, a study conducted in Turkey with 320 clean cases, 454 clean-contaminated cases, 174 contaminated cases, and 69 dirty cases found odds ratios for SSI of 1, 2.8, 3, and 10.7, respectively. The p-values for clean-contaminated, contaminated, and dirty cases were 0.009, 0.001, and 0.0006, respectively [35]. Similarly, a Brazilian study involving 16,882 participants found odds ratios for SSI of 1.5, 2.7, and 2 for clean-contaminated, contaminated, and dirty cases, respectively. The p-values were p<0.001 for the first two categories and 0.001 for the third category [36].

Statistical analysis, considering ASA physical Class I, II, and a combined III/IV group, revealed a significant association between ASA physical status class and SSI as a postoperative outcome. Many similar studies have reported higher risks for SSI among patients classified as ASA III or IV. For example, Kaya E et al., conducted a study with ASA scores of 1 (N=300), 2 (N=564), 3 (N=127), and 4 (N=26). The percentages of SSI were 5%, 9.2%, 15.7%, and 11.5% with odds ratios of 1, 1.9, 3.5, and 2.4, respectively. The p-values were 0.03, 0.0004, and 0.175 for ASA scores 2, 3, and 4 [35].

Bhangu A et al., studied 7,339 participants from high-income countries, 3,918 from middle-income countries, and 1,282 from low-income countries. The odds ratios for ASA scores 2 and 3 were 1.44 and 1.63, respectively, with p-values of <0.001 for both groups [12].

In the present study, statistical analysis revealed a significant association between smoking and SSI, which was consistent with many other studies. Nolan MB et al., evaluated the influence of current smoking status on SSI and found an odds ratio of 1.51 (95% CI, 1.20-1.90; p-value <0.001) [37]. Hawn MT et al., categorised 393,794 patients into never smoked (N=186,632), prior smoker (N=71,421), and current smoker (N=135,741). The percentages of SSI were 2.4%, 3.2%, and 3.4% with odds ratios (95% CI) of 1, 1.11, and 1.18, respectively [38].

Being a prospective study with a limited number of variables, authors were able to collect accurate and complete data. Since the study was conducted in a single centre, well-standardised outcome assessments were possible. These are considered to be the major strengths of this study.

### Limitation(s)

Since the time period for detection SSI was upto 30 days, there was a chance that some SSIs developing after discharge may escape detection. It is generally believed that only healthy older individuals can undergo surgery with reasonable outcomes, and patients with good functional status are more likely to choose the surgical option. Additionally, the number of elderly patients in present study was limited.

### CONCLUSION(S)

This study has revealed an incidence of SSIs that was comparable to other findings. The research identified specific factors associated with a higher likelihood of SSI, including prolonged surgical procedures, contaminated surgical wounds, high ASA class, diabetes mellitus, low preoperative serum albumin, and smoking. Patients with these risk factors should receive special attention before, during, and after surgery to optimise surgical outcomes and mitigate the risk of infection.

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