

Incidence and Risk Factors for Surgical Site Infection after Gastric Surgery: A Multicenter Prospective Cohort Study

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Background: Surgical site infection (SSI) is a potentially morbid and costly complication of surgery. While gastrointestinal surgery is relatively common in Korea, few studies have evaluated SSI in the context of gastric surgery. Thus, we performed a prospective cohort study to determine the incidence and risk factors of SSI in Korean patients undergoing gastric surgery.

Materials and Methods: A prospective cohort study of 2,091 patients who underwent gastric surgery was performed in 10 hospitals with more than 500 beds (nine tertiary hospitals and one secondary hospital). Patients were recruited from an SSI surveillance program between June 1, 2010, and August 31, 2011 and followed up for 1 month after the operation. The criteria used to define SSI and a patient's risk index category were established according to the Centers for Disease Control and Prevention and the National Nosocomial Infection Surveillance System. We collected demographic data and potential perioperative risk factors including type and duration of the operation and physical status score in patients who developed SSIs based on a previous study protocol.

Results: A total of 71 SSIs (3.3%) were identified, with hospital rates varying from 0.0 - 15.7%. The results of multivariate analyses indicated that prolonged operation time ($P = 0.002$), use of a razor for preoperative hair removal ($P = 0.010$), and absence of laminar flow in the operating room ($P = 0.024$) were independent risk factors for SSI after gastric surgery.

Conclusions: Longer operation times, razor use, and absence of laminar flow in operating rooms were independently associated with significant increased SSI risk after gastric surgery.

Key Words: Surgical site infection, Risk factors, Gastric surgery

Received: January 2, 2013 **Revised:** August 22, 2013 **Accepted:** October 23, 2013

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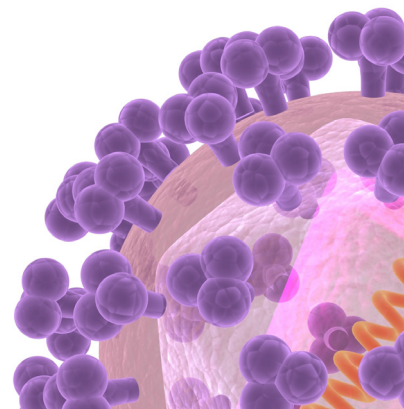
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Introduction

Surgical site infection (SSI) is the most common type of healthcare-associated infection in patients undergoing surgery and remains a major source of postoperative morbidity [1]. Among surgical patients, SSIs account for 38% of healthcare-associated infections [2]. Of 16 million patients undergoing surgical procedures in the United States each year, it is estimated 2 to 5% developed SSIs [3, 4]. SSIs can lead to prolonged hospitalization, increased morbidity and mortality, and increased surgery-related costs [5, 6]. Therefore, to reduce SSIs, it is important to clarify risk factors.

The National Nosocomial Infection Surveillance (NNIS) risk indices for SSIs comprise three crucial measures, namely, the American Society of Anesthesiologists (ASA) classification, wound classification, and operation duration [7-9]. SSI rates correlate with the magnitude of the risk index in 77% (34/44) of NNIS procedure categories [8]. In Korea, the incidence of SSI ranges from 2.0% to 9.7% based on previous studies of various surgical procedures including gastrointestinal, hepatobiliary, orthopedic, gynecologic, and cardiac surgery [10-13].

Risk factors for SSIs have been well studied in various types of gastrointestinal surgery, particularly colorectal surgery [14-16]; however, little information is currently available on risk factors for SSIs after gastrectomy. Gastrointestinal surgery is relatively common in Korea, especially for treatment of gastric cancer. Indeed, according to the 2007 National Survey in Korea, gastric cancer incidence rate in men and women reached 62.8 and 25.7 cases per 100,000 people, respectively [17]. For these reasons, we investigated the incidence rate and characteristics of SSI after gastric surgery.

Materials and Methods

1. Patients and study design

Data were obtained from 10 hospitals in various regions around Korea. Each participating hospital comprised more than 500 beds, and nine were university-affiliated teaching hospitals. All patients who underwent gastric surgery from June 1, 2010 to August 31, 2011 at the Korean hospitals evaluated in this study were prospectively enrolled. Patients with the following criteria were excluded from the evaluation cohort: (1) preoperative identification of infectious disease; (2) febrile status within 24 hours prior to surgery; (3) an ASA score \geq 4; (4) transfer to another hospital during the follow-up period for which data were not collected; (5) emergent sur-

gery; (6) surgery for trauma; (7) more than two surgeries during the same hospital stay; and (8) multiple surgical sites during the same operation.

2. Data collection

The duration of the follow-up period used to identify SSIs was the first 30 days post-operation. Data were collected for the surgical procedure performed and potential SSI risk factors. Data from patients who developed SSIs were collected as previously described [7, 18-21], and these data included demographic characteristics, dates of admission and discharge, presence of anemia (hemoglobin level $<$ 10 mg/dL) during preoperative evaluation, steroid use (at least 6 weeks) within 6 months of surgery, use of immunosuppressive drugs other than steroids within one month of surgery, history of chemotherapy within one month of surgery, current use of antacid medication within one week of surgery, hemoglobin A1c levels for 3 months prior to surgery, operation characteristics (i.e., type, date, and duration of the surgical procedure, ASA physical status score [22], and any use of endoscopic surgical approach), total amount of blood loss during the operation, preoperative hair removal methods, perioperative antimicrobial prophylaxis, presence of drains, occurrence of SSI, the environment of operating rooms, and microbiological data for any SSIs that developed.

3. Definitions

The criteria used to define SSIs and a patient's risk index category were established according to the guidelines of the CDC and NNIS [2, 4, 7, 23, 24]. The NNIS risk index score for each patient was calculated by assigning one point for each contaminated wound according to the CDC definition [25], an ASA score \geq 3, and surgical procedures lasting longer than the NNIS-derived 75th percentile for procedure duration (T time). The NNIS score was modified by subtracting 1 point for cases where the surgery was performed by a laparoscopic approach as suggested by Gaynes et al.[8]. A SSI group was defined as patients who underwent gastric surgery during the study period at any of the participating hospitals and who acquired an SSI according to the CDC criteria.

Antimicrobial prophylaxis was considered optimal if a first- or second- generation cephalosporin was administered intravenously within the 60 min period preceding incision in the absence of a β -lactam allergy, and if prophylactic antimicrobials were discontinued within 24 h after the surgery was completed [26].

4. Statistical analysis

All factors were compared between the SSI group and non-SSI group using Student's *t*-test or Chi-square test. Relationships between dichotomous variables were assessed using Pearson's Chi-square test. Multivariate analysis was also performed using a logistic regression model and stepwise regression to assess the effects of various factors on SSIs. All statistical tests were performed using SPSS software for Windows, version 18.0 (SPSS Inc., Chicago, IL, USA). All *P*-values were two-tailed, and values less than 0.05 were considered statistically significant.

Results

From June 2010 to August 2011, a total of 2,091 patients

who underwent gastric surgery were included in the study. SSIs were noted in 71 of 2,091 (3.3%) patients following gastric surgery, with varying from 0.0% to 15.7% according to each hospital. The clinical characteristics and preoperative status of study participants are summarized in Table 1. There were no significant differences in age and gender between the SSI and non-SSI groups (*P* = 0.290 and 0.312, respectively). Univariate analysis did not find an association between underlying diseases and SSI development in the two groups. Patients with a history of chemotherapy within 1 month of the surgery were noted more frequently in the SSI group compared with the non-SSI group (5.6% vs. 0.8%; *P* < 0.001). In addition, patients with an SSI had a longer median duration of hospital stay (18.5 [14.0-25.0] vs. 10.0 [9.0-13.0] days, *P* < 0.001). The association between methods of surgery-related variables and SSIs are presented in Table 2. Patients with early gastric cancer

Table 1. Baseline characteristics and preoperative status of study patients

	SSI group N = 71	Non-SSI group N = 2,020	<i>P</i> -value
Age, years (mean ± SD)	60.1 ± 13.2	58.5 ± 12.4	0.290 ^a
Gender, male (range)	51 (71.8)	1,274 (63.1)	0.312
BMI, kg/m ²	23.9 (21.9-25.8)	23.1 (21.1-25.4)	0.137 ^b
Comorbidity			
DM	12 (16.9)	284 (14.1)	0.518
Solid Cancer	4 (5.6)	357 (17.7)	0.060
Hematologic malignancy	0 (0.0)	4 (0.2)	1.000
Cardiovascular disease	28 (4.4)	610 (30.2)	0.111
SOT	0 (0.0)	5 (0.2)	> 0.999
Lung disease	2 (2.8)	45 (2.2)	0.763
Renal disease	0 (0.0)	10 (0.5)	0.378
Liver disease	2 (2.8)	62 (3.1)	0.548
Smoking history, yes	20 (28.2)	502 (24.9)	0.534
Total duration of HS, days (range)	18.5 (14.0-25.0)	10.0 (9.0-13.0)	< 0.001 ^b
Type of discharge			0.016 ^c
Discharge after recovery	69 (97.2)	2,016 (99.8)	
In hospital mortality	2 (2.8)	4 (0.2)	
Anemia (Hb <10 mg/dL)	4 (5.6)	70 (3.5)	0.315
Immunosuppressant use			
Steroid	0 (0.0)	8 (0.4)	0.573
Others	0 (0.0)	3 (0.1)	> 0.999
Chemotherapy, yes	4 (5.6)	17 (0.8)	< 0.001
Antacid medication history, yes	16 (22.5)	540 (26.7)	0.417
HbA1c (mean ± SD)	6.37 ± 0.83	6.87 ± 1.33	0.102 ^a

SD, standard deviation; BMI, body mass index; DM, diabetes mellitus; SOT, solid organ transplantation; HS, hospital stay; Hb, hemoglobin; SSI, surgical site infection. Data are expressed as the mean ± SD, number (percent), or median (interquartile range).

^aStudent's *t*-test.

^bMann-Whitney *U* test.

^cFisher's Exact Test.

Table 2. Association between selected variables and surgical site infection following gastric surgery

	SSI group N = 71	Non-SSI group N = 2,020	P-value
Reasons for gastric surgery			
Early gastric cancer	24 (33.8)	998 (49.4)	0.010 ^a
Advanced gastric cancer	44 (62.0)	914 (45.3)	0.005 ^a
Other gastric malignancy	1 (1.4)	84 (4.2)	NS
Benign gastric tumor	2 (2.8)	14 (0.7)	NS
Benign GU without intractable bleeding	0 (0.0)	5 (0.2)	NS
Malignancy of other primary site except stomach	0 (0.0)	2 (0.1)	NS
Benign GU with intractable bleeding	0 (0.0)	1 (0.0)	NS
Other ^b	0 (0.0)	2 (0.1)	NS
Type of operation			
TG with LN dissection	19 (26.8)	260 (12.9)	0.001 ^a
TG without LN dissection	13 (18.3)	219 (10.8)	0.049 ^a
TG, thoracic and abdominal approach with LN dissection	2 (2.8)	14 (0.7)	0.100 ^c
PG with LN dissection	14 (19.7)	470 (23.3)	NS
PG without LN dissection	9 (12.7)	575 (28.5)	0.004 ^a
DG with LN dissection	8 (11.3)	204 (10.1)	NS
DG without LN dissection	5 (7.0)	138 (6.8)	NS
Pylorus preserving STG with LN dissection	0 (0.0)	24 (1.2)	NS
Pylorus preserving STG	1 (1.4)	17 (0.8)	NS
Wedge resection of stomach with LN dissection	0 (0.0)	5 (0.2)	NS
Wedge resection of stomach	0 (0.0)	77 (3.8)	NS
Proximal gastrectomy with LN dissection	0 (0.0)	6 (0.3)	1.000 ^c

GU, gastric ulcer; TG, total gastrectomy; LN, lymph node; PG, partial gastrectomy; DG, distal gastrectomy; STG, subtotal gastrectomy; NS, not significant; SSI, surgical site infection.

^aPearson Chi-square.

^bGastric surgery due to obesity.

^cFisher's Exact Test.

were observed more frequently in the non-SSI group (33.8% vs. 49.4%; $P = 0.010$). Surgery to treat advanced gastric cancer was more common in the SSI group compared with the non-SSI group (62.0% vs. 45.3%; $P = 0.005$). A higher percentage of patients underwent total gastrectomy (TG) with and without lymph node (LN) dissection in the SSI group than the non-SSI group (26.8% vs. 12.9%; $P = 0.001$ and 18.3% vs. 10.8%; $P = 0.049$, respectively).

Univariate analysis of perioperative and postoperative risk factors showed that patients in the SSI group had longer durations of surgery ($P < 0.001$) compared to the non-SSI group, as well as longer durations of surgical drainage ($P = 0.002$) (Table 3). Further, the SSI group had a significantly higher percentage of razor use for preoperative hair removal (52.1% vs. 18.2%, $P < 0.001$) and no surgical drainage was performed in fewer patients in the SSI group than the non-SSI group (9.9%

vs. 29.7%, $P < 0.001$) (Table 3).

Based on our evaluation of operating room environments, SSI risk increased when surgeries were performed in the absence of laminar air-flow (36.6% vs. 7.2%, $P < 0.001$). There were no significant differences between SSI and non-SSI groups among any other operating rooms factors, including high-efficiency particulate air filters, time for complete air exchange, maintenance of positive pressure, and use of instruments for temperature measurement.

Pathogens associated with SSIs were identified in 56 of 71 patients. A total of 68 microbial species were isolated: 29 Gram-positive, 25 Gram-negative, and 14 other species. The Gram-positive species consisted of methicillin-resistant coagulase negative staphylococci ($n = 7$), methicillin-resistant *Staphylococcus aureus* ($n = 7$), *Enterococcus faecalis* ($n = 7$), *Enterococcus faecium* ($n = 4$), methicillin-sensitive *Staphylo-*

Table 3. Perioperative and postoperative risk factors of surgical site infection

	SSI group N = 71 (%)	Non-SSI group N = 2,020 (%)	P-value
ASA score ^a			0.968
1	47 (66.2)	1,268 (62.8)	
2	17 (23.9)	664 (32.9)	
3	7 (9.9)	88 (4.3)	
NNIS risk score			
ASA score ≥ 3	7 (9.9)	88 (4.3)	0.083
Operation classified as either contaminated or dirty-infected, yes	0 (0.0)	9 (0.4)	0.925
Duration of operation > T time, yes	56 (78.9)	1,022 (50.6)	<0.001
Laparoscopic surgery	30 (42.3)	693 (34.3)	0.166
NNIS risk score ≥ 1	35 (49.3)	645 (31.9)	0.002 ^b
Total duration of OP, min (mean ± SD)	255 ± 104	190 ± 72	<0.001 ^c
Total amount of blood loss during OP, mL (range)	125 (50-600)	150 (74-306)	0.196 ^b
Preoperative hair-removal methods			
Razor	37 (52.1)	368 (18.2)	<0.001
Electric clipper	30 (42.3)	1,164 (57.6)	0.010
No shaving	4 (5.6)	249 (12.3)	NS
Unknown	0 (0.0)	239 (11.8)	NS
Surgical drainage, yes			
No use of drain	7 (9.9)	600 (29.7)	<0.001
Closed, suction	35 (39.4)	899 (44.5)	0.398
Closed, non-suction	36 (50.7)	520 (25.7)	NS
Open	0 (0.0)	1 (0.0)	NS
Total duration of surgical drain, days (range)	8.5 (5.0-13.0)	6.0 (5.0-8.0)	0.002 ^b
Prophylactic antibiotics use			
Administration within 1h of the start of surgery (mean ± SD)			0.906
Yes	69 (97.2)	1,927 (95.4)	
No	2 (2.8)	78 (3.9)	
Unknown	0 (0.0)	15 (0.7)	
Total duration of prophylactic antibiotics use, parenteral, days	4 (2-5)	4 (2-5)	0.056 ^b
Optimal antibiotic prophylaxis, yes	31 (43.7)	912 (45.1)	0.805
The environment of operating rooms			
Laminar flow, yes	45 (63.4)	1,874 (92.8)	<0.001
HEPA filter, yes	66 (93.0)	1,897 (93.9)	0.961
Air change > 15 times/hours, yes	66 (93.0)	1,913 (94.7)	NS
Maintenance of positive pressure, yes	69 (97.2)	2,001 (99.1)	NS
Instrument for temperature measurement, yes	69 (97.2)	2,012 (99.6)	NS

ASA, American Society of Anesthesiology; NNIS, National Nosocomial Infection Surveillance; OP, operation; HEPA, high-efficiency particulate air; NS, not significant; SD, standard deviation; SSI, surgical site infection.

Data are expressed as the mean ± SD or number (percent) or median (interquartile range).

^ahealthy, 1; mild systemic disorder, 2; severe systemic disorder, ≥ 3.

^bMann-Whitney *U* test.

^cStudent's *t*-test.

Table 4. Multivariate analysis of SSI risk factors

	Odds ratio	95% CI	P-value
Use of a razor for preoperative hair removal	2.49	1.25 to 5.01	0.010
Duration of operation > T time	2.59	1.40 to 4.79	0.002
Absence of laminar flow in operating room	2.45	1.13 to 5.31	0.024

CI, confidence interval; SSI, surgical site infection.

coccus aureus (n = 3), and methicillin-sensitive coagulase-negative staphylococci (n = 1). The Gram-negative species consisted of *Enterobacter cloacae* (n = 11), *Klebsiella pneumoniae* (n = 5), *Escherichia coli* (n = 4), *Acinetobacter baumannii* (n = 3), and *Pseudomonas aeruginosa* (n = 2).

Table 4 shows multivariate adjusted odds ratios for SSIs after gastric surgery. Independent risk factors for SSIs after gastric surgery were prolonged operation time ($P = 0.002$), use of a razor for preoperative hair-removal ($P = 0.010$), and absence of laminar flow in the operating room ($P = 0.024$).

Discussion

We performed a prospective cohort study to identify risk factors for SSI after gastric surgery. We found that prolonged surgery time, use of a razor for preoperative hair removal, and absence of laminar flow in the operating room were independent risk factors for SSI following gastric surgery. Gastrointestinal surgery is relatively common in Korea, especially to treat gastric cancer. The 2007 National Survey in Korea, reported the incidence of gastric cancer in men and women to be 62.8 and 25.7 cases per 100,000 people, respectively [17]. Therefore, the results of this study on SSI incidence in patients undergoing gastric surgery may be especially meaningful.

The rates of SSI for individual procedures vary widely depending on numerous factors, including population, hospital size, surgeon experience, and post-surgery surveillance methods. In addition, nonteaching hospitals generally have lower SSI rates than teaching hospitals [27]. Several studies have noted an increased risk of SSI in patients with cancer who undergo surgical procedures [28]. Previous studies have reported rate and risk factors for SSIs after gastric surgery in Korea. Kim et al. [29] evaluated a total of 499 cases for SSI between July and December 2007 in 5 teaching hospitals with more than 500 beds. They found an SSI rate of 4.4% (22/499), and reported that diabetes mellitus, reoperation, emergent operation, and transfusion were more frequent in the infected group. Likewise, another prospective study monitored 4,238 patients across 20 Korean hospitals between 2007 and 2009 for SSIs for

30 days after gastric surgery [30], and reported an SSI rate of 4.0% (170/4,068) with *Staphylococcus aureus* and *Klebsiella pneumoniae* as most frequently isolated microorganisms. In addition, male gender, reoperation, combined multiple procedures, prophylactic administration of the first antibiotic dose after skin incision, and prolonged administration (≥ 7 days) of prophylactic antibiotics were all independently associated with increased risk of SSI. Another study monitored a total of 3,286 cases from 23 hospitals in Korea between July 2010 and June 2011 (1 hospital with < 500 beds, 12 hospitals with 700-899 beds, and 10 hospitals with > 900 beds) [31]. In that study, the SSI rate after gastric surgery was 3.5% (115/3,286), and enterococci (n = 19) was the most frequently detected pathogen. In the present study, we observed an SSI rate of 3.3% (71/2,091); staphylococci (n = 14) and enterococci (n = 11) were most frequently isolated. We observed a lower SSI rate after gastric surgery than that found in previous reports; various methods for monitoring nosocomial infections may have contributed to this improved rate.

In our study, using both univariate and multivariate regression analyses, we confirmed that prolonged operation time is a risk factor for SSI after gastric surgery. Our findings were similar to previously reported NNIS data, which included the 75th percentile of operation duration after initial cut point (3 hours)[32, 33].

We found that preoperative hair removal with a razor was a significant and independent risk factor for SSI after gastric surgery. Shaving with a razor before surgery is a well-documented risk factor for SSI, and guidelines from the CDC Healthcare Infection Control Practices Advisory Committee (HICPAC) recommend avoidance of hair removal before surgery when possible and the use of clippers if hair removal is necessary [2]. Despite these guidelines, we were surprised to find that 19.4% (405/2,091) of study patients were shaved with a razor before gastric surgery. Thus, avoiding razor shaving before surgery is a modifiable intervention to reduce the risk of SSIs.

Laminar airflow ventilation systems in operating rooms are frequently recommended for to prevent SSIs. However, for all other types of surgery, there is no evidence from controlled

clinical trials that clean air conditions are beneficial for the prevention of post-surgical infections. HICPAC guidelines for the prevention of SSIs [2], published in 1999, recommended to “consider performing orthopedic implant operations in operating rooms supplied with ultraclean air” which was classified as a category II recommendation. Since then, no further evidence from controlled trials has supported the need for clean air conditions. Consequently, the 2003 HICPAC guidelines for environmental infection control [34] do not recommend recommendation on performing orthopedic implant surgery in rooms supplied with laminar airflow. In 2011, two additional large cohort studies investigated the effects of laminar airflow on SSI rates following orthopedic surgery [35, 36].

Neither study found that SSI rates were lower in patients whose operations were performed under laminar airflow conditions in one study, the opposite was found [35]. On the other hand, some studies have shown that laminar airflow systems reduce bacterial burden in operating room air [37], especially when comparing old and new operating rooms [38]. However, there has been no correlation established between airborne bacteria counts and SSI rates.

In this study, absence of laminar airflow in operating room increased the risk of SSIs by 2.45 fold according to the results of multivariate analysis. Although the benefits of laminar airflow for preventing SSIs is a matter of debate and implementation and continued operation of laminar airflow technology is costly compared with conventional ventilation systems, the results of our study provide strong evidence to support the benefits of laminar airflow in operating rooms.

Perioperative antimicrobial prophylaxis is intended to eliminate most of the pathogens brought into wounds shortly before and/or during surgical procedures and therefore decrease the risk of subsequent SSIs. Gram-positive bacteria should be covered by selected antibiotics for this purpose [39], and timely administration is crucial in order to achieve the highest local concentration of the chosen antibiotic regimen at the beginning time of surgery [40]. However, there were no significant differences between the SSI and non-SSI groups according to optimal antibiotic prophylaxis in our study. Although this lack of benefit from antimicrobial prophylaxis was unexpected, several other studies have reported similar observations [41, 42]. The effectiveness of prophylactic antibiotics varies among types of gastrointestinal surgery. A meta-analysis of laparoscopic cholecystectomies showed that prophylactic antibiotics are ineffective in preventing postsurgical complications, while antibiotic prophylaxis was shown to reduce SSIs in colectomies and appendectomies [26, 43, 44]. In colon sur-

gery, randomized clinical trials to evaluate prophylactic antibiotics were conducted in the 1980s, and placebo groups had SSI rates of approximately 40%, nearly twice the rate of our corresponding group [26]. Although not all of our results are generalizable, improvement of other pre- and intraoperative patient management such as avoiding preoperative shaving and prevention of hypothermia may contribute to reduced risks. In addition, the overall reduction of SSI rates in colectomies may make it difficult to determine the effectiveness of prophylactic antibiotic.

One limitation of this study was that the NNIS was not predictive for SSI occurrence. In addition, we did not evaluate risk factors of SSI in patients with colon surgery; therefore, we could not directly compare differences between risk factors for gastric and colon surgeries.

In conclusion, SSI risk after gastric surgery was mainly associated with prolonged surgeries, use of razors for preoperative hair removal, and absence of laminar flow in operating rooms. These factors are potentially modifiable, and we believe that these results will be helpful in lowering SSI rates after gastric surgery in Korea.

Acknowledgment

This study was supported by a grant of the Korea Healthcare Technology R&D Project, Ministry for Health, Welfare and Family Affairs, Republic of Korea (A102065).

Conflicts of interest

No conflicts of interest.

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