Risk factors for superficial incisional surgical site infection after gastrectomy: analysis of patients enrolled in a prospective randomized trial comparing skin closure methods

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Abstract

Background Surgical site infection is one of the commonest complications of gastrointestinal surgery. The nature of surgical procedures and wound closure methods may influence the incidence of superficial incisional surgical site infection. Patients enrolled in a prospective randomized controlled trial comparing skin closure methods are the best subjects for analyzing surgical site infection risk.

On behalf of the Clinical Study Group of Osaka University on Section of Risk Management.

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Method From a cohort of 1080 patients who had been enrolled in our previous randomized controlled trial, data for 685 patients who had undergone elective open total gastrectomy or distal gastrectomy for gastric cancer were extracted. The incidences of superficial incisional surgical site infection after total gastrectomy and distal gastrectomy were compared and risk factors for superficial incisional surgical site infection were investigated by univariate analyses using logistic regression models.

Results In all, 42 patients (6.1 %) developed superficial incisional surgical site infections after gastrectomy; 15 of 288 patients (5.2 %) developed these infections after total gastrectomy, and 27 of 397 patients (6.8 %) developed these infections after distal gastrectomy—these differences are not significant. According to univariate analysis, age (75 years or older or younger than 75 years) was the only risk factor for superficial incisional surgical site infections ($P = 0.049$). There was a tendency for the incidence of superficial incisional surgical site infection to increase in parallel with age.

Conclusion The incidence of superficial incisional surgical site infection did not differ between total gastrectomy and distal gastrectomy. Advanced age was the only identified risk factor for superficial incisional surgical site infections after gastrectomy.

Keywords Stomach neoplasms · Gastrectomy · Surgical wound infection

Introduction

A surgical site infection (SSI) is a postoperative infection that occurs in the part of the body where a surgical procedure has been performed. According to the surgical

patient component of the 1999 Centers for Disease Control and Prevention (CDC) National Nosocomial Infection Surveillance System manual, the term “surgical site infection” (SSI) includes superficial incisional, deep incisional, and organ/space SSIs [1]; however, the focus has mainly been on superficial incisional SSIs.

Various incidences of superficial incisional SSI following gastrectomy has been reported; they differ greatly because of differences in background factors, operative procedures, and assessment processes. According to the National Healthcare Safety Network of the CDC in the USA, SSIs at primary incision sites occurred following 2.2 % of all gastric surgery procedures in 2006–2008 [2], whereas the Japanese Healthcare Associated Infections Surveillance [3] reported a figure of 3.5 % in 2012 in Japan. The Osaka Gastrointestinal Cancer Chemotherapy Study Group has performed randomized controlled trials (RCTs) in which the primary end points were incidences of SSIs: it found that superficial incisional SSIs occurred in 15 of 231 patients (6.5 %) following total gastrectomy [4] and in six of 355 patients (1.7 %) following distal gastrectomy [5]. Although skin and fascia closing methods were not controlled, these data suggest that total gastrectomy causes more superficial incisional SSIs than does distal gastrectomy. There are no published prospective studies in which many risk factors for SSI were well controlled that compare the incidence of superficial incisional SSIs after total gastrectomy and distal gastrectomy.

Recently, we performed a multicenter open-label phase III RCT to compare subcuticular sutures with staples for skin closure after open gastrointestinal surgery: our results concerning wound complications have been reported (UMIN00002480) [6]. Because only patients who underwent elective open surgery were included, patients with high risk of SSI were excluded, and fascia and skin closure methods were controlled, the patients enrolled in this trial seemed ideal candidates for evaluating risk factors for superficial incisional SSI and for comparing surgical procedures.

We extracted data from the relevant cohort of our previous trial to compare the incidence of superficial incisional SSIs after total gastrectomy and distal gastrectomy and to investigate risk factors for superficial incisional SSI.

Patients and methods

Patients

From 1 June 2009 to 28 February 2012, we conducted a large-scale, multicenter open-label phase III RCT in which 1080 patients from 24 institutions in Japan were enrolled. Eligibility criteria for this trial were patients undergoing

elective upper or lower gastrointestinal tract surgery aged 20 years or older, and with adequate organ function. Patients requiring emergency or laparoscopic surgery; with a history of laparotomy via a midline incision; taking corticosteroid drugs long term; with active infections such as peritonitis, pneumonia, or urinary tract infection; with massive ascites; with coagulopathy or other disorders that would preclude study participation; with uncontrolled or insulin-treated diabetes; with mental illness; with poor general condition; or with severe cardiopulmonary disease; or who were otherwise deemed by surgeons to be inappropriate for participation were excluded. The institutional review boards of all participating hospitals approved the protocol. All patients provided written informed consent before randomization. From the cohort of the enrolled patients, data for 685 patients who had undergone elective open total gastrectomy or distal gastrectomy for gastric cancer were extracted for this analysis (Fig. 1). Among them, 288 patients had undergone total gastrectomy and 397 had undergone distal gastrectomy.

In the original trial, patients were randomly assigned to receive either subcuticular sutures or staples for skin closure and were balanced according to institution, sex, and type of surgery (i.e., upper or lower gastrointestinal tract open surgery). All participating institutions were asked to follow the guidelines concerning prevention of SSIs issued by the CDC [1]. Surgical gloves and instruments were changed before wound closure. Absorbable sutures were used to approximate the fascia, and the subcutaneous space was irrigated with saline without added antibiotics. Approximation of the fat layer was not allowed. Drain placement through a separate incision away from the operative incision was permitted; however, drainage of the wound was not allowed. The skin preparation techniques, prophylactic antibiotic administration, the volume of saline used for intra-abdominal irrigation, the dressing methods, the timing of postoperative staple removal, perioperative care, and wound management were according to the standards of each participating institution.

Definition of SSI

The responsible surgeon checked for the presence or absence of SSIs everyday during the hospital stay and at every outpatient visit until 30 days after surgery. Superficial incisional SSI was defined according to the standardized criteria of the National Nosocomial Infection Surveillance System by the CDC [1] as an infection involving only skin or subcutaneous tissue of an incision with at least one of the following: (1) purulent drainage, with or without laboratory confirmation, from the superficial incision; (2) organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial

Fig. 1 CONSORT diagram showing eligibility criteria. *GI* gastrointestinal, *SSI* surgical site infection

incision; (3) at least one of pain or tenderness, localized swelling, redness, or heat as signs or symptoms of infection and the superficial incision is deliberately opened by the surgeon, unless the incision is culture negative; or (4) diagnosis of superficial incisional SSI by the surgeon or attending physician.

In the original trial, the presence or absence of deep incisional and organ/space SSIs was monitored; however, the evaluation criteria for these SSIs were not clearly defined, and an index of severity, such as Dindo–Clavien scores, was not used. Because there were major differences between institutions regarding the incidences of these SSIs, only the incidence of superficial incisional SSI was evaluated in this study.

Variables for risk analysis

The following clinical and operative variables were investigated as possible risk factors for SSIs: sex, age (75 years or older or younger than 75 years), hemoglobin concentration (10 g/dL or higher or below 10 g/dL), C-reactive protein concentration (0.1 mg/dL or higher or below 0.1 mg/dL), prognostic nutritional index [$10 \times$ serum albumin concentration (mg/dL) + $0.005 \times$ lymphocyte count (/mm³), 40 or higher or below 40] [7],

body mass index (BMI) [body weight (kg)/height (m)², 25 or higher or below 25], thickness of subcutaneous fat (thick or normal/thin according to the surgeon's subjective assessment), extent of gastric resection (total or distal gastrectomy), other organ resection (yes or no), skin closure (subcuticular suture or staples), operation time (240 min or longer or less than 240 min), estimated blood loss (300 g or more or less than 300 g), duration of antibiotic prophylaxis (2 days or more or 1 day), presence of a drain (yes or no), anticoagulation therapy (yes or no), and institution (high-volume institutions that had recruited more than 50 patients or low-volume institutions with fewer than 50 patients).

Statistical analysis

Quantitative variables were compared between total gastrectomy and distal gastrectomy using the Mann–Whitney *U* test. Qualitative variables and the incidences of superficial incisional SSI were compared using the χ^2 test or Fisher's exact probability test. Risk factors for superficial incisional SSI were subjected to univariate analyses using logistic regression models to assess the effects of the factors on SSI. *P* values of less than 0.050 were considered statistically significant. Analyses were performed using

JMP (version 11.0.0 for Windows; SAS Institute, Cary, NC, USA).

Results

The baseline clinical and operative characteristics of the 685 patients who had undergone elective open total gastrectomy or distal gastrectomy for gastric cancer and who were eligible for assessment of superficial incisional SSIs are shown in Table 1. Patients who had undergone total gastrectomy were more likely to have lower BMI, other organ resection, longer operation time, greater intraoperative blood loss, and placement of drains than those who had undergone distal gastrectomy. Superficial incisional SSIs occurred in 42 patients (6.1 %), including 15 patients (5.2 %) following total gastrectomy and 27 patients (6.8 %) following distal gastrectomy. The incidences of superficial incisional SSIs did not differ between the two procedures ($P = 0.387$).

According to univariate analysis of possible risk factors for superficial incisional SSIs, patients aged 75 years or older had significantly higher incidences of superficial incisional SSIs than did younger patients ($P = 0.049$) (Table 2). No other factors were identified as significant risk factors.

The relationship between age and the incidence of superficial incisional SSIs was further investigated by dividing age into four categories: namely, the young (64 years or younger), the young old (65–74 years), the old old (75–84 years), and the oldest old (85 years or older) [8]. The incidence of superficial incisional SSIs tended to increase in parallel with age; however, the differences between these age groups were not significant (Table 3).

Additionally, the incidence of superficial incisional SSIs was analyzed for four BMI categories: namely, underweight ($\text{BMI} < 18.5 \text{ kg/m}^2$, $n = 80$), normal range ($18.5 \text{ kg/m}^2 \leq \text{BMI} < 25 \text{ kg/m}^2$, $n = 445$), overweight ($25 \text{ kg/m}^2 \leq \text{BMI} < 30 \text{ kg/m}^2$, $n = 105$), and obesity ($\text{BMI} \geq 30 \text{ kg/m}^2$, $n = 15$); BMI data were unavailable for 40 patients. The incidences for these BMI categories were 5.0 % (4/80), 6.5 % (29/445), 5.7 % (6/105) and 6.7 % (1/15), respectively; the differences between these groups were not significant ($P = 0.953$).

Discussion

SSI, one of the commonest complications following gastrointestinal surgery, may lead to prolonged hospital stay, increased health care costs, a greater workload for staff, and a deteriorated quality of life. Surgeons should prioritize

Table 1 Clinical and operative characteristics of study patients

Variable	Total gastrectomy ($n = 288$)	Distal gastrectomy ($n = 397$)	P
Sex: male/female	212/76	272/125	0.148
Age (years)	67 (60–74) ^c	68 (61–74) ^c	0.109
Hemoglobin (g/dl)	12.9 (11.0–14.1) ^c	13.1 (11.3–14.3) ^c	0.373
CRP ^a (mg/dl)	0.1 (0.0–0.2) ^c	0.1 (0.0–0.2) ^c	0.184
PNI	49.0 (45.1–52.5) ^c	49.5 (45.5–53.2) ^c	0.301
ASA classification: 1/2/3	117/162/9	156/222/19	0.560
BMI ^b (kg/m^2)	21.9 (19.7–23.6) ^c	22.4 (20.1–24.4) ^c	0.041
Subcutaneous fat: thick/normal or thin	51/237	84/313	0.263
Wound protection: surgical drape/gauze/none	282/3/3	378/7/12	0.156
Other organ resection: yes/no	60/228	15/382	<0.0001
Skin closure: subcuticular suture/staples	145/143	185/212	0.333
Operation time (min)	260 (220–296) ^c	220 (187–254) ^c	<0.0001
Estimated blood loss (g)	341 (200–603) ^c	251 (150–420) ^c	<0.0001
Duration of antibiotic prophylaxis: ≥ 2 days/1 day	94/194	103/294	0.056
Drain: yes/no	285/3	313/84	<0.0001
Anticoagulation therapy: yes/no	40/248	50/347	0.621

Values in *italics* are statistically significant.

ASA American Society of Anesthesiology, BMI body mass index, CRP C-reactive protein, PNI prognostic nutritional index

^a Data missing for one patient

^b Data missing for 40 patients

^c Median, with the interquartile range in *parentheses*

Table 2 Univariate analysis of possible predictors of risk of superficial incisional surgical site infection (SSI) following gastrectomy

Variable	Superficial incisional SSI present (<i>n</i> = 42)	Superficial incisional SSI absent (<i>n</i> = 643)	Univariate analysis		
			RR	95 % CI	<i>P</i>
Sex: male/female	29/13	455/188	0.9	0.5–1.9	0.814
Age (years): ≥ 75 / <75	15/27	141/502	2.0	1.0–3.8	<i>0.049</i>
Hemoglobin (g/dl): ≥ 10 / <10	36/6	569/74	0.8	0.3–2.1	0.598
CRP ^a (mg/dl): ≥ 0.1 / <0.1	22/20	365/277	0.8	0.4–1.6	0.572
PNI	40/2	603/40	1.3	0.4–8.3	0.692
BMI ^b (kg/m ²): ≥ 25 / <25	7/33	113/492	0.9	0.4–2.0	0.848
Subcutaneous fat: thick/normal or thin	9/33	126/517	1.1	0.5–2.3	0.775
Extent of gastric resection: total/distal	15/27	273/370	0.8	0.4–1.4	0.387
Other organ resection; yes/no	5/37	70/573	1.1	0.4–2.7	0.840
Skin closure: subcuticular suture/staples	22/20	308/335	1.2	0.6–2.3	0.574
Operation time (min): ≥ 240 / <240	21/21	304/339	1.1	0.6–2.1	0.732
Estimated blood loss (g): ≥ 300 / <300	21/21	314/329	1.0	0.6–2.0	0.884
Duration of antibiotic prophylaxis (days): ≥ 2 / <2	14/28	183/460	1.3	0.6–2.4	0.505
Drain: yes/no	38/4	560/83	1.4	0.5–4.8	0.508
Anticoagulation therapy: yes/no	4/38	86/557	0.7	0.2–1.8	0.456
Institution: high volume/low volume ^c	22/20	388/255	0.7	0.4–1.4	0.315

The value in *italics* is statistically significant.

BMI body mass index, CI confidence interval, CRP C-reactive protein, PNI prognostic nutritional index, RR relative risk

^a Data missing for one patient

^b Data missing for 40 patients

^c High-volume institutions recruited more than 50 patients and low-volume institutions recruited fewer than 50 patients.

Table 3 Logistic regression model of prediction of risk of superficial incisional surgical site infection (SSI) following gastrectomy by age group

Age (years)	<i>n</i>	Superficial incisional SSI present	RR	95 % CI	<i>P</i>
≤ 64	248	11 (4.4 %)	Reference		
65–74	281	16 (5.7 %)	1.3	0.6–2.9	0.510
75–84	134	12 (9.0 %)	2.1	0.9–5.1	0.080
≥ 85	22	3 (13.6 %)	3.4	0.7–12.1	0.110

CI confidence interval, RR relative risk

reducing the incidence of SSI. According to the clinical guideline for SSI of the National Collaborating Centre for Women's and Children's Health [9], age, underlying illness, obesity, smoking, and wound complications are significant risk factors for SSI.

We found that the incidence of superficial incisional SSI did not differ between total gastrectomy and distal gastrectomy. The National Healthcare Safety Network of the CDC in the USA has reported the overall incidence of SSI following gastric surgery, regardless of the type of gastric resection [2]. In contrast, the Japanese Healthcare Associated Infections Surveillance [3] has classified gastric surgery into three categories: namely, total, distal, and other gastrectomy. In the current study, we found that BMI, other organ resection, operation time, blood loss, and the presence of a drain differed significantly between total gastrectomy and distal gastrectomy. It therefore seems

reasonable to assess total gastrectomy and distal gastrectomy as different procedures when evaluating surgical complications including SSIs, especially organ/space SSI. In this study, the incidence of organ/space SSI was 10.4 % after total gastrectomy and 5.8 % after distal gastrectomy (data not shown in “Results” because organ/space SSI was not clearly defined in the original study and there was considerable evaluation bias between participating institutions). To achieve an accurate evaluation, it is necessary to report the types of SSIs according to the type of surgery and to minimize bias. In contrast to superficial incisional SSI, there is a potential bias for evaluation of organ/space SSIs; thus, evaluation of severity using Dindo–Clavien scores is necessary.

The only significant risk factor for superficial incisional SSI that we identified was age of 75 years or older. One prospective observational study that assessed operative risk

factors for SSI in patients undergoing total hip replacement reported that age older than 75 years was a significant risk factor [10]. One large prospective study ($n = 23,649$ wounds) showed a broad trend toward increasing incidence of SSI with increasing age when the patients were stratified by age group [11]. We also found that the incidence of superficial incisional SSI tended to increase in parallel with age. To reduce the risk of superficial incisional SSI, several publications have proposed procedures involving skin preparation, barrier retractional wound protection, and pulsatile irrigation of wounds before closure [12]. These procedures are now routinely applied during gastrointestinal surgery. Thus, in this study, procedures for wound protection were well controlled, 3M™ Steri-Drape™ wound edge protector (3M, St Paul, MN, USA) having been used in 13 institutions and Alexis® wound protector/retractor (Applied Medical, Rancho Santa Margarita, CA, USA) having been in a further ten of the 24 participating institutions. No wound protection was used in the remaining institution. We found no difference between these two types of wound protection (data not shown). Therefore, we conclude that advanced age is a risk factor for superficial incisional SSI after gastrectomy regardless of the skin closure method and the type of wound protector.

Being overweight is reportedly a risk factor for SSI and other surgical complications [13, 14]. Very low BMI and very high BMI are well-acknowledged risk factors [15, 16]. When we analyzed the incidence of superficial incisional SSIs in four BMI categories, we found no significant differences between the groups, indicating that BMI may not be a risk factor for superficial incisional SSI after gastrectomy.

In conclusion, the incidence of superficial incisional SSI does not differ between total gastrectomy and distal gastrectomy. Advanced age is a risk factor for superficial incisional SSI after gastrectomy.

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Conflict of interest The authors declare no conflicts of interest.

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