

Is it possible to predict the development of an incisional surgical site infection and its severity after biliary tract surgery for benign disease?

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Abstract

Background/purpose Wound infection; that is, incisional surgical site infection (ISSI), is a common complication after biliary tract surgery. The aim of the present study was to identify the various risk factors for wound infection and to establish a formula to predict the development and severity of wound infections.

Methods We analyzed the clinical data on 207 consecutive patients who underwent biliary surgery for benign diseases at our hospital. We identified the factors with the greatest influence on wound infection after biliary tract surgery, based on a statistical procedure. An original scoring system (ISSI predictive score) was proposed based on these risk factors.

Results The incidence of postoperative wound infection was 9.7% (20/207). The patient's performance status; bile culture; perioperative fasting period (days); and intraoperative bile spillage were the most influential risk factors for wound infection. The incidences of wound infection in patients with ISSI predictive scores of >2.7 points and those with scores of 0–2.7 points were 75.0% (12/16) and 4.2% (8/191), respectively. Our score also correlated significantly with the severity of wound infection ($r = 0.488$, $P < 0.001$) and the length of the postoperative hospital stay ($R = 0.508$, $P < 0.001$).

Conclusion Our original scoring system makes it possible to predict not only the development of a wound infection and its severity after biliary tract surgery, but also the length of the postoperative hospital stay.

Keywords Surgical site infection · Prediction of wound infection · Acute cholangitis · Acute cholecystitis · Bile culture

Introduction

Although wound infection; that is, incisional surgical site infection (ISSI), is a common complication after biliary tract surgery, this common complication has been largely overlooked because it has little influence on the postoperative course. However, once an infection develops, it prolongs the hospital stay and reduces the patients' quality of life, and it can lead to various subsequent complications, especially in elderly patients. According to several previous studies regarding wound infection after biliary tract surgery, patient age, comorbid diabetes, positive bile culture, open cholecystectomy, and choledochotomy have been commonly regarded as the factors associated with the greatest risk of developing an infection [1–3]. However, despite these known risk factors, wound infections after biliary tract surgery are still common, and their pathogenesis is still being debated.

It is well known that postoperative wound infection markedly prolongs the duration of hospitalization, and preventing wound infections would be beneficial to both patients and hospitals [4–6]. In particular, deep-seated infections are more likely to prolong the hospital stay than superficial incisional infections [4], and such infections promote the development of incisional hernias [7] and result in unsightly scars.

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Beginning in December of 2005, our institution has prospectively adapted the treatment protocol for benign biliary disease in an effort to reduce infectious complications. However, some patients have still suffered postoperative wound infections, in spite of our efforts. Thus, we initiated a clinical study, using these patients' data, and we have developed an original scoring system to predict the occurrence of infection after biliary tract surgery. We focused on the correlation between two clinical stratifications of acute biliary infectious disease (criteria for the severity of acute cholangitis and/or cholecystitis)—based on Japanese evidence-based clinical practice guidelines [8] and the International Tokyo Guidelines for the management of acute cholangitis and cholecystitis [9, 10]—and the incidence of wound infection. The aim of the present study was to reveal the various risk factors for wound infection and to establish a predictive ISSI score that can be used to predict the likelihood of infection, thus allowing for earlier treatment.

Methods

Patients' characteristics

We analyzed the clinical data of the 207 consecutive patients who underwent biliary surgery for benign diseases at our hospital from December 2005 to November 2010. There were 107 men and 97 women, with a mean age of 68.3 ± 11.0 years (range 20–96 years), and a mean body mass index (BMI) of 22.7 ± 3.3 kg/m². The preoperative Eastern Cooperative Oncology Group (ECOG) performance status (PS) of these patients was Grade 0 or 1 (good) in 148, and 2–4 (bad) in 59 patients.

In terms of the preoperative diagnosis, 71 and 160 patients, respectively, were diagnosed as having common bile duct (CBD) stones and gallbladder stones. In addition, 133 patients were preoperatively diagnosed as having a biliary tract infection (acute cholangitis in 35, acute cholecystitis in 66, both in 32). A total of 7 patients had incidental biliary tract cancers which were undiagnosed preoperatively (gallbladder cancer in 5, bile duct cancer in 1, both in 1). With regard to surgical procedures, laparoscopic surgeries were employed for 58 patients, and a cholecystectomy, choledochotomy, and bilioenteric anastomosis were performed in 181, 49, and 16 patients, respectively (Table 1).

Our treatment protocol for benign biliary tract disease

In the patients with biliary tract disease without biliary tract infection, such as gallbladder polyps, chronic cholecystitis, asymptomatic gallstones, and adenomyomatosis of the

gallbladder, laparoscopic cholecystectomy was initially employed. In the patients with biliary tract infection, we prioritized the resolution of inflammation with antibiotics and/or adequate biliary drainage to prevent the progression of organ dysfunction, especially when we treated elderly patients with acute biliary tract infections, such as acute cholangitis and/or cholecystitis. Based on the Japanese evidence-based clinical practice guidelines published in 2005 and the International Tokyo Guidelines published in 2007, we evaluated the severity of the disease, and for moderate/grade II and severe/grade III patients we employed preoperative bile drainage; percutaneous transhepatic biliary drainage (PTBD), endoscopic nasobiliary drainage (ENBD), and percutaneous transhepatic gallbladder drainage (PTGBD) were used for moderate/grade II and severe/grade III patients. The patients with mild/grade I disease were conservatively treated with adequate antibiotics. Definitive surgeries were carried out after resolution of the acute inflammatory process and stabilization of the patient's general condition.

For the treatment of cholecystolithiasis without CBD stones, we initially tried to perform laparoscopic cholecystectomy, regardless of the severity of inflammation. If there were concurrent CBD stones, the patients were preoperatively treated by endoscopic removal of the CBD stones. However, when CBD stones could not be removed due to a parapapillary diverticulum or previous digestive reconstruction, open choledochotomy or bilioenteric anastomosis was used.

In addition, in order to prevent postoperative wound infection, we usually used sulbactam sodium/cefoperazone sodium (SBT/CPZ) as prophylactic antibiotics. In principle, patients were injected with 1 g SBT/CPZ 30 min before the operation, within an hour following completion of the operation, and on the following morning. Depending on intraoperative findings, such as bile spillage, we administered the same antibiotics (2 g/day) for 2 or 3 days. We habitually used a wound protector for laparotomies and an endocatch device for removing the gallbladder during laparoscopic cholecystectomy.

For glycemic control in the patients with diabetes, we adequately insulinized all patients during the perioperative period and continued close monitoring of insulin and glucose for at least 2–3 days until a sufficient level of oral intake could be maintained. Thereafter, when possible, we changed the insulin-supplement therapy to oral antidiabetic drugs.

Evaluation of the risk factors for ISSI after biliary tract surgery

We observed the wounds of all patients at least once a day after the operation. The diagnosis of wound infection (ISSI)

Table 1 Characteristics of the patients

Variable	N = 207
Background	
Gender (male/female)	110/97
Age (years)	68.3 ± 11.0
BMI (kg/m ²)	22.7 ± 3.3
PS (good: 0, 1/bad: 2, 3, 4)	148/59
Preoperative diagnosis	
Gallbladder stone (yes/no)	160/47
CBD stone (yes/no)	71/136
Biliary tract infection (yes/no)	133/74
Incidental biliary tract cancer (yes/no)	7/200
Severity of biliary tract infection	
Tokyo guideline criteria for acute cholecystitis (grade I/grade II/grade III/others)	79/16/3/109
Tokyo guideline criteria for acute cholangitis (grade I/grade II/grade III/others)	40/19/8/140
Evidence-based clinical practice guidelines for acute cholecystitis (mild/moderate/severe/others)	38/50/10/109
Evidence-based clinical practice guidelines for acute cholangitis (mild/moderate/severe/others)	10/49/8/140
Surgical procedure	
Way of approach (open/laparoscopic)	149/58
Cholecystectomy (yes/no)	181/26
Choledochotomy (yes/no)	49/158
Bilioenteric anastomosis (yes/no)	16/191

BMI body mass index, *PS* performance status, *CBD* common bile duct

was made after discussion among physicians, based on the 1999 Centers for Disease Control and Prevention (CDC) guidelines for the prevention of surgical site infection (SSI) [11]. However, in the present study, we did not assess organ/space SSIs described in the CDC guidelines. Of note, we classified the severity of wound infection (ISSI) into five categories, as follows: Grade 0, no sign of infection; Grade 1, only redness or swelling of the wound, not requiring any treatment; Grade 2, an infection involving only the skin or subcutaneous tissue; Grade 3, infection involving the fascial and muscle layers; and Grade 4, infection invading the organ/space that drains through the incision. We regarded Grade 2 and higher as wound infections.

We selected various patient- and perioperative treatment-derived variables that might influence the development of wound infection. Patient-derived variables included age; gender; BMI; history of diabetes; PS; the presence of gallstones; CBD stones; biliary tract infections; comorbid cancer; laboratory data at the initial visit and just before surgery (white blood cell count, hemoglobin, C-reactive protein, total bilirubin, aspartate aminotransferase, alanine aminotransferase, γ -glutamyl transpeptidase, alkaline phosphatase, serum albumin, serum cholinesterase, serum

cholesterol, blood urea nitrogen, serum creatinine); the perioperative fasting period (days); and the results of blood and bile cultures in the pre-, intra-, and postoperative periods. As for blood and bile culture status (positive or negative), the patients in whom cultures were not performed were assessed as being culture-negative, because they did not need culture examination based on their clinical findings. Perioperative treatment-derived variables included the use of biliary drainage (PTGBD, PTBD, and ENBD), time period from initial treatment to definitive surgery, surgical procedure, length of the operation, intraoperative blood loss, intraoperative bile spillage caused by accidental bile duct injury, and use of a cholangioscope during choledochotomy.

Correlation between the incidence of ISSI and the two clinical stratifications of acute biliary infectious disease

In this study, we also evaluated the correlation between the incidence of wound infection and two clinical stratifications of acute biliary infectious disease: the Japanese evidence-based clinical practice guidelines and the International Tokyo Guidelines for the management of acute cholangitis and cholecystitis.

Proposal for an ISSI predictive score

To predict the occurrence of a wound infection and its severity after biliary tract surgery, we proposed an original scoring system. To create the scoring system, we selected the risk factors most highly associated with the occurrence of wound infection as determined by a multivariate analysis. We also evaluated the correlation between this score and the severity grade of the wound infection, and we also evaluated the correlation between our score and the length of the postoperative hospital stay.

Statistical analysis

The data for continuous variables were expressed as the mean values with SD, and the statistical significance was determined by Student's *t*-test or the Cochran–Cox test. Dichotomous variables were evaluated by the χ^2 test or Fisher's exact test, as appropriate. Only variables that were statistically significant by univariate analysis were included in the multivariate analysis, which was performed using logistic regression analysis. The ISSI predictive score was calculated by using a discriminant regression equation. To determine the correlation between the score and the severity of wound infection or length of hospital stay after surgery, the correlation coefficient test was employed. The optimal cutoff value of the score was determined using diagnostic accuracy measurements and receiver-operating characteristic (ROC) curves. The results were considered significant when the *P* values were <0.05.

Results

Risk factors for ISSI after biliary tract surgery

The incidence of postoperative wound infection was 9.7% (20/207). There were 178 cases of Grade 0, 9 of Grade 1, 15 of Grade 2, 4 of Grade 3, and 1 case of Grade 4 infection. The results of the univariate analysis are summarized in Table 2. The following 13 factors were associated with the development of a wound infection: PS; levels of alkaline phosphatase, albumin, and cholesterol on admission; level of alkaline phosphatase just before surgery; biliary tract infection; blood and bile culture results; presence of CBD stones; the perioperative fasting period (days); use of PTGBD; cholecystectomy; and intraoperative bile spillage.

According to our multivariate analysis (Table 3), the PS, bile culture results, perioperative fasting period (days), and bile spillage were identified as the most influential risk factors for predicting the development of a wound infection.

Correlation between the incidence of ISSI and the two clinical stratifications of acute biliary infectious disease

Based on the results described above, we hypothesized that both the general condition of patients and the severity of inflammation were highly associated with the occurrence of a wound infection. We then determined the correlation between the incidence of wound infection and the established clinical stratifications for acute biliary infectious diseases. As shown in Fig. 1, 30–50% of patients whose severity was classified as 'severe or grade III' developed a wound infection postoperatively, indicating that the pre-operative severity of biliary infection highly influences the occurrence of wound infection.

ISSI predictive score

The PS, bile culture results, perioperative fasting period (days), and bile spillage were all identified as independent factors predicting the occurrence of wound infection based on the multivariate analysis. Figure 2a shows the original formula used to calculate our score by discriminant analysis. As shown in Fig. 2b, our score correlated significantly with the severity of wound infection ($r = 0.488$, $P < 0.001$). According to the ROC curves, the postoperative ISSI predictive score at an optimal cutoff value of 2.7 points showed the highest accuracy in predicting the development of a postoperative wound infection (accuracy: 94.2%, sensitivity: 60.0%, specificity: 97.9%). The incidences of wound infections in the patients with scores of >2.7 points (high-risk group) and those with scores of 0–2.7 points were 75.0% (12/16) and 4.2% (8/191), respectively. Moreover, 25% (4/16) of the patients whose score was higher than 2.7 points developed a severe wound infection or higher than Grade 3, and 80% (4/5) of the patients who developed a severe wound infection had been classified in the high-risk group. All of these patients, unfortunately, required a reoperation. We show findings for a typical case in Fig. 3, to demonstrate that our score was associated with the development of ISSI and length of hospital stay.

Similarly, when we focused on the patients' postoperative hospital stay, the development of a wound infection significantly prolonged the postoperative hospital stay (13.0 ± 10.6 vs. 41.5 ± 32.6 days, $P = 0.0012$), and our score was also strongly correlated with the length of the postoperative hospital stay ($R = 0.508$, $P < 0.001$) (Fig. 4).

Discussion

In this study, we identified 4 major risk factors for postoperative wound infection after biliary tract surgery for

Table 2 Results of the univariate analysis

Variables	ISSI (−) (<i>N</i> = 187)	ISSI (+) (<i>N</i> = 20)	<i>P</i> value
Patient-derived			
Age (years)	67.8 ± 13.8	72.9 ± 12.9	0.12113
BMI (kg/m ²)	23.2 ± 4.1	19.1 ± 5.7	0.13999
PS (good/bad)	141/46	7/13	0.00014*
DM (yes/no)	25/162	4/16	0.63609
WBC on admission (/μl)	9571.1 ± 4960.8	10985.0 ± 5316.2	0.23268
WBC just before operation (/μl)	6411.8 ± 2131.5	5410.0 ± 1474.4	0.13985
Hb just before operation (g/dl)	15.3 ± 31.5	12.3 ± 2.0	0.20846
CRP on admission (mg/dl)	5.8 ± 8.0	10.7 ± 10.2	0.05336
CRP just before operation	2.0 ± 4.4	2.6 ± 5.6	0.67751
T-bil on admission (mg/dl)	2.4 ± 2.8	3.3 ± 2.8	0.16938
AST on admission (IU/l)	115.1 ± 180.4	261.6 ± 356.9	0.09267
ALT on admission (IU/l)	118.4 ± 172.0	57.2 ± 40.7	0.26562
γGTP on admission (IU/l)	231.8 ± 293.7	344.1 ± 286.5	0.10642
ALP on admission (IU/l)	509.9 ± 452.8	956.2 ± 720.7	0.01527*
ALP just before operation (IU/l)	373.6 ± 268.2	598.3 ± 461.0	0.04956*
Albumin on admission (g/dl)	3.9 ± 0.6	3.5 ± 0.6	0.00271*
Cholesterol on admission (mg/dl)	182.7 ± 47.6	152.0 ± 34.5	0.00556*
Ch-E just before operation (IU/l)	258.4 ± 80.4	188.4 ± 67.1	0.05023
BUN just before operation (mg/dl)	13.4 ± 5.1	13.3 ± 5.4	0.91289
Cre just before operation (mg/dl)	0.8 ± 0.3	0.7 ± 0.4	0.80469
Bile culture (positive/negative) ^a	20/167	7/13	0.00216*
Blood culture (positive/negative) ^a	7/180	5/15	0.00077*
CBD stone (yes/no)	60/127	11/9	0.04019*
Biliary tract infection (yes/no)	115/72	18/2	0.02246*
Perioperative fasting period (days)	4.3 ± 6.2	12.4 ± 15.5	0.03468*
Treatment-derived			
PTGBD (yes/no)	24/163	6/14	0.03820*
PTCD (yes/no)	5/182	2/18	0.28370
ENBD (yes/no)	16/171	3/17	0.58834
Duration of the operation (min)	124.0/54.1	158.1/126.9	0.26049
Intraoperative blood loss (ml)	106.1/159.1	275.8/492.4	0.15127
Way of approach (open/laparoscopic)	132/55	17/3	0.27041
Bilioenteric anastomosis (yes/no)	13/174	3/17	0.40063
Cholecystectomy (yes/no)	170/17	14/6	0.00468*
Choledochotomy (yes/no)	41/146	8/12	0.07069
Intraoperative bile spillage (yes/no)	59/128	13/7	0.00283*

ISSI incisional surgical site infection DM diabetes mellitus, Hb hemoglobin, CRP C-reactive protein, T-bil total bilirubin, AST aspartate aminotransferase, ALT alanine aminotransferase, γGTP γ-glutamyl transpeptidase, ALP alkaline phosphatase, Ch-E cholinesterase, BUN blood urea nitrogen, Cre creatinine, PTGBD percutaneous transhepatic gallbladder drainage PTBD percutaneous transhepatic biliary drainage, ENBD endoscopic nasobiliary drainage

* *P* < 0.05

^a The patients for whom culture was not performed were assessed as being culture-negative

benign diseases, as follows: deterioration of PS, positive bile culture, prolonged perioperative fasting period (days), and intraoperative bile spillage (Table 3). The PS was highly influenced by increasing age, and the severity of disease and immunodeficiency, all of which have been

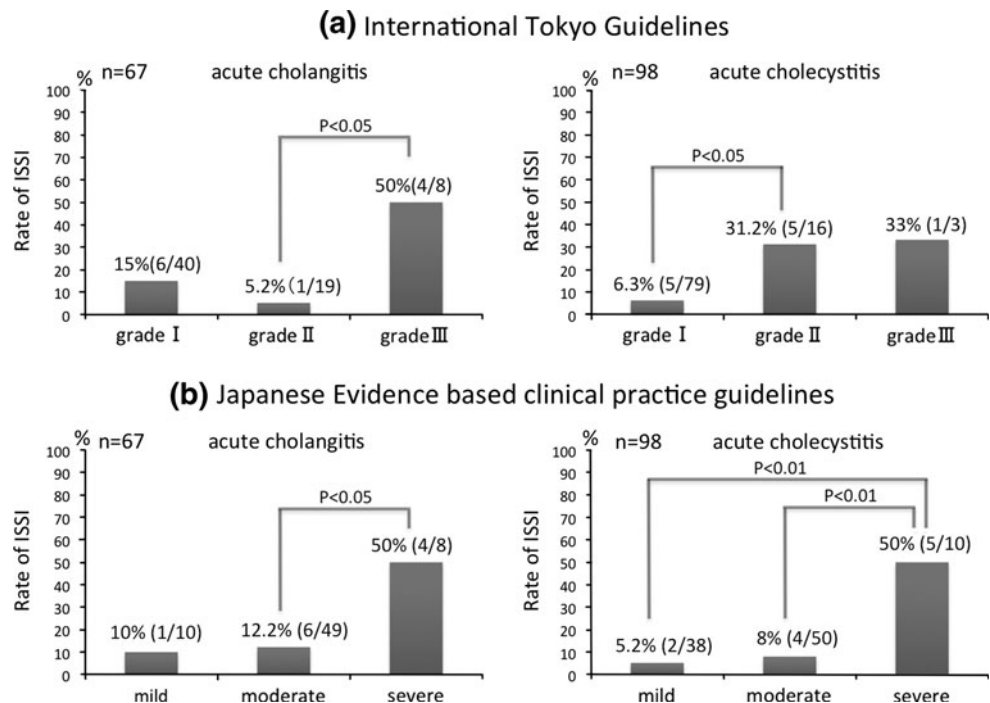
previously shown to be risk factors for postoperative wound infections in general surgery [12, 13]. Regarding the severity of disease, several clinical symptoms arising from acute biliary infection, such as a high-grade fever, disturbed consciousness, and local tenderness, markedly decreased

Table 3 Results of the multivariate analysis

Variables	Odds ratio	95% CI	χ^2	P value
PS				
Good	1		4.04	0.0440
Bad	3.101	0.0153 to 1.134		
Bile culture				
Positive	4.174	0.128 to 1.285	6.41	0.0180
Negative	1			
Fasting period (days)		−0.109 to −0.0149	6.47	0.0089
Intraoperative bile spillage				
Yes	3.63	−2.467 to −0.223	5.26	0.0175
No	1			

CI confidence interval

Fig. 1 The relationship between the rate of wound infection and the severity of acute biliary disease. **a** According to the International Tokyo guidelines. **b** According to the Japanese evidence-based clinical practice guidelines. *SSI* incisional surgical site infection



the PS, particularly in elderly patients. In fact, the wound infection rate in the patients whose severity was classified as ‘severe or grade III’ was significantly higher than that of the patients with other severity classifications. The effect of advanced age on the risk of SSI has been well studied. However, patient age did not affect the incidence of wound infection in our study. Kaye et al. [14] previously revealed that increasing age independently predicted an increased risk of SSI until age 65 years in various procedures such as orthopedic, gastrointestinal, obstetric/gynecologic, and cardiothoracic, but at ages greater than 65 years, increasing age independently predicted a decreased risk of SSI. Therefore, the results of our present study are consistent with this previous study, because the average age of our patients was around 65 years (mean 68.3 ± 11.0 years).

A close association between positive bile culture and a higher rate of SSIs has been demonstrated by various studies [1, 15]. It has also been demonstrated that bile spillage increases the incidence of umbilical wound infections after laparoscopic cholecystectomy [16]. Because these factors directly affect the occurrence of wound infection, surgeons must pay close attention to intraoperative bile spillage when treating patients with a positive bile culture. As for CBD stones, the risk of SSI increases especially when choledochotomy with T-tube drainage is performed, because intraoperative bile leakage cannot be avoided when stones are retrieved. As intraoperative cholangioscopy and intrabiliary lavage for CBD stones facilitate peritoneal bile spillage in patients with acute cholangitis, we have to control the infection as much as possible preoperatively.

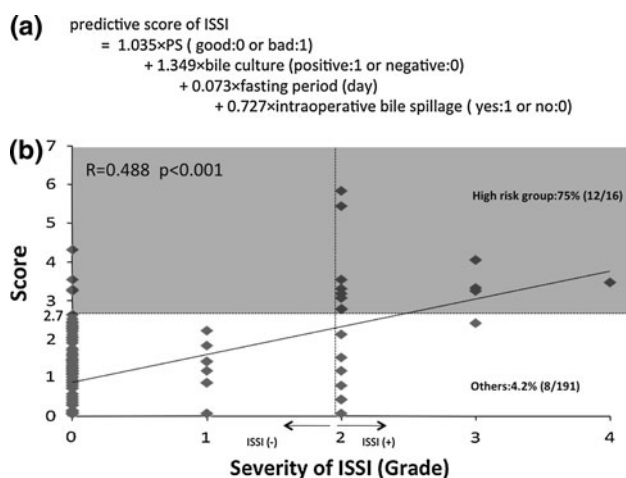


Fig. 2 The original ISSI predictive score to predict the incidence and severity of wound infection. **a** The equation for calculating the score. **b** The relationship between the score and the severity grade of wound infection. A significant positive correlation was evident between the score and the severity of wound infection ($R = 0.488$, $P < 0.001$). In the high-risk group (>2.7 points), 75% of the patients developed a wound infection. *PS* performance status

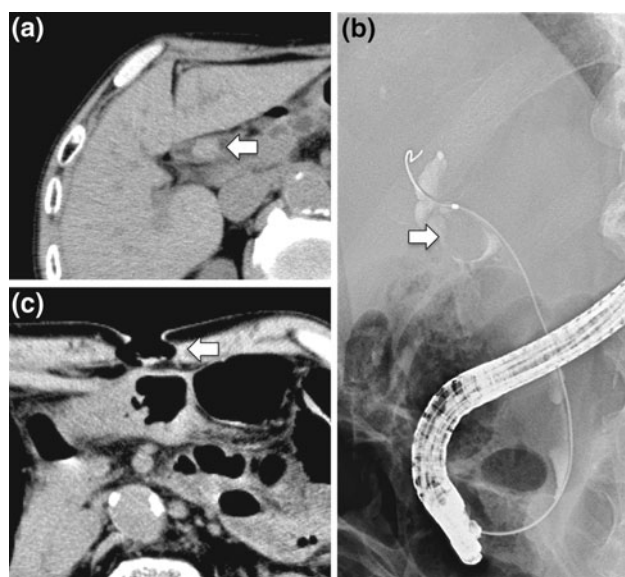


Fig. 3 Images in an 83-year-old man who developed a severe wound infection invading to the intraperitoneum after open choledochoduodenostomy with intraoperative removal of common bile duct (CBD) stones. His ISSI predictive score was 3.476. **a** A preoperative computed tomography (CT) image. The white arrow indicates the CBD stone. **b** Preoperative endoscopic retrograde cholangiography (ERCP) showing CBD stones (white arrow), which could not be removed by a preoperative endoscopic approach, due to parapapillary diverticulum of the duodenum. **c** CT image on postoperative day 8; CT was performed to search for another source of fever and to ascertain the depth of the ISSI. The CT image showed wound disruption and an incisional hernia in the upper abdomen (white arrow), which required an emergency operation for wound repair and led to a prolonged hospital stay

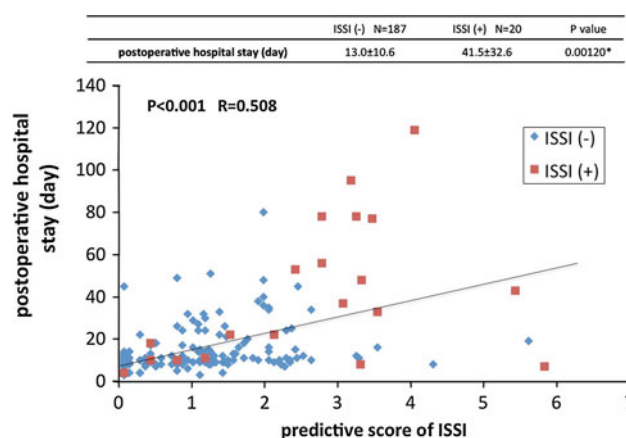


Fig. 4 A significant positive correlation was seen between the ISSI predictive score and the length of the postoperative hospital stay ($P < 0.001$, $R = 0.508$). The hospital stays of patients who developed wound infections were markedly longer than those of patients without signs of infection (41.5 ± 32.6 days vs. 13.0 ± 10.6 , $P = 0.00120$)

A prolonged fasting period impacts a patient's nutritional status, thus resulting in malnutrition, which has been regarded as a predictive factor for SSI in some studies [17, 18]. Malnutrition is also frequently associated with diseases such as cancer, as well as chronic and acute inflammatory diseases, including acute cholecystitis and cholangitis. Deficiencies of some important vitamins and minerals due to malnutrition can significantly alter leukocyte function and the immune response. Thus, a long fasting period indirectly leads to a higher incidence of wound infection, regardless of the type of biliary tract surgery.

The use of laparoscopic or open surgery was reported to be a major factor related to postoperative SSI not only in biliary tract surgery [2, 19], but also in digestive tract surgery [20, 21]. According to a nationwide surveillance study of 54,504 inpatient cholecystectomy procedures in the United States, the overall rate of SSIs was significantly lower for laparoscopic cholecystectomy than for open cholecystectomy. In the present study, however, the incidence of SSI did not significantly differ between laparoscopic cholecystectomy and open surgery. Nevertheless, the wound status of the 3 patients who developed an infection after laparoscopic surgery was less than Grade 2, and all of these patients recovered after conservative treatment within 1 week, while all the patients whose ISSIs were more severe had undergone laparotomy. Therefore, it is considered that the laparoscopic approach contributes to preventing the development of severe wound infections beyond the deep fascia.

Our ISSI predictive score was proposed in order to predict the occurrence of wound infections after biliary tract surgery. A significant positive correlation was found to exist between our score and the incidence of wound

infection. Furthermore, this score was also correlated with the disease severity, as shown in Fig. 2b. Confirming the efficacy of this scoring system, in the high-risk group (whose score was more than 2.7 points), the incidence of postoperative wound infection was 75% (12/16). Furthermore, 80% (4/5) of the patients who developed severe wound infections of higher than Grade 3, so-called “deep incisional SSIs”, belonged to the high-risk group. In the past, other studies have reported some risk factors for predicting postoperative wound infection after biliary tract surgery by uni- and/or multivariate analyses. Nevertheless, to the best of our knowledge, this is the first study focusing not only on the incidence of wound infection, but also its severity, with a numerical-conversion method.

It has been reported in some studies that wound infections prolong the postoperative hospital stay considerably [5, 6], and our study was consistent with these previous results. Interestingly, we observed that the length of the postoperative hospital stay was also correlated with our score, as shown in Fig. 4 ($P < 0.001$; $R = 0.508$). Wound infection also results in increasing medical expenses and economic disadvantages [5, 6], so prevention of this common complication is beneficial not only for patients, but also for hospitals and medical staff. Therefore, our original scoring system is considered to be valuable.

In conclusion, our original scoring system makes it possible to predict not only the likelihood of developing a wound infection after biliary tract surgery, but also its severity and the length of the postoperative hospital stay. To prevent wound infection, surgeons need to pay more attention to the nutritional status of patients, to control infections prior to surgery, and to avoid intraoperative bile spillage.

Conflict of interest The authors declare that they have no conflict of interest.

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