Cohort study

Associated factors with surgical site infections after hepatectomy: Predictions and countermeasures by a retrospective cohort study

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Running title: SSI predictors in hepatectomy

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ABSTRACT

Background: To clarify the factors associated with posthepatectomy surgical site infections (SSIs), the clinicopathological data of 526 patients who underwent hepatectomy was retrospectively examined as a retrospectively cohort study.

Methods: Patient demographics, liver functions, histological findings, surgical records and post-hepatectomy morbidity were compared between non-SSI and SSI groups; the SSI group included superficial and deep SSIs.

Results: The prevalence of SSIs (5-8%) has not changed over an 18-year period. Deep SSIs were significantly more increased in male patients with lower performance statuses and American Society of Anesthesiologists (ASA) scores ($p<0.05$). SSIs tended to be less prevalent, although not significant ($p=0.10$), in patients who underwent laparoscopic hepatectomies compared to those who underwent laparotomies. For patients in whom hemostatic devices were used, the prevalence of superficial SSIs was significantly lower than those in whom the devices were not used ($p<0.05$). Blood loss and transfusion were significantly more frequent in the deep SSI group compared to other groups ($p<0.01$). Hospital stay in the deep SSI group was significantly longer compared to other groups. The incidence of morbidity was more frequent in the SSI groups compared with the non-SSI group ($p<0.001$). A multivariate analysis showed that not using a vessel sealing device was significantly associated with superficial SSIs; male gender, hepatic failure and bile leakage were significantly associated with deep SSIs ($p<0.05$).

Conclusions: SSIs were important indicators of patient outcomes after hepatectomies, and preventing SSI development after surgical procedures is an important step in improving the overall prevalence of SSIs.

KEYWORDS: hepatic resection; surgical site infection; patient outcome; predictors; cohort study

Introduction

Hepatic resection is an invasive operation that can lead to increased blood loss requiring red cell transfusions and that can cause severe physiological stress responses, postoperative complications (e.g., hepatic failure, bile duct leakage, or multi-organ failure). Recently, by understanding pathophysiology and the treatments based on it, perioperative patient management has gradually improved, along with surgical techniques, which have been aided by improved surgical skills and medical devices. Regardless of the improvements in hepatic surgery, hepatectomy-related surgical site infections (SSIs) have not been eradicated.[1] SSIs in deep lesions affecting the organ were supposedly caused by the following factors: 1) collections of fluids, such as bile, pancreas juice, and clotted blood; 2) iatrogenic instruments, such as drainage tubes, tied knots or staples; 3) organ damage, such as necrotic or ischemic areas; and 4) bacterial translocation because of hepatic dysfunction. The incisional SSI in the superficial lesion of the abdominal wall may be caused by the following: 1) exposure of digestive tract fluid or blood; 2) bacterial flora, which is usually located on the patient’s skin; and 3) an exposure to extrinsic bacteria. It is important to clarify the hepatectomy-associated parameters with SSI in the deep and superficial lesion and then to take the necessary measures to avoid infections by recognizing the associated factors. Several investigators have reported on the factors associated with SSI in patients who underwent hepatectomies.[1-5] The intent of the present study was to examine these additional parameters by looking at the temporal trends at a single Japanese cancer institute. Based on the results, it must be considered taking measures to reduce the prevalence of SSI. It was hypothesized that hepatectomy-related SSI could be improved by treating the risk factors clarified by the present study.

In the present cohort study, the perioperative clinical and pathological parameters, surgeon experiences, surgical records and the postoperative morbidity and mortality rates of 526 patients with various liver diseases who underwent hepatic resections between 1994 and 2012 were retrospectively examined. In the 2000s, a chief operator was changed, although the first author treated the same group for the entire study period. In 2007, we started using hemostatic devices and the hanging maneuver systematically. Therefore, the study period was divided into three groups: group 1 (1994-1999), group 2 (2000-2006) and group 3 (2007-2012). Based on the results, the future strategies for SSIs in liver surgery at our institute were considered.

Materials and Methods

Patient demographics

A total of 526 consecutive patients (367 males, 159 females) undergoing hepatic resection in the Division of Surgical Oncology and Department of Surgery at Nagasaki University Graduate School of Biomedical Sciences (NUGSBS) between 1994 and 2012 were analyzed. The mean and median patient ages at the time of surgery were 64.3 ± 11.7 and 67 years (range, 20-86 years), respectively. All patients' in-hospital data was consecutively collected during these follow-up periods but no potential bias. There were no patient selection or matching criteria, and all patients were enrolled for the present study.

The subjects were divided based on time periods: term 1, hepatectomies performed between 1994 and 1999, 137 patients (26%); term 2, hepatectomies performed between 2000 and 2006, 211 patients (40%); and term 3, hepatectomies performed between 2007 and 2012, 178 patients (34%). All of the patients underwent ICG testing to evaluate the operative indications. All of the study protocols were approved by the Human Ethics Review Board of our institution. Informed consent for data collection was obtained from each patient during this period. Anesthetic and patient data were retrieved from the NUGSBS database. There was no conflict of interests and no financial supports from anywhere.

For hepatectomy, the liver volume to be resected was estimated according to results of the indocyanine green retention rate at 15 min (ICGR15). Furthermore, hepatic function for hepatectomy was limited to ICGR15 <40%. The expected liver volume for resection, excluding the tumor, was measured by computed tomography (CT) volumetry. Functional liver volume by 99mTc-galactosyl serum albumin (GSA) scintigraphy has been performed in patients since 1998. The liver uptake ratio at 15 min (LHL15) by ^{99m}Tc-GSA scintigraphy and serum hyaluronic acid level was examined preoperatively.[5] Parenchymal dissection was accomplished using the forceps fracture method under intermittent vascular clamping of the hepatic artery and portal vein in the hepatoduodenal ligament. In case of laparoscopic hepatectomy, forceps fracture method was sometimes applied and, however, the use of the surgicalt devices as the ultrasonic dissectors or vessel sealers to dissect hepatic parenchyma. An evaluation of background liver disease and main liver disease was confirmed by histopathological examination of the resected specimen. The classification system of the General Rules for the Clinical and Pathological Study of Primary Liver Cancer for clinic-pathological parameters or the Liver Damage Grade classification was used in the present study.[6] The main operator was the teaching staff in 361 (69%) cases and the fellowship or resident surgeon in 165 (31%) cases. The operative procedures included hemi-hepatectomies (with varying degrees of resection) (n=197, 38%), sectionectomies or segmentectomies (n=161, 31%) and partial resection (n=168, 32%). All of the hepatic tumors were completely resected without macroscopic exposure of the amputated section to the remaining liver.

Statistics

All continuous data are expressed as the mean ±SD and median value. Differences were examined using a one-way analysis of variance (ANOVA) and Student's t-test. Correlations between the two parameters were examined by calculating the Pearson's correlation coefficient. Categorical data were analyzed using Fisher's exact test, which was the most sensitive analysis. Potentially predictive variables were identified using a significance level of $p<0.05$ by univariate analysis, and the identified factors were then entered into the multiple logistic regression analysis. A two-tailed value of $P<0.05$ was considered statistically significant. SPSS for Windows version 18.0 (SPSS, an IBM Company, Chicago, IL) was used for all the statistical analyses.

Results

There were 257 patients (49%) with normal livers, steatohepatitis in 17 (3%), chronic hepatitis in 223 (42%), including liver cirrhosis in 82, and obstructive biliary jaundice in 29 patients (6%). The following liver diseases were identified: liver metastasis in 166 (32%), hepatocellular carcinoma (HCC) in 228 patients (43%), intrahepatic cholangiocarcinoma (ICC) in 38 (8%), gallbladder carcinoma in 25 (5%), extrahepatic bile duct carcinoma in 41 (8%), and other benign liver diseases in 28 (4%). Regarding the liver functional classification, the Child-Pugh classification was B in 17 patients (3%) and A in 509 patients (97%), and the Japan's liver damage grade, including a parameter of indocyanine green (ICG) test, was grade A in 454 patients (86%) and B in 72 (14%).

Table 1 shows the prevalence of SSI in the different periods. The prevalence of superficial SSI, deep SSI and the total number of SSIs has not changed over an 18-year period.

Table 2 shows the demographics of patients who underwent hepatectomy (for each SSI). In the deep SSI group, the male gender was significantly higher compared to other groups ($p<0.05$). In the deep SSI group, the prevalence of the lower performance status and the lower American Society of Anesthesiologists (ASA) score were significantly higher compared with other groups ($p<0.05$). Patient age and the incidences of background liver, liver disease, co-morbidity and preoperative liver functions were not significantly different between the groups.

Table 3 shows the surgical records and patient outcomes. The incidences of laparoscopic hepatectomy tended to be higher and no laparoscopic hepatectomy were observed in the SSI groups, but these results were not significant ($p=0.102$). The operators and extend of the hepatectomies and combined resections were not different between the groups. Non-use of hemostatic devices was significantly more frequent in the superficial SSI group compared to the other groups ($p<0.05$). The operating and transection times were not different between groups. Blood loss and transfusion occurred significantly more frequently in the deep SSI group compared to the other groups, and the red cell transfusion rate in the deep SSI group was significantly higher compared to the other groups ($p<0.01$).

Hospitalization time in the deep SSI group was significantly longer compared to the other groups. The incidence of total postoperative morbidity was more frequent in the superficial and deep SSI groups compared to the non-SSI group ($p<0.001$). The incidences of hepatectomy-related complications, hepatic failures, long-term ascites, bile leakage and hospital stay deaths in the deep SSI groups occurred significantly more frequently compared to the other groups ($p<0.01$). Table 4 shows the risk ratio of the SSI-associated parameters according to the multivariate analysis. Use of the vessel sealing device was significantly associated with superficial SSIs ($p<0.01$). Male gender was significantly associated with deep SSIs ($p<0.05$), but general status and surgical records were not associated with deep SSIs. With respect to posthepatectomy complications, hepatic failure and bile leakage were significantly associated with deep SSIs ($p<0.05$).

Discussion

Surgical site infection is a major postoperative complication, particularly in hepatobiliary surgery.[1,3,7] This frustrating complication prolongs hospital stays. SSI treatments have been improved by the development of perioperative management but not the use of antibiotics. A recent surgical report still has concerns about SSIs. Arikawa et al. recently reported on each incisional and organ/space SSI; the predictive factors for SSIs in HCC patients were longer operations and bile leakage.[1] Thus, it is necessary to evaluate SSIs separately in the superficial (incisional) and deep (organ space) site, in the present study as well. In this report, we examined hepatectomies in patients with various liver diseases because we wanted to examine different hepatectomy surgeries, such as combined resection of the bile duct, major vessels or other organs.

As postoperative complications might improve based on time period changes, we confirmed differences in the prevalence of SSI based on our experiences. However, the incidence of each SSI did not changed in 3 time periods over 18 years. Therefore, with respect to SSIs at our institute, improvement could not be observed. Previous reports have shown an SSI incidence of approximately 10-15% after hepatectomy; the incidence in the present series (5-8%) was lower than these reports.[1-3] Therefore, our SSI management might be adequate. With respect to preventing postoperative infection, prophylactic antibiotics, such as kanamycin, were administered orally for a couple of days before the operation, and third-generation cephem antibiotics by drip infusion were used for 7 days after hepatectomies in the 1990s in our series. However, these prophylaxes might not be necessary because reliable evidence regarding their effectiveness has not been fully elucidated; therefore, we have not administered prophylactic antibiotics since 2000. As a result, the incidence of infection was not changed at all. Shaving of the body hair has been performed previously to prevent incisional SSI at our institute. However, this procedure has also been stopped since 2002 because the reliable evidence has not been clarified. Since 2004, ties with silk saw have been changed to absorbable materials to prevent SSIs at our institute. When the abdominal wound was closed, we fully wash the intra-abdominal space with a large amount of saline (5000 ml) to remove remaining microorganisms and the incised wound was well washed by a jet stream of saline. With respect to the deep SSI, management of drainage tube is important. In fact, we applied the closed drainage tube and, however, the remarkable management regimen has not been established at our institute. Thus, this management was entrusted by each surgeon for the entire series in the present study. The deep SSI was often confirmed by the infectious fluid via the drainage tube and others were confirmed by the additional puncture drainage. In the deep SSI group, such a drainage tube associated infections were included in the present series. Infections were confirmed by the bacteriological examination. Therefore, the adequate regimen for management of the drainage tube at our institute should be established.

Next, the association between any clinical and surgical features and both superficial and deep SSIs were examined. Although older age, background liver diseases, lower liver functions, or comorbidities before surgery were supposed to be important factors with respect to SSI according to previous reports,[3, 8] these factors were not significantly associated with either superficial or deep SSIs in our series. Current or past histories of cardiovascular diseases tended to be associated with superficial and deep SSIs. Previous reports showed the relationship between SSI and cardiovascular disease; for example, patients with cardiovascular diseases often had acute cholecystitis without stones.[9] Although the causes are still unknown, the physiological stress from treatments, associated vasculitis or organ ischemia might cause this condition.[10] Of the various co-morbidities, this factor might be the factor most associated with SSI, according to our results. The male gender was significantly associated with deep SSIs in the present study. It was speculated that male patients have more various habits, such as alcohol or smoking, compared with female patients, which might affect the systemic organ dysfunctions. However, the mechanism behind this gender difference has not been identified. In the present study, the different characteristics of male patients compared to female patients could not be examined with the present archives at our institute. As in previous reports, the lower performance status or ASA levels were significantly associated with deep SSIs in the present study.[11] Patients with these parameters might have lowered immunity, based on worsened systemic physiological functions.

With respect to the surgical records, the patients who underwent laparoscopic operations did not experience any SSIs. Laparoscopic operations for digestive organs were also associated with lower infections, and the length of the surgical wound was related to bacterial infections.[12] In particular, gram-positive bacteria, such as a methicillin-resistance staphylococcus aureus, was often detected on the surface wound or around foreign objects, such as a drainage tube.[13] Laparoscopic surgery for hepatic surgery has recently increased worldwide, and developing this procedure is necessary from the perspective of avoiding SSIs. Furthermore, the use of hemostatic devices was associated with lower the superficial SSI in the present study. By using such devices, contamination via the operator's figures or the spread of digestive juices on the abdominal wall or skin might be avoided. Using vessel sealing devices decreased bile leakage after hepatectomy in previous reports as well.[14] In case of laparoscopic hepatectomy, the dissecting or hemostatic devises were mainly used for parenchymal transections, which might be influenced the lower prevalence of SSIs in the laparoscopic procedures. Forceps fracture method for open use was considered as a risk factor for SSI via the operator's hands or forceps. Combined resections of the main vessel or biliary tract were alleged SSI risk factors; however, a significant relationship between SSI and these procedures were not observed. In such operations, the surgeons might be more careful about not contaminating the surgical site. Blood loss and related red cell transfusions were significantly associated with deep SSIs in the present results. As in previous reports, these factors influenced the increased morbidity and patient prognosis in cancer patients with liver diseases.[15, 16] Although the remarkable mechanisms of this phenomenon have not been clarified yet, decreased immunity caused by increased blood loss or blood transfusion was thought to be one cause.[15, 16] In any event, preventing blood loss by using recent medical devices or controlling transfusions during the operation would decrease the prevalence of SSIs. From the results of the multivariate analysis, non-use of hemostatic device is an independent prognostic factor that may prevent superficial SSIs. Such a device was preferably used to cut the abdominal wall muscles or peritoneum in the recent periods.

With respect to patient outcomes, SSIs frequently occurred when any postoperative complications were observed. However, superficial SSIs were not significantly associated with hepatectomy-related complications and the length of hospital stay in the present study. The appearance of superficial SSIs was not expected after the hepatectomies. However, deep SSIs were closely associated with any hepatectomy-related severe complication, such as hepatic failure or related hospital-stay death in particular. Hepatic failure frequently causes infection because of the deterioration of the immunological defense mechanism from bacterial translocation or sepsis.[17] Long-term ascites after hepatectomy may cause bacterial peritonitis.[18] Bile juice leakage often causes intra-abdominal infection in the space, except for the drainage area.[1] In the multivariate analysis, bile leakage was the most significant risk factor for deep SSI. Preventing bile leakage from the cystic duct tube might be effective for avoiding SSI.[19] Such a surgical procedure can decrease the occurrence of deep SSIs, and we attempted to use cystic duct drainage tubes to decompress the intra-biliary pressure in cases of anatomical hepatic resections.[20] Hospital-stay length was significantly affected by the high prevalence of post-hepatectomy complications and deep SSIs. Deep SSI was thought to be an important factor affecting patient survival prognosis because this infection causes systemic sepsis and additional multi-organ dysfunctions. Thus, deep SSI is a risk factor for patient outcomes and prolonged hospital stays. The present study was a retrospectively cohort study, in which the present study design might provide some bias in results. Therefore, it is necessary to design a prospective randomized study in each subgroup in the suture step.

In conclusion, it has been demonstrated the prevalence of superficial and deep SSIs and examined their effect in the surgical records and outcomes of patients with various diseases who underwent hepatic resections. SSI prevalence has not been changed in 18 years. Various factors were associated with each SSI, and the multivariate analysis showed that non-use of hemostatic devices and postoperative complications were associated with superficial SSIs, but hospital stays were not significantly prolonged. Male gender, hepatic failure and bile leakage were significantly associated with deep SSIs. Preventing bile leakage with surgical procedures should be important for improving the prevalence of SSIs, and such attempts may decrease patient outcomes after hepatectomy.

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Table 1 Changes of prevalence of SSI in the different periods

	Term 1 (n=137)	Term 2 (n=211)	Term 3 (n=178)	Statistics *(p value)*
Superficial SSI (n=32)	8(2%)	9(2%)	15(3%)	0.229
Deep SSI(n=74)	16(3%)	32(6%)	26(5%)	0.637
Total	24(5%)	41(8%)	41(8%)	0.455

Table 2 Patient demographics, co-morbidity, general status and liver functional parameters in patients with or without SSI

	Non-SSI (n=420)	Superficial SSI (n=32)	Deep SSI (n=74)	Statistics (*p value*)
Age (years)	64.1±11.9	64.5±11.7	64.9±10.5	
Gender				
Male/Female	293/127	16/16	58/16	0.014
Background liver				
Normal/fatty/viral/obstructive jaundice	210/14/176/20	16/2/1/13/2	31/2/34/7	0.710
Liver diseases				
Benign/HCC or ICC/ MLC/BTC	14/210/135/52/9	0/19/8/2/3	2/37/23/12/0	0.122
Obesity (BMI>25)				
No/ yes	293/127	21/11	49/25	0.759
Diabetes				
No/ yes	316/104	27/5	57/17	0.490
Cardiovascular diseases[#]				
No/ yes	401/19	28/4	65/9	0.095
Renal diseases				
No/ yes	412/8	30/2	71/3	0.199
Performance status				
0/ 1	394/26	27/5	64/10	0.022
ASA physiological status[$]				
1/ 2/ 3	256/147/17	20/7/5	41/27/6	0.030
Liver function tests				
Child-Pugh classification (A/B)	405/15	31/1	73/1	0.609
Liver Damage Grade (A/B)	357/63	27/5	70/4	0.085
ICGR15(%)	13.7±9.9	14.2±9.3	11.3±7.1	
LHL15	0.92±0.05	0.92±0.03	0.93±0.03	
Total bilirubin (mg/dl)	1.1±1.1	0.9±0.3	1.2±0.9	
Prothrombin activity (%)	93±14	90±13	94±13	
Platelet counts (/mm^3)	20±10	18±10	20±7	
Hyaluronic acid (ug/ml)	130±130	190±261	136±262	

HCC, hepatocellular carcinoma; ICC, intrahepatic cholangiocarcinoma; MLC, metastatic licer carcinoma; BTC, biliary tract carcinoma. BMI, body mass index; #except hypertension; $American Society of Anesthesiologists; ICGR15, indocyanine green retention rate at 15 minutes; LHL15, liver uptake ratio by ^{99m}-Tc GSA liver scintigraphy at 15 minutes

*p<0.05 *vs.* group 1. **p<0.01 *vs.* group 2 and 3.

Table 3 Relationship between surgical records or patient outcomes and SSI in patients undergoing hepatectomy

	Non-SSI (n=420)	Superficial SSI (n=32)	Deep SSI (n=74)	*Statistics (p value)*
Operator				
Teaching staff/fellow or resident	282/138	21/11	58/16	0.160
Incision				
Laparoscopic/abdominal/thoraco-abdominal	19/335/66	0/26/6	0/56/18	0.102
Extend of hepatectomy				
Partial/segment, section/hemiliver, more	140/124/156	6/13/13	22/24/28	0.478
Combined resection of other organs (No/ yes)	342/78	25/7	59/15	0.861
Biliary reconstruction (No/ yes)	349/71	30/2	66/8	0.137
Combined vascular resection (No/ yes)	380/40	26/6	66/8	0.250
Use of hemostatic devices (No/Yes)	98/322	14/18	16/58	0.029
Operating time (minutes)	419±166	445±199	422±232	
Transection time (minutes)	47±20	43±11	48±24	
Blood loss (ml)	984±886	788±566	1500±1001**	
Red cell transfusion (ml)	303±661	194±342	567±611**	
Transfusion (No/ yes)	296/124	21/11	34/40	0.002
Hospital stay (days)	18±14	23±14	48±38**	
Total complication (No/yes)	278/142	1/31	3/71	<0.001
Hepatectomy-related complication (No/yes)	342/78	26/6	36/38	<0.001
Hepatic failure (No/yes)	408/12	32/0	62/12	<0.001
Long-term ascites (No/yes)	363/57	27/5	55/19	0.048
Bile leakage (No/yes)	401/19	32/0	49/25	<0.001
Hospital death (No/yes)	411/9	32/0	68/6	0.011

**p<0.01 *vs.* non-SSI and superficial SSI

Table 4 Relationship between associated parameters and the superficial and deep SSI by the multivariate logistic regression analysis**.**

	Superficial SSI		Deep SSI	
	OR (95% CI)	P value	OR (95% CI)	P value
Gender				
Male vs. female			2.0(0.98-4.4)	0.051
Performance status				
1 vs. 0	1.9(0.6-5.6)	0.248	1.83(0.6-5.6)	0.287
ASA score				
2, 3 vs. 1			1.1(0.6-2.2)	0.780
Use of vessel sealing device				
No vs. yes	3.1(1.4-6.7)	0.004		
Blood loss				
≥1000ml vs. <1000ml			1.2(0.5-3.0)	0.763
Blood transfusion				
Yes vs. no			1.1(0.4-2.8)	0.844
Hepatectomy related complication				
Yes vs. no			1.9(0.8-4.7)	0.177
Hepatic failure				
Yes vs. no			3.3(1-11.6)	0.049
Uncontrolled ascites				
Yes vs. no			1.5(0.9-2.4)	0.092
Bile leakage				
Yes vs. no			4.8(2.2-10.4)	<0.001