



What are the risk factors of conversion from total cholecystectomy to bailout surgery?

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Abstract

Background Laparoscopic cholecystectomy (LC) is regarded as the first choice for patients with gallbladder diseases, but biliary injury (BDI) still poses serious risks upon implementation of LC. Recently, bailout surgery (BOS; partial cholecystectomy or subtotal cholecystectomy) has been proposed to avoid not only BDI but also major vessels injuries. In this retrospective study, we evaluated the preoperative and perioperative risk factors regarding conversion from total cholecystectomy (TC) to BOS.

Methods A total of 584 patients who underwent elective LC for gallbladder diseases between January 2006 and April 2018 were analyzed. The patients were divided into the TC group (including conversion open TC) and the BOS group. Univariate and multivariate analyses using preoperative and perioperative clinicolaboratory characteristics were performed to investigate the most significant risk factors associated with conversion to BOS.

Results There were a total of 33 patients in the BOS group (35 men and 18 women), with 19 patients who underwent open BOS and 14 patients who underwent laparoscopic BOS. From the univariate analyses, age, albumin level, CRP level, WBC, lymph. ratio, neutro. ratio, platelet count (PLt), neutrophil-to-lymphocyte ratio, platelet-to-lymphocyte ratio, CRP-to-alb ratio, intercurrent acute cholecystitis (AC), and previous biliary tract drainage (PBSD) were considered as risk factors for the conversion to BOS. Multivariate analysis using the 13 parameters selected from the univariate analyses demonstrated that AC ($p=0.04$), albumin level ($p=0.01$) and age ($p=0.04$) were significant risk factors.

Conclusion Patients with PBSD and AC have a high risk upon conversion from LTC to BOS, and for such patients, LC should be performed cautiously.

Keywords Laparoscopic total cholecystectomy · Conversion · Bailout surgery

Laparoscopic cholecystectomy (LC) is a common operation worldwide for gallbladder (GB) diseases [1, 2]. The Tokyo guidelines 18 (TG18) recommends early LC for the treatment of advanced cholecystitis, and thus the frequency of LCs performed to treat advanced cholecystitis, as well as fibrosis, are expected to increase in the near future [3]. However, there are cases of grade III cholecystitis patients in whom laparoscopic total cholecystectomy (LTC) leads to a high risk of severe complications, such as Bile duct injury (BDI), intestinal damage, and intraoperative hemorrhage. TG18 recommends bailout surgery (BOS), such as partial

cholecystectomy or subtotal cholecystectomy, to prevent LC-associated complications in patients with advanced inflammation or fibrosis, in whom securing a critical view of safety (CVS) is difficult [3]. Yet, despite the recommendations by TG18, few reports to date have described the preoperative risk factors or the efficacy of conversion to BOS, and most reports only describe the selection criteria and their details [4, 5]. Therefore, in this study, we retrospectively analyzed the data of LC cases that we have encountered, for risk factors associated with the conversion to BOS, and measured the efficacy of BOS in regard to the risk of complications, such as BDI.

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Materials and methods

Patient population and selection

A total of 584 patients who underwent LC in our department from January 2006 to April 2018 were included in this study. The risk factors for conversion to BOS were analyzed using univariate and multivariate analyses. Patients were divided into two groups, i.e., the BOS group and the total cholecystectomy group.

In our department, elective LC is performed for various GB diseases, such as acute cholecystitis (AC), chronic cholecystitis, and GB polyps. All patients included in the study had been diagnosed as having gallstones or polyps based on imaging modalities, such as ultrasound, computed tomography (CT), and magnetic resonance cholangiopancreatography (MRCP). The diagnosis of acute cholecystitis had been made through physical examinations (tenderness in the right upper quadrant, Murphy's sign, and fever), laboratory findings (increased CRP and WBC, and reduced liver function), and radiological signs of acute cholecystitis on imaging (thickened gallbladder wall, stones, enlarged gallbladder, edema, and abscess). Treatment outcomes were followed in accordance with TG18 for as long as possible [3].

Surgical procedures

LC was performed using the standard 4-port or 3-port 2-handed technique in the American position. Dissection of Calot's triangle and the hepatocystic triangle of the GB from the liver bed was performed using monopolar electrocautery. The CVS technique, which has been utilized as a valuable method to safely implement total cholecystectomy (TC) [6], was performed to expose the GB. Basically, if CVS was not possible owing to severe inflammation or previous operative adhesions, either of the following two options was selected: (1) the procedure was converted from open surgery to TC or BOS, or (2) the BOS procedure was performed via laparoscopy. The BOS technique was performed in accordance with a previous report [4]. Information of all patients were obtained from their surgical records.

Study design

Clinical and operative factors of all patients were analyzed, and specific clinical factors were selected and compared between the two groups. Clinical factors included age, gender, body mass index (BMI), diabetes mellitus (yes/no), previous upper abdominal surgery (yes/no), AC (yes/no), length of hospital stay (LHS), serum levels of aspartate

aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), γ -glutamyltransferase (γ -GTP), c-reactive protein (CRP) and albumin (Alb), white blood cell (WBC) count, platelet count, neutrophil ratio, lymphocyte ratio, neutrophil-to-lymphocyte ratio (NLR), platelet-to-lymphocyte ratio (PLR), and CRP-to-Alb ratio (CAR). Operative factors were BDI (yes/no), emergency or interval operation, operating time, and amount of bleeding. Preoperative MRCP findings were also analyzed, including detection of the cystic duct (yes/no) and GB (yes/no), previous biliary tract drainage (PBSD), percutaneous transhepatic gallbladder drainage, endoscopic retrograde biliary drainage, and endoscopic nasobiliary drainage (ENBD). A definitive diagnosis of AC as well as classification of severity were performed according to the TG18. Patients with AC included those from grades I to III [7]. Patients who completed follow-up examinations were also included in the study.

This study was approved by the Research and Ethics Committee of Tokyo Medical University Ibaraki Medical Center (Study Approval No. 16–35).

Statistical analysis

Statistical analyses were performed using the SPSS statistical software package (version 26.0; SPSS Inc., Chicago, IL). Median values were used to define laboratory and operative parameters, such as AST, ALT, ALP, γ -GTP, CRP and Alb, WBC, PLT, neutrophil ratio, lymphocyte ratio, NLR, PLR, CAR, operating time, amount of blood loss, and LHS. Univariate and multivariate analyses were performed to clarify laboratory parameters and clinical factors that were most significantly associated with the TC group and the BOS group. Univariate analyses, the Mann–Whitney *U* test, and the Fisher exact test were utilized, and odds ratios with 95% CI were calculated using logistic regression model analyses. A *p* value of less than 0.05 was considered to indicate a statistically significant difference between two groups.

Results

A total of 584 patients who had GB diseases and who had undergone elective LC between January 2006 and April 2018 were analyzed. BOS occurred in 33 patients (5.6%), and conventional TC was performed in 551 patients (LC in 531 patients, and conversion from LC to open cholecystectomy in 20 patients) (Fig. 1).

Characteristics of the BOS group

BOS was performed in a total of 33 patients (20 men and 13 women), with a median age of 69.0 years (range

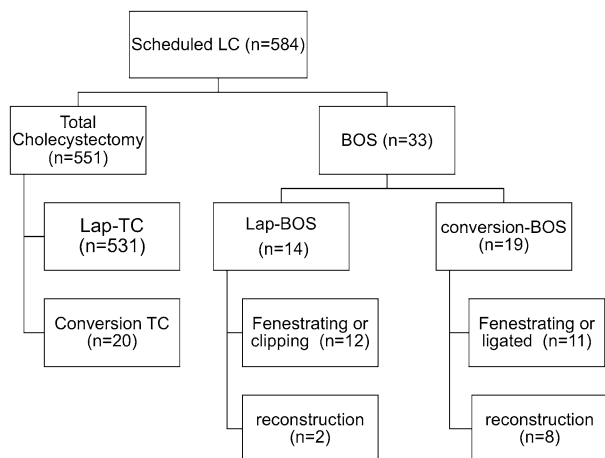


Fig. 1 Characteristics of patients in the bailout surgery group and total cholecystectomy group

30.1–85.2 years). In some patients, we were able to expose and reach the hepatocystic triangle, but this was not possible for all patients undergoing BOS, and for such patients CVS was not attained. The median operative time and amount of bleeding were 146 min and 100 mL, respectively, and the median LHS was 8 days. There were 14 patients who underwent LC-BOS, and 19 patients who underwent conversion from LC to open BOS. Among the patients who underwent LC-BOS, 2 patients underwent subtotal reconstituting cholecystectomy, and 12 patients underwent subtotal fenestrating cholecystectomy or cystic duct clipping cholecystectomy. Of the patients who underwent conversion from LC to open BOS, 8 patients underwent subtotal reconstituting cholecystectomy, and 11 patients underwent subtotal fenestrating or cystic duct-ligating cholecystectomy (Fig. 1).

Patients with BDI

There were 3 patients in whom a BDI was identified (an incidence rate of 0.51%). All 3 patients were in the TC group, and BDI was recognized intraoperatively. Two patients had damage in the common bile duct and posterior biliary duct, and another patient had simple injury of the posterior biliary duct. Conversion to open surgery was necessary in all patients, and therefore we performed CBD-duodenostomy, posterior bile duct jejunostomy, and simple closure of the posterior bile duct. One patient required placement of an ENBD owing to bile leakage 2 days after the operation. There were no mortalities among the 3 patients with a BDI.

Table 1 Characteristics of the patients in each group before surgery

	BOS group (n = 33)	TC group (n = 551)	p value
Age (years)	69 (30–85)	61 (17–91)	0.001*
Gender (M/F)	20/13	282/269	0.19 [†]
BMI	24.1 (16.4–29.8)	24.4 (12.0–38.5)	0.66*
CRP (mg/dL)	0.46 (0.01–11.6)	0.1 (0.01–20.5)	0.0001*
AST (IU/L)	18 (10–113)	21 (10–505)	0.20*
ALT (IU/L)	18 (6–129)	18 (5–354)	0.29*
γ GTP (IU/L)	34 (9–766)	34 (8–713)	0.36*
ALP (IU/mL)	36.3 (4.7–379)	30.3 (5.0–754)	0.11*
Alb (g/dL)	3.7 (2.6–4.7)	4.3 (2.8–5.4)	0.0001*
WBC ($10^3/\mu$ L)	6.2 (3.5–12.9)	5.7 (0.5–18.1)	0.1*
Neutrophils (%)	65.7 (48.5–84.5)	57.4 (30.3–91.1)	0.0001*
Lymphocytes (%)	24.2 (7.5–41.6)	33.1 (5.8–56.1)	0.0001*
PLt ($10^3/\mu$ L)	254 (8.6–517)	228 (68–536)	0.02*
NLR	2.7 (1.2–11.2)	1.7 (0.65–15.7)	0.0001*
PLR	0.18 (0.06–1.24)	0.12 (0.03–1.69)	0.001*
CAR	1.60 (0.01–3.2)	0.23 (0.001–4.8)	0.0001*
PBTD (yes/no)	19/14	97/450	0.0001 [†]
Cystic duct (yes/no) ^{&}	27/6	490/59	0.15 [†]
GB (yes/no) ^{&}	28/4	475/75	0.56 [†]
PAS (yes/no)	1/32	11/540	0.51 [†]
AC (yes/no)	20/13	107/444	0.0001 [†]
DM (yes/no)	6/27	87/461	0.44 [†]
ECDL (yes/no)	9/24	97/454	0.12 [†]

Data are shown as medians and interquartile ranges

BMI body mass index, *CRP* c-reactive protein, *AST* aspartate transaminase, *ALT* alanine aminotransferase, *γ GTP* γ -glutamyl transpeptidase, *ALP* alkaline phosphatase, *Alb* albumin, *WBC* white blood cell count, *PLt* platelet count, *NLR* neutrophil-to-lymphocyte ratio, *PLR* platelet-to-lymphocyte ratio, *CAR* CRP-to-Alb ratio, *PBTD* previous biliary tract drainage, *GB* gallbladder, *PAS* previous upper abdominal surgery, *AC* acute cholecystitis, *DM* diabetes mellitus, *ECDL* endoscopic choledocholithotomy

*Tested by the Mann–Whitney *U* test

[†]Tested by the Fisher exact test

[&]Preoperative MRCP findings were including detection of the cystic duct (yes/no) and GB (yes/no)

Comparison of the BOS group and the TC group

Univariate analysis

Preoperative characteristics

In patients who had AC, older age, and higher levels of Alb, CRP, and WBC, neutrophil ratio, lymphocyte ratio, PLt, NLR, PLR, and CAR were found to be risk factors for the conversion to BOS. PBTD was also considered to be a risk factor for the conversion to BOS (Table 1).

Table 2 Outcomes of patients who underwent BOS or TC

	BOS group (n = 33)	TC group (n = 551)	p value
Operating time (min.)	146 (76–1530)	114 (28–394)	0.001*
Blood loss (g)	100 (1–1530)	1 (1–7084)	0.001*
LHS (days)	8 (3–19)	5 (1–45)	0.001*
BDI (yes/no)	0/33	3/54	0.84 [†]

Data are shown as medians and interquartile ranges

LHS length of hospital stay, BDI bile duct injury

*Tested by the Mann–Whitney *U* test

[†]Tested by the Fisher exact test

Table 3 Multivariate analysis of clinical and chemical factors associated with each procedure

	Odds ratio	95% CI	p value
PBTD (yes/no)	2.66	1.08–6.56	0.03 [#]
AC (yes/no)	2.69	1.09–6.65	0.03 [#]
Alb	0.31	0.09–0.96	0.04 [#]

PBTD previous biliary tract drainage, AC acute cholecystitis, Alb: albumin

[#]Tested by logistic regression model analyses

Operative and postoperative factors

Operating time and LHS were significantly longer, and amount of bleeding was significantly larger in the BOS group than in the TC group ($p=0.001$, 0.001 , and 0.0001 , respectively; Table 2).

Multivariate analysis

Multivariate analyses demonstrated that patients who had AC and PBTD were associated with significant adverse prognostic factors ($p=0.03$ and 0.03 , respectively; Table 3). Low Alb level was also a risk factor for the conversion to BOS ($p=0.04$; Table 3).

Discussion

The TG18 guidelines recommend emergency LC within 72 h of the onset of acute cholecystitis in patients with a good performance status. Patients in whom LC is performed are expected to increase in the future, particularly in difficult cases associated with strong inflammation [3].

LC has become a commonly practiced procedure, and is presently a standard treatment for cholecystectomy. However, BDI and hemorrhage caused by main vessel injury has

been identified as severe complications associated with the treatment of cholecystectomy. CVS was proposed in 2010 to mediate the complications associated with LC [8]. There are few reports to date that have analyzed the efficacy of CVS, but a few mortalities associated with BDI or hemorrhage have been reported. In Japan, the Japan Medical Safety Research Organization reported 7 cases of deaths associated with LC in 2018. Four mortalities out of the 7 were caused by complications of BDI or hemorrhage owing to insufficient CVS, and the patients died soon after the operation. Considering the results of the present study, we stress the importance of securing CVS, and the conversion to open laparotomy if CVS is not possible. The establishment of an optimal operative procedure is anticipated for patients in whom CVS is not attainable, and Strasberg et al. recommended BOS in patients with LC in whom CVS was unattainable owing to advanced fibrosis or inflammation. This operative procedure resects a portion of the GB to avoid BDI or hemorrhage, and does not require total cholecystectomy [4]. Reports have been published in Europe and USA analyzing the outcomes of BOS [8, 9], but there are only few studies evaluating the risk factors or the efficacy of the conversion to BOS [10].

The results of our study demonstrate that preoperative risk factors of the conversion to BOS were AC, low Alb level, and PBTD. We believe patients with 1 or more of the above 3 factors should undergo LC with BOS in mind. In our study, the BOS group was associated with longer hospitalization times, more bleeding, and longer operation times compared with the LTC group, but on the other hand, no patients in the BOS group had BDI. Therefore, we conclude that BOS is an effective method of avoiding BDI.

We suggested that almost all cases of patients with CBD stones and biliary endoprosthesis have falling gallstones, and such patients already have severe inflammation surrounding the cystic duct. Furthermore, patients with AC under PTGBD also have the same condition. Therefore, it is difficult to identify CVS with severe adhesion at the time of LC. We believe that preoperative biliary drainage was not a direct reason for conversion to BOS.

The decision of whether to conduct BOS via open surgery or within LC is difficult. Reconstruction or fenestration of the GB is extremely difficult under LC, and operation under laparoscopy can further increase the risk of complications. We more frequently performed fenestration with clipping and ligation of the cystic duct than reconstitution for patients in the BOS group, because the cystic duct can be identified more easily in these patients than in patients with reconstitution.

In addition, the experience and technical maturity of surgeons may lead to differences in the results among institutions. We recommend surgeons who decide and perform BOS to be specialists with a thorough understanding of

hepatobiliary anatomy and with extensive experience in the resection of hepatobiliary malignancies as well as cholecystectomies. Further multi-institutional studies are necessary to establish standards regarding which patients are suitable for BOS.

This study has several limitations. As it was a retrospective study, the number of patients was small, and the definition of the BOS procedure varied among surgeons. In the future, BOS should be standardized and additional multicenter studies involving larger patient populations are needed before definitive conclusions can be drawn.

Conclusion

Our retrospective analysis of patients who underwent BOS in our hospital clarified the risk factors of transition to BOS, and demonstrated that BOS is an effective procedure to avoid BDI. CVS is thought to be difficult to attain in patients with acute cholecystitis and patients who undergo preoperative biliary drainage, and thus LC should be performed in such patients. However, if LC appears to be difficult to perform, BOS should be selected.

Compliance with ethical standards

Disclosures Mitsugi Shimoda, Ryutaro Udo, Ryouyuke Imasato, Oshiro Yukio, and Shuji Suzuki have no conflicts of interest or financial ties associated with this study.

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