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Impact of timing of bile duct interventions on resource use and clinical outcome of cholecystectomy patients in Japan [6]

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Abstract

Aims Laparoscopic cholecystectomy (LC) is increasingly used for acute cholecystitis, in conjunction with staged bile duct interventions (BDIs). However, few studies have evaluated the impact of BDI timing on costs and clinical outcomes during hospitalization. This study assessed the effects of several types of BDI and their timing on resource utilization and complications.

Methods A total of 13 738 cholecystectomy patients were treated for benign gallbladder diseases in 66 academic and 376 community hospitals in Japan in 2006. Variables analysed included: BDIs including endoscopic retrograde cholangiopancreatography (ERCP), percutaneous gallbladder or common bile duct drainage (external drainage), endoscopic sphincterotomy, clearance of choledocholithiasis (internal drainage); and length of stay (LOS), total charges (TCs), procedure-related complications, and hospital function. Multivariate analysis was used to determine the impact of LC or BDIs on LOS, TCs and complications.

Results A total of 11 690 (85.1%) patients underwent LC. Inflammation was diagnosed in 70.7% of open cholecystectomy (OC) and 42.1% of LC patients. Complications were 7.7% in OC and 5.4% in LC patients. LC was associated with reduced LOS and TCs. BDIs were performed in more OC than LC patients. Preoperative was more costly than postoperative ERCP. Postoperative external drainage was significantly associated with LOS, TCs and complications. Advantages of pre- or postoperative internal drainage were not proven.

Conclusions External drainage should be completed preoperatively. Postoperative ERCP may be preferable for bile duct scrutiny alone. Further evaluation of the timing of cholecystectomy will determine precisely the superiority of pre- or postoperative BDIs in terms of quality of care for complicated patients.

Introduction

Confirmation of the safety and efficacy of laparoscopic cholecystectomy (LC) over conventional open cholecystectomy (OC) have been forcing this forerunner of laparoscopic surgery to take a next challenging step of spreading the indication of LC for the more complicated cases such as acute cholecystitis patients [1–3]. Several studies assessing the clinical and economic aspects of LC compared with mini-laparotomy OC have analysed their relative quality of care. Srivastava and colleagues have acknowledged the superiority of LC over OC, whereas Nilsson and colleagues have reported the limited clinical, economic and health-related quality of life advantages of LC [4,5]. Many studies have explored clinical and economic analysis of LC versus OC for inflammatory gall bladder disease, and have found that LC has clinical or economic benefits, by reducing postoperative pain and resulting in early postoperative mobilization [6–11].

These challenging cases might include acute cholecystitis or suspected choledocholithiasis, and several disease management options exist [12,13]. These strategies include endoscopic

Table 1 Patient characteristics stratified by procedure ($n = 13\ 738$)

		Cholecystectomy		
		Open	Laparoscopic	*P* value
n (number of hospitals)		2048 (372)	11690 (438)	
Age (years)	Median	70 [18]	58 [21]	<0.001*
	65 years or older (%)	1325 (64.7)	4025 (34.4)	<0.001
Gender (%)	Male	1262 (61.6)	5467 (46.8)	<0.001
Ambulance (%)	Transferred	226 (11.0)	391 (3.3)	<0.001
Primary diagnosis (%)				<0.001
	Inflammation	1448 (70.7)	4924 (42.1)	
CCI (%)				0.004
	1	376 (18.4)	1306 (11.2)	
	2 or more	240 (11.7)	455 (3.9)	
Order of additional procedures				
Preoperative ERCP only		109 (5.3)	489 (4.2)	0.005
Postoperative ERCP		17 (0.8)	53 (0.5)	
Preoperative internal drainage only		192 (9.4)	810 (6.9)	<0.001
Postoperative internal drainage		49 (2.4)	116 (1)	
Preoperative external drainage only		296 (14.5)	418 (3.6)	<0.001
Postoperative external drainage		6 (0.3)	12 (0.1)	
Procedure-related complication (%)		157 (7.7)	629 (5.4)	<0.001
TPN (%)		212 (10.4)	239 (2.0)	<0.001
Hospital type (%)				0.024
	Academic	254 (12.4)	1670 (14.3)	
Resource use				
Median length of stay (days)		18 [18]	8 [7]	<0.001*
Median total charge (US$)		8426 [5853]	5438 [2359]	<0.001*

*Kruscal Wallis test, others; chi-squared test. [ ]; Quartile range.
CCI, Charlson comorbidity index; ERCP, endoscopic retrograde cholangiopancreatography; TPN, total parenteral nutrition.

retrograde cholangiopancreatography (ERCP), percutaneous gallbladder drainage (PGBD) or percutaneous common bile duct drainage (PCD), dilation or sphincterotomy of the ampulla of Vater, and stone extraction from the common bile duct. Staged bile duct interventions (BDIs) are critical for achieving successful cholecystectomy, especially LC in cholecystitis patients.

The Survey of National Medical Care Insurance Services, published by the Japanese Ministry of Health, Welfare and Labor (MHWL), has found that the annual number of LC cases has increased from 7000 in 1996 to 45 000 in 2006 (which represents 79% of all cholecystectomies) [14,15]. In Japan, the annual number of cases of endoscopic dilatation or sphincterotomy of the ampulla of Vater rose from 27 000 in 1996 to 39 000 in 2006.

For performance of cholecystectomy via laparotomy or laparoscopy, pre-, peri- or postoperative diagnostic and/or therapeutic strategies for the bile duct system should be established, and would be expected to influence resource use or outcome. However, no study has concurrently compared several different care options from the perspective of resource consumption or clinical outcomes, although some studies have investigated the effect of one or two BDIs [16,17]. Therefore, in the era of treating complex cases with LC, we believe that it is clinically relevant to compare the advantages of LC and OC, through controlling various staged BDIs and measuring the economic impact of pre- or postoperative interventions.

To evaluate the effect of BDI timing on quality of clinical practice for cholecystitis, we compared resource utilization and clinical outcome between several BDIs, as well as between OC and LC. We used multivariate regression analysis to determine the independent effect of LC or BDI on resource utilization and clinical outcome, and to evaluate the superiority of LC over OC.

Materials and methods

Database

We used a Japanese administrative database that was constructed by the MHWL in 2002 to develop a Japanese case-mix classification system. This database has been used to profile hospital performance and to assess hospital payments across 731 hospitals (82 academic and 649 community hospitals) in 2006. These hospitals are responsible for providing acute medical care, promoting medical research, or educating students and postgraduate trainees. This administrative database contains discharge summaries and claims data for each hospital, and information is collected annually between 1 July and 31 December. It has also included the date and level of care delivered since 2004.

Our research project was approved by the ethics committee of the University of Occupational and Environmental Health in Kitakyushu, Fukuoka, Japan. We analysed cases of benign gallbladder disease treated by cholecystectomy at hospitals participating in our research project in 2006.

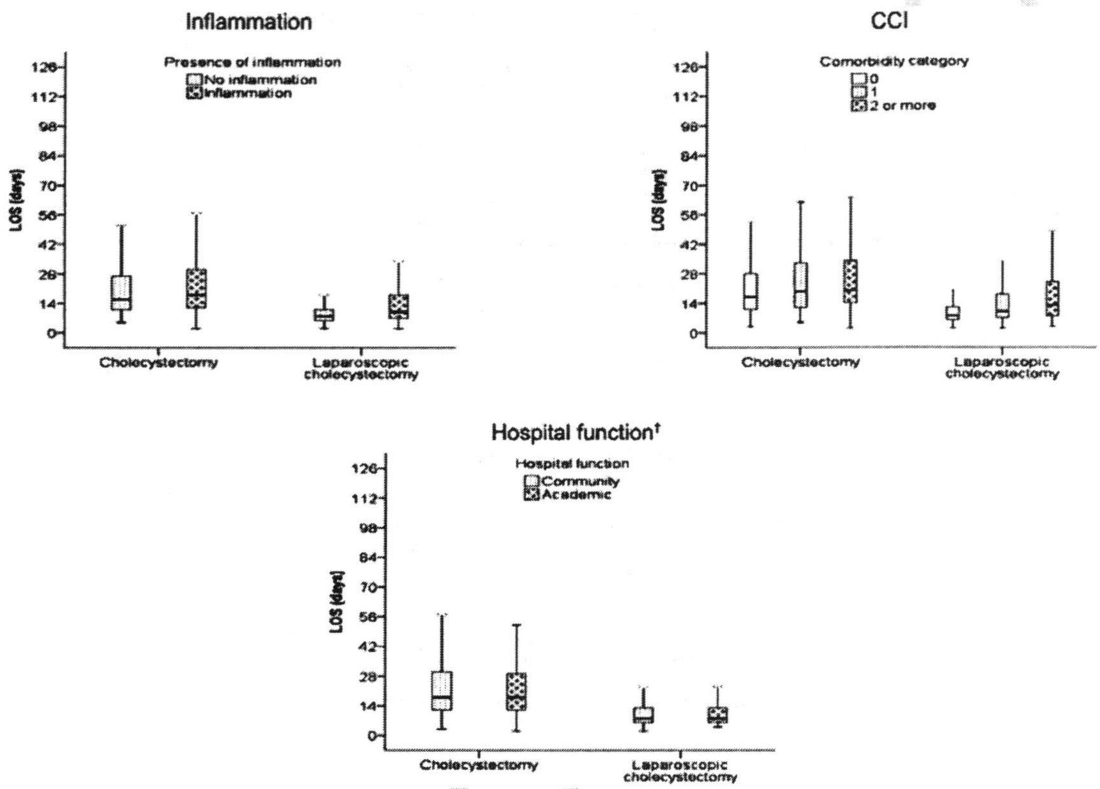

Figure 1 Impact of inflammation, Charlson comorobidity index (CCI) and hospital function on length of stay (LOS) for open and laparoscopic cholecystectomy. †Difference was not significant. Open cholecystectomy; $P = 0.691$, laparoscopic cholecystectomy; $P = 0.687$.

Variables definition

As independent variables, we examined age, gender, use of an ambulance, gallbladder wall inflammation, co-morbidity, surgical technique (LC or OC), BDI, use of total parenteral nutrition (TPN) in patients with severe disease requiring bowel rest, complications attributable to the diagnostic and therapeutic procedures, outcome at discharge and hospital function. Patients were categorized by age into two groups: <65 and ≥65 years of age. We used transfer by ambulance as a proxy for emergency admission.

Diagnoses in this database were reported according to the International Statistical Classification of Diseases, 10th version (ICD-10). Among ICD codes indexing disorders/diseases of the gallbladder (K80$ to K83$), the following codes were considered to indicate the presence of inflammation: K80.0-1, K80.3-4, K81$, K82.1-3 and K830. All other ICD codes were considered to indicate non-inflammatory conditions. The Japanese administrative database records a maximum of four co-morbidities per patient. To assess the severity of chronic co-morbid conditions, the Charlson comorbidity index (CCI) was employed [18]. Furthermore, a maximum of four complications, defined as unexpected events after admission, were also recorded. Procedure-related complications were defined as any of the following ICD-10 codes: procedure-related complications (T80$-T87$), bowel obstruction (K650, K658-9, K660, K913), peritonitis (K560, K562, K565-7), and acute pancreatitis (K85) [19]. The Japanese administrative database also lists up to five operative procedures per hospitalization. We included patients undergoing OC or LC without choledocholithotomy. LC cases converted to OC were counted as OC cases.

Three types of BDI were defined as ERCP, and external and internal drainage. External drainage included PGBD or PCD, whereas internal drainage included balloon dilatation or sphincterectomy of the ampulla of Vater, stent insertion for benign common bile duct stenosis and removal of choledocholithiasis. BDIs before or after cholecystectomy were also evaluated. Cases with post- as well as preoperative BDI were counted as postoperative cases.

For the present study, we used length of stay (LOS) and total charges (TCs; US$1 = ¥100) billed during admission as proxies for total in-hospital cost. In Japan, charges for hospital care are determined by a standardized fee-for-service payment system known as the national uniform tariff table; fees accrued through this system are considered to be good estimates of health care costs

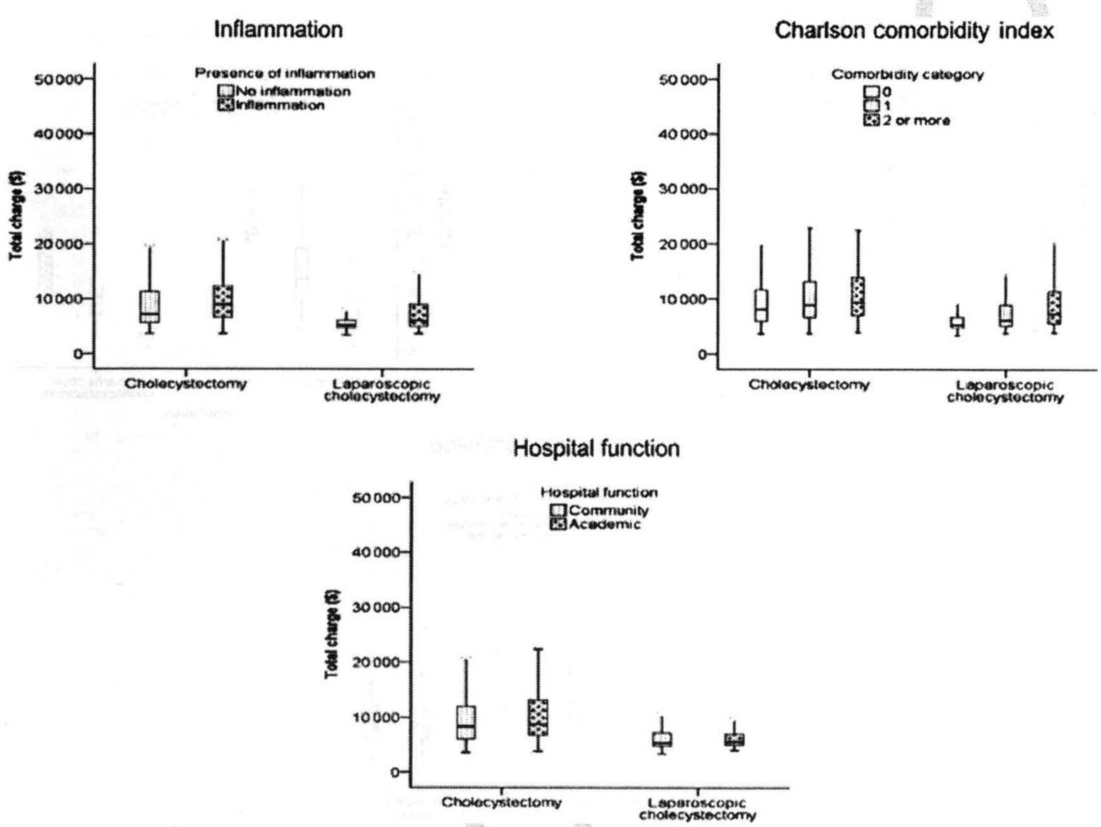

Figure 2 Impact of inflammation, Charlson comorobidity index (CCI) and hospital function on total charge (US$) for open and laparoscopic cholecystectomy.

[20]. TCs in this study included doctor fees, instrument costs, costs of laboratory or imaging tests, and administration fees.

Statistical analysis

All discrete data were reported in frequency and proportion of every study variable. Comparisons were made using Fisher's exact test. Box charts were used to display distributions of LOS and TCs for OC and LC, stratified either with presence of inflammation, CCI, timing of BDI, and hospital function, or with every four BDIs. Continuous variables were compared across OC and LC groups by using the non-parametric test. Multiple linear regression models were used to identify the impact of each surgical technique or BDI on LOS and TCs. The distribution of LOS and TCs were right-skewed therefore these were log10-transformed in this model. A logistic regression model was used to evaluate the relationship between the surgical and interventional procedures described previously and the development of complications. Statistical analysis was performed using SPSS 16.0. All reported *P* values were two-tailed, and the level of significance was set at <0.05.

Results

Among the 1895 249 patients from the 469 hospitals participating in our research project, we identified 13 738 cholecystectomy patients in 442 hospitals (1924 cases from 66 academic hospitals and 11 814 from 376 community hospitals). There were nine fatalities among these cases (six OC and three LC).

Among our patients, 2048 (14.9%) underwent OC and 11 690 (81.2%) underwent LC. Median patient age was 70 years for OC and 58 for LC. OC was the preferred surgical technique for patients older than 65 years of age (64.7%), whereas LC was preferred for younger patients (65.6%). Men represented 61.6% of OC and 46.8% of LC patients. Eleven per cent of OC cases involved an ambulance-transfer, compared with only 3.3% of LC cases. Inflammation was diagnosed in a significantly higher proportion of OC (70.7%) than in LC (42.1%) patients. In the OC patients, 69.9% had no co-morbidity compared with 84.9% of LC patients. Complications occurred in 7.7% of OC and 5.4% of LC patients.

Every type of BDI was performed in more OC than LC patients, and preoperative BDI was more frequent. TPN was more common in OC patients (10.4%) than LC (2.0%). Median LOS was longer

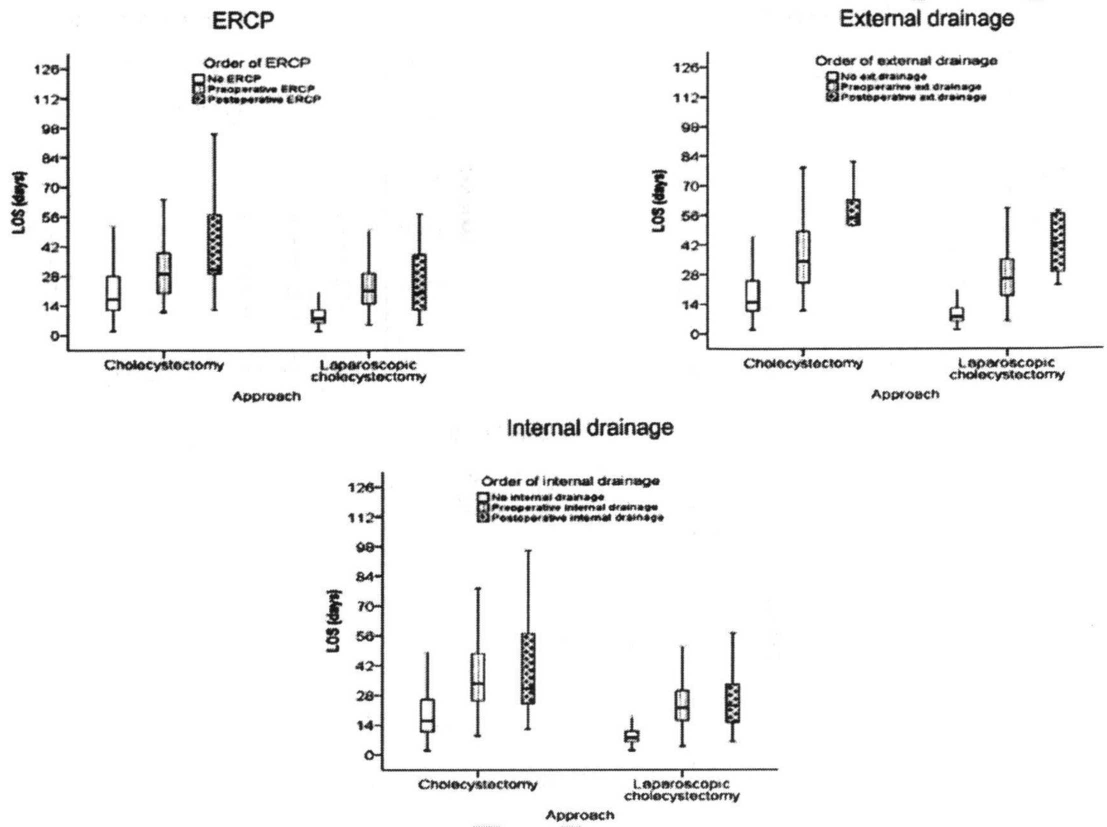

Figure 3 Impact of bile duct interventions on length of stay (LOS) for open and laparoscopic cholecystectomy. ERCP, endoscopic retrograde cholangiopancreatography.

and TCs were higher in OC (18 days or US$8426, respectively) than in LC (8 days or US$5438, respectively) patients. Significant differences between OC and LC were observed across several study variables (Table 1).

A comparison of LOS or TCs across four study variables is shown in Figs 1–4. Statistically significant differences were identified, except for LOS in LC patients at community or academic hospitals ($P = 0.687$).

After adjusting for demographic and clinical variables, procedure-related complications and LC were significantly associated with LOS or TCs (standardized coefficient of complication or LC preoperative internal drainage: 0.051 or –0.182 for LOS, and 0.032 or –0.073 for TCs). Postoperative ERCP was associated with a shorter LOS or lower TCs, while postoperative external drainage had higher TCs. Other BDIs were not significant determinants of resource use (Table 2).

Age, co-morbidity, preoperative ERCP or internal drainage and hospital type were significantly associated with more procedure-related complications. However, inflammation or LC did not predict the development of complications ($P = 0.515$, 0.642, respectively). The odds ratio (OR) for procedure-related complications was higher in academic than in community hospitals (OR: 1.821; 95% confidence interval: 1.522–2.179) (Table 3).

Discussion

As the number of indications for video-assisted surgery of complex cases increases, economic evaluation of conventional and new procedures should continue, because assuring quality of care will provide conclusive technology assessment for novel surgeries. The current analysis demonstrated that LC was still superior to OC, and that the rate of complications following OC or LC was equivalent after adjusting for covariates such as inflammation or pre- or postoperative BDIs. With regard to bile duct examination alone, postoperative ERCP might be less costly and one of the possible care strategies that does not increase complications. In the meantime, postoperative external bile duct drainage seemed to consume more resources and was associated with more complications, which suggests that careful preoperative evaluation of suspected choledocholithiasis should be carried out. This was also true for internal drainage. Internal drainage is often accompanied

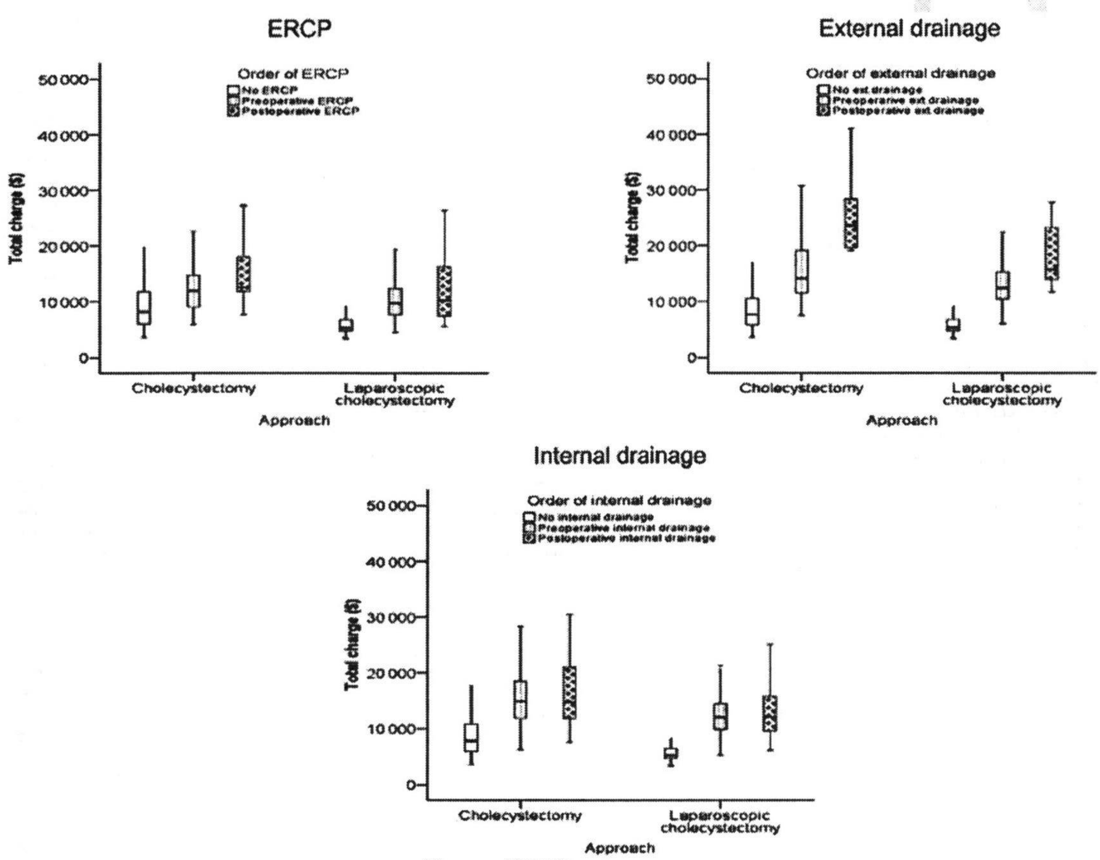

Figure 4 Impact of bile duct interventions on total charge (US$) for open and laparoscopic cholecystectomy. ERCP, endoscopic retrograde cholangiopancreatography.

with ERCP and postoperative ERCP might be only selected for examining the patency of bile duct.

LOS and TCs of LC were estimated to be 34% and 15% less, respectively, than those of OC in this study. This result corresponds to that of Bosch *et al.* [10]. Bosch and colleagues have acknowledged that the relative costs of both procedures were controversial, because studies utilized a wide range of methods for calculating costs, as well as variable patient case-mixes. Disease severity factors, such as presence of inflammation or suspected choledocholithiasis, demand prudent pre- or postoperative treatment strategies and certainly reflect variations in case-mix.

Zacks and colleagues have reported that LC with ERCP generated hospital charges that were 1.47-fold higher than those of LC with intraoperative cholangiography or common bile duct exploration [11]. This was similar to our study, in which TCs for patients with pre- or postoperative ERCP were 1.39- or 1.26-fold higher than those for patients lacking ERCP. Our study, however, did not examine the effect of intraoperative imaging or transcystic common bile duct exploration, which some of our LC patients likely had received. The strength of our finding, nevertheless, was to evaluate the effect of timing of BDI on LOS and TCs.

The standardized coefficient of preoperative ERCP was found to be higher than that of postoperative procedures, even after controlling for procedure-related complications, including ERCP pancreatitis. In earlier research by Zack *et al.* and Schroeppel *et al.* management options for symptomatic cholelithiasis with suspected choledocholithiasis were discussed, although pre- and postoperative BDIs were not compared [11,13].

Despite the fact that postoperative BDI seemed to be less desirable than preoperative BDI in terms of resource use, the interaction of early and delayed cholecystectomy in combination with the indications for BDI were not investigated simultaneously in our study. In particular, preoperative external drainage such as PGBD might be considered as a method for rapid decompression of gallbladder inflammation or diagnostic imaging of the common bile duct. Therefore, the strategy for definitive timing of cholecystectomy and BDI should be determined based on the integrated assessments of the interaction effect.

Table 2 Linear regression analysis of factors associated with log-transformed length of hospital stay (LOS, days) and total charge (TC, $)

	LOS			TC		
Independent variables	Unstandardized coeffcient	95% CI	*P* value	Unstandardized coeffcient	95% CI	*P* value
Intercept	2.062	[2.03–2.094]	0.000	4.469	[4.451–4.487]	0.000
Age under 65 years	0.070	[0.063–0.078]	0.000	0.034	[0.03–0.038]	0.000
Male	0.004	[−0.002 to 0.011]	0.201	0.007	[0.003–0.011]	0.000
Ambulance car used	0.118	[0.101–0.135]	0.000	0.093	[0.084–0.103]	0.000
Primary diagnosis (reference; no inflammation)						
Inflammation	0.046	[0.039–0.053]	0.000	0.038	[0.034–0.041]	0.000
CCI (reference; zero)						
1	0.051	[0.041–0.061]	0.000	0.031	[0.026–0.037]	0.000
2 or more	0.087	[0.071–0.102]	0.000	0.060	[0.052–0.069]	0.000
Procedure-related complication	0.051	[0.036–0.066]	0.000	0.032	[0.024–0.04]	0.000
Procedure (reference; open cholecystectomy)						
Laparoscopic cholecystectomy	−0.182	[−0.192 to −0.171]	0.000	−0.073	[−0.079 to −0.068]	0.000
Order of additional BDIs (reference; preoperative BDIs)						
No ERCP	−0.251	[−0.268 to −0.235]	0.000	−0.142	[−0.151 to −0.133]	0.000
Postoperative ERCP only	−0.090	[−0.139 to −0.04]	0.000	−0.040	[−0.067 to −0.013]	0.004
No internal drainage	−0.296	[−0.31 to −0.283]	0.000	−0.251	[−0.258 to −0.244]	0.000
Postoperative internal drainage	0.011	[−0.022 to 0.044]	0.523	0.015	[−0.003 to 0.033]	0.107
No external drainage	−0.285	[−0.301 to −0.269]	0.000	−0.221	[−0.23 to −0.212]	0.000
Postoperative external drainage	0.061	[−0.034 to 0.155]	0.207	0.054	[0.002–0.106]	0.040
Supportive care						
TPN	0.240	[0.22–0.259]	0.000	0.203	[0.192–0.214]	0.000
Hospital type (reference: community)	−0.002	[−0.012 to 0.007]	0.616	0.013	[0.007–0.018]	0.000

F test for the model; LOS, TC, $P < 0.001$. Determinant of coefficient; LOS, 0.491, TC, 0.691.
CCI, Charlson comorbidity index; BDIs, bile duct interventions; ERCP, endoscopic retrograde cholangiopancreatography; TPN, total parenteral nutrition.

Sekimoto *et al.* have reported that the timing of cholecystectomy varied significantly among nine Japanese hospitals in which initial conservative treatment, followed by delayed cholecystectomy, was the most common care policy in 2001 to 2003, which resulted in an overall mean LOS of 30 days [21]. However, reform of the Japanese health care system, established through this Japanese administrative database, has been shortening LOS dramatically, and median LOS for OC or LC patients with gallbladder inflammation conditions has decreased to approximately 14 days. Thus, we assume that our study included more early cholecystectomy patients, with or without BDI, than did past studies in Japan.

Our administrative database contained the dates of the procedures. We believe that future comparative research, although observational, on resource use or complications among early or delayed cholecystectomy patients, treated with or without BDIs performed pre- or postoperatively for acute cholecystitis, will contribute to evaluating the quality of clinical practice for cholecystectomy patients.

There are several limitations to the methodology and interpretation of the current study. First, information was gathered from discharged patients during only 6 months in 2006, which may have limited the ability to generalize our results. For future research, the Japanese administrative database has increased its sample size each year, with additional hospitals participating, and an extension of the data collection period to several years, through electronically collected claims data.

Second, our study lacked some important clinical data, including detailed pathological information (acute gangrenous or acalculous cholecystitis, gall bladder hydrops) and the presence of obesity – factors that can affect outcome [22]. Nevertheless, we considered that use of the ICD-10-coded diagnosis was a suitable proxy for some disease severity or pathological findings, such as gallbladder perforation. Regarding obesity, the World Health Report (2002) found that body mass index (BMI) was 23.4 in developed Western Pacific countries, including Japan, whereas BMI was 26.7 in developed European countries [23]. As the incidence of obesity in Japan is so low, we believe that the possible future inclusion of obesity data will not significantly alter our results.

Third, LOS for all hospital admissions in Japan is two to four times longer than in hospitals in Western countries [24]. One reason for the increased LOS is that Japanese hospitals generally provide nursing care, in addition to acute medical care. The fiscal impact of longer LOS reflects the real costs consumed during each episode of acute illness in Japan [24,25].

In conclusion, this study used an administrative database to present descriptive characteristics of OC and LC in Japan, and to evaluate differences in resource utilization and clinical outcomes between these surgical techniques. Our analysis demonstrated that LC was still associated with significantly reduced LOS and TCs, and that the rates of procedure-related complications were identical, even after controlling for BDIs and the status of gallbladder inflammation. The impact of preoperative ERCP on LOS and TCs

Table 3 Logistic regression analysis of factors associated with procedure-related complications

Independent variables	OR [95% CI]		P value
Age			
<65 years	1.000		
≥65 years	1.573	[1.349–1.834]	0.000
Sex			
Female	1.000		
Male	1.042	[0.899–1.208]	0.585
Ambulance			
Not used	1.000		
Used	1.257	[0.933–1.694]	0.132
Primary diagnosis			
Non-inflammation	1.000		
Inflammation	1.045	[0.895–1.219]	0.580
CCI			
0	1.000		
1	1.776	[1.471–2.145]	0.000
2 or more	1.960	[1.512–2.541]	0.000
Procedure			
Open cholecystectomy	1.000		
Laparoscopic cholecystectomy	0.974	[0.798–1.189]	0.798
Order of ERCP			
Preoperative ERCP	1.000		
No ERCP	0.635	[0.479–0.841]	0.002
Postoperative ERCP	1.154	[0.562–2.371]	0.697
Order of internal drainage			
Preoperative internal drainage	1.000		
No internal drainage	0.480	[0.388–0.595]	0.000
Postoperative internal drainage	1.363	[0.855–2.172]	0.192
Order of external drainage			
Preoperative external drainage	1.000		
No external drainage	0.887	[0.662–1.187]	0.419
Postoperative external drainage	5.262	[1.875–14.765]	0.002
TPN			
Not used	1.000		
Used	1.276	[0.923–1.765]	0.063
Hospital type			
Community	1.000		
Academic	1.808	[1.51–2.165]	0.000

Hosmer Lemeshow goodness for fit; $P = 0.177$.

CCI, Charlson comorbidity index; ERCP, endoscopic retrograde cholangiopancreatography; TPN, total parenteral nutrition.

was significantly greater than that of postoperative BDIs. Among other BDIs, only preoperative external drainage was a significant predictor of resource use and complications. Further economic studies on the influence of the timing of cholecystectomy as well as of preoperative BDIs will be necessary to determine precisely the approprate timing of BDIs as well as of cholecystectomy.

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Original Article

Variations in the Preoperative Resources Use and the Practice Pattern in Japanese Cholecystectomy Patients

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Abstract

Purpose. There are several preoperative treatment options, such as the staged bile duct intervention (BDI), for the successful completion of a cholecystectomy, regardless of the use of an open cholecystectomy (OC) or a laparoscopic cholecystectomy (LC). However, few studies have investigated how the characteristics of the patient or the hospital affect the preoperative resource use. This study determined the factors, including the hospital characteristics, associated with the preoperative resource utilization or with the treatment process.
Methods. Cholecystectomy patients (n = 12 627) who were treated for benign gallbladder diseases were examined. The study variables were: the patient demographics; the comorbid conditions; the presence of inflammation; the BDI, including endoscopic retrograde cholangiopancreatography, percutaneous gallbladder or common bile duct drainage, endoscopic sphincterotomy, clearance of choledocholithiasis; the preoperative length of stay (LOS) or the total charges; and the hospital region, ownership, and function. A multivariate analysis was used to measure the variables associated with the use of preoperative resources.
Results. A total of 11 690 (85.1%) patients underwent LC. The inflammation was diagnosed in 72.5% of OC and 41.5% of LC patients. Bile duct intervention was performed in more of the OC patients. The preoperative BDI had a significantly greater impact on the LOS. The hospital demographics predicted the preoperative resource use and the implementation of the BDI.
Conclusions. The preoperative BDI involved the use of more preoperative resources. A wide variation of the use of BDI was observed in the hospital demographics. Further study is needed to establish a preoperative treatment strategy for cholecystectomy patients.

Key words Cholecystectomy · Bile duct intervention · Preoperative resource use · Practice variation

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Introduction

Many studies have performed clinical and economic analyses of a laparoscopic cholecystectomy (LC) versus an open cholecystectomy (OC), and have confirmed the safety and efficacy of LC.[1–3] Laparoscopic cholecystectomy has become a popular procedure, and it has also been applied recently to complicated patients, such as those with acute cholecystitis or with a history of a gastrectomy.[4] Laparoscopic cholecystectomy has been shown to have clinical and/or economic benefits, by reducing the postoperative pain, thus enhancing the early postoperative mobilization, and reducing the postoperative or overall hospital use of resources.[5–10] Replacing conventional OC with LC might thus provide a means of delivering more efficient medical care to patients requiring a cholecystectomy.

On the other hand, the use of an early cholecystectomy as another treatment option has been advocated in acute cholecystitis, using laparoscopy or a laparotomy. There are many possible reasons for the marked variation in the preoperative resource use. These possibilities include the patient characteristics (age, presence of comorbidity or emergency), the disease characteristics (e.g., gallbladder wall inflammation), the hospital function (teaching or nonteaching status), and the hospital region or ownership. The regional variation in the patient accessibility to the hospital, the availability of technology, or the adherence to practice guidelines need to be investigated when attempting to improve the quality of care for cholecystectomy patients.

Carbonell et al.[11] reported that the hospital size, the rural location, and the teaching status did not affect the use of resources or the complications or the mortality in cholecystectomy patients. Regarding the indications for the increased performance of LC, however, the preoperative scrutiny of the bile duct system, such as investigating the presence of common bile duct stones, is a cornerstone of successfully completing LC, and it might lead to a greater variation in the preoperative use of resources or the occurrence of postoperative complications.[12–15] Examinations such as gallbladder aspiration or endoscopic retrograde pancreaticocholangiography (ERCP), with or without a sphincterotomy or an extraction of choledocholithiasis, may partly reflect the level of disease severity, although the indications for such types of intervention should be assessed with related clinical information, such as the presence of jaundice or acute pancreatitis.

When surveying the variations in the use of resources, whether preoperatively or during the overall course of hospitalization, these factors should be included in the analysis. Otherwise, the results may be misleading and thus not result in any improvement in quality. This supposedly may explain most of the resource use, and measuring the hospital or regional variation may help to advance the quality improvement in a cholecystectomy, by requesting hospital accountability for the indications for the procedures relevant to a cholecystectomy. The aim of this study was to determine the factors associated with the preoperative resource consumption and then examine the regional or the hospital variations of these factors.

Materials and Methods

Database

We used a Japanese administrative database that was established by the Ministry of Health, Welfare and Labor in 2002 to develop a Japanese case-mix classification system. This database had been used to profile the hospital performance and to assess the hospital payments across 731 hospitals (82 academic hospitals and

	Area (sq. miles)	Population (1000 people)	Number of study hospitals	Number of patients
Hokkaido	32,600	5,572	22	599
Tohoku	24,581	9,533	26	821
Kanto	11,770	28,957	77	2,195
Tokyo metropolitan	821	12,462	33	1,097
Chubu	23,556	21,607	62	1,581
Kinki	12,833	22,511	94	2,672
Chugoku	12,428	7,628	27	876
Shikoku	7,340	4,081	13	384
Kyushu	15,217	13,325	78	2,065
Okinawa	889	1,391	8	337

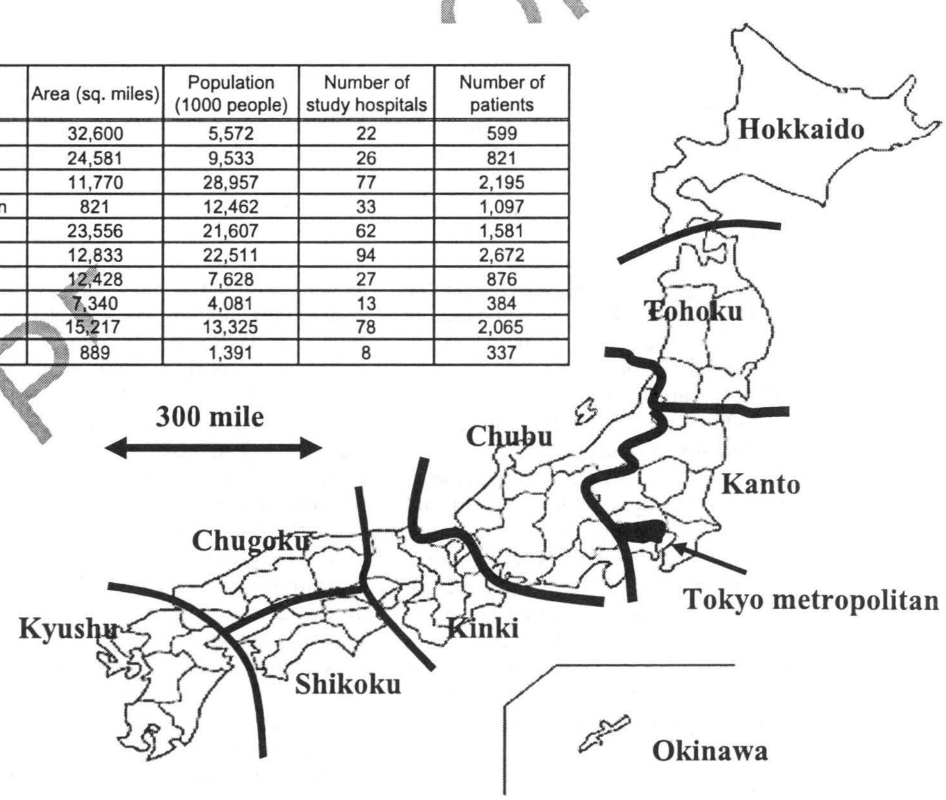

Fig. 1. Geographical regions and the vital statistics in Japan (2008)

649 community hospitals) in 2006. These hospitals provide acute care throughout Japan. Academic hospitals also carry out advanced medical research, and educate students and postgraduate trainees. The database included discharge summaries and claims data, which were collected annually between July 1 and December 31. We analyzed cases of benign gallbladder disease treated by a cholecystectomy at hospitals that participated in our research project in 2006. Our research project was approved by the ethics committee of the University of Occupational and by Environmental Health in Kitakyushu, Fukuoka, Japan.

Table 1. Study variables and the preoperative resource use stratified by the cholecystectomy approach (n = 12627)

	Cholecystectomy		
	Open cholecystectomy	Laparoscopic cholecystectomy	*P* value
Number of hospitals	1762 (354)	10865 (436)	
Age (years)			
Median	70 [18]	58 [21]	<0.001†
≥65 years (%)	1121 (63.6)	3614 (33.3)	<0.001
Sex (%)			
Male	1080 (61.3)	5043 (46.4)	<0.001
Outcome (%)			
Mortal	4 (0.2)	3 (0)	0.009
Ambulance (%)			
Transferred	176 (10.0)	298 (2.7)	<0.001
Primary diagnosis (%)			<0.001
No inflammation	484 (27.5)	6352 (58.5)	
Acute cholecystitis	651 (36.9)	1184 (10.9)	
Chronic cholecystitis	627 (35.6)	3329 (30.6)	
Cholecystitis related comorbidity presence	75 (4.3)	134 (1.2)	<0.001
Charlson Comorbidity Index (%)			<0.001
1	317 (18.0)	1195 (11.0)	
≥2	200 (11.4)	389 (3.6)	
BDI			
Preoperative ERCP	72 (4.1)	362 (3.3)	0.118
Preoperative internal drainage	98 (5.6)	407 (3.7)	<0.001
Preoperative external drainage	247 (14.0)	369 (3.4)	<0.001
Total parenteral nutrition (%)	150 (8.5)	188 (1.7)	<0.001
Region			<0.001
Hokkaido	63 (3.6)	536 (4.9)	
Tohoku	70 (4.0)	751 (6.9)	
Kanto	418 (23.7)	1777 (16.4)	
Tokyo metropolitan	157 (8.9)	940 (8.7)	
Chubu	252 (14.3)	1329 (12.2)	
Kinki	333 (18.9)	2339 (21.5)	
Chugoku	144 (8.2)	732 (6.7)	
Shikoku	45 (2.6)	339 (3.1)	
Kyushu	243 (13.8)	1822 (16.8)	
Okinawa	37 (2.1)	300 (2.8)	
Ownership			0.103
National	141 (8.0)	729 (6.7)	
Municipal	356 (20.2)	2077 (19.1)	
Private for-profit	713 (40.5)	4463 (41.1)	
Private non-profit	552 (31.3)	3596 (33.1)	
Hospital type (%)			0.003
Academic	207 (11.7)	1561 (14.4)	
Preoperative resource use			
Early timing cholecystectomy	591 (33.5)	5476 (50.4)	<0.001
Median preoperative LOS (days)	4 [10]	2 [2]	<0.001†
Median preoperative total charge (US$)	2498 [1677]	1256 [815]	<0.001†

BDI, bile duct intervention; ERCP, endoscopic retrograde cholangiopancreatography; LOS, length of stay
†Mann–Whitney test; others: Chi-square test. []: Quartile range

Definition of the Variables

The study variables were age, sex, transfer by ambulance, gallbladder wall inflammation, comorbidity, surgical procedure (LC or OC), BDI, total parenteral nutrition (TPN) for diseases sufficiently severe to require bowel rest, complications attributable to the diagnostic and therapeutic procedures, outcome at discharge, and hospital region, ownership, and function.

The patients were stratified by age into two groups: <65 years and ≥65 years of age. The transfer by ambulance was indicated as a proxy for emergency admission. The diagnoses in this database were coded according to the International Statistical Classification of Diseases, 10th version (ICD10). Among the ICD10 codes indexing disorders/diseases of the gallbladder (K80$ to K83$), the following codes were considered to indicate the presence of inflammation: K800, K810, and K822 as acute cholecystitis; and K801, K811-9, K820-1, and K823 as chronic cholecystitis. All the other ICD codes were considered to indicate noninflammatory conditions. This administrative database records a maximum of four comorbidities per patient. To assess the severity of the chronic comorbid conditions, we used the Charlson Comorbidity Index.[16] The other cholecystitis-related comorbid conditions were defined as any of the following ICD10 codes: presence of jaundice or elevated liver enzyme (R17, R74$), peritonitis (K65$), and acute pancreatitis (K85). Up to five operative procedures per hospitalization were listed. In the present study, we included patients who received OC or LC without a choledocholithotomy. The LC cases that converted to OC were counted as OC cases.

Three types of BDI were defined as ERCP only, and external or internal drainage with or without ERCP. The external drainage indicated percutaneous gallbladder aspiration or drainage or percutaneous common bile duct drainage, whereas the internal drainage indi-

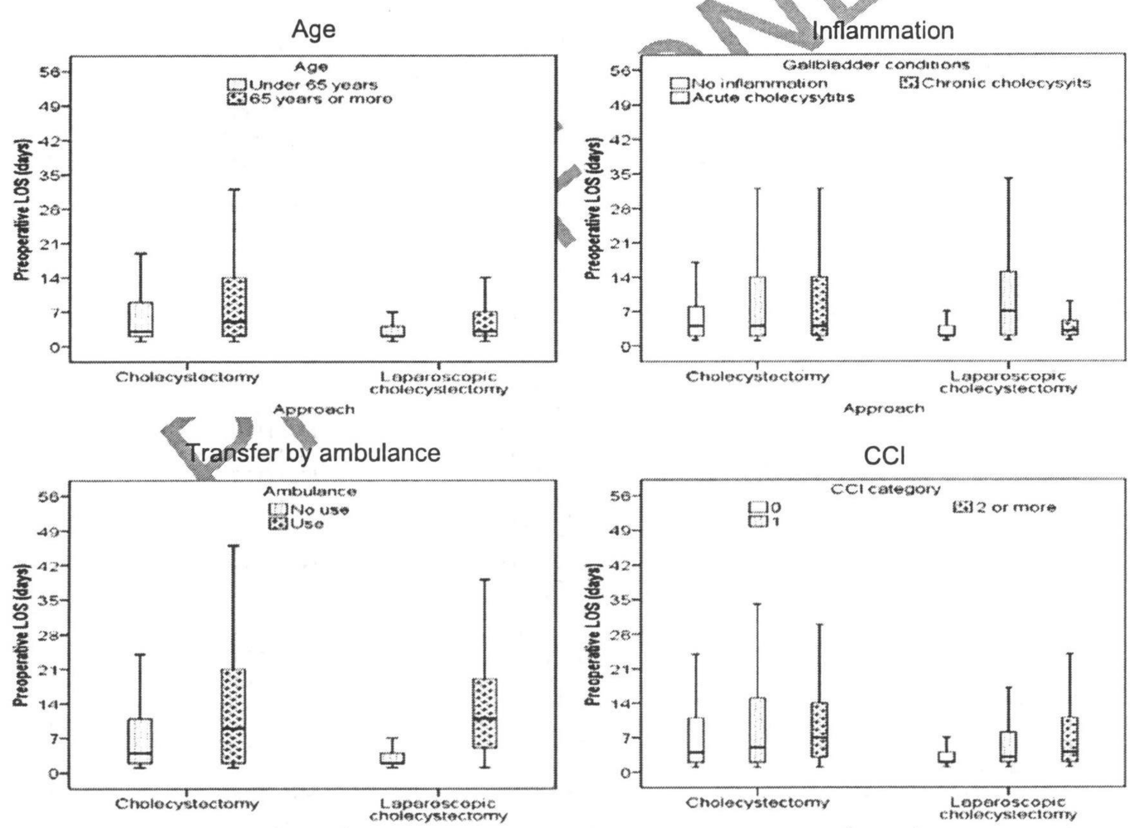

Fig. 2. Effect of age, inflammation, transfer by ambulance, and Charlson comorbidity index (*CCI*) on the length of stay (*LOS*) (days) for an open and laparoscopic cholecystectomy

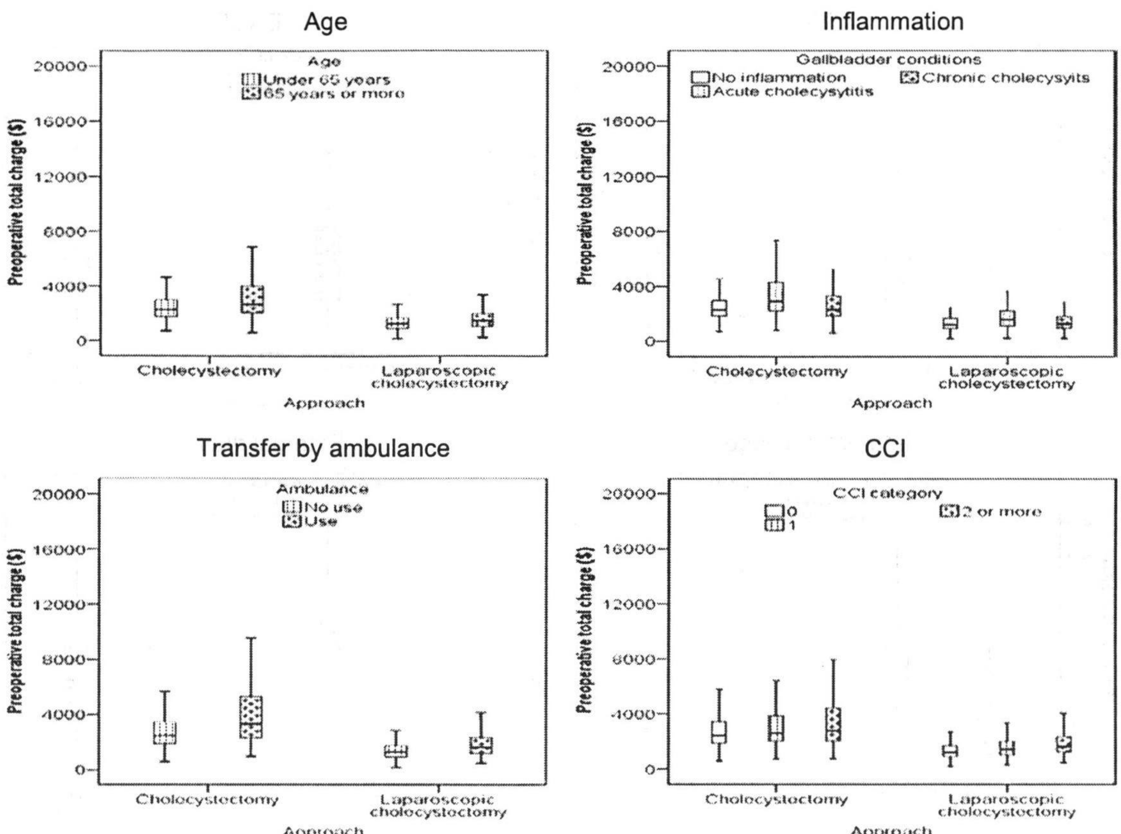

Fig. 3. Effect of age, inflammation, transfer by ambulance, and Charlson comorbidity index (*CCI*) on the total charges ($) for an open and laparoscopic cholecystectomy

cated balloon dilatation or a sphincterectomy for the ampulla of Vater, and a stent insertion for benign common bile duct stenosis. Use of BDI before a cholecystectomy was examined. For the present study, we used the preoperative length of stay (LOS) and the total charge (TC; US$1 = ¥100) billed during admission as proxies for the total cost during admission. In Japan, charges for hospital care are determined by a standardized fee-for-service payment system known as the national uniform tariff table; the fees accrued through this system are considered to be good estimates of the healthcare costs.[17] The TC in this study included the physician fees, the instrument costs, the costs of the laboratory or imaging tests, and the administration fees. An early cholecystectomy was defined as one that needed a preoperative LOS of ≤2 days.

To create a variable for the hospital location or the ownership, we divided Japan into 10 regions: Hokkaido, Tohoku, Kanto, Tokyo metropolitan, Chubu, Kinki, Chugoku, Shikoku, Kyushu, and Okinawa (Fig. 1).[18] With respect to the hospital ownership, the following four types were studied: the national hospitals founded by the Japanese government, the municipal hospitals managed by regional government, the private hospitals managed by non-profit organizations such as the Red Cross Institute, Charity Institute, or public insurer, and the remaining as private for-profit hospitals.

Statistical Analysis

The categorical data were reported for the frequency and the proportion of OC and LC. The comparisons were made using Fisher's exact test. The box charts were used to display the distributions of LOS and TC for OC and LC, stratified either by the age, the degree of inflammation, the use of ambulance, the Charlson Comorbidity Index (CCI), the use of TPN, the three kinds of BDI, and the hospital region, ownership, and function. The continuous variables were compared across either the OC or the LC groups by nonparamet-

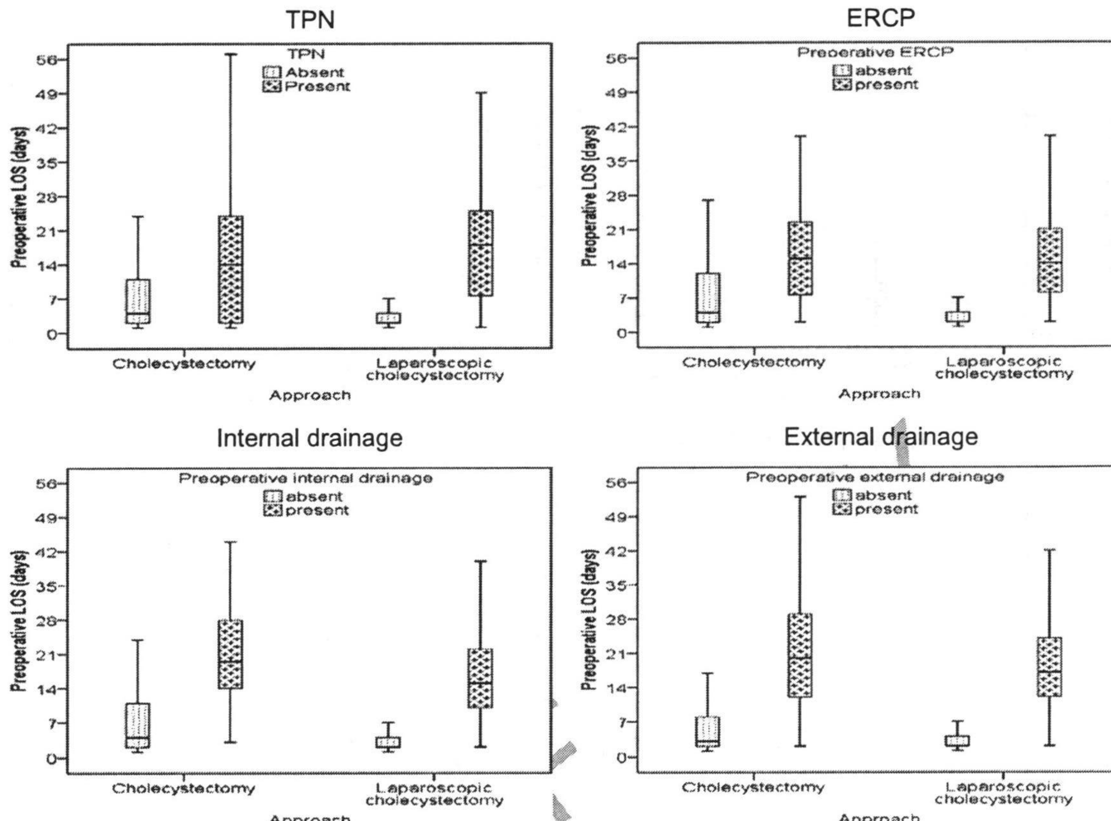

Fig. 4. Effect of the total parenteral nutrition (*TPN*) and the preoperative bile duct interventions on the LOS (days) for an open and laparoscopic cholecystectomy. *ERCP*, endoscopic retrograde cholangiopancreatography

ric tests. The multiple linear regression models were used to identify the impact of every study variable on LOS and TC. Because the distribution of both LOS and TC were right-skewed, these were $\log_{10}$-transformed in this model. A logistic regression model was used to evaluate the relationship between the independent variables and the use of BDI, the indication for OC, and early cholecystectomy. The statistical analysis was performed using SPSS 16.0. All the reported P values were two-tailed, and the level of significance was set at less than 0.05.

Results

Of the 1 895 249 patients from the 469 participating hospitals, we identified 12 627 cholecystectomy patients in 440 hospitals (1768 cases from 65 academic hospitals and 10 859 cases from 375 community hospitals). Seven deaths occurred (four OC and three LC cases). Of the patients in the study, 1762 (14.0%) underwent OC and 10 865 (86.0%) underwent LC. The median patient age was 70 years for OC and 58 years for LC. The OC was the preferred surgical technique for patients older than 65 years of age (63.6%), whereas LC was preferred for younger patients (66.7%). Males represented 61.3% of the OC patients and 46.4% of the LC patients. Ten percent of the OC cases involved an ambulance transfer, in comparison to only 2.7% of the LC cases. Inflammation was diagnosed in 72.5% of the OC patients and 41.5% of the LC patients. The proportion of the cholecystitis-related comorbidity was 4.3% of the OC cases and 1.2% of the LC cases. A total of 70.6% of the OC patients had no chronic comorbidity in comparison to 85.4% of the LC patients.

Every type of BDI was performed in more of the OC patients in comparison to the LC patients. The external drainage was used mostly in 14.0% of the 1762 OC

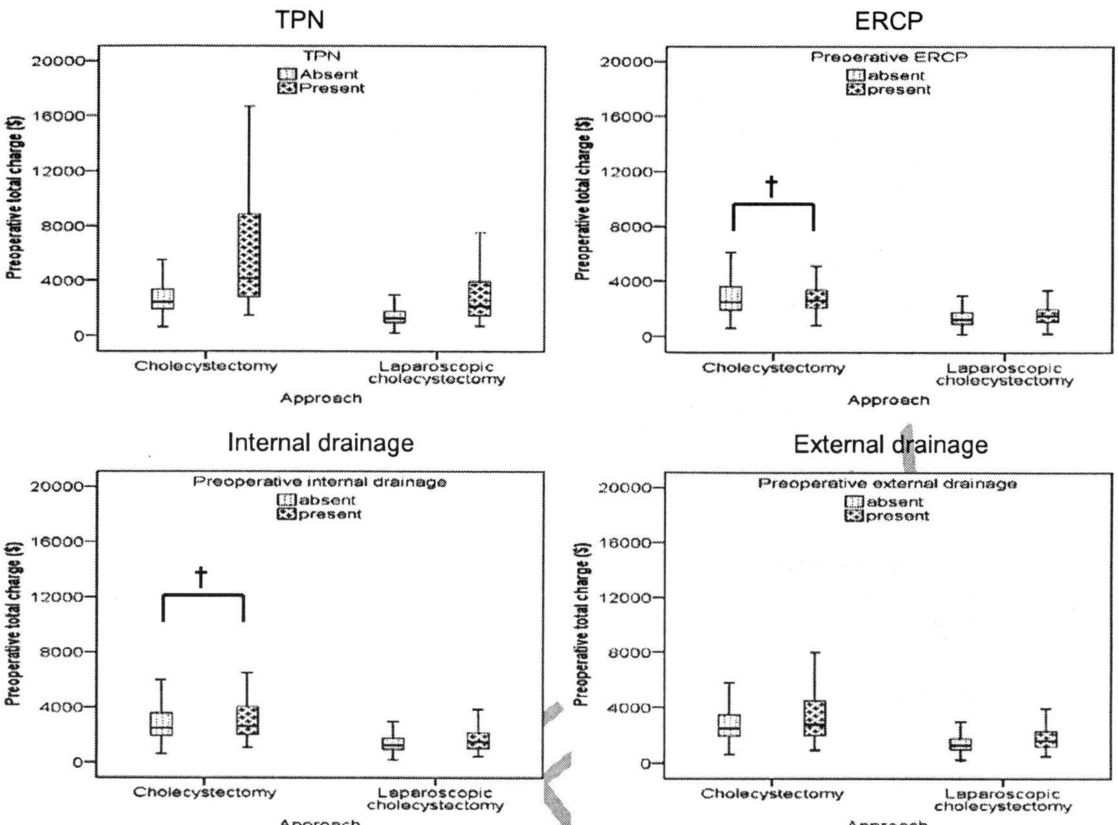

Fig. 5. Effect of the total parenteral nutrition (*TPN*) and the preoperative bile duct interventions on the total charges ($) for an open and laparoscopic cholecystectomy. †Difference was not significant. $P = 0.587$ for endoscopic retrograde cholangiopancreatography (*ERCP*) in open cholecystectomy (OC), $P = 0.339$ for internal drainage in OC

patients. Among the 10865 LC patients, the most frequently used BDI was internal drainage (3.7%). The TPN was more common in the OC patients (8.5%) in comparison to the LC patients (1.7%). The OC was most frequently applied in the Kanto (23.7%) and the LC in the Kinki (21.5%) regions. The proportion of OC and LC differed significantly according to the hospital region and function. The median preoperative LOS and the median preoperative TC were significantly different between OC and LC (OC: 4 days and US$2498; LC, 2 days and US$1256) (Table 1).

A comparison of preoperative LOS and preoperative TC across 11 study variables is shown in Figs. 2–7. Statistically significant differences were identified, except for the TC in the OC patients treated by ERCP and internal drainage ($P = 0.587$ and 0.339, respectively). There was a significant variation in the LOS and TC depending on the hospital region, ownership, and function, except for the LOS for the OC patients with respect to the hospital ownership, and the TC for OC according to the hospital function ($P = 0.074$ and 0.426, respectively).

After adjusting for both demographic and clinical variables, three types of preoperative BDI were the most significant determinants of preoperative LOS, and LC was the most significant determinant of preoperative TC (standardized coefficient of ERCP, internal drainage and external drainage for LOS was 0.481, 0.509 and 0.540, respectively, or that of LC for TC was −0.251). The hospitals in Hokkaido, Chubu, Chugoku, and Kyushu, and the private hospitals and the academic institutions were associated with a longer LOS or a higher TC (Table 2).

The controlling inflammation and comorbidity, and the hospital region, ownership, and function were associated with preoperative BDI. Among the hospital char-

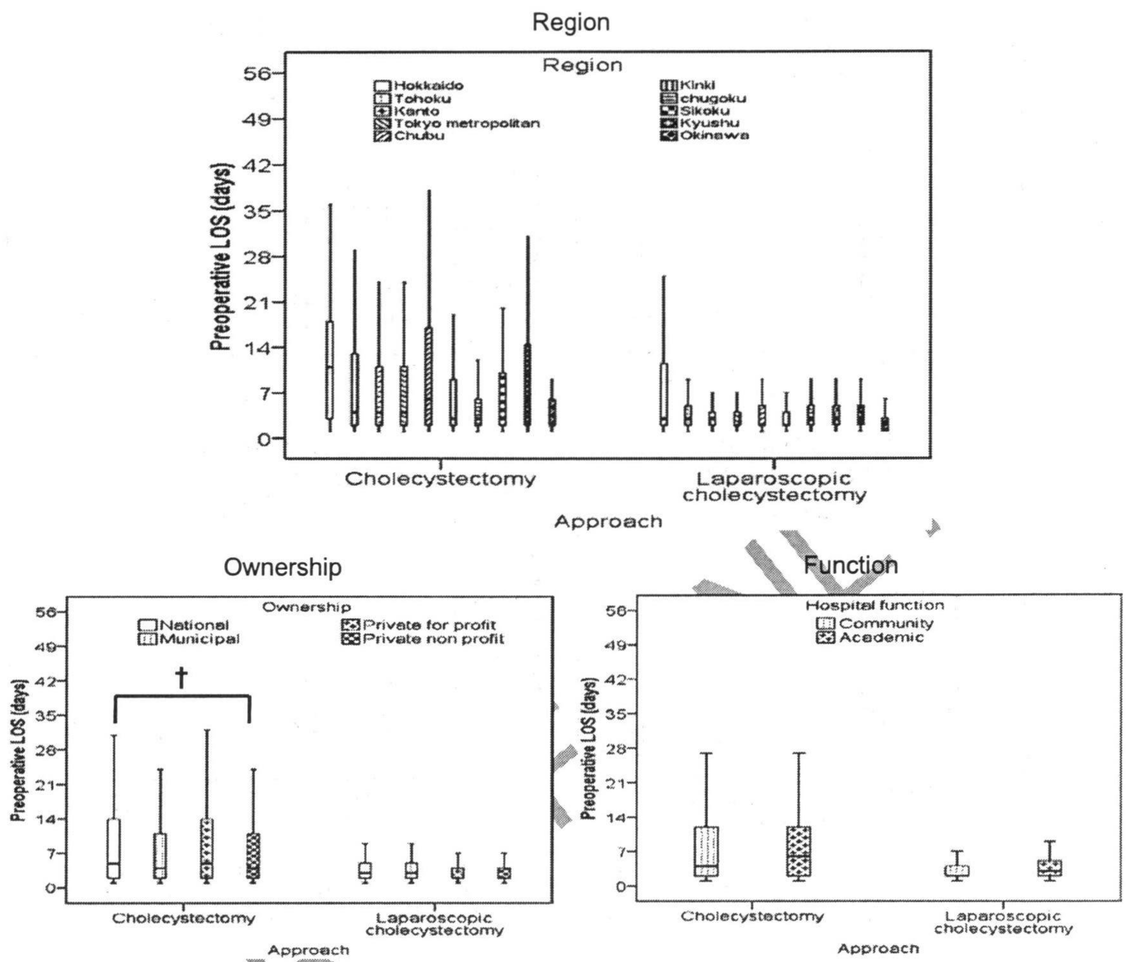

Fig. 6. Effect of the region, the ownership, and the function of the hospitals on the LOS (days) for an open and laparoscopic cholecystectomy. †Difference was not significant. $P = 0.074$ for ownership in OC

acteristics, Hokkaido, Chubu, and Kyushu were the top three determinants for the use of BDI (Odds ratio [OR] and 95% confidence interval [CI]: 4.611 [2.543–8.360], 4.553 [2.694–7.692], and 3.873 [2.290–6.551], respectively). In addition, the private for-profit and the academic hospitals also explained the variations in the use of BDI (OR and 95% CI: 1.646 [1.060–2.555] and 1.572 [1.164–2.122]) (Table 3).

Discussion

This study demonstrated that ERCP, and internal and external drainage, explained most of the variation in LOS, while LC explained most of the variation in TC. When examining the variation in the preoperative resource consumption, many patients, and the disease or the hospital factors, had to be considered because the study population contained a wide variety of cases. Even after adjusting for the disease severity, including the degree of inflammation or the cholecystitis-related comorbidity, there was still a significant hospital regional variation in the preoperative resource use or in the use of BDI. Hokkaido, Chubu, and Kyushu were such broad areas among the 10 hospital region categories that the patient's accessibility to the institutions may have necessitated a preoperative bile duct scrutiny during hospitalization. The data of the geographic or the

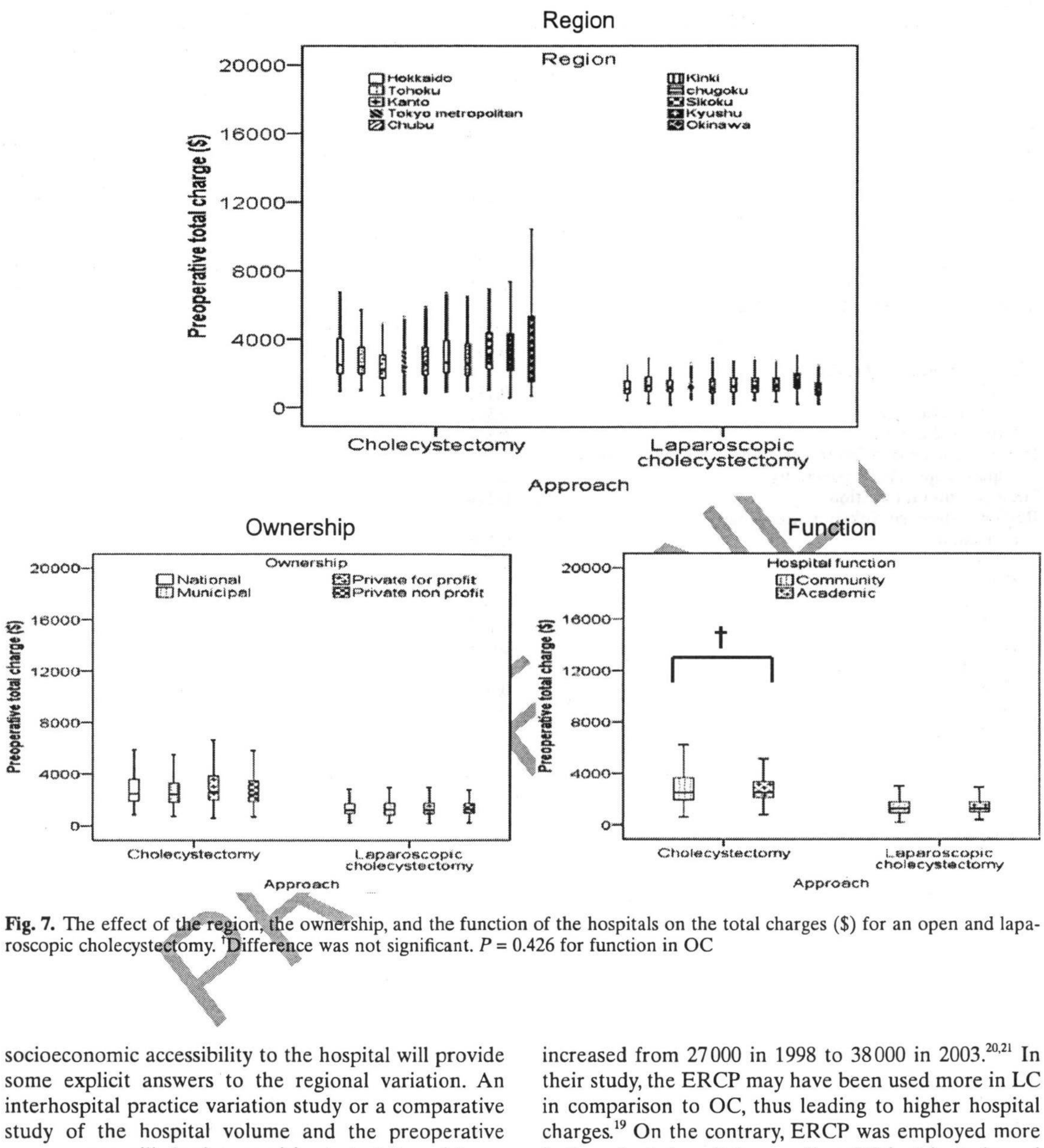

Fig. 7. The effect of the region, the ownership, and the function of the hospitals on the total charges ($) for an open and laparoscopic cholecystectomy. †Difference was not significant. $P = 0.426$ for function in OC

socioeconomic accessibility to the hospital will provide some explicit answers to the regional variation. An interhospital practice variation study or a comparative study of the hospital volume and the preoperative resource use will also be promising to test the existence of the hospital's or the surgeon's practice beliefs.

The prevalence of LC may have increased the use of BDI, especially ERCP.[19] The Survey of National Medical Care Insurance Services, published by the Japanese Ministry of Health, Welfare and Labor (MHWL), found that the annual number of LC cases has more than doubled, from 7000 in 1998 to 16000 in 2003. In comparison, the annual cases of endoscopic dilatation or a sphincterotomy of the ampulla of Vater increased from 27000 in 1998 to 38000 in 2003.[20,21] In their study, the ERCP may have been used more in LC in comparison to OC, thus leading to higher hospital charges.[19] On the contrary, ERCP was employed more in the private hospitals as well as OC in this study, and the use of BDI differed significantly according to the hospital ownership or function.

Sekimoto et al.[22] reported that the timing of surgery was determined mainly by the institutional policy in Japan, rather than by the clinical course of the patient. They also indicated that the prevalence of the preoperative ERCP differed according to LC propensity, which was very different among the nine general hospitals that were studied. The LC was selected as an independent

Table 2. Factors associated with the $\log_{10}$-transformed preoperative length of stay (LOS) and the total charge (TC) ($)

	Preoperative LOS			Preoperative TC ($)		
	Unstandardized coefficient	SE	*P*	Unstandardized coefficient	SE	*P*
Intercept	0.516	0.021	<0.001	3.530	0.016	<0.001
Age <65 years	0.042	0.005	<0.001	0.062	0.004	<0.001
Male	0.008	0.005	0.099	−0.001	0.004	0.747
Ambulance used	0.109	0.013	<0.001	0.071	0.010	<0.001
Primary diagnosis (reference: No inflammation)						
Acute cholecystitis	0.092	0.008	<0.001	0.085	0.006	<0.001
Chronic cholecystitis	0.051	0.006	<0.001	0.022	0.004	<0.001
Cholecystitis related comorbidity presence	0.058	0.019	0.003	0.039	0.015	0.008
Charlson Comorbidity Index (reference: 0)						
1	0.059	0.008	<0.001	0.044	0.006	<0.001
≥2	0.115	0.012	<0.001	0.091	0.009	<0.001
BDI (reference: No procedure)						
ERCP only	0.481	0.014	<0.001	0.008	0.010	0.458
Internal drainage	0.509	0.013	<0.001	0.020	0.010	0.039
External drainage	0.540	0.012	<0.001	0.014	0.009	0.128
Procedure approach (reference: Open cholecystectomy)						
Laparoscopic cholecystectomy	−0.031	0.008	<0.001	−0.251	0.006	<0.001
Total parenteral nutrition	0.214	0.016	<0.001	0.243	0.012	<0.001
Region (reference: Tokyo metropolitan)						
Hokkaido	0.108	0.014	<0.001	−0.016	0.011	0.137
Tohoku	0.020	0.013	0.136	0.024	0.010	0.018
Kanto	0.033	0.010	0.002	0.005	0.008	0.548
Chubu	0.016	0.011	0.148	−0.002	0.008	0.812
Kinki	−0.015	0.010	0.144	0.033	0.008	<0.001
Chugoku	−0.038	0.013	0.003	0.026	0.010	0.009
Shikoku	0.038	0.017	0.023	0.041	0.013	0.001
Kyushu	0.039	0.011	<0.001	0.099	0.008	<0.001
Okinawa	−0.144	0.017	<0.001	−0.051	0.013	<0.001
Ownership (reference: National)						
Municipal	−0.033	0.012	0.006	−0.009	0.009	0.355
Private for-profit	−0.073	0.011	<0.001	0.011	0.008	0.208
Private non-profit	−0.075	0.012	<0.001	0.016	0.009	0.080
Hospital type (reference: Community)						
Academic	0.020	0.008	0.016	0.023	0.006	<0.001

SE, standard error; BDI, bile duct intervention; ERCP, endoscopic retrograde cholangiopancreatography
F test for the model: LOS, TC, $P < 0.000$. Coefficient of determination, LOS, 0.414; TC, 0.304

variable in the present study because it was considered to be a possible proxy of the hospital practice beliefs, which meant that the hospitals delivered more efficient and less invasive procedures, concomitantly with a challenge for more complex preoperative conditions. Even after controlling for the cholecystectomy approach or the BDIs, a significant variation of the preoperative resource use in the hospital function still remains.

Carbonell et al.[11] demonstrated that the teaching hospitals are associated with a longer LOS and higher charges, and a lower prevalence of LC. They explained that the academic hospitals are tertiary referral centers and tend to accommodate the sicker cholecystectomy patients, although the comorbid status at admission was not available in their study. The present study revealed that the academic hospitals spent more resources, after controlling for all the other covariates, including comorbidity. The academic hospitals were a significant determinant of an early cholecystectomy (OR and 95% CI: 0.698 [0.613–0.794]) (Table 4). We need to further evaluate the reasons for the deterred cholecystectomy and for the efficiency of the care process.

Sekimoto et al.[22] reported that nine study hospitals had a markedly longer preoperative LOS (10–15 days), and that the preoperative LOS was significantly shorter in the hospital with the lowest use of LC in 2001–2003. They suggested that a reform of the medical care system was necessary to facilitate a standardization of the treatment for acute cholecystitis, based on scientific evidence. Since the introduction in Japan of the per diem prospective reimbursement in 2003, MHWL announced that the mean LOS for OC and LC were 9.7 and 21.2

Table 3. Logistic regression analysis of the factors associated with the preoperative BDIs

Independent variables	Odds ratio	[95% CI]
Age		
<65 years	1.000	
≥65 years	1.325	[1.082–1.623]
Sex		
Female	1.000	
Male	1.104	[0.908–1.344]
Ambulance		
Not used	1.000	
Used	1.682	[1.156–2.448]
Primary diagnosis		
No inflammation	1.000	
Acute cholecystitis	2.234	[1.712–2.916]
Chronic cholecystitis	1.244	[0.985–1.570]
Cholecystitis related comorbidity		
Absent	1.000	
Present	2.542	[1.586–4.076]
Charlson Comorbidity Index		
0	1.000	
1	1.237	[0.944–1.620]
≥2	1.209	[0.804–1.818]
Procedure approach		
Open cholecystectomy	1.000	
Laparoscopic cholecystectomy	1.301	[0.978–1.732]
Region		
Tokyo metropolitan	1.000	
Hokkaido	4.611	[2.543–8.360]
Tohoku	1.993	[1.030–3.857]
Kanto	2.565	[1.505–4.373]
Chubu	4.553	[2.694–7.692]
Kinki	1.415	[0.809–2.475]
Chugoku	2.851	[1.561–5.209]
Shikoku	1.510	[0.615–3.708]
Kyushu	3.873	[2.290–6.551]
Okinawa	1.665	[0.679–4.084]
Ownership		
National	1.000	
Municipal	1.387	[0.851–2.259]
Private for-profit	1.646	[1.060–2.555]
Private non-profit	1.290	[0.802–2.077]
Hospital type		
Community	1.000	
Academic	1.572	[1.164–2.122]

CI, confidence interval; CBD, common bile duct; BDI, bile duct intervention
Hosmer Lemeshow goodness for fit: $P = 0.112$

days, respectively, in 2006, and 9.8 and 18.9 days in 2007.[23] The median preoperative LOS in this study was strikingly shortened to 2–4 days. To achieve quality of care for all cholecystectomy patients, clinical experts need to start a comparative study for the preoperative treatment strategy, and they therefore need to clarify the indications for BDI, under these circumstances of the progressively increasing application of LC for more complicated cholecystitis. Preoperative or postoperative BDI, or intraoperative common bile duct imaging or exploration, should be assessed in terms of cost effectiveness.[24] Furthermore, a preoperative clinical strategy should also be established and implemented if possible.

Some limitations to the methodology and the interpretation of this study must be mentioned. First, the information was gathered from only the patients who had been discharged during the 6-month period of this study in 2006, which may have limited our ability to generalize the results. However, for future research efforts this administrative database has increased its sample size each year, with additional hospitals partici-