double counting in *Ps* calculations. Statistics were performed using SPSS (Chicago, IL) 16.0, with a level of significance set a priori at *P* less than .05.

3. Results

3.1. Demographic and clinical characteristics

Of 1 895 249 patients discharged in 2006, 83 382 trauma-related case-mix patients were identified from 465 hospitals (12 783 cases from 70 academic hospitals and 70 599 from 395 community facilities). Among these, 8207 cases with a calculated *Ps* were eligible in this study (1029 cases from 35 academic hospitals and 7178 from 129 community facilities). The largest group of patients (31.7%) had a *Ps* of at least .9900, whereas the smallest group of patients (3.0%) had a *Ps* of .9500 to .9600. In addition, 12% of patients had *Ps* less than .9400. The proportion of age, sex, ambulance use, location and number of injured organs, CCI, and surgical technique required was statistically different among *Ps* categories. Patients with a *Ps* of .9600 to .9700 had the highest median age and percentage of females. The proportion of injuries in "extremities, pelvic girdle" and "head and neck" regions was greater in the groups with *Ps* of .9600 to .9700 and with *Ps* less than .9400, respectively. Observed mortality at discharge was higher than predicted in groups with *Ps* of at least .9400, but lower than predicted in the group with *Ps* less than .9400. The mortality on days 1 and 2 was 16 cases (15%) (Table 1).

Table 3 Linear regression analysis of factors associated with log10-transformed TC on days 1 and 2

	Estimation	SE	*P*
Intercept	2.981	0.010	<.001
Male	0.020	0.006	.001
Outcome on days 1 and 2 (for alive)	0.058	0.064	.364
Ambulance	0.043	0.006	<.001
Injured organ (for external)			
Head and neck	0.017	0.009	.056
Face	−0.025	0.011	.025
Chest	−0.007	0.009	.444
Abdomen, pelvic contents	−0.012	0.011	.283
Extremity, pelvic girdle	0.059	0.007	<.001
Ps (for .9900 or more)			
.9800-.9899	0.021	0.012	.074
.9700-.9799	−0.034	0.008	<.001
.9600-.9699	0.011	0.009	.231
.9500-.9599	0.024	0.018	.172
.9400-.9499	0.020	0.017	.245
<.9400	0.047	0.011	<.001
No. of PEC (for zero)			
1	−0.030	0.009	.001
≥2	−0.055	0.018	.002
ICU care on days 1 and 2	0.319	0.009	<.001
Use of OR on days 1 and 2	0.482	0.009	<.001
Ventilation on days 1 and 2	−0.008	0.019	.647
Blood transfusion on days 1 and 2	0.273	0.015	<.001
Hospital (for community)			
Academic	0.036	0.010	<.001

F test for the model. *P* less than .001. Coefficient of determination, 0.502.

3.2. Trauma severity, care characteristics, and resource use

Probability of survival was positively correlated with RTS and negatively correlated with ISS, with the exception that the median ISS (interquartile range [IQ]) was 1 (15) in *Ps* of .9800 to .9899 and that the median RTS (IQ) was 7.55 (0.94) in *Ps* of .9500 to .9599. The highest proportion of patients requiring transfusion and ICU admission on days 1 and 2 was in those groups with *Ps* less than .9400, whereas the highest proportion of patients requiring ventilation was in groups with *Ps* of .9500 to .9599. Use of OR on days 1 and 2 was most frequent in groups with *Ps* of at least .9900. Amount of transfusions, OR time, and TC on days 1 and 2 were statistically different among *Ps* categories (Table 2 and Fig. 1).

3.3. Multivariate analysis

The multiple regression analysis showed that use of OR was the variable with the strongest association with TC on days 1 and 2 and that ICU care and blood transfusion had a greater impact on TC. Among the *Ps* categories, a *Ps* less than .9400 or from .9700 to .9799 was a stronger determinant of TC. Among injury location, "extremity, pelvic girdle" had the highest association with TC; and "face" had the lowest association. The coefficient of determination for TC on days 1 and 2 was 0.502 (Table 3).

Mortality cases on days 1 and 2 and *Ps* less than .9400 were stronger determinants of use of ventilation on days 1 and 2, and *Ps* from .9400 to .9499 or less than .9400 was a stronger determinant of use of blood transfusion on days 1 and 2. Injury location at the "head and neck" or "chest" was a significant predictor for use of ventilation on days 1 and 2; and injury location at the "abdomen, pelvic contents" or "extremities, pelvic girdles" was a stronger predictor of use of blood transfusion (Table 4).

4. Discussion

This study presents descriptive characteristics of trauma patients and assessed the independent effects of *Ps* on early

Table 4 Logistic regression analysis of factors associated with study care process on days 1 and 2

		ICU care		OR		Ventilation		Blood transfusion	
		Odd ratio	(95% CI)	Odd ratio	(95% CI)	Odd ratio	(95% CI)	Odd ratio	(95% CI)
Sex	Female	1.000		1.000		1.000		1.000	
	Male	1.444	(1.232-1.693)	1.476	(1.278-1.703)	1.383	(0.961-1.992)	0.621	(0.475-0.810)
Outcome	Alive	1.000		1.000		1.000		1.000	
	Mortality	0.310	(0.067-1.433)	0.381	(0.097-1.496)	23.098	(4.621-115.463)	0.985	(0.289-3.361)
Ambulance	Not used	1.000		1.000		1.000		1.000	
	Used	5.643	(4.631-6.875)	0.351	(0.298-0.412)	3.107	(1.645-5.865)	1.971	(1.428-2.721)
Injured organ									
	External	1.000		1.000		1.000		1.000	
	Head and neck	5.643	(4.631-6.875)	0.357	(0.28-0.455)	2.559	(1.723-3.799)	0.606	(0.429-0.855)
	Face	4.040	(3.371-4.842)	1.413	(1.103-1.811)	1.056	(0.668-1.670)	0.965	(0.626-1.487)
	Chest	1.278	(1.012-1.614)	0.402	(0.306-0.528)	1.985	(1.369-2.879)	0.948	(0.674-1.332)
	Abdomen, pelvic contents	2.362	(1.931-2.889)	0.860	(0.647-1.143)	0.866	(0.551-1.361)	2.351	(1.651-3.347)
	Extremity, pelvic girdle	2.849	(2.233-3.634)	1.593	(1.332-1.906)	0.542	(0.374-0.784)	1.698	(1.265-2.280)
Ps									
	.9900 or more	1.000		1.000		1.000		1.000	
	.9800-.9899	0.715	(0.602-0.849)	0.410	(0.301-0.559)	3.299	(1.450-7.503)	5.173	(2.784-9.611)
	.9700-.9799	1.219	(0.944-1.575)	0.349	(0.290-0.421)	2.605	(1.138-5.965)	4.354	(2.536-7.474)
	.9600-.9699	0.654	(0.518-0.826)	0.232	(0.181-0.297)	2.648	(1.047-6.698)	8.905	(5.209-15.223)
	.9500-.9599	0.789	(0.603-1.034)	0.273	(0.158-0.470)	7.066	(2.890-17.277)	11.027	(5.586-21.768)
	.9400-.9499	1.363	(0.934-1.99)	0.260	(0.148-0.455)	5.412	(2.119-13.823)	15.137	(7.545-30.367)
	<.9400	1.824	(1.282-2.594)	0.694	(0.546-0.883)	14.855	(7.439-29.663)	12.103	(7.146-20.499)
No. of PEC									
	Absent	1.000		1.000		1.000		1.000	
	1	1.539	(1.213-1.952)	0.768	(0.604-0.975)	1.558	(1.006-2.412)	0.869	(0.611-1.235)
	≥2	0.906	(0.715-1.149)	0.331	(0.159-0.689)	0.106	(0.011-1.028)	1.346	(0.677-2.676)
ICU care on days 1 and 2									
	Absent	1.000		1.000		1.000		1.000	
	Present	[a]		1.736	(1.368-2.203)	6.626	(4.181-10.500)	5.009	(3.569-7.030)
OR on days 1 and 2									
	Absent	1.000		1.000		1.000		1.000	
	Present	1.376	(1.082-1.75)	[a]		5.861	(3.997-8.595)	6.027	(4.598-7.900)
Ventilation on days 1 and 2									
	Absent	1.000		1.000		1.000		1.000	
	Present	4.510	(2.817-7.221)	7.853	(5.507-11.198)	[a]		4.510	(3.109-6.542)
Blood transfusion on days 1 and 2									
	Absent	1.000		1.000		1.000		1.000	
	Present	4.755	(3.393-6.662)	6.967	(5.309-9.144)	4.447	(2.975-6.646)	[a]	
Hospital									
	Community	1.000		1.000		1.000		1.000	
	Academic	9.675	(8.033-11.653)	1.265	(1.019-1.570)	2.311	(1.647-3.242)	0.857	(0.624-1.175)
Hosmer-Lemeshow goodness of fit model test		<0.001		<0.001		0.791		0.458	

CI indicates confidence interval.

[a] Not included in the model.

resource utilization. After controlling for covariates including mortality, early indication of critical care except ventilation on days 1 and 2 had a greater impact on TC on days 1 and 2. A *Ps* less than .9400 or from .9700 to .9799 and injured "extremities, pelvic girdle" or "face" were found to be highly correlated to early TC. Critical care rather than *Ps* is a potential predictor of early resource use, although an inverse linear correlation was not observed among *Ps* groups. However, *Ps* did significantly influence early indication of ventilation or blood transfusion. When divided according to site of injury, "head and neck" or "chest" impacted early use of ventilation; and "extremities, pelvic girdle" impacted use of blood transfusion.

Traumatic brain injury associated with or without multiple injuries is the frequently assessed parameter in health care research on short- or long-term outcome, the latter of which especially is assumed to be a greater economic burden in general health [1,2,16,17]. In this study, "head and neck" or lower *Ps* somewhat corresponding to lower Glasgow Coma Scale could indicate an association with ventilation as a therapeutic intervention, which, however, did not result in higher early resource use. The effect of ventilation may be masked by other aspects of critical care; and injury site or *Ps* explained the variability of TC up to day 2 to a moderate extent, possibly indicating that trauma-related severity index or anatomically damaged organs are dominated variables in predicting costs in the early phase.

Probability of survival and injured organ were significantly associated with use of critical care consuming TC on days 1 and 2, which showed a wider range for *Ps* less than .9400 (Fig. 1). Total charges on days 1 and 2 showed a narrower range and lower median for *Ps* from .9600 to .9699. Probability of survival itself was expected to contain a wide variety of case-mix relevant to trauma, vital signs determining prompt indication or quantity of critical care as well as anatomical damage necessitating some operative repair or enough OR time.

In addition, recent criticisms of ISS or RTS in mortality prediction models at admission have brought into question the validity of *Ps* and have proposed modifications or new models to enhance accuracy of scoring [18,19]. In the current study, we revealed that injury site significantly differed between the *Ps* categories, shown in Table 1. For example, "extremity, pelvic girdle" was dominant in *Ps* from .9600 to .9699 and associated with females, higher PEC, and transfusion during hospitalization (Table 1). Thus, a discrete AIS or even ISS, if it was the same value, might not predict the precise outcome variation including resource use. Christensen et al (2008) [3] determined costs based on a multivariate regression model using ISS, where the covariates explained only 28% of the variation of hospital costs. Coefficient of determination for TC in our study using *Ps* was 50%, and our model might have superiority of estimating costs. To unravel the miasma of *Ps*, the interaction of *Ps* and damaged organs should be evaluated (Annex Table 1). "Head and neck" or "extremities or pelvic girdle" for *Ps* less than .9400 was a strong predictor of early resuscitative care including critical time-sensitive resource use such as intracranial pressure monitor or embolization. Our model attempted to eliminate both effect of surgical procedures at OR and use of critical care so that conservative management for injured "chest" or "abdomen, pelvic contents" would not be expected to increase costs during critical periods.

The Therapeutic Intervention Scoring System–28 or the Simplified Acute Physiology Score might be a promising clinical indicator for measuring the appropriate indication for time-sensitive intensive care for critical patients [7]. Assuming that the payments for or monitoring appropriateness of ICU care for trauma patients would be performed on the basis of TRISS alone, caution should be paid in cases of *Ps* less than .9900. Because *Ps* groups included a wide variety of case-mix, "head and neck" or "pelvic structures" should not be ignored when assessing quality of ICU care. This is due to the fact that careful monitoring of presence of ongoing retroperitoneal bleeding or intracranial pressure may need appropriate or timely use of diagnostic or laboratory tests resulting in greater costs for the efficient care process. A study similar to the current study would overcome to some extent the disadvantage of TRISS caused by the limitation of ISS and concurrently suggest the possibility of sophisticating TRISS to make the most effective use of the trauma care system.

The application of our results must be interpreted in light of several limitations. First, eligible patients represented only 10% of the trauma case-mix population; and the study period was limited to 6 months, which may not reflect a broader population. A comparison of the 10% of cases in the study population and the other 90% of cases might reveal that the study population in general comprised severer cases of older patients, higher rates of ambulance use, and more resources spent overall (Annex Table 2). Because many variables are required to calculate *Ps*, the study population might comprise patients mainly from hospitals focused on quality of trauma care and acute medicine. Thus, we may have introduced some bias toward institutions that provide injury and critical care medicine. Under the guidance of the Japanese Association for the Surgery of Trauma, the trauma registry and database used in this study have increased in sample size yearly to represent more hospitals and to more rigorously apply AIS coding, thereby allowing for greater access to information for future studies [20].

Second, we targeted a study population after admission and did not count the resource use spent on emergency department or outpatient facilities. This might underestimate costs during the early resuscitative period, although practice patterns as the first aid were so limited that they would not influence TC. Our administrative database included the detailed care process before hospitalization in the same format as in this study, and it is possible to resolve this limitation.

5. Conclusions

Our analysis demonstrated that use of ICU care, OR, and blood transfusion was associated more strongly with TC on days 1 and 2 than *Ps* or injury site. Probability of survival was a strong predictor of use of critical care. Quantity of critical care or TC differed significantly between *Ps* categories and showed a wide range in *Ps* less than .9400. "Extremity, pelvic girdles" caused this variation of costs or use of critical care. Probability of survival combined with injury site might contribute to fair payment for ICU care and should be taken into account when measuring quality of ICU care. To further refine the cost estimation model in any period during hospitalization, future studies should confirm the impact of *Ps* on resources spent or on indication of critical care by using both TRISS and other variables like location or number of damaged organs. In turn, such a refined prediction model may offer policy implications on how to optimize facility or staff reallocation or practice patterns in trauma management.

Appendix A

Annex Table 1 Interaction of Ps and injured organ and log10-transformed TC on days 1 and 2

	Estimation	SE	*P*
Interaction of *Ps* and injured organ (for *Ps* > .9900 * external)			
Ps .9800-.9899 * external	−0.001	0.018	.967
Ps .9700-.9799 * external	0.014	0.020	.470
Ps .9600-.9699 * external	−0.044	0.031	.147
Ps .9500-.9599 * external	0.055	0.041	.177
Ps .9400-.9499 * external	0.103	0.108	.343
Ps < .9400 * external	−0.040	0.021	.053
Ps > .9900 * head and neck	−0.015	0.014	.265
Ps .9800-.9899 * head and neck	0.023	0.019	.234
Ps .9700-.9799 * head and neck	0.040	0.019	.032
Ps .9600-.9699 * head and neck	0.022	0.025	.372
Ps .9500-.9599 * head and neck	0.027	0.030	.364
Ps .9400-.9499 * head and neck	0.046	0.023	.044
Ps < .9400 * head and neck	0.065	0.015	.000
Ps > .9900 * face	−0.035	0.017	.039
Ps .9800-.9899 * face	0.003	0.033	.928
Ps .9700-.9799 * face	−0.012	0.029	.691
Ps .9600-.9699 * face	−0.136	0.050	.007
Ps .9500-.9599 * face	−0.002	0.048	.964
Ps .9400-.9499 * face	−0.026	0.108	.813
Ps < .9400 * face	−0.013	0.026	.628
Ps > .9900 * chest	0.009	0.018	.621
Ps .9800-.9899 * chest	0.002	0.025	.929
Ps .9700-.9799 * chest	−0.038	0.020	.055
Ps .9600-.9699 * chest	0.045	0.027	.102
Ps .9500-.9599 * chest	−0.010	0.038	.800
Ps .9400-.9499 * chest	0.023	0.041	.571
Ps < .9400 * chest	−0.040	0.021	.056
Ps > .9900 * abdomen, pelvic contents	0.023	0.021	.286
Ps .9800-.9899 * abdomen, pelvic contents	0.009	0.034	.799
Ps .9700-.9799 * abdomen, pelvic contents	−0.072	0.019	.000
Ps .9600-.9699 * abdomen, pelvic contents	0.010	0.040	.796
Ps .9500-.9599 * abdomen, pelvic contents	−0.014	0.051	.779
Ps .9400-.9499 * abdomen, pelvic contents	−0.014	0.087	.872
Ps < .9400 * abdomen, pelvic contents	0.002	0.027	.936
Ps > .9900 * extremity, pelvic girdle	0.059	0.010	.000
Ps .9800-.9899 * extremity, pelvic girdle	0.084	0.021	.000
Ps .9700-.9799 * extremity, pelvic girdle	0.019	0.010	.057
Ps .9600-.9699 * extremity, pelvic girdle	0.065	0.011	.000
Ps .9500-.9599 * extremity, pelvic girdle	0.041	0.025	.102
Ps .9400-.9499 * extremity, pelvic girdle	0.039	0.033	.230
Ps < .9400 * extremity, pelvic girdle	0.089	0.015	.000

F test for the model. *P* less than .001. Coefficient of determination, 0.505. Controlling for study variables indicated in Table 3.

Annex Table 2 Comparison of patient characteristics and critical care on days 1 and 2 between the inclusion and exclusion population (n, %)

		Exclusion	Inclusion	*P*
Overall		75 175 (90.2)	8207 (9.8)	
Age	<15 y	7044 (9.4)	686 (8.4)	<.001
	≥55 y	41 878 (55.7)	4970 (60.6)	
Age, mean, SD		53.5 (26.8)	56.4 (26.7)	<.001[a]
Sex				
	Male	38 498 (51.2)	4280 (52.2)	.106
Ambulance				
	Used	24 671 (32.8)	4419 (53.8)	<.001
Mechanism of injury				
	Blunt	74 322 (98.9)	7608 (92.7)	<.001
No. of PEC				
	0	64 514 (85.8)	6933 (84.5)	.004
	1	8860 (11.8)	1054 (12.8)	
	≥2	1801 (2.4)	220 (2.7)	
Procedure				
	Present	52 174 (69.4)	5568 (67.8)	.004
Hospital				
	Academic	11 558 (15.4)	1029 (12.5)	<.001
Outcome				
	Mortality (n on days 1 and 2)	1062 (66)	173 (17)	.078
Critical care, n (% of overall cases)				
Blood transfusion				
	n (%)	1646 (33.7)	379 (41.2)	<.001
Ventilation				
	n (%)	808 (64.2)	281 (77.4)	<.001
ICU care				
	n (%)	4907 (81.4)	1567 (93.6)	<.001
Use of OR				
	n (%)	15 867 (21.8)	1280 (65.8)	<.001
Blood transfusion, mL	Median (IQ)	800 (800)	800 (1200)	<.001[b]

Annex Table 2 (*continued*)

		Exclusion	Inclusion	*P*
OR time, min	Median (IQ)	120 (90)	135 (99)	<.001[b]
TC on days 1 and 2, US $	Median (IQ)	1173 (1491)	1301 (1862)	<.001[b]

[a] Compared by *t* test.
[b] Compared by Mann-Whitney test. Others by Fisher exact test.

References

[1] Harris IA, Young JM, Rae H, et al. Predictors of general health after major trauma. J Trauma 2008;64:969-74.

[2] Gabbe BJ, Simpson PM, Sutherland AM, et al. Functional measures at discharge. Are they useful predictors of longer term outcomes for trauma registries? Ann Surg 2008;247:854-9.

[3] Christensen MC, Ridley S, Lecky FE, et al. Outcomes and costs of blunt trauma in England and Wales. Critical Care 2008;12:R23.

[4] Boyd CR, Tolson MA, Copes WS. Evaluating trauma care: the TRISS method. J Trauma 1987;27:370-8.

[5] Champion HR, Copes WS, Sacco WJ, et al. A new characterization of injury severity. J Trauma 1990;30:539-46.

[6] Champion HR, Sacco WJ, Copes WS, et al. A revision of the trauma score. J Trauma 1989;29:623-9.

[7] Organisation und Datenverwaltung für landesgesundheitsfondsfinanzierte Krankenanstalten. Handbuch zur Dokumentation in Landesgesundheitsfonds-finanzierten Krankenanstalten (Anhang1) Available at http://www.bmgfj.gv.at/cms/site/attachments/0/7/6/CH0719/CMS1159518265839/anhang1_-_aufbau_und_inhalt_der_datenmeldungen.pdf

[8] Champion HR, Sacco WJ, Copes WS. Injury severity scoring again. J Trauma 1995;38:94-5.

[9] Murphy JG, Cayten CG, Ayten MD, et al. Controlling for the severity of injuries in emergency medicine research. Am J Emerg Med 1990;8:484-91.

[10] Ruger JP, Lewis LM, Richter CJ. Identifying high-risk patients for triage and resource allocation in the ED. Am J Emerg Med 2007;25:794-8.

[11] MacLennan P, Jones B, McGwin G, et al. Trauma center resource consumption and mortality. Am Surg 2006;72:1-6.

[12] Hirose M, Imanaka Y, Ishizaki T, et al. Profiling hospital performance of laparoscopic cholecystectomy based on the administrative data of four teaching hospitals in Japan. World J Surg 2005;29:429-35.

[13] Sundararajan V, Henderson T, Perry C, et al. New ICD-10 version of the Charlson Comorbidity Index predicted in-hospital mortality. J Clin Epidemiol 2004;57:1288-94.

[14] Sundararajan V, Quan H, Halfon P, et al. Cross-national comparative performance of three versions of the ICD-10 Charlson Index. Med Care 2007;45:1210-5.

[15] Lynne Moore L, Lavoie A, Sage NL, et al. Using information on preexisting conditions to predict mortality from traumatic injury. Ann Emerg Med 2008;52:356-64.

[16] Wu J, Sheng L, Ma Y, Gu J, et al. The analysis of risk factors of impacting mortality rate in severe multiple trauma patients with posttraumatic acute respiratory distress syndrome. Am J Emerg Med 2008;26:419-24.

[17] Colantonio A, Escobar MD, Chipman M, et al. Predictors of postacute mortality following traumatic brain injury in a seriously injured population. J Trauma 2008;64:876-82.

[18] Kilgo PD, Osler TM, Meredith W. The worst injury predicts mortality outcome the best: rethinking the role of multiple injuries in trauma outcome scoring. J Trauma 2003;55:599-607.

[19] Osler T, Glance L, Buzas JS, et al. A trauma mortality prediction model based on the anatomic injury scale. Ann Surg 2008;247:1041-8.

[20] AIS: Available at http://www.jast-hp.org/ [access 4 November 2008].

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Impact of timing of cholecystectomy and bile duct interventions on quality of cholecystitis care

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ABSTRACT

Background: Laparoscopic cholecystectomy (LC), with or without staged bile duct interventions (BDIs), is increasingly used in acute cholecystitis. However, few studies have concurrently evaluated the timing of cholecystectomy procedures and BDIs, and quality of cholecystectomy care in cholecystitis patients. We investigated the effects of timing of BDIs and cholecystectomy on resource utilization, in order to assess the suitability of procedure timing or approach as quality indicators.

Methods: In 2006, 5914 cholecystectomy patients were treated for cholecystitis at 423 hospitals in Japan. We analyzed patient demographics, BDIs (including endoscopic retrograde cholangiopancreatography, percutaneous gallbladder or common bile duct drainage, endoscopic sphincterotomy, and extraction of choledocholithiasis), procedure-related complications, hospital teaching status, postoperative length of stay (LOS) and charges (TC). Multivariate analysis was used to measure the impact of study variables on LOS, TC and complications.

Results: Open cholecystectomy (OC) was performed in 1318 patients and LC in 4596. Acute inflammation was diagnosed in 52% of OC and 28% of LC patients. The incidence of complications was 8.1% for OC and 5.5% for LC. BDIs were more frequent in LC patients, especially preoperatively. Early cholecystectomy was associated with lower resource use. Postoperative BDIs had a significant impact on LOS and complications. Laparoscopic early cholecystectomy was associated with fewer postoperative BDIs. Hospital variation was found among postoperative resource use and outcomes.

Conclusions: Delayed cholecystectomy and postoperative BDIs are not recommended. Use of postoperative BDIs might be a promising quality indicator for monitoring quality of preoperative care when performing early laparoscopic cholecystectomy in cholecystitis patients.

1. Introduction

Laparoscopic cholecystectomy (LC) is the preferred technique for patients with cholelithiasis, though controversies exist concerning its safety and efficacy in comparison with conventional, open cholecystectomy (OC).[1,2] As the use of LC increases, even in complicated cases, additional procedures for gallbladder or common bile duct complications will continue to be important for the successful completion of LC.

Debates have focused on the superiority of early, compared with delayed, cholecystectomy, laparoscopic methods versus laparotomy, the safety of LC for acute cholecystitis, and suitable management strategies for cholecystectomy patients.[3–14] The advantages and disadvantages of bile duct interventions (BDIs), including percutaneous gallbladder aspiration (PGBD) and endoscopic retrograde pancreaticocholangiography (ERCP), have also been discussed, and it has been suggested that the former procedure should be abandoned, and that the latter be performed

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preoperatively.[3,5,11,14] According to reports by the Ministry of Health, Welfare and Labor (MHWL) in Japan, the use of several types of BDIs has increased during the era of LC. The annual number of cases of endoscopic dilatation or sphincterotomy of the ampulla of Vater rose from 27,000 in 1996 to 38,000 in 2001.[15,16]

Most studies, however, have compared the clinical and economic aspects of LC, OC, or BDIs, or the effects of their timing, individually.[5,8,14] In addition, the definition of early cholecystectomy has varied from 24 to 96 h, either from the onset of symptoms or presentation at hospitals, to the start of cholecystectomy.[4,6,7,9,10,12,13] A comprehensive overview of the benefits of LC and OC, taking into account the timing of the procedures, including BDIs, is needed to determine their effects on length of hospital stay (LOS) and postoperative costs.[8]

It would be helpful to compare the advantages and disadvantages of preoperative and postoperative BDIs, from the viewpoint of resource use, and to determine the use of postoperative BDIs or delayed cholecystectomy as possible markers of quality of cholecystectomy care. The aims of the current study were to compare the quality of preoperative and postoperative BDIs, in terms of postoperative resource use and complications, and to measure the impact of factors associated with postoperative BDIs and complications in order to suggest an indicator of the quality of care for cholecystitis patients.

2. Materials and methods

2.1. Database

Information on patients with benign gallbladder disease treated by cholecystectomy at hospitals participating in our research project in 2006 was retrieved from the Japanese administrative database and analyzed. This database was used by MHWL to develop a Japanese case-mix classification system in 2002 and to profile hospital performance and assess hospital payments across 731 hospitals (82 academic hospitals and 649 community hospitals) in 2006. These hospitals provide acute care and participate in medical research and student and postgraduate education and training throughout Japan. The database contains discharge summaries and claims data for each hospital, and information is collected annually between July 1 and December 31. Our research project was approved by the ethics committee of the University of Occupational and Environmental Health in Kitakyushu, Japan.

2.2. Definition of variables

Study variables included age, gender, use of an ambulance, presence of acute or chronic inflammation of the gallbladder wall, presence of comorbidities, surgical technique (LC or OC), use of BDIs, use of total parenteral nutrition (TPN) in patients with severe disease requiring bowel rest, complications attributable to diagnostic and therapeutic procedures, outcome at discharge, and hospital teaching status. Patients were classified by age into two groups: <65 years of age and ≥65 years of age. Transfer by ambulance was used as an indicator of emergency admission.

Diagnoses in the database were coded according to the International Statistical Classification of Diseases, 10th version (ICD10). Of the ICD codes indexing disorders/diseases of the inflammatory gallbladder (K80.0-1, K80.3-4, K81S, K82.0-3, to K830), the following codes were considered to represent acute inflammation: K80.0, K80.3-4, K81.0, K82.2, and K83.3. All other ICD codes were considered to represent chronic inflammatory conditions.

Up to four comorbidities per patient were recorded. We used the Charlson Comorbidity Index (CCI), which was translated from its original ICD-9CM form into ICD10 code, to assess the severity of chronic comorbid conditions.[17] 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 (T80S-T87$), bowel obstruction (K650, K658-9, K660, K913), peritonitis (K560, K562, K565-7), and acute pancreatitis (K85).[18]

The database also lists five operative procedures per hospitalization. In the present study, we included patients receiving OC or LC without choledocholithotomy. Choledocholithotomy patients were excluded because they require different treatment options, such as T-tube management, and also require a longer postoperative LOS than cholecystectomy patients. LC cases converted to OC were considered as OC cases.

The timing of cholecystectomy was divided into three categories: cholecystectomy started within 48 h after admission was classified as early cholecystectomy, cholecystectomy started between 48 and 96 h was classified as intermediate cholecystectomy, and cholecystectomy started later than 96 h was classified as delayed cholecystectomy.

The three main types of BDIs were described as ERCP alone, external drainage, or internal drainage. External drainage involved PGBD or percutaneous transhepatic cholangiography and drainage (PTCD). Internal drainage involved balloon dilatation or sphincterectomy for the ampulla of Vater, extraction of common bile duct (CBD) stones, and stent insertion for benign CBD stenosis. BDIs performed either before or after cholecystectomy were counted. Cases with both post- and pre-operative BDIs were counted as postoperative cases.

We calculated the postoperative LOS (days) and total charges (TC; $1 = ¥100) as measures of total postoperative in-hospital cost. Preoperative or total LOS and TC were also calculated. Charges for hospital care in Japan are determined by a standardized fee-for-service payment system; fees accrued through this system are considered to be good estimates of healthcare costs.[19]

2.3. Statistical analysis

Categorical data on the frequency and proportion of every study variable were reported. Comparisons were made using Fisher's exact test. Box charts were used to display distributions of postoperative LOS and TC by timing of cholecystectomy and timing of various types of BDIs, stratified either by OC or LC. Continuous variables were compared using non-parametric tests. Multiple linear regression models were used to analyze the impact of combinations of timing and type of cholecystectomy on LOS and TC. Because the distributions of both LOS and TC were right-skewed, these values were $\log_{10}$-transformed in this model. Logistic regression analysis was applied to determine the relationships between cholecystectomy timing and approach and the occurrence of complications and use of postoperative BDIs. 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.

3. Results

Of the 1,895,249 patients from the 469 hospitals in the Japanese administrative database 2006, 5914 cholecystectomy patients were identified who had a diagnosis of cholecystitis at admission to 423 hospitals (including 664 cases treated at 63 academic hospitals and 5250 cases treated at 360 community hospitals). Five cholecystectomy patients died (three OC and two LC cases). Out of the 5914 cholecystectomy cases, 1318 (22.3%) patients underwent OC, and 4596 (77.7%) received LC. The median patient age was 71 years for OC and 60 years for LC. There were 890 patients >65 years of age in the OC group (67.5%) and 1780 (38.7%) in the LC group. There were

811 males in the OC group (61.5%) and 2341 (50.9%) in the LC group. Ambulance transfer patients accounted for 171 (13.0%) OC cases and 260 (5.7%) LC cases. Acute cholecystitis was diagnosed in a significantly higher proportion of OC (680; 51.6%) than LC patients (1299; 28.4%)). There were no comorbidities in 918 (69.7%) OC and 3804 (82.8%) LC patients.

Delayed cholecystectomy was prevalent in the OC group (667; 50.6%), whereas early cholecystectomy was more frequent in LC cases (1946; 42.3%). Preoperative BDIs were more frequent than postoperative BDIs. External drainage was the most common preoperative BDI procedure in OC patients (18.3%), while internal drainage was the preferred preoperative BDI (28.8%) among LC patients. Complications occurred in 107 (8.1%) OC and 252 (5.5%) LC patients. TPN was employed in 134 (10.2%) patients in the OC group. Median postoperative LOS was longer in OC (10 days) than in LC patients (5 days), and median postoperative TC was higher in OC ($5384) than in LC patients ($4349). Differences in median preoperative or total LOS and TC between OC and LC patients were statistically significant (Table 1).

A comparison of LOS and TC across four study variables is shown in Figs. 1 and 2. Statistically significant differences among several study variables were observed among both OC and LC patients.

After adjusting for demographic and clinical variables, laparoscopic cholecystectomy, at any point, was associated with significantly shorter postoperative LOS (standardized coefficients: delayed −0.372, intermediate period −0.338, early −0.573). Early to intermediate laparoscopic cholecystectomy resulted in lower postoperative TC (standardized coefficients: early −.0.538, intermediate period −0.337). All types of postoperative BDIs were associated with longer LOS but lower TC than preoperative BDIs. Acute inflammation and comorbidities were also predictors of higher postoperative use of resources (Table 2).

Among the study variables, postoperative ERCP and external drainage were stronger determinants of complications. Cholecystectomy timing and approach were not predictive of complications. Laparoscopic cholecystectomy was predictive of the use of postoperative BDIs. Academic hospitals were associated with more complications and postoperative BDIs (Table 3).

Table 1
Patient characteristics stratified by procedure ($N = 5914$).

	Cholecystectomy		p
	Open	Laparoscopic	
N (number of hospitals)	1318 (317)	4596 (406)	
Age (years)			
Median	71 [16]	60 [21]	<0.001[a]
≥65 years (%)	890 (67.5)	1780 (38.7)	<0.001
Gender (%)			
Male	811 (61.5)	2341 (50.9)	<0.001
Ambulance (%)			
Transferred	171 (13.0)	260 (5.7)	<0.001
Primary diagnosis (%)			<0.001
Acute cholecystitis	680 (51.6)	1299 (28.3)	
Charlson Comorbidity Index (%)			<0.001
0	918 (69.7)	3804 (82.8)	
1	261 (19.8)	576 (12.5)	
≥2	139 (10.5)	216 (4.7)	
Timing of cholecystectomy			<0.001
Early cholecystectomy	457 (34.7)	1946 (42.3)	
Intermediate period cholecystectomy	194 (14.7)	928 (20.2)	
Delayed cholecystectomy	667 (50.6)	1722 (37.5)	
Type or timing of BDIs			
Preoperative ERCP only	59 (4.5)	214 (16.2)	0.705
Postoperative ERCP	10 (0.8)	26 (2.0)	
Preoperative internal drainage only	100 (7.6)	379 (28.8)	<0.001
Postoperative internal drainage	31 (2.4)	41 (3.1)	
Preoperative external drainage only	241 (18.3)	358 (27.2)	0.405
Postoperative external drainage	4 (0.3)	7 (0.5)	
Procedure-related complications (%)	107 (8.1)	252 (5.5)	<0.001
Total parenteral nutrition (%)	134 (10.2)	135 (2.9)	<0.001
Hospital type (%)			<0.001
Academic	127 (9.6)	537 (11.7)	
Resource use			
Median preoperative length of stay (days)	5 [12]	3 [8]	<0.001[a]
Median preoperative total charge ($)	2620 [1955]	1351 [953]	<0.001[a]
Median postoperative length of stay (days)	10 [6]	5 [3]	<0.001[a]
Median postoperative total charge ($)	5384 [4644]	4349 [3191]	<0.001[a]
Median overall length of stay (days)	18 [18]	10 [10]	<0.001[a]
Median overall total charge ($)	8738 [5486]	6007 [3804]	<0.001[a]

[ ], Quartile range. BDI, bile duct intervention; ERCP, endoscopic retrograde pancreaticocholangiography.
[a] Non-parametric test, others; Chi-square test.

4. Discussion

Comparison of conventional and new procedures using more realistic economic evaluations, as well as monitoring of the quality of care, should take account of the effects of appropriate treatment strategies and of additional interventions needed for the successful completion of surgery. Our analysis demonstrated that preoperative BDIs were preferable to postoperative BDIs in terms of LOS, but not in terms of TC. Examination of the CBD should be completed preoperatively, rather than postoperatively, from the point of view of complications. Early cholecystectomy should be also recommended in order to reduce resource use. No patient or disease characteristics were associated with use of postoperative BDIs. Variations between hospitals were observed in terms of postoperative resource use, complications, and use of postoperative BDIs.

In our study, postoperative LOS and TC in patients undergoing early cholecystectomy, via laparotomy or laparoscopy, were estimated to be 12.7–13.3% (1.07–1.12 days) shorter and 41.5% ($6976–$6495) less, respectively, than in patients undergoing delayed cholecystectomy. These findings were similar to the results of previous research on laparoscopic cholecystectomy.[4,6] Furthermore, acute cholecystitis required postoperative stays that were 12.7% longer (1.07 days) than those required for chronic cholecystitis, which was in agreement with the results reported by Pessaux et al.[6]

In contrast, Low and colleagues found that delayed surgery was associated with 1-day shorter postoperative stays, and that delays in LC of more than 72 h could be allowed without reducing safety or cost-effectiveness.[12] The delay in surgery in the study by Low et al. might have included the period of 72–96 h, which was classified as intermediate timing for cholecystectomy in our study. The inclusion of patients who underwent cholecystectomy after 72–96 h might have affected the conclusions of Low et al., and the discrepancy between these and our results could be due to wide variations in the definition of timing of cholecystectomy or the use of preoperative BDIs. In addition, Low and colleagues acknowledged the role of PGBD in high-risk patients undergoing delayed cholecystectomy.

The use of ERCP, with or without intervention for stones in the CBD, should not be ignored, whether in cases of acute, inflamed gallbladder or cholecystitis with suspected stones in the CBD. Bosch and colleagues acknowledged that the costs associated with both OC and LC were controversial, because different studies utilized variable patient case-mixes, as well as a wide variety of methods for calculating costs.[20] Disease severity factors, such as presence of inflammation or suspected choledocholithiasis, demand prudent pre- or postoperative treatment strategies, which reflect variations in patient case-mixes.[21] Published research reports evaluating the relative economic benefits of LC versus OC might not have taken into account pre- or postoperative BDI procedures.

Several recent research reports focusing on treatment strategies of biliary surgery, however, have mentioned pre-, peri-, or postoperative applications of ERCP, internal drainage, or external drainage.[11] In earlier research by Zacks et al. and Schroeppel et al.,

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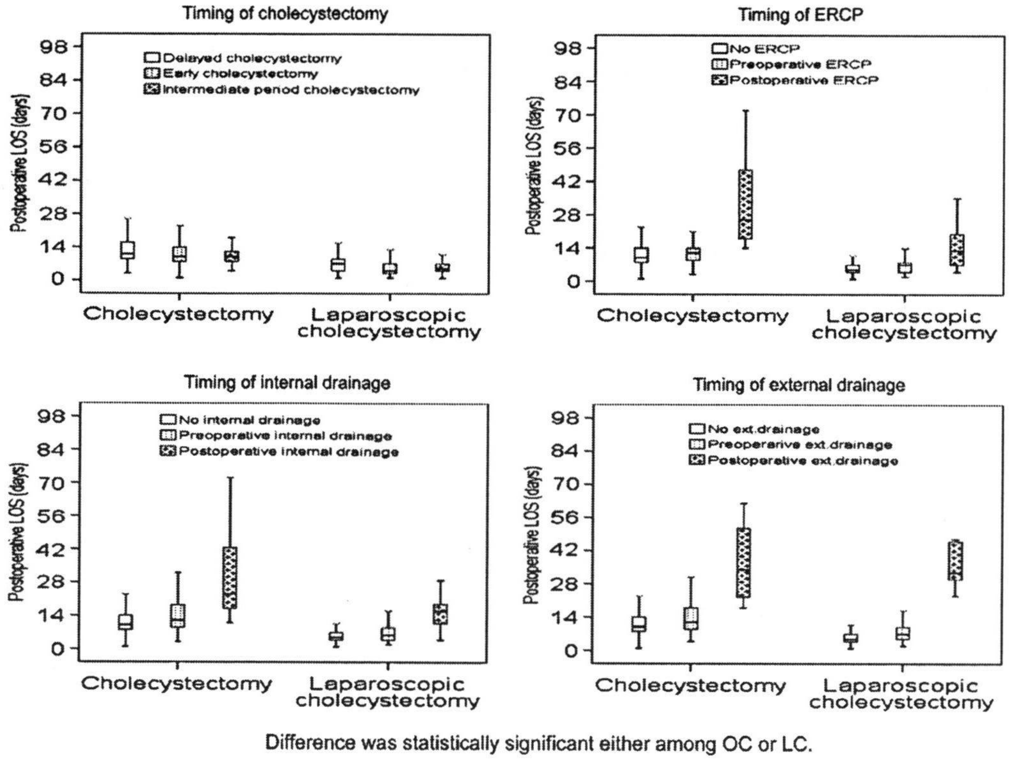

Fig. 1. Impact of timing of cholecystectomy and of bile duct interventions on length of stay (LOS) for open cholecystectomy (OC) vs. laparoscopic cholecystectomy (LC).

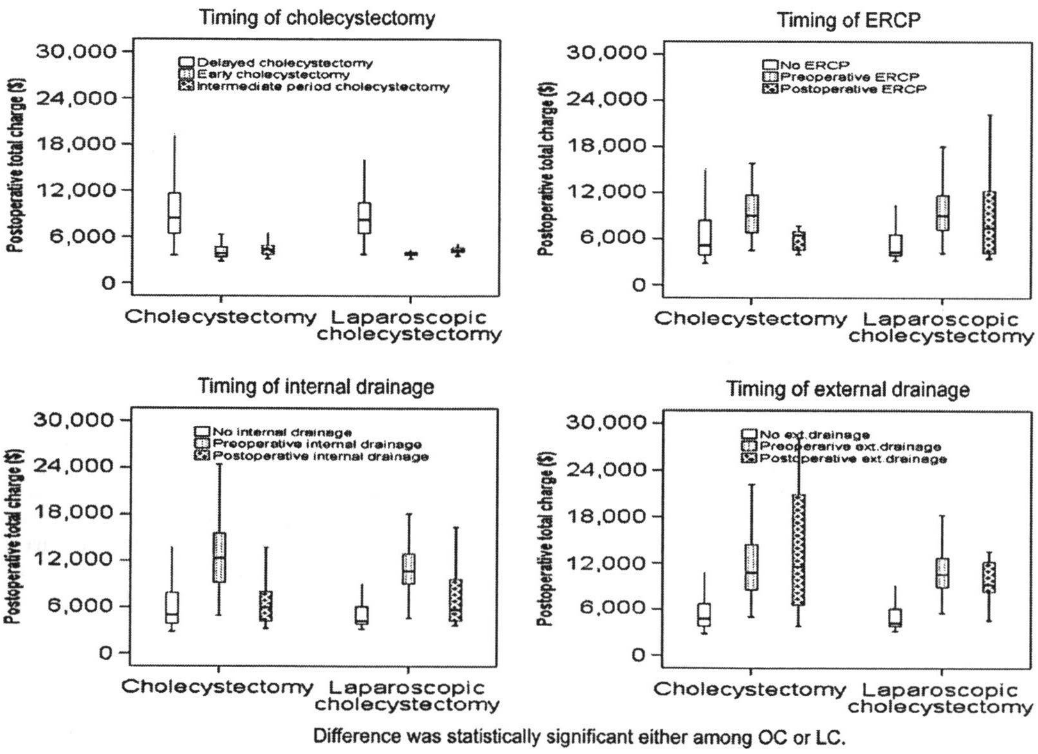

Fig. 2. Impact of timing of cholecystectomy and of order of bile duct interventions on total charges ($) for open cholecystectomy (OC) vs. laparoscopic cholecystectomy (LC).

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Table 2
Linear regression analysis of factors associated with log10-transformed postoperative length of stay (LOS) and total charge.

Independent variables	Postoperative LOS			Postoperative total charge		
	Unstandardized coefficient	Standardized coefficient	*p*	Unstandardized coefficient	Standardized coefficient	*p*
Intercept	0.926	0.000	<0.001	4.214	0.000	<0.001
Age ≥65 years	0.069	0.127	<0.001	0.012	0.031	<0.001
Male	−0.001	−0.002	0.830	0.004	0.010	0.089
Primary diagnosis (reference: chronic cholecystitis)						
Acute cholecystitis	0.052	0.090	<0.001	0.028	0.069	<0.001
Ambulance used	0.044	0.042	<0.001	0.035	0.047	<0.001
Charlson Comorbidity Index (reference: 0)						
1	0.027	0.035	0.001	0.009	0.016	0.006
≥2	0.061	0.053	<0.001	0.019	0.023	<0.001
Timing and cholecystectomy approach (for open delayed cholecystectomy)						
Laparoscopic delayed cholecystectomy	−0.222	−0.372	<0.001	0.007	0.015	0.106
Open intermediate period cholecystectomy	−0.040	−0.026	0.025	−0.197	−0.182	<0.001
Laparoscopic intermediate period cholecystectomy	−0.252	−0.338	<0.001	−0.178	−0.337	<0.001
Open early cholecystectomy	−0.059	−0.058	<0.001	−0.233	−0.323	<0.001
Laparoscopic early cholecystectomy	−0.331	−0.573	<0.001	−0.221	−0.538	<0.001
Timing of ERCP (reference: preoperative ERCP only)						
No ERCP	0.025	0.021	0.066	−0.084	−0.097	<0.001
Postoperative ERCP	0.316	0.090	<0.001	−0.060	−0.024	<0.001
Timing of internal drainage (reference: preoperative internal drainage only)						
No internal drainage	0.028	0.030	0.009	−0.169	−0.255	<0.001
Postoperative internal drainage	0.366	0.148	<0.001	−0.131	−0.075	<0.001
Timing of external drainage (reference: preoperative external drainage only)						
No external drainage	−0.026	−0.029	0.011	−0.164	−0.259	<0.001
Postoperative external drainage	0.435	0.069	<0.001	−0.058	−0.013	0.028
Total parenteral nutrition	0.177	0.136	<0.001	0.125	0.135	<0.001
Procedure-related complications	0.072	0.063	<0.001	0.006	0.007	0.215
Hospital type (reference: community)	−0.011	−0.013	0.193	0.015	0.024	<0.001

F test for the model: $p<0.001$; Coefficient of determination: LOS, 0.393; TC, 0.802. ERCP, endoscopic retrograde pancreaticocholangiography.

management options for symptomatic cholelithiasis with suspected choledocholithiasis were discussed, and preoperative ERCP or intraoperative BDIs were preferred, though pre- and postoperative BDIs were not compared.[8,21] A strength of our research design was the evaluation of the effects of timing of several types of BDIs on LOS and TC, by adjusting for factors such as inflammation and timing of cholecystectomy.

Several other studies have concluded that postoperative LOS was identical in PGBD groups and non-PGBD groups, and that the use of PGBD did not shorten hospital stay.[5,14] Our study, which found higher postoperative TC despite controlling for relevant covariates, also failed to find any advantage of PGBD.

Zacks and colleagues reported that LC with ERCP generated hospital charges that were 1.47-fold higher than those for LC without preoperative ERCP, but with intra-operative cholangiography or common bile duct exploration.[8] This result is in accordance with our study, in which TC for patients with pre- or post-operative ERCP were 1.21-fold or 1.06-fold higher, respectively, than TC for patients without ERCP.

Due to higher postoperative TC, preoperative ERCP or internal drainage might not be recommended. However, postoperative BDIs were shown to be associated with more complications and longer postoperative LOS, and were not predicted by any study variables except laparoscopic early cholecystectomy or hospital teaching status. The timing of BDIs could therefore act as a possible quality indicator in patients undergoing cholecystectomy. In the case of laparoscopic early cholecystectomy, use of postoperative BDIs might be a useful indicator for monitoring whether or not a hospital should plan a prudent preoperative treatment strategy for patients with cholecystitis.

There were some limitations of the methodology and interpretations in the current study. First, information was gathered from patients discharged during only a 6-month period in 2006, which could limit the ability to generalize from our results. However, the Japanese administrative database has now increased its annual sample size, with the addition of more participating hospitals, electronic collection of claims data, and an extension of the data collection period.

Second, our study was a cross-sectional, observational study-that lacked data on intention to treat (ITT). Using ITT methodology, more LC cases would have been counted. However, the demonstrated advantage of LC was so great that the conclusion would not have been affected by the use of this methodology.

In conclusion, this study used a Japanese administrative database to investigate the characteristics of OC and LC cases, with or without several kinds of BDIs, and to estimate differences in resource utilization associated with timing and approach of cholecystectomy, through controlling for timing of BDIs. Delayed cholecystectomy was associated with significantly higher resource use, after controlling for both the timing of BDIs and the status of gallbladder inflammation. Preoperative BDIs were preferable because of the shorter LOS and lower rate of complications. Fewer postoperative BDIs were associated with laparoscopic early cholecystectomy. Hospital variation was observed in terms of postoperative resource use, complications, and

Table 3
Factors associated with complications, postoperative bile duct interventions(BDIs) and delayed cholecystectomy.

Independent variables	Complications		Postoperative BDIs	
	Odds ratio	[95% CI]	Odds ratio	[95%CI]
Age				
<65 years	1.000		1.000	
≥65 years	1.409	[1.118–1.776]	1.435	[0.959–2.149]
Gender				
Female	1.000		1.000	
Male	1.121	[0.897–1.401]	1.338	[0.904–1.979]
Ambulance				
Not used	1.000		1.000	
Used	1.332	[0.936–1.896]	1.023	[0.533–1.962]
Primary diagnosis				
No inflammation	1.000		1.000	
Acute cholecysytitis	1.325	[1.048–1.674]	1.256	[0.838–1.883]
Timing and cholecystectomy approach				
Open delayed cholecystectomy	1.000		1.000	
Laparoscopic delayed cholecystectomy	1.148	[0.814–1.620]	0.888	[0.499–1.578]
Open intermediate period cholecystectomy	1.712	[0.978–2.995]	1.098	[0.422–2.861]
Laparoscopic intermediate period cholecystectomy	0.835	[0.521–1.337]	0.746	[0.357–1.558]
Open early cholecystectomy	1.087	[0.664–1.779]	1.185	[0.570–2.461]
Laparoscopic early cholecystectomy	0.852	[0.561–1.293]	0.368	[0.175–0.772]
Charlson Comorbidity Index				
0	1.000		1.000	
1	1.890	[1.445–2.472]	1.090	[0.652–1.823]
≥2	1.880	[1.298–2.722]	1.643	[0.889–3.036]
BDIs				
No ERCP	0.637	[0.418–0.972]	1.000	
Preoperative ERCP only	1.000		0.700	[0.276–1.775]
Postoperative ERCP	2.621	[1.102–6.233]	***	***
No internal drainage	0.523	[0.376–0.728]	1.000	
Preoperative internal drainage only	1.000		1.248	[0.676–2.305]
Postoperative internal drainage	1.916	[0.994–3.695]	***	***
No external drainage	0.994	[0.699–1.412]	1.000	
Preoperative external drainage only	1.000		0.763	[0.404–1.441]
Postoperative external drainage	5.684	[1.541–20.972]	***	***
Hospital type				
Community	1.000		1.000	
Academic	1.512	[1.114–2.053]	1.684	[1.015–2.795]

***Not included in the model. CI, confidence interval; BDI, bile duct intervention; ERCP, endoscopic retrograde pancreaticocholangiography.
Hosmer Lemeshow goodness of fit: Complications, $p = 0.139$, postoperative BDIs, $p = 0.873$.

use of postoperative BDIs. Postoperative BDIs used in conjunction with a laparoscopic approach could act as a possible quality indicator for scrutinizing the preoperative care process in patients receiving cholecystectomy for cholecystitis.

Conflicts of interest

None of the authors have any conflicts of commercial interest.

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Ethical approval

Approved by the ethics committee of the University of Occupational and Environmental Health, in Kitakyushu, Japan.

References

1. Johansson M, Thune A, Nelvin L, Stiernstam M, Westman B, Lundell L. Randomized clinical trial of open versus laparoscopic cholecystectomy for acute cholecystitis. *Br J Surg* 2005;**92**:44–9.
2. Purkayastha S, Tilney HS, Georgiou P, Athanasiou T, Tekkis PP, Darzi AW. Laparoscopic cholecystectomy versus mini-laparotomy cholecystectomy: a meta-analysis of randomised control trials. *Surg Endosc* 2007;**21**:1294–300.
3. Bergamaschi R, Tuech JJ, Braconier L, et al. Selective endoscopic retrograde cholangiography prior to laparoscopic cholecystectomy for gallstones. *Am J Surg* 1999;**178**:46–9.
4. Eldar S, Eitan A, Bickel A, et al. The impact of patient delay and physician delay on the outcome of laparoscopic cholecystectomy for acute cholecystitis. *Am J Surg* 1999;**178**:303–7.
5. Kim KH, Sung CK, Park BK, Kim WK, Oh CW, Kim KS. Percutaneous gallbladder drainage for delayed laparoscopic cholecystectomy in patients with acute cholecystitis. *Am J Surg* 2000;**179**:111–3.
6. Pessaux P, Tuech JJ, Rouge C, Duplessis R, Cervi C, Arnaud JP. Laparoscopic cholecystectomy in acute cholecystitis: A prospective comparative study in patients with acute vs chronic cholecystitis. *Surg Endosc* 2000;**14**: 358–61.
7. Chandler CF, Lane JS, Ferguson P, Thompson JE, Ashley SW. Prospective evaluation of early versus delayed laparoscopic cholecystectomy for treatment of acute cholecystitis. *Am Surg* 2000;**66**:896–900.
8. Zacks SL, Sandler RS, Rutledge R, Brown Jr RS. A population-based cohort study comparing laparoscopic cholecystectomy and open cholecystectomy. *Am J Gastroenterol* 2002;**97**:334–40.
9. Madan AK, Aliabadi-Wahle A, Tesi D, Flint LM, Steinberg SM. How early is early laparoscopic treatment of acute cholecystitis? *Am J Surg* 2002;**183**: 232–6.
10. Stevens KA, Chi A, Lucas LC, Porter JM, Williams MD. Immediate laparoscopic cholecystectomy for acute cholecystitis: no need to wait. *Am J Surg* 2006;**192**:756–61.
11. Hong DF, Xin Y, Chen DW. Comparison of laparoscopic cholecystectomy combined with intraoperative endoscopic sphincterotomy and laparoscopic exploration of the common bile duct for cholecystocholedocholithiasis. *Surg Endosc* 2006;**20**:424–7.
12. Low JK, Barrow P, Owera A, Ammori BJ. Timing of laparoscopic cholecystectomy for acute cholecystitis: Evidence to support a proposal for an early interval surgery. *Am Surg* 2007;**73**:1188–92.
13. Siddiqui T, MacDonald A, Chong PS, Jenkins JT. Early versus delayed laparoscopic cholecystectomy for acute cholecystitis: a meta-analysis of randomized clinical trials. *Am J Surg* 2008;**195**:40–7.

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14. Ezer A, Nursal TZ, Colakoglu T, Noyan T, Moray G, Haberal M. The impact of gallbladder aspiration during elective laparoscopic cholecystectomy: a prospective randomized study. *Am J Surg* 2008;**196**:456–9.
15. Ministry of Health. *Welfare and Labor. Survey of National Medical Care Insurance Services 1996*. Tokyo, Japan: Health and Welfare Statistics Association; 1998 (in Japanese).
16. Ministry of Health. *Welfare and Labor. Survey of National Medical Care Insurance Services 2001*. Tokyo, Japan: Health and Welfare Statistics Association; 2003 (in Japanese).
17. Sundararajan V, Henderson T, Perry C, Muggivan A, Quan H, Ghali WA. New ICD-10 version of the Charlson Comorbidity Index predicted in-hospital mortality. *J Clin Epidemiol* 2004;**57**:1288–94.
18. Zhan C, Miller MR. Administrative data based patient safety research: a critical review. *Qual Saf Health Care* 2003;**12**:58–63.
19. Hirose M, Imanaka Y, Ishizaki T, et al. Profiling hospital performance of laparoscopic cholecystectomy based on the administrative data of four teaching hospitals in Japan. *World J Surg* 2005;**29**:429–35.
20. Bosch F, Wehrman U, Saeger HD, Kirch W. Laparoscopic or open conventional cholecystectomy: clinical and economic considerations. *Eur J Surg* 2002;**168**:270–7.
21. Schroeppel TJ, Lambert PJ, Mathiason MA, Kotharl SN. An economic analysis of hospital charges for choledocholithiasis by different treatment strategies. *Am Surg* 2007;**73**:472–7.

Please cite this article in press as: Kuwabara K, et al., Impact of timing of cholecystectomy and bile duct interventions on quality of cholecystitis care, International Journal of Surgery (2009), doi:10.1016/j.ijsu.2009.04.003

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Contribution of bile duct drainage on resource use and clinical outcome of open or laparoscopic cholecystectomy in Japan

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Abstract

Aims Laparoscopic cholecystectomy (LC) is replacing conventional open cholecystectomy (OC) as a preferred surgical method for treating complicated biliary tract disorders. However, there have been few studies assessing the impact of staged bile duct drainage (BDD) on costs and clinical outcomes for either surgical approach. This study evaluated the impact of surgical technique and BDD on resource utilization and complication rates.
Methods This study included 2778 cholecystectomy patients treated for benign biliary tract diseases in 80 academic and 81 community hospitals. For both OC and LC patients, the following variables were analysed: demographics, clinical data, length of stay (LOS), total charges (TC; US$), procedure-related complications and hospital type. Multivariate analyses were used to determine the impact of BDD on LOS, TC and complication rates.
Results Of the 2778 cholecystectomy patients in the study, 2255 (81.2%) underwent LC. Inflammation was diagnosed in 55.6% of OC patients and 36.0% of LC patients. Complication was 9.4% in OC cases and 4.7% in LC cases. BDD was performed in 14.5% of OC cases and in 7.6% of LC cases. Diagnosis of inflammation, presence of co-morbidities and BDD each had a significant impact on LOS and TC. After risk adjustment, LC was associated with a reduction in LOS and TC, while BDD resulted in greater LOS and TC. LC and BDD were significantly associated with complications.
Conclusions The study suggested that BDD utilized more resources and had higher rates of complications. LC remains an appropriate procedure for cholecystectomy patients. Further study will be needed to evaluate the effect of pre-operative or post-operative BDD on quality of care.

Introduction

Following the introduction of laparoscopic approaches to cholecystectomy, these techniques surely reduce post-operative pain and allow patients to regain mobility more quickly, thereby decreasing opportunity costs and improving post-operative quality of life [1–6]. Despite ongoing controversies around the indications and contraindications for laparoscopic cholecystectomy (LC), multiple studies on the clinical and economic impact of LC have been conducted. Moreover, one study has compared laparoscopic approaches with minimally invasive approaches such as mini-laparotomy cholecystectomy for outcomes, including clinical practice variation and quality of care [7]. As the range of cases and levels of severity for which LC is used continues to grow, this surgical technique will face additional scrutiny regarding its contribution to efficiency and quality of care [8–13].

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 cases in 1998 up to 16 000 cases in 2003 (79% of all cholecystectomies). By comparison, annual cases of endoscopic dilatation or sphincterotomy of the ampulla of Vater rose from 27 000 in 1998 to 38 000 in 2003 [14,15]. As surgeons gain experience with laparoscopic approaches, the range of indications for LC has spread. This technique is now increasingly employed in complicated patients with previous abdominal surgery, acute cholecystitis or suspected choledocholithiasis. Alternate approaches such as bile duct examination are options for treatment of the latter disease state, which is why much attention has been focused on determining the economic and clinical implications of LC versus open cholecystectomy (OC). Where multiple procedures appear to be clinically beneficial, researchers have also evaluated the appropriate order of use [16,17].

Strategies for diagnosis and treatment of biliary tract diseases include the intra-operative or percutaneous transhepatic cholangiogram, dilation or sphincterotomy of the ampulla of Vater, and removal of common bile duct stones, often accompanied with the use of endoscopic retrograde cholangiopancreatography (ERCP). Among these strategies, staged bile duct drainages (BDDs) are critical for performing successful cholecystectomies in patients with acute cholecystitis, cholangitis or asymptomatic common bile duct stones. Because LC has been indicated in these types of complex cases, it is important to assess the impact of BDD in evaluating outcome measures for LC patients. To date, however, few studies have evaluated the effect of staged BDD on resource utilization or clinical outcomes for OC or LC patients. To account for the variation in resource consumption between LC and OC, particularly for more complicated cases, multiple factors must be included in the analytic model: patient demographics, presence of co-morbidities, level of urgency, presence of gall bladder inflammation, additional interventions such as BDD and hospital teaching status (academic or community) [13].

In this study, a Japanese administrative database was used to compare resource utilization and clinical outcome data between LC and OC cases. We used multivariate regression analysis to determine the independent effect of BDD on resource utilization and clinical outcomes, and we investigated the superiority of LC to OC and the contribution of BDD to cholecystectomy.

Materials and methods

This was a secondary data analysis that was embedded in the government research project on development of Japanese case-mix classification system. Anonymous claim and clinical data, provided by the MHWL authority with research contract, was collected annually only between 1 July and 31 October. This administrative database was constructed in 2002 and has been used to profile hospital performance and assess hospital payments across 82 academic hospitals (80 university hospitals, the National Cancer Center and the National Cardiovascular Center) and 92 community hospitals. Scattered throughout Japan, these academic hospitals deliver acute care, advance medical research, and educate students and residents. In this study, we analysed cholecystectomy cases treated for benign biliary tract diseases at participating hospitals.

Variable definition

Independent study variables included age, gender, use of an ambulance, presence of gallbladder wall inflammation, presence of co-morbidities, surgical technique (LC or OC), presence of BDD, need for total parenteral nutrition (TPN), complications attributable to the underlying procedures, outcome at discharge and hospital function (academic or community). We used length of stay (LOS) and total charges (TC; US$1 = ¥100) billed during admission as proxies for calculating the total in-hospital cost. In Japan, charges for hospital care are determined by a standardized fee-for-service payment system known as the national uniform fee table; fees accrued through this system are considered to be good estimates of health care costs [8]. TC in this study included doctor's fees, instrument costs, the costs of laboratory or imaging tests, and administration fees. Patients were stratified by age into two groups: under 65 years and 65 years or older. We used transfer by ambulance as a proxy for emergency admission. Diagnoses in the Diagnosis Procedure Combination (DPC) database were coded according to the International Statistical Classification of Diseases 10th version (ICD-10). Among ICD codes indexing disorders of the gallbladder or biliary tract, the following were considered to indicate inflammation as present: K80.0-1, K80.3-4, K81$, K82.1-3 and K830. All other codes were considered to indicate non-inflammatory conditions. The DPC database records a maximum of four co-morbidities per patient. To assess the severity of chronic co-morbid conditions, we used the Charlson Co-Morbidity Index (CCI), which was translated from its original ICD-9CM form into ICD-9 code [18,19]. A maximum of three 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). The database also tracks up to five operative procedures per hospitalization. We selected those patients receiving OC or LC without choledocholithotomy for inclusion in this study. LC cases that were converted to OC were counted as OC. BDD in this study was defined as percutaneous transhepatic gall bladder or common BDD (intermittent or continuous), balloon dilatation or sphincterotomy of the ampulla of Vater, removal of common bile duct stones or stent insertion for benign biliary tract stenosis. Patients receiving ERCP alone were also excluded.

Statistical analysis

All categorical 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 TC by surgical technique, presence of inflammation, CCI, presence of BDD, and hospital function. Continuous variables were compared across the OC and LC groups using a non-parametric test. We used multiple linear regression models to identify the impact of each surgical technique on LOS and TC. Because the distribution of both LOS and TC were right skewed, all data were log transformed in this model. A logistic regression model was used to evaluate the relationship between each surgical technique and the development of complications. Statistical analysis was performed using SPSS 16.0 (SPSS Inc, Chicago IL, USA). All reported *P*-values were two-tailed, and the level of significance was set at less than 0.05.

Results

Of the 441 142 patients discharged between 1 July and 31 October 2003, we identified 2778 cholecystectomy patients across 161 hospitals (1449 cases from 80 academic hospitals and 1279 from 81 community hospitals). There were three mortalities recorded (one OC case and two LC cases). A total of 523 patients (18.8%) underwent OC, and 2255 (81.2%) underwent LC. The median patient age was 65 years for OC and 57 years for LC (quartile range 19 and 20 years, respectively). OC was the preferred surgical technique in patients older than 65 years (50.7% of cases), while LC was preferred in younger patients (66.9%). Males accounted for 61.8% of OC cases and 47.5% of LC cases. Approximately 8.8% of OC cases involved an ambulance-transfer patient, as compared with only 3.2% of LC cases. Inflammation was diagnosed in a significantly higher proportion of OC cases (55.6%) than LC cases (36%). Of the patients who underwent OC, 72.3% had no co-morbidities, compared with 84.5% of patients who underwent LC. Complications occurred in 9.4% of OC cases and 4.7% of LC cases. BDD was performed in 14.5% of OC and 7.6% of LC. TPN was more common in OC (15.1%). The majority of OC were performed at academic hospitals (54.1%), whereas the majority of LC were performed at community hospitals (55.8%). There were significant differences between OC and LC across a number of independent variables (Table 1).

A comparison of LOS and TC across four study variables is shown in Figs 1 and 2. No statistically significant differences were identified in LOS for LC patients at either community or academic centers ($P = 0.175$). For both surgical techniques, the variables of inflammation, BDD and CCI were found to be statistically significant predictors of LOS and TC.

After adjusting for demographic and clinical variables, LC and BDD were most significantly associated with LOS and TC. The standardized coefficient of LC was −0.237 for LOS and −0.169 for TC, whereas that of BDD was 0.252 for LOS and 0.350 for TC. The presence of complications was a predictor of LOS and TC (Tables 2 & 3).

Age, inflammation, LC, BDD and hospital type were all significantly associated with procedure-related complications. Among them, the odds ratio (OR) for procedure-related complications was highest for hospital function [3.965, 95% confidence intervals (CI) = 2.614–6.016] and lowest for LC (OR = 0.569, CI = 0.385–0.842). BDD was also significantly associated with complications (OR = 2.291, CI = 1.482–3.542) (Table 4).

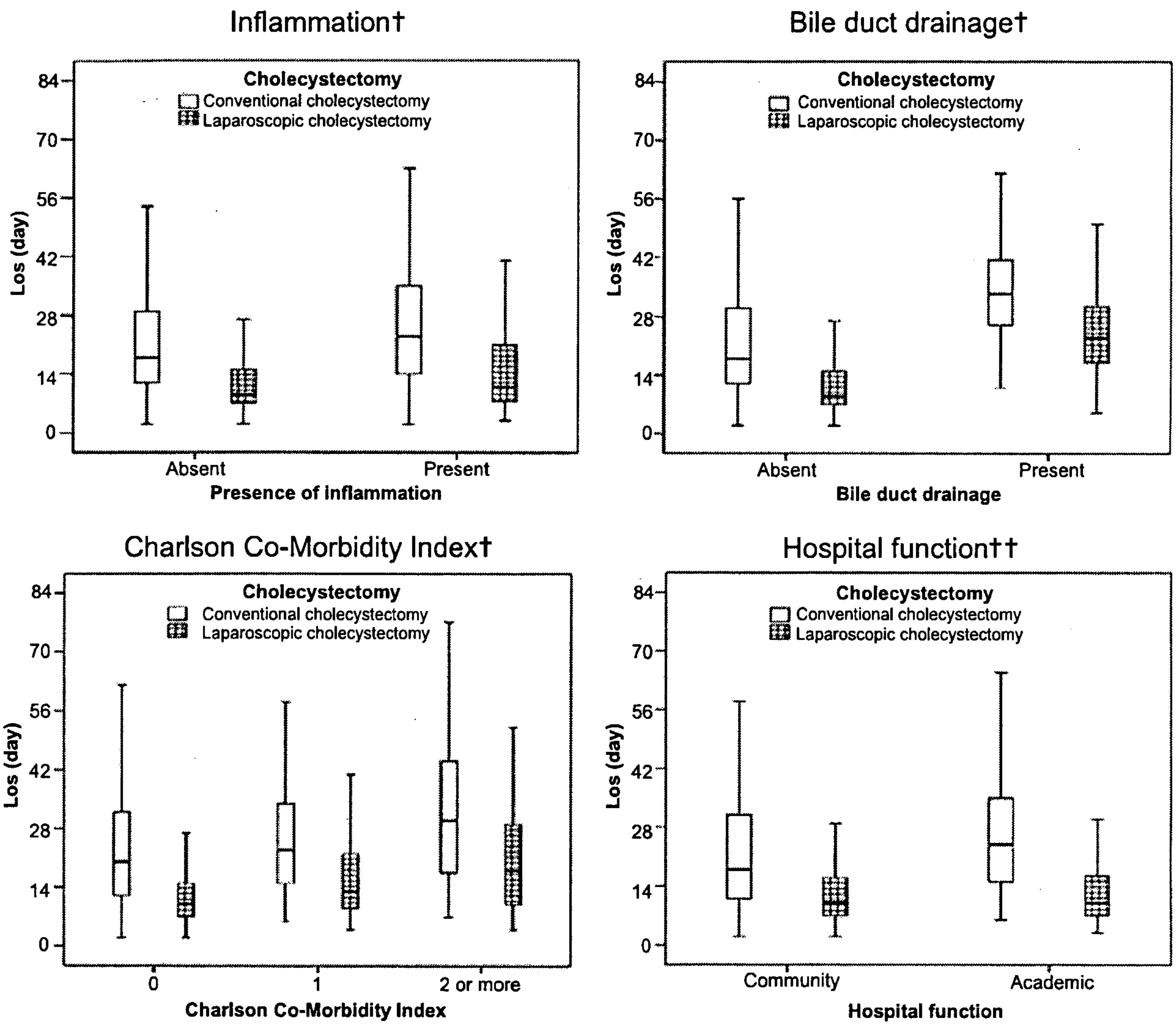
Discussion

Using an administrative database of 161 hospitals in Japan, this study presents the descriptive characteristics of cholecystectomy cases and assesses the independent effects of LC, OC and BDD on

Table 1 Characteristics of biliary surgery patients ($n = 2778$), stratified by procedure

	Cholecystectomy		
	Open	Laparoscopic	*P*-value
n (total hospitals)	523 (240)	2255 (1259)	
Age (years)			
Median	65 [19]	57 [20]	0.000*
65 years or older (%)	265 (50.7)	747 (33.1)	0.000
Gender (%)			0.000
Male	323 (61.8)	1072 (47.5)	
Ambulance (%)			0.000
Transferred	46 (8.8)	72 (3.2)	
Primary diagnosis (%)			0.000
Inflammation	291 (55.6)	812 (36.0)	
Charlson Co-Morbidity Index (%)			0.000
0	378 (72.3)	1905 (84.5)	
1	94 (18)	256 (11.4)	
2 or more	51 (9.8)	94 (4.2)	
Procedure-related complication (%)	49 (9.4)	106 (4.7)	0.000
Bile duct drainage (%)	76 (14.5)	172 (7.6)	0.000
Total parenteral nutrition (%)	79 (15.1)	57 (2.5)	0.000
Hospital type (%)			0.000
Academic	283 (54.1)	996 (44.2)	
Community	240 (45.9)	1259 (55.8)	
Resource use			
Median length of stay (days)	21 [21]	10 [9]	0.000*
Academic	24 [20]	10 [10]	0.000*
Community	18 [20]	10 [9]	0.000*
Median total charge (US$)	9 474 [6773]	6156 [3067]	0.000*
Academic	10 693 [6863]	6295 [2989]	0.000*
Community	8 555 [6506]	5997 [3115]	0.000*

*Kruskal–Wallis test; *P*-values without asterisks were obtained using chi-square test.
Values inside square brackets represent the quartile range.



† : statistically significant ($P < 0.001$) for each type of cholecystectomy.
†† : statistically significant ($P < 0.001$) for conventional cholecystectomy, $P = 0.175$ for laparoscopic cholecystectomy

Figure 1 Impact of inflammation, Charlson Co-Morbidity Index, bile duct drainage and hospital function on LOS (laparoscopic cholecystectomy versus open cholecystectomy). LOS, length of stay.

LOS, TC and complications. After controlling for the severity of co-morbid conditions, inflammation, hospital function and other independent co-variables, LC was still found to have a significantly shorter LOS, lower TC and lower complication rate, as compared with OC. BDD was the single independent variable to raise LOS, TC and complication rates.

There are some limitations to this study. First, information was gathered from discharged patients for only 4 months in 2003, which may limit the generalizability of these results. For future research efforts, however, the DPC database has increased its sample size each year, with additional participating hospitals and an extension of the data collection period to 6 months. Second, patients undergoing both pre-operative and post-operative phases of BDD were combined into a single group, which may distort the findings around resource utilization. Claims data, including procedure dates, are now being electronically collected throughout the year; this growing database will eventually allow researchers to parse out the impact of each BDD phase on LOS and TC. Third, this study lacked some important clinical data, including the results of any pathological findings or the presence of obesity [20]. We felt, however, that the ICD-10-coded diagnosis was a suitable proxy for disease severity and pathologic findings. In addition, the 2002 World Health Report found that the average body mass index is 23.4 in developed Western Pacific countries including Japan, and 26.7 in developed European countries [21]. Because the incidence of obesity in Japan is so low, we felt that this data would not significantly alter our results.

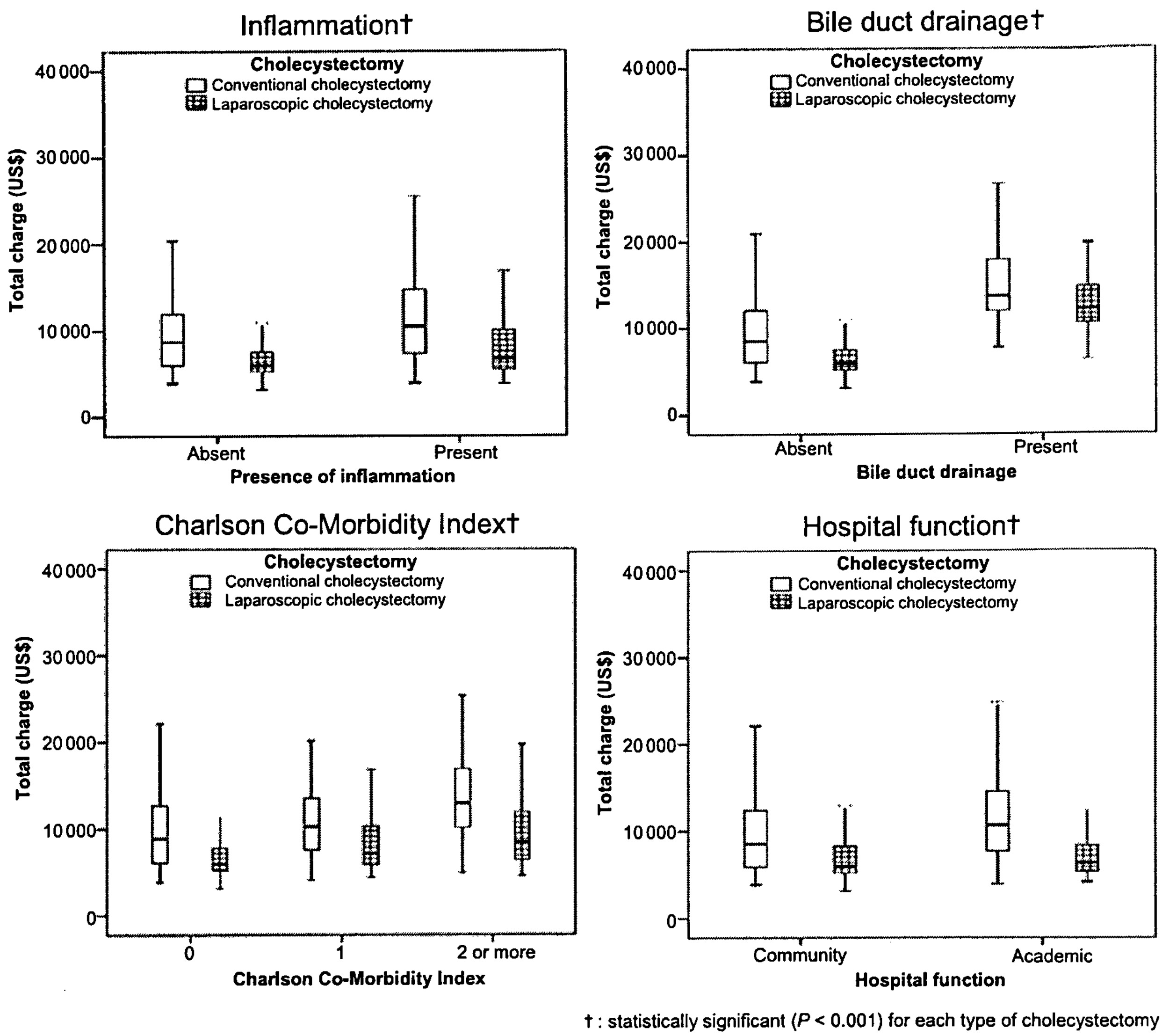


Figure 2 Impact of inflammation, Charlson Co-Morbidity Index, bile duct drainage and hospital function on total charges (US$) (laparoscopic cholecystectomy versus open cholecystectomy).

From an administrative and clinical standpoint, this description of cholecystectomy cases with and without BDD will provoke additional scrutiny around the effectiveness of LC versus OC, a matter that remains controversial because of the increasing use of LC in complicated cases. Our results support, in part, findings from a similar study conducted by Zacks *et al.* This study examined 43 433 cholecystectomy patients (OC 35–87% and LC 13–65%) from a population-based database between 1991 and 1995 [13]. They reported a mean LOS of 7.4 days and a mean TC of US$12 125 for OC cases, as compared with 4.1 days and US$9139 for LC cases. They also found that the risk-adjusted TC was US$3868 lower for LC (95% CI = US$1115–1690) than for OC. Based on these findings, they concluded that LC was the treatment of choice for acute and chronic cholecystitis. While our results also found a lower rate of resource utilization for LC procedures, their study did not evaluate the impact of biliary tract procedures such as BDD, and may have therefore overestimated the effect of LC.

Another critique of the Steven *et al.* study was that their analysis did not include hospital function as a variable. The importance of this variable was noted in a recent paper by Carbonell *et al.* [9]. Geographic hospital location and hospital teaching status can significantly impact resource utilization and clinical outcomes. In our study, complication rates ranged from 2.5% in community hospitals to 8.2% in academic hospitals. By comparison, Carbonell reported that complication rates varied by nearly 11% between teaching and non-teaching hospitals. While inconsistent definitions of complications do not allow direct comparison of the

Table 2 Linear regression analysis of factors associated with log-transformed length of stay

Independent variables	Unstandardized coefficient	95% confidence interval	Standardized coefficient	*P*-value
Intercept	1.108	[1.080, 1.136]		0.000
Age under 65 years	0.108	[0.089, 0.127]	0.180	0.000
Male	−0.001	[−0.019, 0.016]	−0.002	0.900
Ambulance car used	0.100	[0.055, 0.144]	0.070	0.000
Reference: non-inflammatory primary diagnosis				
Inflammation	0.048	[0.029, 0.067]	0.081	0.000
Reference: Charlson Co-Morbidity Index of 0				
1	0.053	[0.026, 0.080]	0.061	0.000
2 or more	0.132	[0.092, 0.172]	0.102	0.000
Procedure-related complication	0.074	[0.035, 0.113]	0.059	0.000
Reference: open cholecystectomy				
Laparoscopic cholecystectomy	−0.175	[−0.199, −0.152]	−0.237	0.000
Bile duct drainage	0.255	[0.223, 0.286]	0.252	0.000
Supportive care				
Total parenteral nutrition	0.232	[0.190, 0.275]	0.174	0.000
Hospital type (reference: community)	0.020	[0.002, 0.038]	0.035	0.032

F-test for the model; $P < 0.001$, $R^2 = 0.346$.

Table 3 Linear regression analysis of factors associated with log-transformed total charges (US$)

Independent variables	Unstandardized coefficient	95% confidence interval	Standardized coefficient	*P*-value
Intercept	3.834	[3.817, 3.850]		0.000
Age under 65 years	0.062	[0.051, 0.073]	0.163	0.000
Male	0.007	[−0.003, 0.017]	0.019	0.193
Ambulance car used	0.102	[0.076, 0.128]	0.113	0.000
Reference: non-inflammatory primary diagnosis				
Inflammation	0.036	[0.025, 0.047]	0.097	0.000
Reference: Charlson Co-Morbidity Index of 0				
1	0.032	[0.017, 0.048]	0.059	0.000
2 or more	0.090	[0.067, 0.114]	0.110	0.000
Procedure-related complication	0.030	[0.007, 0.053]	0.038	0.009
Reference: open cholecystectomy				
Laparoscopic cholecystectomy	−0.079	[−0.093, −0.065]	−0.169	0.000
Bile duct drainage	0.223	[0.205, 0.242]	0.350	0.000
Supportive care				
Total parenteral nutrition	0.196	[0.171, 0.221]	0.233	0.000
Hospital type (reference: community)	0.022	[0.011, 0.032]	0.060	0.000

F-test for the model; $P < 0.001$, $R^2 = 0.434$.

findings, the repeated conclusion that hospital status significantly impacts clinical outcomes raises important questions. Should general surgeons be permitted to perform LC, or should the procedure be restricted to surgeons specializing in upper gastrointestinal or hepatopancreaticobiliary fields [22]?

A few reports have assessed post-operative quality of life as a dependent variable in the comparison of LC and OC. Nilsson *et al.* used the EuroQOL (EQ-5D) (patient mobility, self-care, activity, pain/discomfort and mood) and the visual analogue scale (VAS) to evaluate perceived health status for patients pre-operatively and then at time-points of 1 week, 1 month and 1 year following the operation [12]. This group reported no differences between surgical techniques in patient general well-being by the VAS or across the five dimensions of EuroQol at post-operative month 1. In Japan, LOS for all hospital admissions is two to three times longer than in Western countries [23,24]. One reason for the increased LOS is that Japanese hospitals generally provide wound management and nursing home service in addition to acute medical care. The fiscal impact of these longer LOS include the real costs consumed during each episode of acute illness as well as the reduced burden on family members after discharge. The adjusted gain in resource utilization for LC, as compared with that for OC, was approximately 7 days and US$1800 in our study, corresponding to the results reported by Bosch *et al.* [11,13]. (5 days and US$800) and Zacks *et al.* (3 days and US$3000). The implications of Nilsson *et al.*'s conclusion for our study, however, suggest that the overall health gain attributable to the LC technique may be unexpectedly small, and that the affordability of LC may be question-

Table 4 Logistic regression analysis of factors associated with procedure-related complications

Independent variables	Odds ratio	95% confidence interval	*P*-value
Age			
<65 years	1.000		
≥65 years	2.147	[1.518, 3.037]	0.000
Sex			
Female	1.000		
Male	0.941	[0.670, 1.323]	0.727
Ambulance			
Not used	1.000		
Used	0.793	[0.375, 1.674]	0.543
Primary diagnosis			
Non-inflammatory	1.000		
Inflammatory	1.706	[1.201, 2.423]	0.003
Charlson Co-Morbidity Index			
0	1.000		
1	1.797	[1.195, 2.701]	0.005
2 or more	1.337	[0.722, 2.476]	0.356
Procedure			
Open cholecystectomy	1.000		
Laparoscopic cholecystectomy	0.569	[0.385, 0.842]	0.005
Bile duct drainage			
Not used	1.000		
Used	2.291	[1.482, 3.542]	0.000
Total parenteral nutrition			
Not used	1.000		
Used	0.771	[0.403, 1.478]	0.434
Hospital type			
Community	1.000		
Academic	3.965	[2.614, 6.016]	0.000

Hosmer–Lemeshow goodness for fit; $P = 0.653$.

able for those Japanese hospitals demanding longer LOS [25]. Another study to determine the advantage of laparoscopic approaches may therefore be necessary in this laparoscopic generation. Future research efforts could assess whether pre-operative or post-operative staging of BDD, by aid of ERCP, would offer higher quality of care for LC patients.

In conclusion, this study used an administrative database to present the descriptive characteristics of OC and LC cases in Japan and to evaluate the differences in resource utilization and clinical outcomes between these surgical techniques. Our analysis demonstrated that LC was associated with significantly reduced LOS, TC and procedure-related complications, as compared with OC. The impact of staged BDD on LOS and TC, moreover, was significantly greater than the choice of surgical technique. Further study on the influence of pre-operative or post-operative BDD staging on quality of LC or OC will be needed to more efficiently utilize current technology in this flowering era of laparoscopic surgery.

References

1. Nakata, M., Saeki, H., Yokoyama, N., Kurita, A., Takiyama, W. & Takashima, S. (2000) Pulmonary function after lobectomy: video-assisted thoracic surgery versus thoracotomy. *Annals of Thoracic Surgery*, 70 (3), 938–941.
2. Olmi, S., Magnone, S., Bertolini, A. & Croce, E. (2005) Laparoscopic versus open appendectomy in acute appendicitis: a randomized prospective study. *Surgical Endoscopy*, 19 (5), 1193–1195.
3. Katkhouda, N., Mason, R. J., Towfigh, S., Gevorgyan, A. & Essani, R. (2005) Laparoscopic versus open appendectomy: a prospective randomized double-blind study. *Annals of Surgery*, 242 (3), 439–448.
4. Guller, U., Hervey, S., Purves, H., Muhlbaier, L. H., Peterson, E. D., Eubanks, S. & Pietrobon, R. (2004) Laparoscopic versus open appendectomy. Outcome comparison based on a large administrative database. *Annals of Surgery*, 239 (1), 43–52.
5. Johansson, M., Thune, A., Nelvin, L., Stiernstam, M., Westman, B. & Lundell, L. (2005) Randomized clinical trial of open versus laparoscopic cholecystectomy for acute cholecystitis. *British Journal of Surgery*, 92 (4), 44–49.
6. Urbach, D. R., Harnish, J. L., McIlroy, J. H. & Streiner, D. L. (2006) A measure of quality of life after abdominal surgery. *Quality of Life Research*, 15 (6), 1053–1061.
7. Purkayastha, S., Tilney, H. S., Georgiou, P., Athanasiou, T., Tekkis, P. P. & Darzi, A. W. (2007) Laparoscopic cholecystectomy versus mini-laparotomy cholecystectomy: a meta-analysis of randomised control trials. *Surgical Endoscopy*, 21 (8), 1294–1300.
8. Hirose, M., Imanaka, Y., Ishizaki, T., Sekimoto, M., Harada, Y., Kuwabara, K., Hayashida, K., Oh, E. H. & Evans, S. E. (2005) Profiling hospital performance of laparoscopic cholecystectomy based on the administrative data of four teaching hospitals in Japan. *World Journal of Surgery*, 29 (4), 429–435.
9. Carbonell, A. M., Lincourt, A. E., Kercher, K. W., Matthews, B. D., Cobb, W. S., Sing, R. F. & Heniford, B. T. (2005) Do patient or hospital demographics predict cholecystectomy outcomes? A nationwide study of 93 578 patients. *Surgical Endoscopy*, 19 (6), 767–773.
10. Poulose, B. K., Arbogast, P. G. & Holzman, M. D. (2006) National analysis of in-hospital resource utilization in choledocholithiasis management using propensity scores. *Surgical Endoscopy*, 20 (2), 186–190.

11. Bosch, F., Wehrman, U., Saeger, H. D. & Kirch, W. (2002) Laparoscopic or open conventional cholecystectomy: clinical and economic considerations. *European Journal of Surgery*, 168 (5), 270–277.
12. Nilsson, E., Rosa, A., Rahmqvist, M., Backman, K. & Carlsson, P. (2004) Cholecystectomy: costs and health-related quality of life: a comparison of two techniques. *International Journal for Quality in Health Care*, 16 (6), 473–482.
13. Zacks, S. L., Sandler, R. S., Rutledge, R. & Brown, R. S. Jr (2002) A population-based cohort study comparing laparoscopic cholecystectomy and open cholecystectomy. *American Journal of Gastroenterology*, 97 (2), 334–340.
14. Ministry of Health, Welfare and Labor (1998) Survey of National Medical Care Insurance Services 1996 (in Japanese). Tokyo: Health and Welfare Statistics Association.
15. Ministry of Health, Welfare and Labor (2003) Survey of National Medical Care Insurance Services 2001 (in Japanese). Tokyo: Health and Welfare Statistics Association.
16. Hadad, S. M., Vaidya, J. S., Baker, L., Koh, H. C., Heron, T. P. & Thompson, A. M. (2007) Delay from symptom onset increases the conversion rate in laparoscopic cholecystectomy for acute cholecystitis. *World Journal of Surgery*, 31 (6), 1298–1301.
17. Schroeppel, T. J., Lambert, P. J., Mathiason, M. A. & Kothari, S. N. (2007) An economic analysis of hospital charges for choledocholithiasis by different treatment strategies. *American Surgeon*, 73 (5), 472–477.
18. Sundararajan, V., Henderson, T., Perry, C., Muggivan, A., Quan, H. & Ghali, W. A. (2004) New ICD-10 version of the Charlson Comorbidity Index predicted in-hospital mortality. *Journal of Clinical Epidemiology*, 57 (12), 1288–1294.
19. Zhan, C. & Miller, M. R. (2003) Administrative data based patient safety research: a critical review. *Quality & Safety in Health Care*, 12, 58–63.
20. Simopoulos, C., Botaitis, S., Karayiannakis, A. J., Tripsianis, G., Pitiakoudis, M. & Polychronidis, A. (2007) The contribution of acute cholecystitis, obesity, and previous abdominal surgery on the outcome of laparoscopic cholecystectomy. *American Surgeon*, 73 (4), 371–376.
21. Rodgers, A. (2002) *The world health report 2002 – reducing risks, promoting healthy life. Statistical annex.* Available at: http://www.who.int/whr/2002/en/whr02_en.pdf (last accessed 22 October 2008).
22. Boddy, A. P., Bennett, J. M., Ranka, S. & Rhodes, M. (2007) Who should perform laparoscopic cholecystectomy? A 10-year audit. *Surgical Endoscopy*, 21 (9), 1492–1497.
23. Matsui, K., Fukui, T., Hira, K., Sobashima, A., Okamatsu, S., Nobuyoshi, M., Hayashida, N. & Tanaka, S. (2001) Differences in management and outcomes of acute myocardial infarction among four general hospitals in Japan. *International Journal of Cardiology*, 78 (3), 277–284.
24. Ishizaki, T., Imanaka, Y., Hirose, M., Kuwabara, K., Ogawa, T. & Harada, Y. (2002) A first look at variations in use of breast conserving surgery at five teaching hospitals in Japan. *International Journal for Quality in Health Care*, 14 (5), 411–418.
25. Cothren, C. C., Moore, E. E., Johnson, J. L., Moore, J. B., Ciesla, D. J. & Burch, J. M. (2005) Can we afford to do laparoscopic appendectomy in an academic hospital? *American Journal of Surgery*, 190 (6), 950–954.