

Table 4. Factors associated with open cholecystectomy and early cholecystectomy

Independent variables	Early cholecystectomy		Open cholecystectomy	
	Odds ratio	[95% CI]	Odds ratio	[95% CI]
Age				
<65 years	1.000		1.000	
≥65 years	0.751	[0.693–0.815]	2.809	[2.509–3.145]
Sex				
Female	1.000		1.000	
Male	0.954	[0.883–1.030]	1.572	[1.406–1.759]
Ambulance				
Not used	1.000		1.000	
Used	0.459	[0.353–0.596]	1.664	[1.330–2.081]
Primary diagnosis				
No inflammation	1.000		1.000	
Acute cholecystitis	0.678	[0.596–0.770]	4.959	[4.270–5.759]
Chronic cholecystitis	0.875	[0.803–0.955]	2.091	[1.831–2.389]
Cholecystitis related comorbidity				
Absent	1.000		1.000	
Present	0.964	[0.679–1.371]	2.295	[1.650–3.193]
Charlson Comorbidity Index				
0	1.000		1.000	
1	0.650	[0.575–0.735]	1.424	[1.224–1.658]
≥2	0.485	[0.397–0.592]	2.772	[2.266–3.390]
Preoperative BDIs				
No ERCP	1.000			
Preoperative ERCP only	0.039	[0.023–0.065]	0.783	[0.587–1.044]
No internal drainage	1.000			
Preoperative internal drainage	0.028	[0.016–0.050]	0.875	[0.681–1.124]
No external drainage	1.000			
Preoperative external drainage	0.013	[0.006–0.030]	1.690	[1.391–2.053]
Region				
Tokyo metropolitan	1.000		1.000	
Hokkaido	0.542	[0.431–0.682]	0.587	[0.419–0.823]
Tohoku	0.939	[0.766–1.152]	0.415	[0.299–0.576]
Kanto	0.672	[0.572–0.789]	1.522	[1.218–1.902]
Chubu	1.164	[0.979–1.383]	1.006	[0.791–1.280]
Kinki	1.401	[1.197–1.640]	0.807	[0.642–1.014]
Chugoku	1.245	[1.016–1.525]	0.846	[0.639–1.119]
Shikoku	0.721	[0.558–0.933]	0.689	[0.469–1.014]
Kyushu	0.778	[0.660–0.916]	0.694	[0.545–0.884]
Okinawa	2.429	[1.802–3.272]	0.762	[0.504–1.151]
Ownership				
National	1.000		1.000	
Municipal	1.598	[1.321–1.933]	0.722	[0.557–0.935]
Private for-profit	2.479	[2.079–2.956]	0.577	[0.455–0.731]
Private non-profit	2.399	[1.993–2.887]	0.547	[0.426–0.703]
Hospital type				
Community	1.000		1.000	
Academic	0.698	[0.613–0.794]	0.695	[0.573–0.845]

CI, confidence interval; CBD, common bile duct; BDI, bile duct intervention

Hosmer Lemeshow goodness for fit: early cholecystectomy, $P = 0.058$; open cholecystectomy, $P = 0.042$

pating and an extension of the data collection period through electronic collection of the claims data. Second, our study lacked the data on intention to treat (ITT), where more of the LC cases would have been counted. The proportion of LC was so great that the impact of the BDIs or the results from this study would not be changed. Third, our study lacked some important clinical data, including detailed pathological information

(acute gangrenous or acalculous cholecystitis, chronic cholecystitis or hydrops). Nevertheless, we thought that use of the ICD10-coded diagnosis was a suitable proxy for some disease severity or for the pathological findings, such as gallbladder perforation.

In conclusion, this study used an administrative database to present the variation in preoperative resource use in cholecystectomy patients in Japan, and to evalu-

ate the variation between the hospitals. Our analysis demonstrated BDI to still be associated with a significantly longer LOS, and that the hospital region, ownership, and function determined the use of BDI. Both the treatment strategies as well as some clinical guidelines for selecting the optimal preoperative care should therefore also be investigated in the future.

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Impact of Hospital Case Volume on the Quality of Laparoscopic Colectomy in Japan

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Abstract

Introduction The increased use of laparoscopic colectomy for colon cancer requires the evaluation of hospital case volume, quality care, and training systems, considering the difficulty of this surgery for various tumor locations.

Materials and methods We assessed the quality of this procedure in Japan, based on hospital case volume and tumor location. A total of 3,765 patients were enrolled across 567 hospitals between July and December 2007. We analyzed patient characteristics, postoperative surgical complications, the administration of stapling devices or chemotherapy, hospital volume and teaching status, postoperative length of stay, total charges, and operating room time. Hospitals were classified into four case-volume categories: high (≥ 5 cases per month), intermediate to high (3–4), low to intermediate (1–2), and low (< 1). Multivariate analysis was used to test the impact of hospital category and tumor location.

Results Ten high-volume hospitals performed 401 cases, while 355 low-volume hospitals did 903. Hospital case volume, operating time, and complications affected postoperative stay and total costs. Longer procedural time was an independent predictor of complications. Tumor location, case volume, and teaching status explained the variations in procedural time individually but not complications. Training systems highlighting the applicability of techniques are important to promote the quality of laparoscopic colectomy.

Keywords Laparoscopic colectomy · Hospital volume ·
Tumor location · Quality

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Introduction

Short- or long-term outcomes derived from observational or randomized control studies in single or community-based hospitals have confirmed the benefit of laparoscopic colectomy (LC). This has gained a reputation of greater safety and efficacy than conventional open colectomy.^{1–9} In Japan, the number of LCs performed has increased from about 5,000 in 2003 to 8,400 in 2007.^{10,11}

The diffusion of innovative surgical practices such as LC has required much training in operating room (OR) or skill-based laboratories, and effective training programs in endoscopic surgery need to be developed by clinical experts or societies. However, working time restrictions might limit the smooth progress of surgical training. In addition, the demand for efficiency in healthcare economics has forced institutions to reprocess or redeploy single-use devices for performing LC.^{12,13} These are complex circumstances concerning newly emerging surgery, and questions about the relationship between hospital case volume and the quality of patient care following LC procedures must be answered.

Previous randomized control studies on LC have often excluded cases involving surgery on the transverse colon. Moreover, there are different levels of difficulty in performing LC for the cecum through the sigmoid colon. Typically, difficulty has been measured by operative time, which might bias the results of any study on the association between case volume and healthcare quality for patients undergoing LC.^{14,15} Furthermore, high case-volume hospitals often accommodate healthier patients, even though such hospitals tend to attract integrated multidisciplinary teams who can offer quality care during the peri- or postoperative periods.^{16,17} There should be attention paid to the analysis of patient mix and disease mix, as these might cause variations in resource use or OR time associated with postoperative complications such as surgical site infection.¹⁸ Otherwise, centralization of complex surgery or technical credentialing toward high-volume hospitals or surgeons might diminish patient accessibility or adversely affect the appropriate care or timing in hospitals expected by healthcare decision makers.

In this context, it would be helpful to explore the association of hospital volume and the quality of LC by examining the effects of tumor location and procedural time on postoperative resource use or on complication rates. This would allow healthcare administrators to evaluate the contribution of hospital case volume to outcomes and to updating LC training systems. In addition, it will help in determining policies for the valid regionalization of surgical procedures. The aims of this study were to analyze the descriptive characteristics of patients with colonic cancer who were treated by LC, according to hospital case-volume category. We also examined the effect of OR time on the

rate of complications as well as the relationship between hospital volume, OR time, and complications.

Materials and Methods

Database

We used the Japanese administrative healthcare database to analyze cases including patients treated by LC for colonic cancer at hospitals participating in our research project during 2007. The Ministry of Health, Labor, and Welfare originally constructed this database to develop the Japanese case-mix classification system in 2002. This was used to profile hospital performance and to assess hospital payments across 1,428 hospitals (83 academic hospitals and 1,345 community hospitals) in 2007.

These hospitals deliver acute care, further the aims of medical research, and educate students and postgraduate trainees. The database includes discharge summaries and claims data for every hospital. This information is collected between July 1 and December 31 annually. Our research project, covering 965 voluntary attending hospitals (84 academic hospitals and 891 community hospitals), was for the purpose of refining Japanese case-mix classification as well as the contribution to the health policy. This project was approved by the ethics committee of the University of Occupational and Environmental Health in Kitakyushu, Fukuoka, Japan.

Definitions of Variables

The study variables included age, gender, mortality, presence of comorbidities, tumor location, administration of chemoagents, the quantity of blood transfused, the number of days postoperative pain control needed, use of stapling devices (circular or linear staplers), and the hospital case volume or function. We also examined complications attributable to the diagnostic and therapeutic procedures, operating room time (in minutes), postoperative length of stay (LOS, in days), and total costs (TC; US\$1=¥100). Postoperative care processes or resource usage were counted from the first postoperative day.

Patients were categorized by age into two groups: <65 and ≥65 years of age. Therapeutic chemoagent use was used as a proxy indicating an advanced gastric cancer stage. Diagnoses in this database were coded according to the International Statistical Classification of Diseases, 10th version (ICD10). Up to four comorbidities were recorded per patient. We used the Charlson Comorbidity Index (CCI) to measure the severity of chronic comorbid conditions.¹⁹ A maximum of four complications were also recorded, defined as unexpected events after admission. Postoperative surgical complications were defined as any of the following ICD10 codes: bleeding or hematoma (T810); bowel

obstruction (K650, K658-9, K660, K913); peritonitis or intra-abdominal abscesses (K560, K562, K565-7); acute pancreatitis (K85); perforations (T812) or wound infections (T813, T816).²⁰ LC cases that were converted to open colectomy (OC) were recorded as OC cases. This database also contains the date of medical practices administered. We calculated the postoperative LOS or TC billed during admission, which are deemed as proxies for in-hospital costs. Japanese charges for hospital care are determined by a standardized fee-for-service payment system and are considered good measures of overall healthcare costs.²¹ TC in this study included physician fees, instrument costs, costs of laboratory or imaging tests, and administration fees, all of which are listed in the national uniform tariff table. OR time was defined as the total time required for anesthesiologists' procedures, for preparation and positioning of video-images, and active operative time by the surgeons.

Based on the number of LCs performed in a 6-month study period, hospitals were classified into four case-volume groups. Any hospital providing fewer than one LC per month was considered a low case-volume hospital (LVH). Hospitals providing one through two LCs per month were deemed low to intermediate (LIVH), and those providing three to four LCs per month were recorded as intermediate to high (IHVH). Those delivering five or more LC per month were deemed high volume hospitals (HVH).¹⁷ They were also divided into community and academic (teaching) hospitals.

Statistical Analysis

Categorical data were reported in number and proportion by hospital case-volume category and compared using Fisher's exact test. Continuous variables were compared across hospital volume categories using analysis of variance. A multiple linear regression model was used to determine the effect of hospital volume on postoperative LOS, TC, and OR time. Multiple logistic regression models were used to identify the impact of hospital volume or OR time on the occurrence of complications. Statistical analysis was performed using SPSS version 16.0 (SPSS Inc., Chicago, IL, USA). All reported *p* values were two-tailed, and the level of significance was set to 0.05.

Results

Of 2,716,219 patients from the 965 hospitals in this administrative database, 3,765 undergoing LC were identified for primary colonic cancer treatment across 567 hospitals (698 cases from 66 academic hospitals and 3,067 cases from 501 community hospitals). Ten HVHs treated 401 patients, 43 IHVHs treated 939 patients, 159 LIVHs treated 1,522 patients, and 355 LVHs treated 903

patients (median LC caseload per 6 months: HVH=36.5, IHVH=21, LIVH=9, and LVH=2). For the patient characteristics, the mean patient age, proportion of patients aged ≥ 65 years, proportion of male patients, mortality rate, and tumor locations were not statistically different across hospital volume categories. The overall proportion of postoperative surgical complications was also not statistically different (3.7% in HVH, 4.8% in IHVH, 5.3% in LIVH, and 5.6% in LVH, $p=0.502$). HVHs accommodated more patients with no chronic comorbid conditions (84.3%), while IHVHs treated the fewest (71.6%). The proportion of patients treated in academic hospitals was higher in HVHs than in LVHs (Table 1).

Regarding postoperative care, the proportions of patients receiving a blood transfusion and the amounts of blood transfused did not vary significantly between hospital categories ($p=0.210$ and 0.115 , respectively). The use of stapling devices was more frequent in HVHs, whereas there was less administration of chemoagents, less indication of epidural anesthesia, and fewer postoperative fasting days in HVHs. Once indicated, days of epidural anesthesia were longer in HVHs. Postoperative LOS and TC were all significantly greater in LVHs (15.5 days and US\$ 3,907, respectively) than in IHVH (12.2 days and US\$ 3,305, respectively). OR time was significantly longer in LVHs (283 min) than in HVHs (270 min; Table 2).

Tumor location, use of stapling devices, and hospital case-volume category were not significantly related with the occurrence of complications. Longer OR time was a significant determinant of more frequent complications (adjusted odds ratio [aOR] 1.003, 95% confidence intervals [CI] 1.002–1.005). No significant difference in complication rate was observed between academic and community hospitals (aOR 0.780; 95% CI 0.515–1.183; Table 3).

After adjusting for covariates, having a CCI score recorded, complication rate, use of chemoagents, and longer OR times were significantly associated with more postoperative LOS and TC. Among tumor location categories, the transverse colon was a significant determinant only for postoperative LOS. In terms of hospital volume, IHVHs consumed fewer postoperative resources. Transverse and descending colon locations were significant predictors of longer OR time. HVHs recorded significantly shorter OR times than LIVHs or LVHs, and the academic hospitals used longer OR times than did community hospitals (Table 4).

Discussion

Using this large Japanese administrative healthcare database, we investigated the relationship of case volume in community-based hospitals to the quality of care among patients receiving LC. This study disclosed

Table 1 Patient Characteristics by Hospital Case-Volume Category

Hospital case volume	High	Intermediate to high	Low to intermediate	Low	<i>P</i>
<i>N</i>	401	939	1,522	903	
Number of hospitals, median number of LC cases	10, 36.5	43, 21	159, 9	355, 2	
Age					
Mean [SD]	67.2 [11.4]	67.6 [11.4]	67.7 [11.1]	67.3 [10.7]	0.819 ^a
65 years or more	243 (60.6)	585 (62.3)	972 (63.9)	576 (63.8)	0.593
Gender					
Male	220 (54.9)	516 (55)	827 (54.3)	521 (57.7)	0.433
Outcome					
Mortality	3 (0.7)	3 (0.3)	3 (0.2)	2 (0.2)	0.319
Tumor location: <i>n</i> (%)					0.425
Cecum to ascending colon	150 (37.4)	361 (38.4)	627 (41.2)	341 (37.8)	
Transverse colon	63 (15.7)	121 (12.9)	179 (11.8)	118 (13.1)	
Descending colon	29 (7.2)	69 (7.3)	121 (8.0)	62 (6.9)	
Sigmoid colon	159 (39.7)	388 (41.3)	595 (39.1)	382 (42.3)	
Charlson comorbidity index: <i>n</i> (%)					<0.001
1	25 (6.2)	125 (13.3)	189 (12.4)	126 (14.0)	
2	16 (4.0)	67 (7.1)	105 (6.9)	64 (7.1)	
3 or more	22 (5.5)	75 (8.0)	96 (6.3)	36 (4.0)	
Postoperative surgical complications: <i>n</i> (%)					
Overall	15 (3.7)	45 (4.8)	80 (5.3)	51 (5.6)	0.502
Peritonitis or intra-abdominal abscess	9 (2.2)	28 (3.0)	34 (2.2)	33 (3.7)	0.185
Bowel obstruction	5 (1.2)	16 (1.7)	34 (2.2)	15 (1.7)	0.510
Bleeding or hematoma	1 (0.2)	10 (1.1)	10 (0.7)	7 (0.8)	0.422
Others	2 (0.5)	7 (0.7)	21 (1.4)	10 (1.1)	0.310
Hospital category					
Academic	142 (35.4)	246 (26.2)	236 (15.5)	74 (8.2)	<0.001

LC laparoscopic colectomy

^a Compared by analysis of variance; others by Fisher's exact test

instructive findings different from some previous articles, which had demonstrated that hospital case volume influenced postoperative resource use, but not the occurrence of procedure-related complications. Surgery to the transverse or descending colon and procedures carried out in ILVHs and LVHs consumed more OR time, which led to greater postoperative resource usage and more complications.

The OR time in this study was 60 to 120 min longer than in previous reports based on a single center or a highly selected institution.^{2,4,14,17,22,23} This was because additional time was counted as being spent on procedures by the attending anesthesiologists, the preparation of video images, or positioning of patients in addition to the actual procedural "skin-to-skin" time. To access the efficiency advantages of laparoscopic surgery over conventional open surgery or to clarify the time-consuming problems in operating room, we believe that additional "real" costs

such as the OR time included in our study should be included in any future analysis. Such an economic or quality evaluation in healthcare should clarify the comparative benefits of laparoscopic surgery or the contributions of sophisticated skill training or team expertise. However, the procedural time in our study was still slightly longer than those noted in the studies by Austin et al.²² or the COLOR Study Group.¹⁴ The latter study reported that median OR theater time ranged from 190 min in high-volume hospitals to 240 min in low-volume ones.^{14,23} That might be because our study was community based or because some of the participating hospitals might prioritize lymph node dissection or the completion of a totally laparoscopic procedure.

Hospital case volume did not correlate directly with complications but with OR time and postoperative resource use, which was also associated with the complication rate. Supposing that hospital case volume might exert an indirect

Table 2 Care Processes and Resource Use by Hospital Case-Volume Category

Hospital case volume	High	Intermediate to high	Low to intermediate	Low	P
Blood transfusion					
<i>n</i> (%)	15 (3.7)	59 (6.3)	74 (4.9)	44 (4.9)	0.210
Total mL, mean [SD]	1,013 [639]	1,354 [2,040]	892 [542]	855 [513]	0.115 ^a
Use of stapling devices					
<i>n</i> (%)	352 (87.8)	790 (84.1)	1,191 (78.3)	666 (73.8)	<0.001
Mean [SD]	2.5 [1.5]	2.3 [1.4]	2.2 [1.5]	2.0 [1.6]	<0.001 ^a
Administration of chemoagents					
<i>n</i> (%)	13 (3.2)	58 (6.2)	89 (5.8)	78 (8.6)	0.002
Postoperative fasting period (days)					
Mean [SD]	3.3 [2.3]	3.6 [1.8]	4 [2.1]	4.5 [2.5]	<0.001 ^a
Use of epidural anesthesia					
<i>n</i> (%)	279 (69.6)	742 (79.0)	1,256 (82.5)	708 (78.4)	<0.001
Days, mean [SD]	5.1 [2.8]	4.5 [2.7]	4.2 [2.4]	4.4 [2.9]	<0.001 ^a
Operating room time (min)					
Mean [SD]	270.0 [69.1]	272.2 [75.2]	279.6 [80.7]	283.0 [81.0]	0.004 ^a
Postoperative LOS (day) [SD]	13.2 [10.5]	12.2 [8.0]	14.0 [8.6]	15.5 [9.6]	<0.001 ^a
Postoperative TC (\$) [SD]	3,504 [3,920]	3,305 [4,129]	3,473 [2,399]	3,907 [2,879]	0.001 ^a

[SD] standard deviation. LOS length of stay, TC total charges

^a Compared by analysis of variance, others by Fisher's exact test

impact on complications, we should pay careful attention to this factor. This is because it would include surgeons' or hospital experience such as proficient procedures or skill training delivered, as well as expert teams providing multidisciplinary medical care throughout hospitalization.^{16,17} Contrary to the finding by Chen et al. that operative time is a poor surrogate measure for evaluating the quality of LC, the OR time in this series was significantly associated with the occurrence of complications and resource use.^{18,23} Tumor location also helped explain the variations in OR time and postoperative LOS. Regardless of the surgeon's skill training level or operating staff education, either in the operating theater directly or in a skill-training laboratory, there might still be many important aspects relevant to the credentialing of surgical organizations. These would include the mastery of many steps of LC, skillful use or appropriate delivery of auxiliary devices for reducing blood loss or operating theater time, along with attempts to complete surgery totally by laparoscope.^{14,24–26} Through measuring the OR time, the present study also included a quantitative comparison of the difficulty of performing LC for four types of tumor locations, providing evidence relevant to that of the qualitative study by Jamali et al.²⁷ Development of some targeted skill training for resource-intensive type of colectomy would help diminish the difference of OR time between the groups according to teaching status or case volume.

Given the demands of a case-volume-based referral policy, the need to assure patient safety and pressure on the medical staff or hospitals to reduce costs, imprudent "quality improvement initiatives" could inhibit appropriate access to general surgery beyond LC. This would not help the goals of good medical practice or outcomes, especially in the evolving field of laparoscopic surgery.^{28,29} Health-care policy makers should make more efforts to resolve the "miasma" of the volume–quality relationship in laparoscopic surgery and to supply sufficient financing for medical staff education.

There were some limitations to the methodology of this study. First, it was purely observational, and information was gathered from discharged patients during only 6 months in 2007, which may limit our ability to generalize from these results. However, this database also covered around one half of all LCs performed in Japan in 2007, and almost all of the hospitals delivering LC were covered in this study.¹¹ Moreover, every hospital case-volume category in this study included sufficient caseload to allow valid comparisons with other studies. Second, there was a shortage of some important clinical data, including cancer stage or body mass index. In fact, tumor stages were gathered voluntarily in this administrative database, but there were many missing values. This database did not adhere to the "intention-to-treat" principles, and conversion rate was not considered. Registries managed by some relevant clinical societies should be included to improve

Table 3 Factors Associated with Postoperative Surgical Complications

	Odds ratio	[95% CI]	<i>p</i>
Age			
Under 65 years	1.000		
65 years or more	1.064	[0.777–1.456]	0.699
Gender			
Female	1.000		
Male	1.920	[1.39–2.652]	<0.001
Charlson comorbidity index			
Absent	1.000		
1	1.537	[1.034–2.285]	0.033
2	1.497	[0.89–2.517]	0.128
3 or more	1.233	[0.675–2.255]	0.496
Location of primary tumor			
Cecum to ascending colon	1.000		
Transverse colon	1.012	[0.645–1.59]	0.957
Descending colon	0.919	[0.521–1.623]	0.772
Sigmoid colon	0.788	[0.56–1.11]	0.173
Chemoagent use			
Absent	1.000		
Present	1.042	[0.576–1.885]	0.891
Postoperative pain control			
Absent	1.000		
Present	0.925	[0.642–1.333]	0.677
Number of stapling devices			
Hand sewing	1.000		
1	0.744	[0.42–1.316]	0.309
2	1.399	[0.893–2.194]	0.143
3	1.037	[0.605–1.778]	0.893
4 or more	1.077	[0.699–1.66]	0.737
Operating room time			
1 min	1.003	[1.002–1.005]	<0.001
Case volume			
	1.000		
Intermediate to high	1.154	[0.629–2.117]	0.643
Low to intermediate	1.233	[0.692–2.195]	0.477
Low	1.273	[0.694–2.336]	0.435
Hospital type			
Community	1.000		
Academic	0.780	[0.515–1.183]	0.243
Goodness of fit for the model			0.916

CI confidence intervals

data on the quality of surgical procedures, in cooperation with the Japanese administrative database. In terms of body mass, obesity does not have a significant effect on operative time, according to the findings by Austin et al.^{22,30}. Asian people tend to be leaner than those in western countries, so we believe that this factor would not change the general applicability of the ordinal results derived from this study. Third, postoperative LOS for all hospital admissions in Japan is double that of hospitals in Western countries

because Japanese hospitals generally supply nursing services in addition to acute medical care.^{2,4,5,31} The fiscal impact of a longer LOS thus reflects the real costs in LCs.

Conclusions

We used an administrative database to analyze LC procedures in Japan among four categories of hospital case

Table 4 Factors Associated with Postoperative Length of Hospital Stay (Days), Total Charge (in US\$) and Operating Room Time

	Postoperative LOS			Postoperative TC			OR time		
	Estimation	95% CI	<i>p</i>	Estimation	95% CI	<i>p</i>	Estimation	95% CI	<i>p</i>
Intercept	7.5	[6–9]	<0.001	1,503	[957–2,049]	<0.001	235.0	[223.1–246.9]	<0.001
Age	1.3	[0.7–1.8]	<0.001	331	[131–530]	0.001	0.0	[–5.1 to 5.2]	0.989
Male	0.0	[–0.5 to 0.6]	0.900	38	[–155 to 231]	0.700	15.5	[10.5–20.4]	<0.001
Charlson comorbidity index (for zero)									
1	1.1	[0.3–1.9]	0.009	340	[45–634]	0.024	15.7	[8.1–23.3]	<0.001
2	0.3	[–0.8 to 1.4]	0.579	192	[–193 to 577]	0.328	10.7	[0.7–20.6]	0.035
3 or more	1.9	[0.8–3.1]	0.001	831	[425–1,237]	<0.001	10.5	[0.0–20.9]	0.050
Postoperative surgical complications									
Present	11.0	[9.8–12.2]	<0.001	3,553	[3,118–3,988]	<0.001	– ^a		
Location of primary tumor (for cecum to ascending colon)									
Transverse colon	1.0	[0.2–1.9]	0.015	184	[–123 to 491]	0.241	10.0	[2–17.9]	0.014
Descending colon	0.4	[–0.7 to 1.4]	0.464	–4	[–389 to 381]	0.983	34.8	[24.9–44.7]	<0.001
Sigmoid colon	–0.3	[–0.9 to 0.3]	0.311	–30	[–247 to 187]	0.787	2.6	[–3.0 to 8.2]	0.367
OR time									
More than one minute	0.011	[0.008–0.015]	<0.001	4	[3–5]	<0.001	– ^a		
Chemoagent use									
Present	9.3	[8.2–10.4]	<0.001	2,849	[2,454–3,244]	<0.001	4.1	[–6.1 to 14.3]	0.435
Postoperative pain controll									
Present	0.5	[–0.1 to 1.2]	0.111	90	[–148 to 328]	0.458	6.4	[0.3–12.6]	0.040
Number of stapling devices (for hand sewing)									
1	1.3	[0.4–2.2]	0.006	416	[85–748]	0.014	20.4	[11.8–28.9]	<0.001
2	0.5	[–0.4 to 1.3]	0.261	110	[–190 to 411]	0.471	7.5	[–0.2 to 15.3]	0.057
3	1.7	[0.7–2.6]	<0.001	779	[440–1,118]	<0.001	6.0	[–2.8 to 14.7]	0.180
4 or more	0.2	[–0.6 to 0.9]	0.639	125	[–148 to 399]	0.370	5.4	[–1.7 to 12.4]	0.136
Case volume (for high)									
Intermediate to high	–1.6	[–2.6 to –0.6]	0.001	–378	[–729 to –27]	0.035	2.6	[–6.4 to 11.7]	0.571
Low to intermediate	0.2	[–0.7 to 1.1]	0.723	–185	[–519 to 150]	0.279	12.6	[4.0–21.2]	0.004
	1.4	[0.5–2.4]	0.004	193	[–168 to 554]	0.294	17.4	[8.1–26.7]	<0.001
Hospital (for community)									
Academic	–0.3	[–1 to 0.4]	0.448	136	[–120 to 392]	0.299	18.7	[12.1–25.2]	<0.001

F test for the model; *p*<0.001. Coefficient of determination: postoperative LOS, 0.189; TC, 0.146; OR, 0.050

CI confidence interval

^aNot included in the model

volume. We estimated the effects of tumor location, case volume, and procedural time on complication rates and on postoperative resource use, using multivariate analysis. Our analysis demonstrated that hospital case volume was not significantly associated with complication rates but with postoperative resource use and operating room time. Procedural time was an independent determinant of complication rates. Tumor location, hospital case volume, and hospital teaching status were also associated with operating room time. To further the use of innovative technologies such as LC, training systems to develop skills by attending medical staff including surgeons are required. Health policy makers

and clinical experts should acknowledge the risk of extended procedural times and tumor location rather than the impact of hospital case volume. Clinical experts should develop focused skill training programs in performing LC efficiently for difficult and resource-intensive tumor locations. Sufficient financing for innovative skill education should be assured by healthcare policy makers before hastening to a case-volume-based set of qualifications for surgeons or hospitals.

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Hospital Volume and Quality of Laparoscopic Gastrectomy in Japan

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Key Words

Laparoscopic gastrectomy · Complications · Operating room time · Hospital volume

Abstract

Background: Laparoscopic gastrectomy (LG) has become the prevailing surgery of choice for gastric cancer, but the impact of hospital volume or operating room (OR) time has not been evaluated. An observational study was conducted to assess the quality of LG based on hospital volume and OR time. **Methods:** 3,054 LG patients were enrolled in 420 hospitals throughout Japan. Analyzed variables included patient demographics, complications, use of stapling devices or chemotherapy, hospital volume, and teaching status. Hospitals were categorized into high- (≥ 4 LG per month), intermediate- (1–3) and low- (<1) volume hospitals. Multivariate analysis was used to measure hospital volume and OR time impact. **Results:** 259 laparoscopic total gastrectomies (LTGs) were performed. Complications were observed in 269 cases (8.8%). High-volume hospitals treated less severe cases. OR time, but not hospital volume, was associated with complications. Hospital volume, teaching status and stapling devices explained variations in OR time. **Conclusion:** OR time was a more significant predictor of complications than hospital volume. OR time was consumed more in

the employment of stapling devices and LTG. To promote LG efficiency, training curricula highlighting the applicability of these techniques should be considered by clinical experts.

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Introduction

Short- or long-term outcome studies from single to multiple institutes have been conducted on laparoscopic gastrectomy (LG), which has gained a reputation of greater safety and efficacy compared with conventional open gastrectomy [1–6]. With an increasing number cases having more complications or a more advanced cancer stage that would benefit from LG, it has often been proposed to gather evidence about the quality control of complex or major gastrointestinal surgery, as well as conduct training on these novel laparoscopic procedures, in high-volume centers [7–14].

Under increasing demand to expand for a standardized education model, the American College of Surgeons has announced the usability of skill curricula outside of the operating room (OR) [13]. Tokunaga et al. [14] have verified the quality assurance of an LG systemic training system just inside the OR. These endeavors should

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involve surgeons who wish to acquire these evolving techniques regardless of their level of skill, which would surely help make these techniques become more widespread.

However, these attempts by the public domain cannot avoid the consequent discussion about the effects of hospital volume on patient outcome, which would include surgeries such as LG [7–12]. Regardless of the quality assurance protocols in place to reduce postoperative complications or the resources available for efficient training in skill laboratories, the time required in a real or virtual OR theater is a common factor with promising covariates to estimate the competency of hospitals or trainees. However, there have been few studies that evaluated the impact of OR time and hospital volume on clinical outcomes or resource use. When assessing a population-based volume-quality relationship, patient or hospital mix, including the presence of comorbidities or teaching status, should be considered with caution because centralization of cancer surgeries may cause undesirable referral selection bias, meaning high-volume institutions care for the healthier patients on average [7, 9, 11]. Therefore, it is necessary to test whether more OR time for LG causes a greater occurrence of postoperative complications by evaluating relevant variables such as the extent of gastric resection for gastric cancer.

These studies may lead to an updated laparoscopic surgery training system and volume outcome comparison in the general population. In that sense, the aims of this study were to present descriptive characteristics of patients with gastric cancer who underwent LG. We also examined the effect of OR time on the rate of complications as well as the relationship between hospital volume, OR time and complications.

Materials and Methods

Database

The Japanese administrative database was utilized to analyze patients with gastric cancer who received LG at hospitals participating in our research project during 2007. This database was originally developed as a Japanese case-mix classification system in 2002 by the Japanese Ministry of Health, Labor and Welfare, and was utilized to profile hospital performance and assess hospital payments across 1,428 hospitals (84 academic hospitals and 1,344 community hospitals) in 2007.

These hospitals provide acute care, promote medical research and educate students and postgraduate trainees. The database contains discharge summaries and claims data for each hospital; 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, Fukuoka, Japan.

Variables Definition

Study variables included age, gender, mortality, presence of comorbidities, surgical technique (laparoscopic partial or total gastrectomy, LPG or LTG), administration of chemoagents, the amount of blood transfused, the number of days postoperative pain control was needed, use of stapling devices (circular or linear stapler), and the hospital volume or function.

We examined complications attributable to diagnostic and therapeutic procedures, OR time (min), total or postoperative length of stay (LOS; days) and total or postoperative charge (TC; 1 EUR = 130 JPY).

Patients were categorized by age into 2 groups: <65 years of age and ≥ 65 years of age. Chemoagent use was used as a proxy to identify participants in an advanced gastric cancer stage. Diagnoses in this database were coded according to the International Statistical Classification of Diseases, 10th Version (ICD10). Up to 4 comorbidities per patient were recorded. To assess the severity of chronic comorbid conditions, we used the Charlson Comorbidity Index (CCI) [15]. Furthermore, a maximum of 4 complications, defined as unexpected events after admission, were also recorded. Procedure-related complications were defined as any of the following ICD10 codes: complications (T81–T87 USD), bowel obstruction (K650, K658–K659, K660, K913), peritonitis (K560, K562, K565–K567) and acute pancreatitis (K85) [16]. This database also listed 5 operative procedures per hospitalization. LG cases who were converted to open gastrectomy were considered as open gastrectomy cases. This database contained the date of study procedures and we calculated the postoperative LOS and the TC billed during admission, which acted as proxies for in-hospital costs. Japanese charges for hospital care were determined by a standardized fee-for-service payment system and were considered to be good estimates of healthcare costs [17]. TC in this study included physician fees, instrument costs, costs of laboratory and imaging tests, and administration fees, which were listed in the national uniform tariff table. OR time totaled the summation of time required for anesthetization, preparation and positioning of video-images and operative time by surgeons.

Hospitals were classified into 3 groups based on the number of LGs performed in a 6-month time period: 5 or fewer were considered to be a low-volume hospital (LVH), 6–23 were intermediate (IVH) and 24 or more were high (HVH). As for hospital function, we divided them into community and academic hospitals.

Statistical Analysis

Categorical data were reported by number and proportion in the hospital volume category and presence of complications. Comparisons were made using Fisher's exact test. Box charts were used to display distributions of OR time by LPG and LTG, stratified either with CCI, complication, hospital volume or teaching status. Continuous variables were compared across either the LPG or LTG groups using a nonparametric test. Multiple logistic regression models were used to identify the impact of OR time on complications. A multiple linear regression model was used to determine the effect of hospital volume on OR time, which was normally distributed. Statistical analysis was performed using SPSS 16.0. All reported p values were 2-tailed, and the level of significance was set to 0.05.

Results

Of 2,716,219 patients from the 965 hospitals in this administrative database, 3,054 LG patients who received primary gastric cancer treatment from 420 hospitals were identified (812 cases from 63 academic hospitals and 2,242 cases from 357 community hospitals). Twenty-three HVHs contained 837 patients (349 patients from 9 academic hospitals), 155 IVHs saw 1,677 patients (415 patients from 35 academic hospitals) and 242 LVHs saw 540 patients (48 patients from 19 academic hospitals). A total of 682 LPGs and 155 LTGs were performed in 23 and 20 HVHs, respectively; 1,550 LPGs and 127 LTGs were performed in 154 and 66 IVHs, respectively; and 527 LPGs and 13 LTGs were performed in 239 and 13 LVHs, respectively.

The median patient age and the proportion of individuals aged >65 were not statistically different across hospital volume categories ($p = 0.051$ and 0.104 , respectively). Twelve patients died (2 from HVH, 7 from IVH and 3 from LVH). Gender and mortality were not statistically different ($p = 0.998$ and 0.638 , respectively). As for the care process, type of gastrectomy, proportion of blood transfused, number of stapling devices, postoperative fasting period, use of pain control and OR time varied significantly among hospital volume categories, except for the use of chemotherapy and amount of blood transfused ($p = 0.271$ and 0.988 , respectively). LOS and TC were also statistically different (table 1).

Table 2 lists patient/hospital characteristics and care process stratified by the presence of procedure-related complications. A total 269 complication cases (8.8%) were identified. There was a significant difference in the number of complications between the teaching status of the hospitals [172 patients (7.7%) in academic hospitals and 92 patients (11.9%) in community hospitals had complications], but hospital volume categories were not statistically different [15 in HVH (9.2%), 76 in IVH (8.3%) and 53 in LVH (9.8%)]. People with complications tended to be older patients and those with a higher CCI. There was no statistical difference between the type of gastrectomy performed and whether or not chemoagents were administered. Bivariate analysis indicated that complications were more likely with increased OR time. Resource use increased in the group with complications.

OR time was statistically different between CCI groups, complication classifications, hospital volume categories and teaching status in either LPG or LTG (fig. 1).

A higher CCI, no use of postoperative pain control, 1 stapling device, greater OR time and surgeries performed

in an academic hospital were significantly associated with complications. Gastrectomy type, use of chemoagents and hospital volume were not predictors of complications. Use of stapling devices and LTG procedures were significant determinants for a longer OR time. IVH, LVH and academic hospitals also were associated with a longer OR time. The effect of hospital variables on OR time, however, was comparatively lower than that of the use of stapling devices or LTG (table 3).

Discussion

Using a large Japanese administrative database, we examined the volume-outcome relationship in LG. This study disclosed instructive findings, which differed from many previous articles, where HVHs demonstrated a higher quality of surgical practice compared with IVHs or LVHs. Complications were not encountered more often as hospital volume increased. A higher OR time was associated with more complications, which resulted in a higher consumption of resources. Furthermore, the use of stapling devices, LTG procedures, hospital volume and teaching status were significant predictors of OR time. However, care processes themselves were more likely to produce a greater impact than hospital-related variables.

OR time in this study was 40–60 min longer than in other previous reports, as not only the time for LG was counted, but also the time for LTG as well. Adjusted OR time for LTG was approximately 60 min longer, which seemed to partially correspond with other combined studies that reported LTG being 20–60 min longer than LPG [18–20]. These studies evaluated data from a single high-volume center, while the findings of our study were from community-based centers and the variation of OR time between LPG and LTG was reasonable. Low- to intermediate-volume hospitals tended to accommodate older patients or patients with more comorbidities, which also corresponds with reports by Gordon et al. [7] and Smith et al. [9].

Overall, surgical complications occurred in 269 patients [8.8%; 139 in IVHs (8.3%) and 53 in LVHs (9.8%)], which was lower than those reported from Western countries, but similar to other Asian studies. However, complications were restricted to surgical or procedure-related, but not medical, complications [18, 19]. Hospital teaching status explained the variation of complications, while hospital volume was not associated with complications. Longer OR time induced more complications even

Table 1. Patient/hospital characteristics and care process by hospital volume category

	High	Intermediate	Low	p
Hospitals/patients, n	23/837	155/1,677	242/540	
Hospitals/patients according to hospital teaching status, n				
Community	14/488 (58.3)	120/1,262 (75.3)	223/492 (91.1)	<0.001
Academic	9/349 (41.7)	35/415 (24.7)	19/48 (8.9)	
Age				
Median [IQ]	65 [16]	65 [16]	67 [17]	0.051*
65 years or more	423 (50.5)	886 (52.8)	305 (56.5)	0.104
Gender				
Male	527 (63)	1,055 (62.9)	339 (62.8)	0.998
Outcome				
Mortality	2 (0.2)	7 (0.4)	3 (0.6)	0.638
CCI, n				
0	693 (82.8)	1,277 (76.1)	427 (79.1)	0.004
1	86 (10.3)	253 (15.1)	74 (13.7)	
2 or more	58 (6.9)	147 (8.8)	39 (7.2)	
Gastrectomy				
LPG	682 (81.5)	1,550 (92.4)	527 (97.6)	<0.001
LTG	155 (18.5)	127 (7.6)	13 (2.4)	
Administration of chemoagent, n				
Present	26 (3.1)	43 (2.6)	21 (3.9)	0.271
Blood transfusion				
Number	34 (4.1)	52 (3.1)	35 (6.5)	0.002
Milliliter, median [IQ]	800 [900]	800 [1,200]	800 [800]	0.988
Stapling devices [IQ], n				
Total	3 [1]	3 [2]	3 [2]	<0.001*
Circular staplers	0 [1]	1 [1]	0 [1]	<0.001*
Linear staplers	3 [1]	3 [1]	3 [2]	<0.001*
Postoperative fasting period, days				
Median [IQ]	4 [2]	4 [2]	4 [3]	<0.001*
Use of pain control				
Number	652 (77.9)	1,411 (84.1)	413 (76.5)	<0.001
Days, median [IQ]	3 [2]	4 [3]	4 [4]	<0.001*
OR time				
Minutes, median [IQ]	315 [105]	332 [133]	325 [160]	0.002*
Resource use, median [IQ]				
Postoperative LOS, days	12 [5]	12 [7]	14 [9]	<0.001*
LOS, days	16 [9]	17 [9]	19 [11]	<0.001*
Postoperative TC, EUR	2,402 [1,135]	2,338 [1,284]	2,567 [1,620]	<0.001*
TC, EUR	9,971 [2,723]	9,855 [2,295]	9,970 [2,983]	0.021*

Figures in parentheses represent percentages; figures in brackets represent interquartile ranges. * By Kruskal-Wallis test; others by Fisher's exact test. LOS = Length of stay; IQ = interquartile range.

when adjusted for the use of stapling devices, which were employed to diminish blood loss or to attempt to totally complete laparoscopic gastrectomies. These explained more variations in OR time. These findings provide a rationale to develop or improve the quality of training systems for LG. These results might also present reasons to invest in trainee education to learn how to handle stapling devices either in box-trainer equipment or virtual

operating theaters. Patients with complications were found to require more blood transfusions, which was likely caused by accidental splenic lacerations [20]. Clinical experts should measure the qualitative or quantitative difficulties every surgical practice needs to address before the completion of LG, which may also contribute to the sophistication of skill curricula [21].

Table 2. Patient or hospital characteristics and care process by presence of complications

	No complications	Complications	p
Overall	2,785	269	
Hospital category, hospital number (%)			
Teaching status			<0.001
Academic	63, 2,070 (74.3)	26, 172 (63.9)	
Community	346, 715 (25.7)	108, 97 (36.1)	
Hospital volume			0.495
High volume	23, 760 (27.3)	15, 77 (28.6)	
Intermediate volume	155, 1,538 (55.2)	76, 139 (51.7)	
Low volume	231, 487 (17.5)	44, 53 (19.7)	
Age			
Median [IQ]	65 [16]	67 [16]	0.029*
65 years or more	1,456 (52.3)	158 (58.7)	0.043
Gender			
Male	1,739 (62.4)	182 (67.7)	0.091
Outcome			
Mortality	9 (0.3)	3 (1.1)	<0.001
Charlson comorbidity index			
0	2,221 (79.7)	176 (65.4)	0.047
1	360 (12.9)	53 (19.7)	
2 or more	204 (7.3)	40 (14.9)	
Gastrectomy			
Laparoscopic partial gastrectomy	2,517 (90.4)	242 (90.0)	0.826
Laparoscopic total gastrectomy	268 (9.6)	27 (10.0)	
Administration of chemoagent			
Present	85 (3.1)	5 (1.9)	0.269
Blood transfusion			
Number (%)	105 (3.8)	16 (5.9)	0.080
Milliliter, median [IQ]	800 [1,000]	1,100 [1,700]	0.089*
No. of stapling devices [IQ]			
Total	3 [2]	3 [2]	0.810*
Circular staplers	1 [1]	1 [1]	0.622*
Linear staplers	3 [1]	3 [1]	0.511*
Postoperative fasting period, days			
Median [IQ]	4.4 [3.1]	6.6 [9]	0.001*
Use of pain control			
Number (%)	2,282 (81.9)	194 (72.1)	<0.001
Days, median [IQ]	4 [4]	4 [4]	<0.875*
Operating room time			
Minute, median [IQ]	324 [124]	350 [126]	<0.001*
Resource use, median [IQ]			
Postoperative LOS, days	12 [6]	16 [21]	<0.001*
LOS, days	17 [9]	21 [25]	<0.001*
Postoperative total charge, EUR	2,373 [1,203]	3,222 [3,704]	<0.001*
Total charge, EUR	9,852 [2,358]	11,018 [5,690]	<0.001*

* By Mann-Whitney test. Others by Fisher's exact test. IQ = Interquartile range.

We examined OR theater time, not the operative time required by surgeons, nor the time required by anesthesiologists and OR nurses. LG requires more OR time to prepare for video monitor positioning and time to set up a greater number of clumsy instruments. Since clinicians

stress team-based training for laparoscopic surgery, handling this equipment should be emphasized in training programs because the reduction of OR time might decrease the presence of complications. Clinical societies and this administrative database should examine both

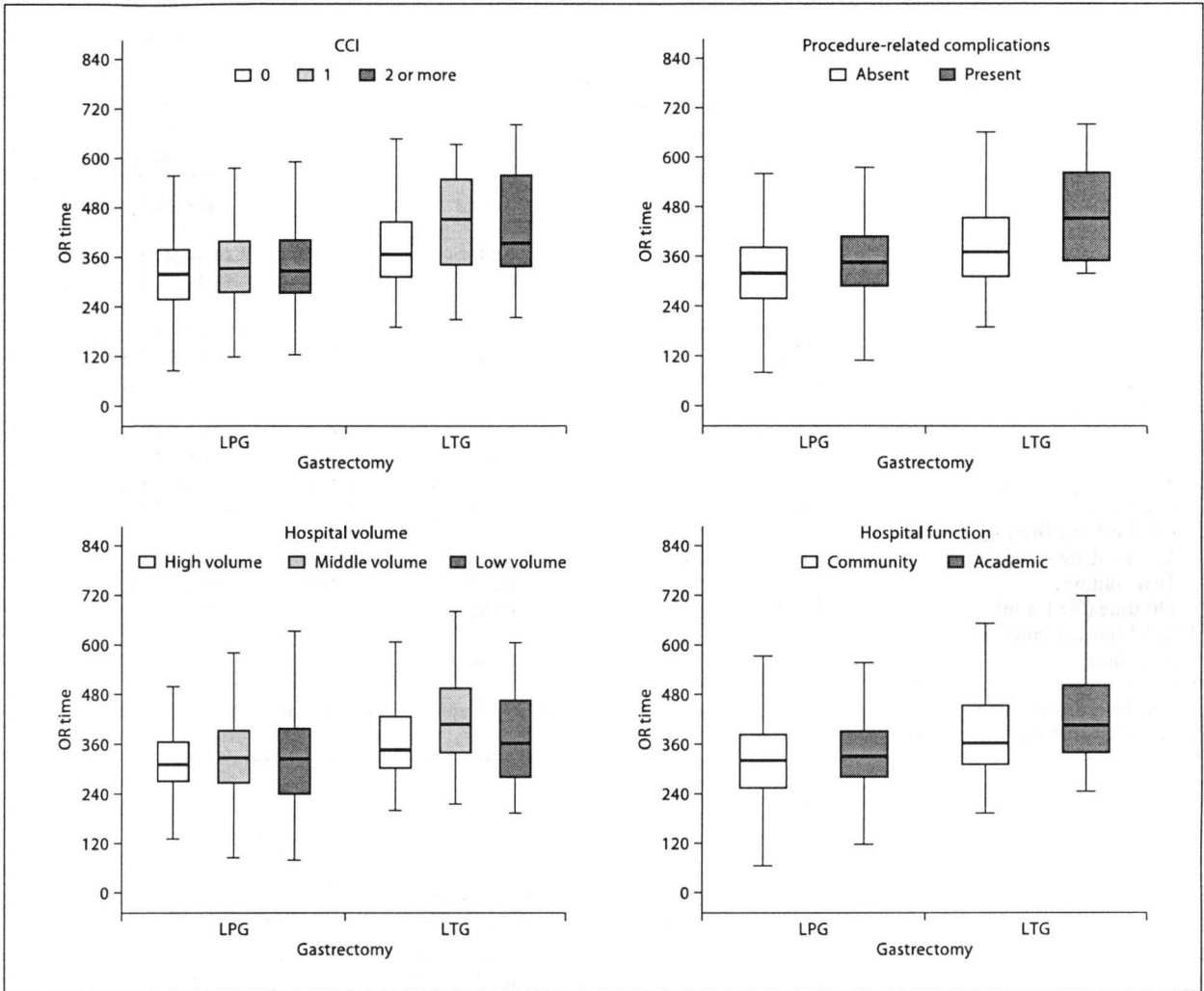


Fig. 1. OR time (min) and LPG or LTG, stratified by CCI, complications, hospital volume and teaching status. OR time was statistically different between LPG and LTG.

the impact of the anesthetic time as a surrogate to assess the experience of attending operating staff and of the surgeons' volume on the quality of LG. Those findings would contribute to the sophistication of training curricula development.

Some limitations to the methodology of this study should be mentioned. First, this study was observational and information was only gathered from discharged patients over 6 months in 2007, which may limit the ability to generalize our results. However, this database also contained around two thirds of the LGs performed in the latter 6 months of 2007 [22]. Also, information concern-

ing LG was collected from 2006 to 2008. A longitudinal study to evaluate quality of LG care among hospital categories, which is promising and possible, would provide greater detail to assess priorities to be managed in LG training systems.

Second, there was a shortage of some clinical data, including cancer stage. In fact, tumor stages were only voluntarily gathered and there were many missing values. The cancer registry database managed by clinical societies, through collaboration with this administrative database, examines both the impact of clinical information such as BMI or presence of radical intent on short-term

Table 3. Multivariate analysis of factors associated with complications and OR time (min)

	Complications			OR time		
	odds ratio	95% CI	p	estimation	95% CI	p
Intercept				195.4	(179.4–211.3)	<0.001
Age (for under 65 years)	1.213	(0.934–1.576)	0.147	–5.6	(–12.5 to 1.2)	0.108
Male	1.138	(0.865–1.497)	0.356	23.4	(16.3–30.5)	<0.001
CCI (for zero)						
1	1.676	(1.199–2.342)	0.003	14.6	(4.5–24.8)	0.005
2 or more	2.379	(1.623–3.489)	<0.001	15.2	(2.4–27.9)	0.020
Procedure (for LPG)						
LTG	0.996	(0.628–1.581)	0.987	62.7	(50.4–75)	<0.001
Chemoagent	0.506	(0.199–1.286)	0.153	19.0	(–1.3 to 39.3)	0.067
Postoperative pain control	0.612	(0.456–0.823)	0.001	–8.7	(–17.6 to 0.1)	0.053
Stapling devices, n						
1	2.616	(1.340–5.105)	0.005	108.6	(91.9–125.3)	<0.001
2	1.277	(0.628–2.594)	0.499	100.1	(84.4–115.7)	<0.001
3	1.645	(0.899–3.008)	0.106	106.1	(93.1–119.2)	<0.001
4 or more	1.479	(0.801–2.728)	0.211	116.9	(103.7–130.1)	<0.001
Hospital volume (for high volume)						
Intermediate volume	0.974	(0.713–1.332)	0.870	26.6	(18.4–34.9)	<0.001
Low volume	1.279	(0.854–1.915)	0.233	22.7	(11.7–33.7)	<0.001
OR time (for 1 min)	1.002	(1.001–1.004)	<0.001		***	
Hospital (for community)						
Academic	1.479	(1.109–1.973)	0.008	20.4	(12.3–28.5)	0.000

OR time: F test for the model, $p < 0.001$; coefficient of determination: 0.163; complications: Hosmer-Lemeshow goodness-of-fit model, 0.784. *** Not included in this model.

quality of laparoscopic care. People in Asian countries, however, tend to have a leaner build compared with people in Western countries, and BMI might be assumed to change the cardinal, not ordinal, results of this study [23]. Third, LOS for all hospital admissions in Japan is 3–4 longer than in hospitals in Western countries [24]. One reason for the increased LOS is that Japanese hospitals generally supply nursing service in addition to acute medical care [24]. The fiscal impact of longer LOS reflects the real and precise costs consumed during each episode of acute illness in Japan.

In conclusion, this study used an administrative database to present descriptive characteristics of cases receiving LPG or LTG in Japan among 3 hospital volumes with or without complications. We estimated the effect of hospital volume and OR time on complications and OR time by multivariate analysis. Our analysis demonstrated that hospital volume was not associated with complications, but OR time was associated with hospital teaching status. After controlling for patient characteristics, the employment of stapling devices and performing a LTG were sig-

nificant determinants of longer OR time. Hospital volume and teaching status also affected OR time, but only to a modest extent compared with the former 2 independent variables. To further the use of these innovative technologies like LG, training systems to develop LG skills are required. Health policy makers or clinical experts should acknowledge the risk of procedure maneuvers a priori, rather than the impact of hospital volume. Further studies about the integrated measurements of difficulties observed in performing LG, such as assessing lymphadenectomy, will be necessary to develop skill curricula.

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Quantitative Comparison of the Difficulty of Performing Laparoscopic Colectomy at Different Tumor Locations

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Abstract

Background Laparoscopic approaches of colectomy for colonic cancer are increasingly surpassing the mainstream open colectomy approach. Impact of disease variables, such as tumor location, has not been adequately measured in quality improvement initiatives. Quantitative analysis concerning the difficulty performing these procedures and differences in postoperative care depending on tumor site will contribute to the development of training programs and to the assessment of quality of care strategies.

Methods A total of 3,765 cases received laparoscopic colectomy (LC). Patient demographics, weighted comorbidities, procedure-related complications, stapling devices, operating room (OR) time, postoperative length of hospital stay (LOS), or total charges (TC) were categorized and compared based on tumor location: cecum to ascending, transverse, descending, and sigmoid colon. Multivariate analyses determined the impact of tumor location on postoperative LOS, TC, OR time, and complications.

Results Sigmoid colon was the most frequent tumor placement (40.5%). Significant differences in age, gender, frequency of blood transfusion, use of stapling devices, OR time, and postoperative LOS were observed among tumor locations. Transverse colon was the most significant determinant of postoperative LOS and TC, whereas descending colon tumors correlated with increased OR time. Greater OR time was associated with more postoperative resource use and complications.

Conclusions Tumor location, complications, and OR time affected postoperative resource use, whereas greater OR time signified an increased occurrence of complications. Developers of LC training programs or healthcare policy makers should consider the quantitative impact of tumor locations when attempting to improve effective skill training or to survey the quality of LC performance.

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Introduction

Many types of studies have compared conventional open colectomy (OC) with laparoscopic colectomy (LC) for the treatment of colon cancer to confirm the advantages of LC in terms of oncologic and short- or long-term outcomes [1, 2]. Irrespective of whether the study designs were from

a single center, randomized control, or observational studies, the benefits to patients have been confirmed to be so great that a preference for LC is prevailing [3–5].

Community-based longitudinal studies also have supported the growing nationwide trends and merits of LC, resulting in an increased use of LC in standard practice [6–9]. Nevertheless, to perform LC effectively, sophisticated training in terms of advanced laparoscopic surgical skills, irrespective of skill in a laboratory or operation room, is required because the location of a tumor may vary from the colon attached to the retroperitoneum, the ascending or descending colon, and the mobile transverse or sigmoid colon. Stapling devices, such as linear or circular stapling, have been applied much more for the purpose of preventing more blood loss or completing LC intracorporeally, such that the effects of these devices should be considered in terms of the evaluation of the quality of LC as well as skill training [10, 11].

Accordingly, Jamali et al. qualitatively evaluated the degree of difficulty of laparoscopic colorectal surgery and concluded that laparoscopic sigmoid colectomy seemed to be a relatively simple procedure [12]. However, the degree of difficulty, regardless of whether laparotomy or laparoscopy is involved, should be confirmed quantitatively in terms of operating room time, complications, and resource use. Furthermore, there are likely to be several confounding variables, such as preexisting comorbidities, the use of stapling devices, or pain control for early mobilization, which need to be addressed.

To contribute to the ability to determine the priority or quality of postoperative management strategies and learning skills, we investigated the degree of difficulty of performing LC stratified by the localization of the primary malignant tumor.

Materials and methods

In this retrospective analysis, we used a Japanese administrative database incorporated in a government project concerning the development of a Japanese case-mix classification system. Anonymous health insurance claim data with detailed clinical information were collected annually between July 1 and December 31, 2007 for this database, and the data were provided to our research team. These data were used to assess hospital performance and hospital payments and were derived from 82 academic hospitals and 649 community hospitals located throughout Japan, providing acute care, advance medical research, and educating students and postgraduate trainees. This project was approved by the ethical committee of the University of Occupational and Environmental Health.

Variable definitions

Study variables included age, gender, discharge outcome, tumor location in principal diagnosis, comorbidities, blood transfusion, stapling devices, including linear or circular staplers, administration of chemo-agent (proxy of advanced cancer staging), postoperative pain control by epidural anesthesia, procedure-related complications, and hospital category (academic or community).

Our administrative database contained the dates or number of days that care was provided in addition to clinical information. We also calculated postoperative fasting periods (days), operating room time (OR time; min), which included induction of epidural anesthesia and preparation of video images or patient positioning, postoperative time (from 1 day after operation to discharge), length of in-hospital stay (LOS; days), and total charges (TC; US\$1 = ¥100) billed during admission, which has been considered to be a good estimate of healthcare costs [13]. TC included fees for physician consultation and administration, and costs of instruments, laboratory tests, and imaging.

Patients were stratified into two age groups: younger than 65 years, and 65 years or older. Study diagnosis was coded by the International Classification of Disease 10th version (ICD code). The database records four comorbidities or four complications per patient. To assess the severity of preexisting comorbid conditions, we used the Charlson comorbidity index (CCI) [14]. Patients were grouped into four groups with a CCI score of 0 to 3 or more. With ICD codes, we categorized tumor location as follows: cecum including the appendix to the hepatic flexure (C180-3), transverse (C184), splenic flexure to the descending (C185-6), and sigmoid colon (C187). Tumors involving the rectosigmoid colon to the rectum were not assessed. Procedure-related complications or surgical complications included wound complications, anastomosis leakage, hematoma or others (T81-T87), bowel obstruction (K650, K658-9, K660, K913), peritonitis (K560, K562, K565-7), and acute pancreatitis (K85) [3, 15]. Patients who died within 24 hr after hospitalization were originally excluded from this administrative database.

Statistical analysis

Frequencies and proportions for categorical data were compared by Fisher's exact test. Continuous variables were compared across tumor location using analysis of variance. Multiple linear regression analysis was used to identify the association between tumor location and postoperative LOS or TC, and OR time. Logistic regression was used to evaluate associations between tumor locations and procedure-related complications. Statistical analyses were