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Laparoscopic cholecystectomy: a multicenter study of 17 hospitals.

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Laparoscopic cholecystectomy: a multicenter study of 17 hospitals.*

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Abstract

A study of 1,254 laparoscopic cholecystectomies performed at 17 hospitals affiliated with the Liver, Gallbladder, and Pancreas Research Group of the First Department of Surgery at Okayama University was undertaken to assess the current status and safety of this procedure. The data for 336 patients, comprising the initial 20 laparoscopic cholecystectomies performed at each institution, were compared with the data from the remaining 918 patients. Comparison of the two groups revealed the following: 1. the rates of intraoperative conversion to open cholecystectomy were 11.3% and 5.1% ($P < 0.05$), 2. the complication rates were 5.7% and 3.4%, and 3. the rates of bile duct injury were 2.4% and 1.1%, respectively. Compared with the first group, the bile duct injuries resulting from a lack of experience decreased in the second group, however, the incidence of these injuries occurring during avulsion of the gallbladder in difficult cases increased. These results suggest that the experience acquired during the initial 20 laparoscopic cholecystectomies led to a reduction in the rate of intraoperative conversion to open cholecystectomy, but it did not reduce the rate of complications, and that the risk of bile duct injury was always present.

KEYWORDS: laparoscopic cholecystectomy, cholelithiasis, bile duct injury

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Laparoscopic Cholecystectomy: A Multicenter Study of 17 Hospitals

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A study of 1,254 laparoscopic cholecystectomies performed at 17 hospitals affiliated with the Liver, Gallbladder, and Pancreas Research Group of the First Department of Surgery at Okayama University was undertaken to assess the current status and safety of this procedure. The data for 336 patients, comprising the initial 20 laparoscopic cholecystectomies performed at each institution, were compared with the data for the remaining 918 patients. Comparison of the two groups revealed the following: 1. the rates of intraoperative conversion to open cholecystectomy were 11.3% and 5.1% ($P < 0.05$), 2. the complication rates were 5.7% and 3.4%, and 3. the rates of bile duct injury were 2.4% and 1.1%, respectively. Compared with the first group, the bile duct injuries resulting from a lack of experience decreased in the second group, however, the incidence of these injuries occurring during avulsion of the gallbladder in difficult cases increased. These results suggest that the experience acquired during the initial 20 laparoscopic cholecystectomies led to a reduction in the rate of intraoperative conversion to open cholecystectomy, but it did not reduce the rate of complications, and that the risk of bile duct injury was always present.

Key words: laparoscopic cholecystectomy, cholelithiasis, bile duct injury

Laparoscopic cholecystectomy is widely performed due to its low invasiveness, and it has become a common surgical technique in patients with benign gallbladder disease (1-4). At institutions which frequently perform this procedure, laparoscopic cholecystectomy appears to be as safe as the conventional open procedure and the complication rate is reported to be quite low (5-

10). However, reports from the referral centers treating patients with iatrogenic bile duct injuries have suggested that laparoscopic cholecystectomy is not necessarily as safe as open cholecystectomy (11-13). Investigation of data from multiple institutions has suggested that bile duct injury is more likely to occur during the initial 10-15 procedures performed by various surgeons, implicating the need for a certain training period in order to acquire the necessary skill to safely perform laparoscopic cholecystectomy (14-16). In contrast, Deziel *et al.* (17) reported that the rate of bile duct injury was significantly lower at institutions where more than 100 procedures had been performed compared with those performing fewer, but bile duct injury still occurred more frequently than during the open procedure.

Laparoscopic cholecystectomy was first performed in Japan in the spring of 1990, and quickly became widespread after April 1992 when the procedure was approved by the National Health Insurance system (18). This study was conducted to compare the incidence of complications during laparoscopic cholecystectomy performed at 17 medical institutions in our local area. This was done by separately evaluating the safety of the first 20 procedures performed at each institution and the subsequent procedures.

Patients and Methods

A questionnaire regarding laparoscopic cholecystectomy, including the type of gallbladder disease, the surgeons involved, the associated diseases, intraoperative conversion to open cholecystectomy, and complications, was sent to 17 medical institutions affiliated with the Liver, Gallbladder, and Pancreas Research Group of the First Department of Surgery at Okayama University. The data from all 17 hospitals were collected and analyzed. The number of patients treated at each of the 17

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Table 1 Overall summary of the data on laparoscopic cholecystectomy

Hospital	Number of procedures	No. of Surgeons	Associated disease	Conversions ^a	Complications	Bile duct injury
A	228	6	12 (5.3)	3 (1.3)	2 (0.9)	0
B	171	8	21 (12.3)	10 (5.8)	5 (2.9)	2 (1.2)
C	153	10	2 (1.3)	9 (5.9)	16 (10.5)	6 (3.9)
D	108	9	7 (6.5)	14 (13.0)	4 (3.7)	2 (1.9)
E	103	2	17 (16.5)	5 (4.9)	5 (4.9)	2 (1.9)
F	99	5	1 (1.0)	6 (6.1)	2 (2.0)	1 (1.0)
G	70	8	10 (14.3)	5 (7.1)	1 (1.4)	0
H	60	1	7 (11.7)	6 (10.0)	2 (3.3)	1 (1.7)
I	48	3	3 (6.3)	2 (4.2)	1 (2.1)	0
J	42	5	4 (9.5)	4 (9.5)	1 (2.4)	1 (2.4)
K	32	2	2 (6.3)	2 (6.3)	0	0
L	32	3	3 (9.3)	6 (18.8)	1 (3.1)	0
M	25	3	2 (8.0)	4 (16.0)	1 (4.0)	0
N	25	5	3 (12.0)	2 (8.0)	1 (4.0)	0
O	22	6	0	1 (4.5)	3 (13.6)	0
P	20	2	0	3 (15.0)	3 (15.0)	2 (10.0)
Q	16	5	0	3 (18.8)	2 (12.5)	1 (6.3)
Total	1254	83	94 (7.6)	85 (6.8)	50 (4.0)	18 (1.4)

Figures in parentheses are percentages.

^a: "Conversion" refers to intraoperative conversion from laparoscopic to conventional open cholecystectomy.

institutions ranged from 16 to 228 (mean: 73.6), with a total of 1,254 (Table 1). The number of surgeons who performed the procedure at each institution ranged from 1 to 10 (mean: 4.9), with a total of 83. Associated diseases were present in 94 patients (7.6 %). The procedure was converted to open cholecystectomy in 85 cases (6.8 %) and complications arose in 50 (4.0 %). Among these 50 complications, bile duct injury accounted for 18 cases (1.4 %). The 1,254 patients were divided into two groups: the initial 20 cases of laparoscopic cholecystectomy performed at each institution ($n = 336$, group I), and all subsequent cases ($n = 918$, group II). Each of the surgeons performing laparoscopic cholecystectomy was contacted by telephone in order to obtain detailed information on the incidence and management of bile duct injuries.

Statistical comparison was performed using the chi-square test. Statistical significance was accepted when P was less than 0.05.

Results

Gallbladder diseases. Laparoscopic cholecystectomy was performed in patients with the following gallbladder diseases: cholelithiasis in 1,102 cases, gallbladder polyp in 111 cases, gallbladder adenomyomatosis in 31 cases, gallbladder carcinoma in 6 cases, and chronic cholecystitis in 4 cases. A comparison of group I with group II shows that there was no statistically significant difference in the incidence of these diseases between the two groups (Table 2).

Surgeons. A total of 40 surgeons performed laparoscopic cholecystectomy in group I, and this number increased to 77 in group II (Table 3). The overall trend seen in Table 3 is that a greater number of surgeons with relatively less experience, especially under 5 years of experience, were performing laparoscopic cholecystectomy in group II compared with group I.

Associated diseases. Diseases which met the

Table 2 Gallbladder diseases in the patients undergoing laparoscopic cholecystectomy

Disease	Group I	Group II	P value
Cholelithiasis	291 (86.8)	811 (88.3)	NS
Gallbladder polyp	33 (9.8)	78 (8.5)	NS
Gallbladder adenomyomatosis	10 (3.0)	21 (2.3)	NS
Gallbladder carcinoma	0	6 (0.7)	NS
Chronic cholecystitis	2 (0.6)	2 (0.2)	NS
Total	336 (100.0)	918 (100.0)	

Figures in parentheses are percentages.

Abbreviation: NS, not significant.

Table 3 Level of experience of the surgeons performing laparoscopic cholecystectomy

Years of experience	Surgeons		Procedures		P value
	Group I	Group II	Group I	Group II	
< 5	2	13	9 (2.7)	172 (18.7)	<0.001
5 ~ 10	6	15	10 (3.0)	75 (8.2)	<0.01
10 ~ 15	8	21	90 (26.8)	318 (34.7)	<0.01
15 ~ 20	14	18	148 (44.0)	227 (24.7)	<0.001
20 <	10	10	79 (23.5)	126 (13.7)	<0.001
Total	40	77	336 (100.0)	918 (100.0)	

Figures in parentheses are percentages.

criteria of a "relative contraindication", as defined by Bailey *et al.* (8), were present in 25/336 (7.4 %) patients in group I and in 69/918 (7.5 %) patients in group II, virtually identical between the two groups (Table 4). The rate of patients with acute cholecystitis was significantly higher in group II than in group I, but there was a significant decrease in the rate of patients with previous upper abdominal surgery in group II compared with group I.

Conversion to open cholecystectomy.

Intraoperative conversion to open cholecystectomy occurred in 38/336 (11.3 %) patients in group I and 47/918 (5.1 %) patients in group II (Table 5). There was a significant reduction in the rate of conversion to the open procedure in group II compared with group I, because the

percentages of adhesions due to chronic inflammation, bleeding from the cystic artery, and intraabdominal carcinoma other than gallbladder carcinoma were higher in group I.

Complications. Complications occurred in 19/336 (5.7 %) patients in group I and in 31/918 (3.4 %) patients in group II, with the rate being lower for group II (Table 6). However, the difference between the two groups was not significant. Eight cases of bile duct injury (2.4 %) were reported in group I and 10 cases (1.1 %) occurred in group II. Three cases (0.9 %) of bile duct injury were recognized intraoperatively and five (1.5 %) were recognized postoperatively in group I, whereas five cases each (0.5 %) of bile duct injury were recognized intraoperatively and postoperatively in group II. Although there was a reduction in the rate of bile duct injury in group II, the difference between the two groups was not significant. The rates of bile leakage, wound infection, and postoperative bleeding were approximately the same in both groups.

Some other complications were reported in group I, but not in group II, including two cases (0.6 %) of massive intraoperative bleeding, one case (0.3 %) of pleural effusion, and one case (0.3 %) of liver dysfunction. On the other hand, complications observed in group II but not in group I included 2 cases (0.2 %) of bowel injury, one case (0.1 %) of unexplained abdominal pain, and one case (0.1 %) of drug allergy. The differences in the rates of these complications between the two groups were not significant.

One patient (0.08 %) died of cerebral infarction among the 1,254 cases reviewed. Re-hospitalization was required in four cases (0.32 %): one patient had bile peritonitis following damage to the bile duct by an electrotome, one

Table 4 Associated diseases in the patients undergoing laparoscopic cholecystectomy

Disease	Group I	Group II	P value
Acute cholecystitis	9 (2.7)	50 (5.4)	<0.05
Liver cirrhosis	5 (1.5)	10 (1.1)	NS
Previous upper abdominal surgery	7 (2.1)	5 (0.5)	<0.05
Common bile duct stone	5 (1.5)	4 (0.4)	NS
Total	25 (7.4)	69 (7.5)	NS

Figures in parentheses are percentages.

Abbreviation: NS, not significant.

Table 5 Reasons for conversion to open cholecystectomy

Reason	Group I	Group II	P value
Adhesions due to acute inflammation	4 (1.2)	9 (1.0)	NS
Adhesions due to chronic inflammation	13 (3.9)	17 (1.9)	< 0.05
Adhesions due to previous abdominal surgery	2 (0.6)	2 (0.2)	NS
Bleeding from the cystic artery	4 (1.2)	2 (0.2)	< 0.05
Bleeding from the dissection site	2 (0.6)	4 (0.4)	NS
Bile duct injury	3 (0.9)	5 (0.5)	NS
Bowel injury	0	1 (0.1)	NS
Choledocholithiasis	0	1 (0.1)	NS
Stone loss	2 (0.6)	1 (0.1)	NS
Confluence stone	2 (0.6)	0	NS
Cystic duct injury	1 (0.3)	1 (0.1)	NS
Biliary tract anomaly	0	1 (0.1)	NS
Gallbladder carcinoma	0	2 (0.2)	NS
Other intraabdominal carcinoma	3 (0.9)	0	< 0.05
Bleeding after trocar insertion	1 (0.3)	0	NS
Mechanical problems	1 (0.3)	1 (0.1)	NS
Total	38 (11.3)	47 (5.1)	< 0.01

Figures in parentheses are percentages.

Abbreviation: NS, not significant.

had pleural effusion, and two had bile duct stricture. The one death and the case of bile peritonitis occurred in group II, while the remaining three patients requiring readmission were in group I. There were no significant differences in these rates between the two groups.

Bile duct injury. The causes of the 18 bile duct injuries in two groups were classified as: a) complete common bile or hepatic duct transection, b) electrotome damage to the bile duct, c) hepatic duct injury during gallbladder avulsion, d) bile duct stricture or laceration after clipping, and e) laceration of the cystic duct junction (Table 7). The rates of occurrence of bile duct injury due to the four causes other than hepatic duct injury during gallbladder avulsion were lower in group II, however, there were no significant differences in these rates between the two groups.

Complete common bile or hepatic duct transection due to mistaking the common duct for the cystic duct occurred in 3 cases (0.9 %) in group I and 3 cases (0.3 %) in group II. These six patients had no associated diseases and

were technically simple cases for laparoscopic cholecystectomy. Intraoperative conversion to laparotomy was performed in four cases, but in the remaining two cases these injuries were discovered postoperatively when bile leakage was detected. Five of these injuries were repaired by end-to-end anastomosis and hepaticojejunostomy was performed in the remaining patient. Two of the five patients who underwent end-to-end anastomosis showed good recovery, however, one of the other three patients developed an anastomotic stricture which required hepaticojejunostomy, and liver dysfunction occurred in the other two patients. Postoperative anastomotic stricture developed in the patient who had undergone hepaticojejunostomy as the first repair procedure, necessitating re-hospitalization for percutaneous transhepatic insertion of a metal stent.

Bile duct injury caused by the electrotome was reported in 3 cases (0.9 %) in group I and 3 cases (0.3 %) in group II. Bile peritonitis due to the resulting perforation was recognized postoperatively in all six patients, and suture repair was performed in five cases and a T-tube was used in the remaining case. All of these patients showed good recovery.

Accidental bile duct injury during avulsion of the gallbladder from the liver bed occurred in 3 cases (0.3 %) in group II, with two patients developing injuries of the

Table 6 Complications of laparoscopic cholecystectomy

Complication	Group I	Group II	P value
Bile duct injury	8 (2.4)	10 (1.1)	NS
Recognized intraoperatively	3 (0.9)	5 (0.5)	NS
Recognized postoperatively	5 (1.5)	5 (0.5)	NS
Bile leakage	3 (0.9)	9 (1.0)	NS
Wound infection	3 (0.9)	7 (0.8)	NS
Postoperative bleeding	1 (0.3)	1 (0.1)	NS
Intraoperative bleeding	2 (0.6)	0	NS
Pleural effusion	1 (0.3)	0	NS
Liver dysfunction	1 (0.3)	0	NS
Bowel injury	0	2 (0.2)	NS
Unexplained abdominal pain	0	1 (0.1)	NS
Drug allergy	0	1 (0.1)	NS
Total	19 (5.7)	31 (3.4)	NS

Figures in parentheses are percentages.

Abbreviation: NS, not significant.

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Table 7 Bile duct injury during laparoscopic cholecystectomy

Cause	Group I	Group II	P value
Complete common bile or hepatic duct transection	3 (0.9)	3 (0.3)	NS
Electrotome damage to the bile duct	3 (0.9)	3 (0.3)	NS
Hepatic duct injury during gallbladder avulsion	0	3 (0.3)	NS
Bile duct stricture or laceration after clipping	1 (0.3)	1 (0.1)	NS
Laceration of the cystic duct junction	1 (0.3)	0	NS
Total	8 (2.4)	10 (1.1)	NS

Figures in parentheses are percentages.

Abbreviation: NS, not significant.

right hepatic duct and one suffering damage to the common hepatic duct. Two of the three patients had fibrous adhesions in Calot's triangle at laparoscopic cholecystectomy. These bile duct injuries were recognized intraoperatively in two cases and postoperatively in the remaining case. All of these injuries were sutured, and a T-tube was inserted into the common bile duct in one patient. These three patients subsequently made a good recovery.

Among the two patients in whom the bile duct was clipped accidentally, one (0.3 %) in group I developed bile duct stricture postoperatively and underwent hepaticojunctionostomy. However, postoperative anastomotic stricture resulted in the need for percutaneous transhepatic stent insertion. In the second case (0.1 %) in group II, the clip was removed during laparoscopic cholecystectomy. However, the bile duct sustained a laceration, which was sutured after intraoperative conversion to laparotomy and resulted in good recovery.

Laceration of the cystic duct junction occurred in one patient (0.3 %) in group I. This patient then underwent intraoperative conversion to laparotomy with suture repair of the leak, which resulted in good recovery.

Discussion

As the number of laparoscopic cholecystectomies performed increased at each of the institutions studied, the number of surgeons performing this procedure nearly doubled from 40 in group I to 77 in group II. Although 67.5 % of the procedures in group I were performed by

surgical team leaders with over 15 years of experience, the number of procedures performed by resident surgeons with less than 5 years of experience increased to 18.6 % in group II compared to 2.7 % in group I. Since the number of experienced specialists is limited, the increase in the number of procedures would require that residents with less experience perform the operation. However, the lower rate of conversion to open cholecystectomy and the lower rate of complications in group II compared with group I indicates that the involvement of resident surgeons did not negatively affect the outcome. Probably, because it is possible for several surgeons to observe laparoscopic cholecystectomy using a monitor, the residents may have acquired sufficient training while working as part of a team (7).

Conversion to open cholecystectomy is always a possibility when performing laparoscopic cholecystectomy and the rate of conversion can be high in patients who have cholelithiasis complicated by associated diseases (19). Especially in acute cholecystitis, the rate of conversion has been reported to be high because inflammation obscures the anatomy of Calot's triangle and makes dissection difficult, and the conversion rate exceeds that for patients who have undergone previous upper abdominal surgery (20, 21). Major hospitals where this procedure is commonly performed report conversion rates of 1.8 % to 5.8 % (5-10), whereas in previous multicenter studies the reported rates were 3.2 % to 6.9 % (14, 15, 22-25). The present study revealed that the overall average rate of conversion to open cholecystectomy was 6.8 %. Despite an increase in the rate of patients with acute cholecystitis and a reduction in the rate with previous upper abdominal surgery in group II, the overall conversion rate was 5.1 % compared to 11.3 % for group I, representing a significant reduction. This marked reduction in the number of conversions necessitated by adhesions due to chronic cholecystitis or cystic artery hemorrhage in group II suggests that the surgeons improved their laparoscopic technique to some degree. However, the rate of conversion to the open procedure ranged between 1.3 % and 18.8 % at the 17 institutions reviewed, revealing large differences among these hospitals. Although the conversion rate generally decreased to approximately 4-5 % as the number of laparoscopic cholecystectomies increased, perhaps variations in the level of skill and enthusiasm for the procedure at the individual institutions accounted for the wide variation.

The complication rate for laparoscopic cholecys-

tectomy is 1-8 % according to data from single institutions (6-10). On the other hand, recent studies have shown that the complication rate for conventional open cholecystectomy is 3.6-4.5 % (26-28). The complication rate for laparoscopic cholecystectomy is not much higher compared with conventional open cholecystectomy (29). We used the same standards for defining surgical complications as those employed by the Southern Surgeons Club (14), and our data revealed a complication rate of 4.0 %. This is similar to the range of 1.6 % to 5.1 % previously reported in multicenter studies (14, 15, 22, 23, 25). In group I, the complication rate was 5.7 %, and it decreased to 3.4 % in group II, but this difference was not significant, so the safety of the procedure has not significantly improved over time.

Bile duct injury as a major complication of laparoscopic cholecystectomy has been extensively discussed in the literature (11-13). Single institution studies have reported bile duct injury rates ranging from 0.6 % to 1 % (5-8), while multicenter studies give a range of 0.25 % to 0.5 % (14, 15, 23, 25). The rate of bile duct injury in our series was 1.4 %, which was higher than in previous studies. Closer investigation revealed that bile duct injuries tended to occur during relatively simple laparoscopic cholecystectomy procedures in group I, and such injuries primarily involved mistaking the common bile or hepatic duct for the cystic duct or electrotome damage to the bile duct. These results showed that bile duct injury resulting from a lack of experience occurred most frequently among the first 20 patients at each institution. The rate of bile duct injury was reduced to 1.1 % in group II, but the rate was still higher than for conventional open cholecystectomy (0.09 %) (29). Bile duct injuries still occurred among the 21st and subsequent patients due to rough and forcible avulsion of the gallbladder in difficult cases.

Reports from tertiary care hospitals involved in the treatment of large numbers of bile duct injuries have indicated an increase in the number of complex injuries that are difficult to manage (11-13, 30). However, our study found that most bile duct injuries could be treated by simple suturing. Although long-term observation of these patients is necessary to detect the development of bile duct stricture, the postoperative course has usually been good. This difference may have arisen because studies based on tertiary care hospitals are limited to patients with difficult bile duct injuries, while our series included a large number of simpler injuries occurring in

routine practice. However, complete common duct transections require either end-to-end anastomosis or hepaticojejunostomy, and bile duct or anastomotic stricture occasionally occurs in these patients and necessitates further surgery or stent insertion (31). Such a complication not only upsets the patient and family who had hoped that only cholecystectomy would be necessary, but may also lead to bile duct stenosis, cholangitis, or calculus formation if an adequate anastomosis cannot be produced at the time of repair (30).

The mortality rate of laparoscopic cholecystectomy is lower than that for conventional open cholecystectomy and the cause of death is often unrelated to the laparoscopic surgery itself (17, 29). In the present series, there was only one death (due to cerebral infarction), resulting in a very low mortality rate of 0.08 %. A readmission rate of 0.9 % was reported by the Southern Surgeons Club (14), while our study gave a rate of 0.32 %. The lower readmission rate in the present study was thought to be because hospital costs are lower in Japan and, as a result, the duration of hospitalization for surgical patients is longer (typically 1 week) (32).

Conversion to open cholecystectomy, complications, and bile duct injury were all more common in group I, presumably due to insufficient technical skill, and these problems were reduced in group II as a result of increased experience. However, bile duct injury continued to occur in difficult cases even after the improvement of surgical skills, possibly because the surgeons began to perform riskier procedures. Since some bile duct injuries can be difficult to treat, surgical team leaders should keep the possibility of bile duct injury in mind, and conversion to open cholecystectomy may have to be considered in approximately 4-5 % of laparoscopic cholecystectomies in order to achieve a safer outcome. Although many reports described that the rate of bile duct injury from a surgeon's 10-15th patient onwards was very low, we believe that such favorable data is not a reason to throw caution to the wind. We suggest that many surgeons at each institution should not perform the laparoscopic cholecystectomy, although such a method is adapted in the conventional open cholecystectomy, but rather a specialist in laparoscopic cholecystectomy should be trained at each institution to improve the safety of this procedure.

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