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• *BRIEF REPORTS* •

A randomized controlled trial of laparoscopic versus open cholecystectomy in patients with cirrhotic portal hypertension

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Abstract

AIM: To evaluate the characters, risks and benefits of laparoscopic cholecystectomy (LC) in cirrhotic portal hypertension (CPH) patients.

METHODS: Altogether 80 patients with symptomatic gallbladder disease and CPH, including 41 Child class A, 32 Child class B and 7 Child class C, were randomly divided into open cholecystectomy (OC) group (38 patients) and LC group (42 patients). The cohorts were well-matched for number, age, sex, Child classification and types of disease. Data of the two groups were collected and analyzed.

RESULTS: In LC group, LC was successfully performed in 36 cases, and 2 patients were converted to OC for difficulty in managing bleeding under laparoscope and dense adhesion of Calot's triangle. The rate of conversion was 5.3%. The surgical duration was 62.6±15.2 min. The operative blood loss was 75.5±15.5 mL. The time to resume diet was 18.3±6.5 h. Seven postoperative complications occurred in five patients (13.2%). All patients were dismissed after an average of 4.6±2.4 d. In OC group, the operation time was 60.5±17.5 min. The operative blood loss was 112.5±23.5 mL. The time to resume diet was 44.2±10.5 h. Fifteen postoperative complications occurred in 12 patients (30.0%). All patients were dismissed after an average of 7.5±3.5 d. There was no significant difference in operation time between OC and LC group. But LC offered several advantages over OC, including fewer blood loss and lower postoperative complication rate, shorter time to resume diet and shorter length of hospitalization in patients with CPH.

CONCLUSION: Though LC for patients with CPH is difficult, it is feasible, relatively safe, and superior to OC. It is important to know the technical characters of the operation, and pay more attention to the meticulous perioperative managements.

Key words: LC; CPH; OC

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INTRODUCTION

The advantages of laparoscopic cholecystectomy (LC) have been extensively published, and LC has become the "golden standard" in treating benign gallbladder diseases[1-4]. When LC began in the early 1990s, cirrhosis and pregnancy, previous abdominal surgery, obesity, acute cholecystitis were considered absolute contraindications for performance of the laparoscopic technique. Growing experience has allowed the use of LC in more complex procedures, such as in cirrhotic patients[5,6]. In recent years, several studies have reported good results and suggested liberal use of LC in patients with symptomatic gallbladder disease and cirrhosis[7-10]. However, its feasibility, benefits and successful use in patients with cirrhotic portal hypertension (CPH) are meagerly well-documented. Based on our previous studies on the influence of LC on the hepatic function and our experience with LC for cirrhotic patients, we have successively performed LC in patients with CPH. The present study is a retrospective analysis comparing the results of OC and LC in patients with symptomatic gallbladder disease and CPH.

MATERIALS AND METHODS

Eligibility of patients

Altogether 80 patients, including 65 male and 15 female, aged 52.3±12.2 years, were all diagnosed as symptomatic gallbladder disease and CPH. The diagnosis was mainly according to the disease history and ultrasound, spiral CT and esophageal barium swallow examination results, combined with laparoscopic examination results of the typical modular lesions in liver lobes. Clinical signs included megaspleen (62 cases), widened portal vein (diameter over 14 mm) (52 cases), ascites (27 cases), varices of esophagus and gastric fundus veins (31 cases). Seventy-one patients were hepatic cirrhosis (hepatitis B in 58 and hepatitis C in

13). Nine other patients had alcoholic cirrhosis. The Child-Pugh classification system was used to assess the severity of CPH. On preoperative assessment, 41 patients were classified as Child class A, 32 were Child class B and 7 were Child class C. Significant comorbidity was present in 25 (31.3%) patients, including cardiac disease (12 cases), respiratory compromise (10 cases), diabetes mellitus (6 cases), and renal impairment (3 cases). Nine (11.3%) patients had disease in more than two organ systems. No previous upper abdominal operation had been conducted in these patients. Randomization was done before operation by use of sealed envelopes. Patients were randomly divided into OC group (42 cases) and LC group (38 cases). The patients' characteristics of the two groups are listed in Table 1. These two groups were well-matched for number, age, sex, Child classification and types of disease. The study was approved by the local hospital ethics committee. Written informed consent to participate in the study was obtained from all patients.

Table 1 Comparison of patients' characteristics between two groups

	LC group (n = 38)	OC group (n = 42)	P
Age (yr)	50.2±11.6	53.8±14.2	0.606
Sex			0.943
Male	31	34	
Female	7	8	
Child classification			0.432
A	19	22	
B	15	17	
C	4	3	
Type of disease			0.761
Gallbladder polypus	3	2	
Gallbladder stones	35	40	

Methods

Patients underwent standard preoperative workup, including conventional blood tests, chest radiograph, electrocardiogram, ultrasonography, spiral CT scan, and/or esophageal barium swallow examination. No special preparation before operation was needed for Child class A cases. Hepatic function protection and supporting, ascites controlling and portal vein pressure reduction were considered individually for most Child class B and C cases. If the patient had class C cirrhosis, attempts were made to improve the patient's hepatic function to near class B level. Only after that, surgical operations arranged were allowed for a safer elective operation.

The patients were put in the supine position under general anesthesia with intratracheal intubation. A standard four ports laparoscopic procedure was performed for all LC cases by using two 5-mm and 10-mm ports after pneumoperitoneum was established using a Veress needle. The intraabdominal CO_2 pressure was controlled at about 1.33 kPa. The OC was completed with a 10-14 cm subxiphoid incision. A silicon drain was placed in the operation field for all patients, which was usually pulled out in 24-72 h after operation.

The patients inhaled oxygen after returning to the ICU ward. Changes of vital signs were monitored for 24-48 h. Fluid infusion, anti-inflammation, hemorrhage prevention, liver function protection and analgesics treatments were prescribed. Data on these two groups were collected and analyzed.

Statistical method

SPSS10.0 statistics software was used to establish the database. Statistical comparisons between OC and LC groups were made with Student's t test for categorical variables. Statistical significance was defined as $P<0.05$.

RESULTS

In LC group, LC was successfully performed in 36 of 38 cases, including three laparoscopic subtotal cholecystectomies. Two conversions to OC were necessary. One was due to difficulty in managing bleeding in the gallbladder bed under laparoscope and another for dense adhesion of Calot's triangle. The rate of conversion was 5.3%. The mean operative time was 62.6±15.2 min. The operative blood loss was 75.5±15.5 mL. The mean time to resume diet was 18.3±6.5 h. Seven postoperative complications occurred in five patients (13.2%). They were tracker infection (one case), respiratory system infection (one case), urinary system infection (one case), upper gastrointestinal bleeding (one case), mild hepatic encephalopathy (one case) and ascites aggravation (two cases). All patients were cured and dismissed after 4.6±2.4 d.

While in OC group, the mean operative time was 60.5±17.5 min. The operative blood loss was 112.5±23.5 mL. The mean time to resume diet was 44.2±10.5 h. Fifteen postoperative complications occurred in 12 patients (30.0%). They were wound infection (two cases), respiratory system infection (four cases), urinary system infection (two cases), mild hepatic encephalopathy (two cases) and ascites worsening (five cases). All patients were cured and dismissed after 7.5±3.5 d.

Comparison of perioperative parameters of two groups is listed in Table 2. There was no significant difference in operative time between the two groups. But LC offered several advantages over OC, including fewer blood loss and lower postoperative complication rate, shorter time to

Table 2 Comparison of perioperative parameters of two groups

Group	Operative time (min)	Blood loss (mL)	Time to resume diet (h)	Postoperative complication rate (%)	Length of hospitalization after operation (d)
LC group (n = 38)	62.6±15.2	75.5±17.5	18.3±6.5	13.2	4.6±2.4
OC group (n = 40)	60.5±17.5	112.5±23.5[b]	44.2±10.5[b]	30.0[b]	7.5±3.5[a]

[a]$P<0.05$, [b]$P<0.01$ *vs* LC.

resume diet and shorter hospital stay in patients with CPH.

DISCUSSION

In a review of 4 895 postmortem records, Bouchier[11] found that the frequency of gallbladder stone in patients with cirrhosis was 29.4%, more than twice the noncirrhotic frequency. Factors implicated in the higher incidence of gallbladder disease in these patients include: hypersplenism, increased levels of estrogen, and increased intravascular hemolysis with a reduction in gallbladder emptying and motility. Though there is no definite data on the frequency of gallbladder diseases in patients with CPH, it is estimated that the frequency might be 2-5 times higher than the noncirrhotic's. Most of these patients remain asymptomatic. Nevertheless, the management of symptomatic gallbladder diseases in patients with CPH has remained problematic. In the early 1980s, OC in cirrhotic patients was associated with a postoperative mortality ranging from 7% to 26%. The increased risks led to reluctance to undertake elective cholecystectomy in patients with cirrhosis and symptomatic gallbladder disease. By the late 1980s, better surgical results had been published for cirrhotic patients who underwent elective cholecystectomy[12]. OC was subsequently considered as an acceptable therapeutic option in cirrhotic patients with relatively normal hepatic function. Since the introduction of LC in 1990s, the question of whether cirrhotic patients might benefit from this less invasive approach has arisen[13,14]. It is well known that LC allows for shorter hospital stay and operative time, faster operative rehabilitation, and reduced wound complications for noncirrhotic patients when compared with OC. Several recent studies have also demonstrated that LC in Child A and B cirrhosis was safer and better tolerated than OC[15-18]. Cholecystectomy for patients with CPH is more complicated than that for cirrhotic cases. Excessive blood loss, postoperative liver failure, and sepsis were the most prominent problems for these special patients[19]. There have been few reports with limited cases of OC for patients with CPH. The results were relatively acceptable. But there has been no such report of LC for patients with CPH.

In our previous series studies, we have observed that laparoscopic surgery had obvious influence on the hepatic function. We have also demonstrated in our animal experiments that ischemia-reperfusion injury caused by pneumoperitonium played an important role in liver impairment. Methods to diminish this injury, for example, lowering pneumoperitonium pressure, shortening operation time, perioperative liver function protection and supporting were also proposed thereafter. We have carefully performed more than 200 LCs in cirrhotic patients since 1999. Based on the clinical and experimental experience, we tried LC in patients with CPH since 2001. This study was designed to prospectively compare the characters, risks and benefits of LC and OC in patients with CPH. We found that there was no significant difference in surgical duration between LC and OC groups. But LC offered several advantages over OC, including less amount of intraoperative hemorrhage and lower postoperative complication rate, reduced time to resume diet and hospital stay after operation. The results of our present study confirm that LC is a relatively feasible and safe operative approach, and it is superior to OC for patients with CPH. We speculate that LC can offer the following advantages for patients with CPH: (1) LC is a minimally invasive operation, which has little influence on patients, and ensures a quicker recovery. So it can improve the patient's tolerability for cholecystectomy, and thus extend the indication for cholecystectomy for patients with CPH[20,21]. (2) Ascitic infection which occurs frequently after OC, can result in intra-abdominal sepsis and death. Access to the sterile peritoneal cavity by millimetric (5 and 10 mm) channels may have an important role in the prevention of inadvertent bacterial seeding and contamination of the ascites. (3) Laparoscopy has the ability of magnification, which is helpful to make observation of minute organ structures more clearly. It is also beneficial to the observation of dilated and twisted portal vein branches in the operation field and congested gallbladder bed, thus can effectively avoid meaningless injury of blood vessel and the following bleeding. (4) LC is reported to have fewer postoperative complications, such as wound infection, incisional hernia and respiratory, urinary system infection. Reduction of these common complications is especially important for patients with CPH[22]. (5) Many patients with CPH also had various hepatitis virus infection. During laparoscopic surgical operation, the surgeon did not directly touch the patient's blood and viscera, so that the possibility of iatrogenic infections could be reduced. (6) Some patients with CPH may accept liver transplantation in the future. LC, without opening abdominal cavity, offers the potential for fewer right upper quadrant adhesions postoperatively. This will benefit liver transplantation.

LC still has shortages and our management measures to overcome them for patients with CPH included: (1) During LC, CO_2 pneumoperitonium can cause ischemia-reperfusion injury to the internal organs, such as liver and kidney. This may aggravate the damage of the hepatic function. Since this injury was positively correlated with the pressure of pneumoperitonium[23-25], we routinely establish the pneumoperitonium with a lower flow of CO_2, maintain the intra-abdominal pressure at about 1.33 kPa, and gradually relieve the pneumoperitonium after LC. We think these can reduce further damage to hepatic function. It has been reported that gasless pneumoperitonium can avoid ischemia-reperfusion injury to the internal organs. But we have no such experience. It may be worth trying. (2) It may not be as direct and convenient for LC in managing bleeding under laparoscope, especially when extensive bleeding and permeating bleeding occurred. We think it is critical for operators to proficiently master laparoscopic techniques as compression, electronic coagulation, and transfix. On the other hand, complete preparation of various laparoscopic apparatus is suggested. (3) Sometimes CPH can lead to atrophy-hypertrophy and displacement of liver lobes. This may cause inconvenient exposure of operative field under laparoscope. Adjustment of the tracker location is usually needed in this situation.

The results of this series indicated that LC for patients with CPH in the management of symptomatic gallbladder diseases is feasible and relatively safe. Nevertheless, the

procedure is still complicated and highly difficult which associates with significant morbidity compared with that of patients without cirrhosis[26]. LC for patients with CPH should be performed by experienced laparoscopic surgeons. We think that more attention should be paid to the following aspects: (1) Functions of important organs, such as liver, kidney, heart, lung, should be carefully checked before the operation to make clear patients' general status. Individual preoperative preparation should be conducted mainly based on patients' Child classification. Generally, no special preparation was needed for Child class A cases. Special individual measures should be taken to improve the patient's liver function for class B and C cases. For the patients with class C cirrhosis, attempts should be made to improve the patients' hepatic function to near class B, then surgical operation was arranged. Attempts which we have made included hepatic function protection, control of ascites, nutritional support, coagulation function amelioration and portal vein pressure reduction to allow for a safer elective operation. Correction of coagulopathy with platelets or fresh frozen plasma before surgery is advised, and availability of these products intraoperatively is essential. (2) Bleeding complications are significantly more common in patients with CPH. Several technical modifications should be made[27]. At the commencement of the laparoscopic procedure, special care should be taken during trocar insertion to avoid injury to dilated abdominal wall veins. The subxiphoid 5-mm port was placed more to the right of the midline to completely avoid the falciform ligament and its accompanying umbilical vein. Portal hypertension with large venous collaterals in the liver hilum provides a major challenge in the surgical management of the biliary tract[28]. This pathology is a major source of intraoperative and postoperative complications. We believe that meticulous care be taken to maintain hemostasis. Extreme caution with constant control of hemostasis was the hallmark of the procedure. Blunt dissection was avoided to minimize bleeding once the cystic duct was identified and divided and all tissues were clipped/ligated and cut. A variety of techniques other than unipolar electrocautery, including argon beam coagulation, ultrasonic dissection, and thrombin spray are available for use[29,30]. In a few cases, involving large collateral veins around the gallbladder, when severe bleeding is likely from large varices, subtotal cholecystectomy could be performed to prevent massive blood loss from the gallbladder bed[31,32]. This technique avoids dissection in the hepatic hilum. In our patient population, this maneuver was necessary in three patients. Surgeons should be aware of this procedure to lessen the risk of excessive blood loss during LC. All access ports were checked internally for bleeding just before completion of the procedure. Drainage of the operative field was performed routinely for all patients in this study, which was pulled out in 24-48 h after operation. This is helpful for postoperative observation and management. (3) In recent reports, conversion rates during LC ranged from 0% to 9%[33]. In this study, the rate of conversion to OC was 5.3%, which was similar to published data for LC conversion in a noncirrhotic patient population. A low threshold for conversion from LC to OC should be maintained. Conversion is not a complication, but a means to prevent more serious problems. Absolute indications for conversion include bleeding not readily controlled laparoscopically and an inability to recognize the anatomy properly[34,35]. The surgeon should not be reluctant to convert immediately to OC when there is uncertainty about the safety and efficiency of the operative procedure.

Our study has demonstrated the feasibility and advantages of LC in well-compensated patients with CPH. In the hands of an experienced surgical team, LC should be the procedure of choice in the treatment of gallbladder disease in these patients. We believe that along with further understanding of LC technique characteristics in patients with CPH, continuous improvements in the perioperative management, the expansive application of new surgical operation apparatus (such as ultrasound knife), as well as improvement of operator's technical skills, more and more patients with CPH will benefit from LC in the near future.

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