

ORIGINAL ARTICLE

LAPAROSCOPIC VERSUS OPEN CHOLECYSTECTOMY IN CIRRHOTIC PATIENTS: A PROSPECTIVE RANDOMIZED STUDY

Saleh El-Awadi, Ayman El-Nakeeb, Amir Fikry, Tito Abd El-Hamed, Hosam Ghazy, Kamal Abd el Elah, Mohamed Farid

Departments of General Surgery, Mansoura University Hospital, Mansoura, Egypt

Correspondence to: Amir Fikry, Email: amrikry@yahoo.com

Aim: Improved laparoscopic experience and techniques have made laparoscopic cholecystectomy (LC) feasible options in cirrhotic patients. This study was designed to compare the risk and benefits of open cholecystectomy (OC) versus LC in compensated cirrhosis.

Method: A randomized prospective study, in the period from October 2002 till December 2006, where 110 cirrhotic patients with symptomatic gallstone were randomly divided into OC group (55 patients) and LC group (55 patients).

Results: There was no operative mortality. In LC group 4(7.33%) patients were converted to OC. Mean surgical time was significantly longer in OC group than LC group (96.13 + 17.35m vs. 76.13+ 15.12) P <0.05, associated with significantly higher intraoperative bleeding in OC group (P<0.01), necessitatating blood transfusions to 7 (12.72%) patients in OC group. The time to resume diet was 18.36+8.18h in LC group which significantly earlier than in OC group 47.84+14.6 h P <0.005. Hospital stay was significantly longer in OC group than LC group (6+1.74 days vs. 1.87+1.11 days) P <0.01 with low postoperative morbidity.

Conclusion: LC in cirrhotic is still complicated and highly difficult which associates with significant morbidity compared with that of patients without cirrhosis. However, It offers lower morbidity, shorter operative time; early resume dieting with less need for blood transfusion and reducing hospital stay than OC.

Keywords: Liver cirrhosis, Child-Pugh, Postcholecystectomy

INTRODUCTION

The advantage of laparoscopic cholecystectomy (LC) have been extensively published, and LC has become the gold standard in treating benign gallbladder diseases.^(1,2) Growing experience has allowed the use of LC in more complex procedures, such as in cirrhotic patients.⁽³⁾

The technical challenge and the risk of performing open cholecystectomy (OC) in patients with compensated cirrhosis and symptomatic gallstone disease have been documented.⁽⁴⁻⁷⁾ LC may offer a better option because the magnification and availability of newer instrument like Ligasure and the ultrasonic shears.^(3,8,31)

Infection with hepatitis C virus (HCV) has become the most important public health problem in Egypt. Chronic viral hepatitis C and infection with schistosoma mansoni are the two major causes of chronic liver disease in Egypt.⁽⁹⁾ The severity of cirrhosis, assessed with Child-Pugh classification, is a major determinant in deciding which treatment approach is optimal.⁽¹⁰⁾

The present study is a prospective randomized study comparing the result of OC and LC in patients with compensated cirrhotic and symptomatic gallstone disease.

PATIENTS AND METHODS

Altogether 110 patients with compensated cirrhosis and

EJS, Vol 26, No 1, Jan., 2007

By

symptomatic gallstone, in the period from October 2002 till December 2006, were randomly divided into open cholecystectomy group (55 patients) and laparoscopic cholecystectomy group (55 patients) at Mansoura university hospital, Mansoura, Egypt. OC group include 30 (54.5%) males and 25 (45.5%) females, with mean age 44.62 +10.2 years while LC group include 26 (47.3%) males and 29 (52.7%) females with mean age 46.49+8.6 years.

All patients were subjected to thorough history and clinical examination focused on manifestation of gallstone disease and chronic liver disease. The following investigations were performed:

- whole blood picture
- liver function tests (serum albumin, SGOT, SGPT, prothrombine time, INR).
- creatinine, urine and stool analysis.
- HCV and HBV markers.
- Abdominal ultrasound to show the state of the liver, portal vein, gall bladder, and CBD.

In OC group, the diagnosis of cirrhosis had been proven on ultrasound finding, and intra-operative appearance in 18(32.72 %) patients and liver biopsy in 37 (67.3 %) patients. In LC group, cirrhosis was diagnosed by means of liver biopsy in 42 (76.36 %) patients and preoperative ultrasound and intraoperative appearance in 13(23.63 %) patients. The Child – Pugh classification system was used to assess the severity of cirrhosis. No patient in this study had a Child class C cirrhosis.

Randomization was performed using "sealed envelops" technique. The envelops were drawn and opened by operating room nurse not otherwise engaged in the study just before surgery.

All patients were performed under general anesthesia; hepatotoxic drugs were avoided. A standard 4 ports laparoscopic_procedure was performed for all LC group by using two 5 mm ports and two 10 mm ports after pneumoperitoneum was established using a veress needle. The intraabdominal CO2 pressure was controlled at the level of 14 mm Hg. The OC was completed with 14 cm subcostal incision in 33 patients and right upper paramedian incision in 22 patients. Hemostasis was achieved with electrocautary and ligasure. Abdominal drain was placed in the operative field for all patients.

The finite end points were conversion rate and surgical time was documented as well as intraoperative findings. Intraoperative bleeding recorded as less than 250 mL, 250 to 500 mL, and more than 500mL, and Blood transfusion. Times to resume diet and postoperative subjective pain score using VAS (visual analogue scale) were recorded

(measured on the $1^{\rm st}, 3^{\rm rd}, 7^{\rm th}$ postoperative days. $^{(11)}$ Hospital stays and postoperative complications were recorded.

The patients were followed up weekly for the 1st month, monthly for first three months and every three months for one year, clinically, laboratory (liver function) and radiological (abdominal ultrasound)

SPSS 10.0 statistics software was used to establish the data base. Statistical comparison between OC and LC group were made with students T test for categorical variables, and Wilcoxon's rank sum test for variable with continuous or ordinal distributions. Statistical significance was defined as p < 0.05.

RESULTS

The demographic data and clinical presentation for both groups were shown in Table 1. With no statistical difference observed between the both groups as regard to age, sex, clinical presentation Table 1. And severity of liver cirrhosis Table 2.

Table	1.	Patient's	demographic	data	and	clinical
preser	itat	ion.				

patients	OC group n (%)	LC group n (%)	P value
Age mean + SD	44.62+10.29	46.49+8.6	0.604
Sex			
male	30(54.5%)	26(47.3%)	0.543
female	25 (45.5%)	29(52.7%)	
Clinical presentation			
Biliary colic	49(89%)	53(96.4%)	0.431
Acute cholecystitis	6(10.9%)	2(3.6%)	

Table 2. Severity of hepatic cirrhosis.

patients	OC group n (%)	LC group n (%)	P value
Child Pugh class			
А	43(78.2%)	47(85.5%)	0.672
В	12(21.8%)	8(14.5%)	
С	0	0	

Laparoscopic cholecystectomy was successfully completed in 51 out of 55 cases. Four cases (7.33%) were converted to open cholecystectomy, because of uncontrollable liver bed bleeding in two patients and insufficient visualization of Calot's triangle in another two patients.

Mean surgical times were significantly shorter in LC group. The mean + SD (in minutes) of OC group and LC group was 96.13 + 17.33 versus 76.13 + 15.13, respectively,

(P < 0.05). The mean time to resume diet (hours) was 18.36+8.1 in LC group was significantly earlier than in OC group 47.84+14.97 (P < 0.005). Also, pain score measured in 1st, 2nd and7th day significantly reduced in LC group (P<0.05). The length of hospital stay (days) was significantly longer in OC group with a mean hospital stay 6+1.74, compared with a mean hospital stay 1.87+1.11 for LC group as shown in Table 3.

Tables 3. Comparison of perioperative variables of two groups.

	OC group	LC group	P Value
Operative time (min)	96.13+17.33 (61- 142)	76.13+15.13 (53 -96)	<0.05
Hospital stay (days)	6+1.74(3-9)	1.87+1.11 (1-5)	<0.01
Time to resume diet (h)	47.84+14.97	18.36+8.1	< 0.005
Postoperative pain			
1st day	7.93+1.09	4.12+0.67	< 0.05
2nd day	5.84+1.08	2.34+0.66	< 0.05
7th day	4.41+0.77	1.1+0.65	< 0.05

Estimated intraoperative bleeding of more than 250 ml occurred in 28 (50.9%) patients in OC group and 13 (23.63 %) patients in LC group, the difference between the two groups was statistically significant (P = 0.01) Table 4. Patients in LC group didn't require blood transfusion during hospital stay, but 7 patients (12.72%) in the OC group required 1 to 2 units blood during surgery .The estimated postoperative blood loss was statistically insignificant between both group Table 4.

Table 4. Intraoperative and postoperative blood loss.

	OC group	LC group	P value
Intraoperative			
<250	27(49.1%)	42(76.36%)	
250-500	19(34.5%)	11(20%)	< 0.01
>500	9(16.4%)	2(3.64%)	
Blood transfusion	7(12.72%)	0	< 0.05
postoperative			
<250	46(83.61%)	52(94.5%)	
250-500	5(9.1%)	3(5.5%)	< 0.238
>500	4(7.3%)	0	

Postoperative complications for each group were presented in Table 5. In LC group, 13 postoperative complications occurred in 7 patients. While In OC group, 46 postoperative complications occurred in 19 patients. Patients' morbidity was more frequent in OC group than LC group, statistically significant difference observed in wound complication (P<0.05) and deterioration of liver function (P<0.05). No operative mortality in both groups. **Table 5. Postoperative complications rate.**

	OC group	LC group	P value
morbidity	19patients	7 patients	
Pulmonary infections	5(9.1%)	3(5.5%)	<0.561
Deterioration of liver function	9(16.4%)	3(5.5%)	< 0.05
Ascitic <u>l</u> eak	6(10.9%)	2(3.6%)	<0.062
Bile leak	3(5.5%)	3(5.5%)	<0.452
Mild encephalopathy	3(5.5)	0	<0.437
Wound infections	10(18.2%)	1(1.8%)	< 0.05
Incisional hernia	8 (14.5)	1(1.8%)	< 0.05
Internal hemorrhage	2(3.6%)	0	<0.42
Total	46	13	

DISCUSSION

Cholethiases in patients with cirrhosis occurs twice as often as in general population.⁽¹²⁻¹⁴⁾ That's caused by increased intravascular hemolysis, hypersplenism and increased level of estrogen with reduction in gallbladder emptying and motility.^(13,15) Worthwhile cholecystectomy in cirrhotic is associated with high rate of mortality (7-20%) and morbidity (5-23%) related to excessive blood loss, postoperative liver failure, and sepsis.^(16,17) The increased risks led to reluctance to undertake elective cholecystectomy in patients with cirrhosis and symptomatic gallstones disease.⁽¹⁰⁻¹⁷⁾

Since the introduction of LC, the question of whether cirrhotic patients might benefit from this less invasive approach has arisen. It is well known that LC allows for shorter hospital stays and operative times, faster operative rehabilitation, reduced wound complications and less total costs for non cirrhotic patients when compared with open cholecystectomy.^(18-20,31)

In this study, the patients who underwent LC had significantly shorter surgical times, hospital stay and less postoperative pain than in OC group also, absence of intraoperative intestinal retraction and less pain in LC group explain the low occurrence of postoperative ileus and early resume to diet. This state also confirmed by WU J et al,⁽²²⁾ Saeki H et al,⁽²¹⁾ and Poggio et al.⁽⁷⁾

In recent reports, conversion rates during LC ranged from 0% to 9%.^(23,24,32) Our rate of conversion to open cholecystectomy (7.33%) was similar to published data for LC in non cirrhotic patients population.^(18,25) Conversion is not a complication, but a mean for to prevent more serious problems. Absolute indications to convert include bleeding not readily controlled laparoscopically and inability to recognize the anatomy properly.

At the commencement of laparoscopic procedure, special care should be taken during trocar insertion to avoid injury to dilated abdominal wall veins. The subxiphoid ports was placed more to the right of the midline to avoid the falciform ligament and accompanying umbilical vein. We believe in meticulous care to maintain hemostasis so, blunt dissection was avoided to minimize bleeding once and variety of techniques other than electrocautary, including Ligasure is available.

In this study the reduced blood loss in LC group, whether operative or postoperative, is related to meticulous dissection (magnified surgical field) and pneumoperitonum barohemostatic effect and using Ligasure in dissection. These data correlate with finding of WU J et al,⁽²²⁾ Poggio J et al,⁽⁷⁾ and Yardel etal.⁽³⁾

Wound problems such as infections, dehiscence, and postoperative hernia are complications that rise postoperative morbidity for OC in cirrhotics as Bloch et al⁽¹⁰⁾ reported an incidence of 12%. Only two wound complications of our LC group in contrast to an 18 wound complication in OC group. The elimination of wound related complication in LC contributed to a more favorable postoperative outcome in patients with cirrhosis. Also, the absence of parietal incision in LC group declines the incidence of pulmonary complications as reported by Poggio et al.⁽⁷⁾ Also, the reduced bleeding (anoxic and toxic effect), minimal dissection, short operative and anesthetic time, all explain the lake of deterioration of liver function in LC group than OC group. This finding also reported by Poggio J et al⁽⁷⁾ and Schiff etal.⁽²⁴⁾

The results of this study indicated that LC for cirrhotic patient with symptomatic gallstones is feasible and relatively safe. Nevertheless, the procedure is still complicated and highly difficult which associates with significant morbidity especially bleeding complication compared with that of patients without cirrhosis 22.26.

LC in cirrhotic patients also, offers fewer hypervascular adhesions postoperatively, this will be advantage for patients having liver transplantation⁽²⁷⁻²⁹⁾ and lessen the contamination risk to medical and paramedical personnel.⁽³⁰⁾

In conclusion an elective LC should be considered for every patient with Child class A and early B cirrhosis having symptomatic gall stone. The results of our study confirm that LC is a safe operative approach in most patients with Child class A and B and symptomatic gallstone disease. LC offers the following advantages shorter anesthetic and surgical times, reduced hospital stay, reduce blood loss, fewer operative and postoperative complications. To achieve these advantages in patients with cirrhosis, this complicated and difficult procedure should be only performed by experienced laparoscopic surgeon.

REFERENCES

- Curet MJ, Conter M, Weber DM, Abrecht R. Laparoscopic cholecystectomy. Surg Endosc. 2002;16:453-7.
- 2. Fernado R: Laparoscopic cholecystectomy. World J Surg. 2002;26:1401.
- Yardel MA, Koksoy C, Aras N. Laparoscopic versus open cholecystectomy in cirrhotic patients, a prospective study. Surg.lapro.Endo. 1997;7:483-6.
- Kogut K, Aragoni T, Ackermen NB. Cholecystectomy in patients with mild cirrhosis a more favorable situation. Arch Surg. 1985;120:1310-1.
- Zacks SL, Sandler RS, Rutledge R, Brown RS Jr: A population-based cohort study comparing laparoscopic cholecystectomy and open cholecystectomy. Am J Gastroenterol. 2004;99:1399.
- Sirinek KR, Burk RR, Brown M, Levine BA. Improving survival in patients with cirrhosis undergo major abdominal operation. Arch Surg. 1987;122:271-3.
- Poggio JL, Rowland CM, Gores GJ, Nagorney DM, Danohre JA. A comparison of_laparoscopic and open cholecystectomy in patients with compensated cirrhosis and symptomatic gallstones disease. Surgery. 2000;127:405-11.
- Yeh CN, Chen MF, Jan Y. laparoscopic cholecystectomy in 226 cirrhotic patients, experience of a single center in Taiwan. Surg Endosc. 2002;16:1583-7.
- Halim AB, Garry RF, Dash S. Effect of shistosomasis and hepatitis on liver disease. Am J. Trop Med. Hyg. 1999;915-20.
- Bloch RS, Allaben RD, Walt AJ. Cholecystectomy in patients with cirrhosis. A surgical challenge. Arch Surg. 1985:120:669-72.
- 11. Huskisson EC. Measurement of pain. Lancet. 1974:1127-31.
- Bouchier IA. Postmortem study of the frequency of gallstones in patients with cirrhosis. Gut. 1969:10:705-10.
- Conte D, Barisani D, Mandelli P, Bodini P, Borzoi M, Pistoso S. Cholethiases in cirrhosis. Analysis of 500 cases. Am.J.Gastroenterology. 1991;86:1629-32.

- Tuech JJ, Pessaux P, Regenet N, Rouge C, A rnaud JP. Laparoscopic cholecystectomy in cirrhotic patients . Surg Laprosc End. 2002;4:227-31.
- 15. Schesinger WH, Kurtin WE, Levine. Cirrhosis and alcoholism as pathogenic factors in pigmented gallstones formation. Ann Surg. 1985;201:319-22.
- Morino M, Cavuotin G, Migliettic C, Simone P. Laparoscopic cholecystectomy in cirrhosis : contraindication or privileged indications?. Laparosco.Endosc. 2000;10:360-3.
- 17. Aranha GV, Sontag SJ, Greenlee HB. Cholecystectomy in cirrhotic patients: a formidable operation. Am. J Surg. 1982;143:55-60.
- Colonval P, Navez B, Cambier E, Richir C, Scohy JJ, DE Pi Erpont B. Is laparoscopic cholecystectomy effective and reliable in acute cholecystectomy? Results of postoperative study of 221 pathologically documented cases. Ann Chir. 1997:51:689-96.
- Lujan JA, Parrilla P, Robles R, Marin P, Torralba. Laparoscopic cholecystectomy versus open cholecystectomy in treatment of acute cholecystitis a prospective study. Arch of Surg. 1998; 133:173-5.
- Wu Ji, Ling-Tang Li, Xun-Ru Chen, Jie-Shou Li, Nanjing, China. Application of laparoscopic cholecystectomy in patients with cirrhotic portal hypertension. Hepatobilary pancreat Dis Int. 2004;3:270-4.
- Saeki H, Korenga D, Yamaga H, Mawatari K, Orita H, Itasak H. A comparison of open and <u>laparoscopic</u> cholecystectomy for patients with cirrhosis. Surg Today. 1997;27:411-3.
- Wu Ji, Ling-Tang Li, Zhi-Ming Wang, Zhu-Fu Quan, Xun-Ru Chen, Jie-Shou Li. A randomized controlled trial of laparoscopic versus open cholecystectomy in patients with cirrhotic portal hypertensions. World J Gastroenterol. 2005;11:2513-17.
- Cucinotta E, Lazzan S, Melita G. Laparoscopic cholecystectomy in cirrhotic patients. Surg Endosc. 2003;17:1958-60.
- 24. Schiff J, Misra G, Rendon J, Rothschild S, Schwaitzeberg. Laparoscopic cholecystectomy in cirrhotic patients. Surg Endosc. 2005;19:1278-81.
- Mcgee JM, Malnar KF, Bellefeuiilli CE, Berry B, Katsis SD. Longitudinal cholecystectomy study: patterns of care in a total community experience. J Laproendosco Adv. Surg Tech. 1997;7:99-109.
- Kao LS, Aaron BC, Dellinger EP. Trials and tribulations: current challenges in conducting clinical trials. Arch Surg. 2003;10:172-5.
- D'Albuquerque LA, de Miranda MP, Genzini T Copstein JL, de Olivera e Silva A. Laparoscopic cholecystectomy in cirrhotic patients. Surg Laparosc Endosc. 1995;272-6.

- Gugenheim J, Casaccia M Jr, Mazza D, Toouli J, Laura V, Fabiani P. Laparoscopic cholecystectomy in cirrhotic patients. HPB Surg. 1996;10:79-82.
- 29. Mansour A, Shayani V, Pickleman J. Abdominal operations in patients with cirrhosis still a major surgical challenge. Surgery. 1997;122:730-6.
- En barks, Newman L, Luas S. reduction of HIV transmission during laparoscopic procedure: Surg Lapar. Endosc. 1993;3:2-5.
- Puggioni A, Wong LL. A Metanalysis of laparoscopic cholecystectomy in patients with cirrhosis. J Am Coll Surg. 2003;197:921-26.
- Ibrahim S, Hean TK, Ho LS, Ravintharan T, Chye TN, Chee CH. Risk factors for conversion to open surgery in patients undergoing_laparoscopic cholecystectomy.World J of Surg. 2006;30:1698-704.

EJS, Vol 26, No 1, Jan., 2007