Egyptian Journal of Surgery Vol 27, No 1, January, 2008

ORIGINAL ARTICLE

SONAR GUIDED MINI-LAPAROTOMY CHOLECYSTECTOMY VERSUS LAPAROSCOPIC CHOLECYSTECTOMY: A PROSPECTIVE, RANDOMIZED STUDY

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Aim: ***To analyze outcomes after open small-incision surgery (minilaparotomy) guided by ultrasonography and laparoscopic surgery for gallstone disease.***
Methods: ***This study was a randomized trial comparing laparoscopic cholecystectomy (LC) to sonar guided minilaparotomy cholecystectomy (SMC) at El-Minia University Hospital and carried out in 60 patients from March 2005 to February 2006. LC was a routine procedure at El-Minia University hospital, whereas SMC was introduced recently.***
Results: ***Of 60 patients, 30 were randomized to LC and 30 to SMC. The groups were well matched for age and sex. Median operating times were 100 and 48 minutes for LC and SMC, respectively. Median hospital stay was nearly equal in both groups. Intraoperative complications were less frequent in the SMC group, but there was no difference in the postoperative complication rate between the groups. Costs for operation, other health care costs, costs due to sick-leave and total costs were calculated and proved to be significantly higher in LC group. There was no bile duct injury in each group and no deaths.***
Conclusions: ***Operating time was longer and costs were higher for LC compared with SMC. Further analyses of LC versus SMC are necessary regarding surgical training, surgical outcome, and health economy.***

Keywords: *Gall stones, laparoscopy, minilaparotomy.*

INTRODUCTION

Gallbladder disease is the most costly of all digestive disorders requiring hospitalization, and cholecystectomy is the most common abdominal operation undertaken.[1] Gallstones are often asymptomatic, increasing in prevalence with age. At 60 years of age 30% of women and 15% of men in European populations have gallstones.[2]

During the 1980s and in the early 1990s, it was shown that the conventional large subcostal incision in cholecystectomy could be replaced by a much smaller incision, giving a shorter convalescence.[3-5] When laparoscopic cholecystectomy (LC) was introduced in the late 1980s, it rapidly became the dominant procedure for gallbladder surgery in the industrialized world. The main reason was that the new method was followed by a smoother postoperative course than conventional cholecystectomy.[6-8]

It was concluded that laparoscopic cholecystectomy could be performed at a treatment cost that was equal to or

slightly less than that of open cholecystectomy, and with substantial cost savings to the patient and society due to the reduced loss of time from work.[9] However, the cost of laparoscopic cholecystectomy and small-incision open cholecystectomy or minilaparotomy cholecystectomy, has been compared in four randomized controlled trials with divergent results.[10-13] However, the extent to which conclusions could be generalized to the entire population was not analysed in these studies.[14,15]

PATIENTS AND METHODS

During the one year period from March 2005 to February 2006, 60 patients underwent cholecystectomy either laparoscopically (LC) or by sonar guided mini-laparotomy (SMC) in the Department of Surgery, El-Minia University Hospital. All patients advised to undergo a cholecystectomy were considered for inclusion (30 patients for LC and 30 for SMC). Exclusion criteria were age younger than 18 years, jaundice, obesity (body mass index > 45), pregnancy, cirrhosis of the liver, suspected or proven malignancy, and previous upper gastrointestinal tract surgery. Informed consent was obtained from each patient after verbal and written information was given.

Since the early 1990s, LC had been practiced at El-Minia University Hospital. In this study, LC was performed according to routines at El-Minia University Hospital (Fig. 1). Our patients investigated by u/s and we select those with gall stones with normal CBD diameter and not in acute state

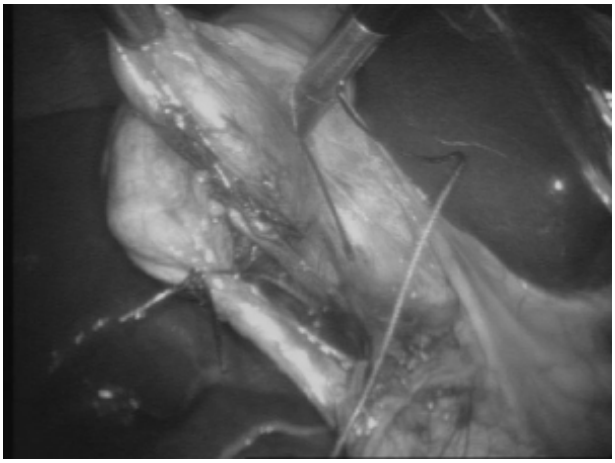

Fig 1. Ligation of cystic duct.

SMC was defined as cholecystectomy performed through a laparotomy incision less than 8 cm long16 guided by ultrasonography to locate the fundus of gallbladder (Fig. 2). SMC was done through short oblique subcostal incision (Figs. 3-6). The incision centered on the point of the fundus of the gall bladder.previously determined by u\s and started as 4cm nearly and later on extended according to the case. We used long and narrow retractors to explore the calot"s triangle then dissection of cystic duct and artery was done then ligation and devision of them inbetween sutures. Preoperative, perioperative, and postoperative data for all cholecystectomies, were recorded. Randomized patients answered questionnaires before surgery and 1 week, 1 month, and 1 year after the operation. The questionnaires included items concerning gastrointestinal symptoms, postoperative pain, time for return to work and normal daily activity, and overall and cosmetic satisfaction with the operation. Endpoints were operating time, hospital stay, sick leave, intraoperative and postoperative complications, costs (Costs for minilaparotomy cholecystectomy and laparoscopic cholecystectomy are based on detailed calculations including laparoscopic instruments and excluding surgeons), pain intensity, use of analgesics, and overall patient satisfaction with the procedure.

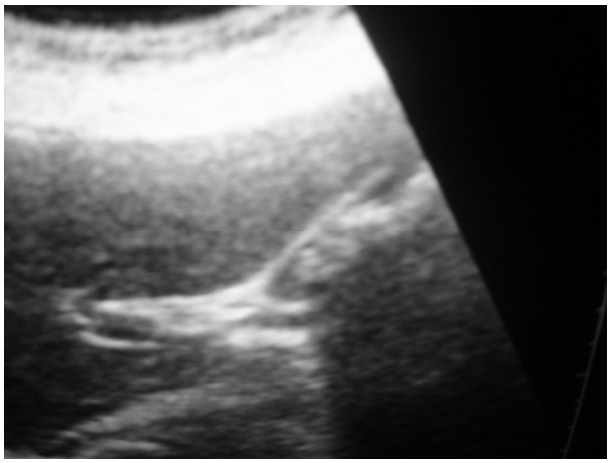

Fig 2. U/S picture of a case of gall stone.

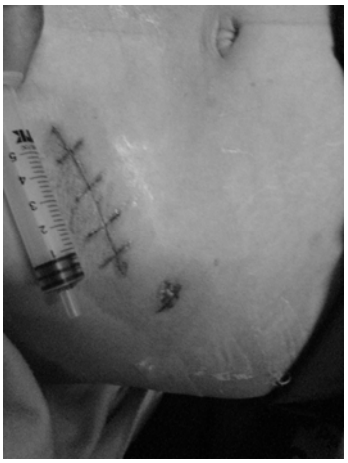

Fig 3. SMC (5 cm incision).

Fig 4. SMC after healing.

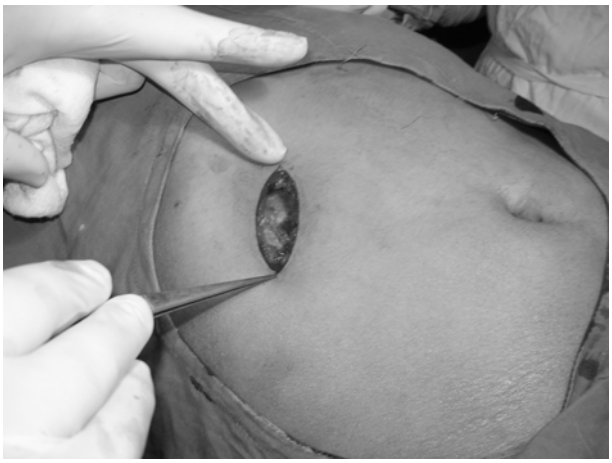

Fig 5. SMC (Before closure of the wound).

Fig 6. SMC (After removal of gall bladder).

Statistical analysis: Categorical variables were compared with the X2 or Fisher's exact test when appropriate. Continuous variable were presented as median values and were compared with the Mann-Whitney U test. Survival data were analyzed using Kaplan-Meier method, and factors were compared with the log rank test. $P<0.05$ was considered statistically significant.

RESULTS

During the study period, 60 patients underwent a cholecystectomy according to the inclusion and exclusion criteria mentioned previously. Of these patients, 30 were randomized to LC and 30 to SMC. They were 39 females and 21 males, mean age was 46+14.7. The groups were well matched for age and sex.

Infiltration anesthesia of wounds was more frequently used in the SMC group. Of all LCs, 6 (20%) were converted to open cholecystectomy {one case (3.3%) with gallbladder mass proved later on to be malignant, 2 cases (6.6%) with extensive adhesions, 2 cases (6.6%) with slipped cystic artery ligature and one case (3.3%) with bleeding from gallbladder bed} and 1 (3.3%) of the SMCs had an incision that exceeded 8 cm to control bleeding from cystic artery ($P < 0.01$). Mean operating times for the LC and SMC groups were 109 ± 44 and 40 ± 15 minutes, respectively ($P < 0.001$). Intraoperative complications are presented in Table 1. There was at least one intraoperative complication in 7 (23.3%) LCs and 2 (6.6%) SMC ($P < 0.001$). Accidental puncture of the gallbladder (LC, 2/30; SMC, 1/30) and stones left in the abdomen (LC, 1/30; SMC, 0/30) were more frequent in LC. One case of bowel injuries was recognized in LC group, it was non penetrating repaired during surgery with an uneventful postoperative course. There were no deaths in either group within 30 days of surgery. At least one postoperative complication was identified in 6.6% of LCs and 6.6% of SMC. There were 2 complications per group Table 2. One patient in the LC group had bleeding episodes requiring percutaneous drainage. One SMC patient had postoperative pancreatitis treated with endoscopic sphincterotomy. One patient in each group had superficial wound infection treated by daily dressing and antibiotics. Bile duct injuries and bile leaks occurred in two patients; one in each group. In LC patient, there was cystic leak detected postoperatively and managed by endoscopic sphincterotomy. In SMC patient, there was bile leak from accessory bile duct detected postoperatively and managed by percutaneous drainage.

Table 1. Intraoperative complications (bile duct injuries excluded).

Complications	LC (n=30)	SMC (n=30)
Perforation of gallbladder	2	1
Bleeding	3	1
Stone left in abdomen	1	0
Vascular injury	0	0
Bowel injury	1	0
Hepatic injury	0	0

Table 2. Postoperative complications.

Complications	LC (n=30)	SMC (n=30)
Bleeding that required drainage	1	0
Postoperative pancreatitis	0	1
Abdominal infection/abscess	0	0
Superficial wound infection	1	1
Pulmonary	0	0
Renal	0	0
Cardiovascular	0	0
Thromboembolism	0	0
Central nervous system	0	0

Postoperative endoscopic sphincterotomy was performed in one LC patient for postoperative cystic leak and one SMC patient for relieve of postoperative pancreatitis. Percutaneous drainage for bleeding was performed in one LC patient for blood and one SMC patient for bile Table 3.

Table 3. Postoperative interventions.

Complications	LC (n=30)	SMC (n=30)
ERCP	1	1
Percutaneous drainage	1	1
Reoperation	0	0

Mean hospital stay was nearly equal after LC and SMC (mean 2.1+0.5 days). Conversion and extended incision prolonged the hospital stay in the LC and SMC groups, respectively. For converted and not-converted LC, the hospital stay was 4.9 ± 3.7 days and 2.2 ± 0.4 days, respectively. The hospital stay for SMC with and without extended incision was 2 ± 0.5 days and 2.8 ± 5.3 days, respectively. One week after surgery, patients in the LC group had less pain and discomfort ($P < .001$), but after 1 month these differences had disappeared. Costs for operation, other health care costs, costs due to sick-leave and total costs were calculated and proved to be significantly higher in LC group ($P<0.05$) Table 4.

Table 4. Costs for operation, other health care costs, costs due to sick-leave and total costs.

	LC	SMC	P Value
Operation costs (median)	1150 EGP	350 EGP	
Other health care costs (median)	400 EGP	550 EGP	
Loss of production costs (median)	50 EGP	60 EGP	
Total costs (median)	**1600 EGP**	**960 EGP**	**<0.05**

DISCUSSION

Both LC8 and SMC17 have been shown to offer advantages over conventional large-incision cholecystectomy. The gallbladder was perforated more often and gallstones were lost and left in the abdomen more often in LC. The study was not large enough to compare the low incidence of serious bile duct complications, but we recognized one such injury per group. There were two cases of bile leak, one LC patient due to cystic leak detected postoperatively and managed by endoscopic sphincterotomy and one SMC patient due to leak from accessory bile duct detected postoperatively and managed by percutaneous drainage. Therefore, great care is necessary in cystic duct closure. Strasberg et al18 reported that the common bile duct may have been dissected circumferentially and thereby devascularized before the incision, leading to later stricture development. There is also a gradual transition from a lateral incision to complete transection of a thin duct. In this study, CBD injury was not reported. There was no significant difference in the postoperative complication rate between the two groups. The complication rates were high compared with previous studies.[12,13,16,19,20] Operating time were longer in this trial as regard LC group (median values 100), may be due to wide inclusion criteria and high conversion rates, however, Operating time were shorter as regard SMC group (48 minutes) than in previous reports,[12,13,16,20] this may be due to accurate localization and incision guided by ultrasonography, and actually closure of wound 4 cm nearly take half the time for closure of wound 8 cm. so wound extension was not needed except in one case due to extensive adhesions. The longer operating time for LC versus SMC is in accordance with findings of previous randomized trials; with one exception.[19] Postoperative hospital stay was nearly equal for SMC and LC. Of three previous trials with 200 or more patients randomized, two trials found no difference in hospital stay between LC and MC[12,16] whereas LC was associated with a shorter hospital stay in one trial.[13] As in other controlled trials, patients in the LC group had less pain for a shorter duration than patients in the MC group during the first postoperative week. One month after surgery, however, no

difference in perceived pain could be detected between the two groups.

In conclusion LC is nearly similar to SMC but with longer time to perform. Fewer intraoperative complications and shorter operating time were recorded in the SMC group. There was no difference in the postoperative complication rate between LC and SMC. Costs of SMC were significantly less than LC. Further analyses of LC versus SMC are necessary regarding surgical training, surgical outcome, and health economy.

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