



RESEARCH ARTICLE

CHOLECYSTECTOMY OR GALLBLADDER IN SITU AFTER ENDOSCOPIC REMOVAL OF BILE DUCT STONE

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ABSTRACT

Background: Symptomatic cholelithiasis is a common gastrointestinal surgical entity having the complication of accumulation of gall stones. For patients with residual stones in the gallbladder after endoscopic stone removal, the subsequent management of the gallbladder has been subject to debate. Many authors have advocated a wait-and-see policy after ES for these patients because only an estimated 10% of them experience recurrent biliary symptoms. It is hypothesized that early planned LC after ES prevents recurrent biliary complications and reduces operative morbidity.

Method: This randomized study included 100 patients with choledochocystolithiasis who underwent endoscopic retrograde cholangiopancreatography (ERCP). After ERCP patients were randomly assigned to laparoscopic cholecystectomy (LC) within six weeks of ERCP (Group I) or wait-and-see conservative management (W&S) with cholecystectomy performed only if indicated (Group II). The patients were followed for two years to record any biliary-related event.

Results: In present study there was 34% of expectantly managed patients developed at least one recurrent biliary event after sphincterotomy during 2 years of follow up, compared with 4% who underwent laparoscopic cholecystectomy. In present study there were no cases underwent cholecystectomy on demand in group I (LC) but there was 18.0% in group II (W&S) underwent cholecystectomy on demand.

Conclusion: Earlier laparoscopic cholecystectomy has been shown to improve outcomes after endoscopic sphincterotomy for choledochocystolithiasis. A wait-and-see policy after endoscopic sphincterotomy cannot be recommended as standard treatment.

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INTRODUCTION

Common bile duct stones are a frequent complication of gallstones and are often associated with cholangitis and cholestatichepatitis. The traditional management of patients with these stones is endoscopic sphincterotomy, and subsequent laparoscopic cholecystectomy is often recommended for patients with gallbladder stones in situ in order to prevent biliary complications such as acute cholecystitis, biliary colic, recurrent biliary stones, cholangitis, and biliary pancreatitis (Jian-Han Lai, 2017). The subsequent treatment of patients who have residual stones in the gall bladder after endoscopic sphincterotomy has been the source of some controversy. Studies report that only about 10 percent of these patients develop biliary symptoms, leading to the wait-and-see policy of performing cholecystectomy only if the calculi become symptomatic. By contrast, the low rate of subsequent biliary symptoms could be attributed to limited follow-up.

In this scenario, early cholecystectomy would avoid significant complications such as biliary colic, cholangitis, cholecystitis, and pancreatitis from the residual stones (AAFP, 2003). There have been several studies about the prevalence of and the risk factors for recurrent choledocholithiasis after endoscopic sphincterotomy, but little data is available on CBD stone recurrence after cholecystectomy. The incidence of recurrent cholelithiasis after cholecystectomy is estimated to be 2–10%, whereas the incidence of recurrent cholelithiasis after endoscopic retrograde cholangiopancreatography (ERCP) amounts to 4–24% (u Hyun Oak, 2012). Dilated common bile duct, gall bladder stone, biliary stricture, angulation of the CBD, previous open cholecystectomy, and perampullary diverticulum are factors contributing to the recurrence of CBD stone after endoscopic treatment (Keizman, 2006). Risk factors for development of at least one recurrent biliary event after endoscopic sphincterotomy have been reported, such as multiple small gallbladder stones, a non-patent cystic duct, cholangitis upon presentation, and young age. However, reports are controversial, and the decision whether to operate or not seems largely empirical (Williams, 2008 and Djemila Boerma, 2002).

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To assess whether a wait-and-see policy after endoscopic sphincterotomy is justified, we did a randomised trial in which we compared elective laparoscopic cholecystectomy with a wait-and-see policy after successful endoscopic sphincterotomy and extraction of common bile-duct stones.

MATERIALS AND METHODS

This randomized study was carried out in the period from July 2014 to July 2015 at department of general surgery, Aswan University Hospital, Egypt. It included 100 patients with cholelithiasis and a possibility of choledocholithiasis who underwent Endoscopic retrograde cholangiopancreatography (ERCP). Patients who fulfilled any of the following criteria were included in this study: history of obstructive jaundice, high serum bilirubin, elevated liver enzymes, dilated common bile duct (CBD) (diameter \geq 8mm by ultrasonography) and CBD stones diagnosed by ultrasonography.

(ES) was performed and the stones were extracted using either Dormia basket or balloon catheter. Mechanical lithotripsy was done in cases of large stones.

After ERCP patients were randomly assigned to laparoscopic cholecystectomy (LC) within six weeks of ERCP (Group I) or wait-and-see conservative management (W&S) with cholecystectomy performed only if indicated (Group II). The patients were followed for two years to record any biliary-related event. The outcome of LC, the rate of conversion to an open procedure, operative time and hospital stay were recorded. The operating time was calculated from the start of the incision to placement of the last suture. The operative time, intraoperative findings, postoperative complications and hospital stay were taken into account.

RESULTS

A total of 100 patients were studied. Of them 50 patients had undergone ERCP followed by laparoscopic cholecystectomy

Table 1. Characteristics of patients according to procedure

Characteristics	group I (LC) "n=50"	group II (W&S) "n=50"	P.value
Age (Years \pm SD)	54.2 \pm 11.2	56.2 \pm 14.1	P=0.705n.s
Sex:			
Male	9(18.0%)	7 (14.0%)	P=0.563n.s
female	41(82.0%)	43 (86.0%)	
Proportion of abnormal LFTs (%)	45(90.0%)	40(80.0%)	P=0.736n.s
US findings:			
1- Dilated CBD (diameter \geq 8mm)	36 (72%)	30 (60.0%)	P=0.483n.s
2- CBD stone (s)	31 (62.0%)	26(52.0%)	P=0.425n.s
At presentations			
1-Cholangitis	7 (14.0%)	3 (6.0%)	
2-Pancreatitis	2(4.0%)	4(8.0%)	P<0.04*
Post-ERCP pancreatitis	0(0.0%)	2(4.0%)	P=0.795n.s

Table 2. Biliary events during follow-up

Item	group I(LC) "n=50"	group II (W&S) "n=50"	P.value
Prophylactic Cholecystectomy	50	0	
biliary event:			
1. Uncomplicated pain	2(4.0%)	11(22.0%)	P<0.001**
2. Cholecystitis	0	3(6.0%)	P=0.583n.s
3. Cholangitis	0	1(2.0%)	P=0.758n.s
4. Pancreatitis	0	0	--
5. Obstructive jaundice	0	2(4.0%)	P=0.584n.s
6. Gallstone ileus	0	0	--
7. Carcinoma	0	0	--
Biliocutaneous fistula	0	0	--
Cholecystectomy on demand	0	9(18.0%)	P<0.04*
Additional ERCP	2 (4.0%)	3(6.0%)	P=0.473n.s
Death	0	0	--

Management of choledocholithiasis in hospital passed through the following steps:

- All patients were subjected to complete evaluation through detailed history, complete physical examination, laboratory investigations and imaging study (US and/or MRCP).
- Investigations done for all patients on admission: complete blood counts (CBC), liver function tests (LFT), urea, electrolytes and blood sugar, ABO grouping, coagulation profile, abdominal ultrasound, urine analysis and chest X-ray & ECG for patients above 35 years
- Confirmed choledocholithiasis cases were managed in our unit by ERCP. ERCP was performed to all patients under general anesthesia. Endoscopic sphincterotomy

within six weeks ERCP (Group I) and the remaining 50 had ERCP followed by wait-and-see conservative management with cholecystectomy performed only if indicated (Group II). The profile of these cases is shown in Table 1. The completion rate of ERCP was 100%. There were 89 patients (89%) who had CBD stones on cholangiography, and 82(82%) of these patients went on to have a successful ductal clearance. The remaining 7 patients (7%) underwent stenting, and ductal clearance was achieved at a second ERCP. Post-procedural pancreatitis developed in 2 patients. There were no instances of perforation or death. The total complication rate was 2%. These data are summarized in Table 4. The completion rate of ERCP was 100%. There were 89 patients (89%) who had CBD stones on cholangiography, and 82(82%) of these patients went on to have a successful ductal clearance. The remaining 7 patients (7%) underwent stenting, and ductal clearance was achieved at a second ERCP.

Table 3. Outcome of patients

Item	group I(LC) (n=50)	group II (W&S) (n=9)	p-value
Operative time (min) mean \pm SD	47.0 \pm 11.4	79.4 \pm 16.8	P<0.01*
Conversion to open(rate)	1(2.0%)	2 (22.2%)	P<0.03*
Length of post-operative hospital stay (days).	2.1 \pm 1.6	4.4 \pm 2.1	P<0.02*
Post-operative complications:			
•bleeding	0	0	
•bile leak	2(4.0%)	1(11.1%)	P<0.02*
•wound infection	0	1(11.1%)	

No (%)

Table 4. ERCP outcomes

ERCP parameter	No. (%)
Completion rate	100(100%)
CBD stones	89 (89%)
Successful clearance	85 (85%)
Stented	4(4%)
Post-procedural pancreatitis	2 (2%)
Complication rate	2(2%)

Post-procedural pancreatitis developed in 2 patients. There were no instances of perforation or death. The total complication rate was 2%. These data are summarized in Table 4.

Group I (LC) outcome

This group included 50 patients, 9 male and 41 female, with a mean age of 54.2years, Table 1. 36patients had CBD dilatation based on US examination, with a mean bilirubin level of 5.2 mg/dl.

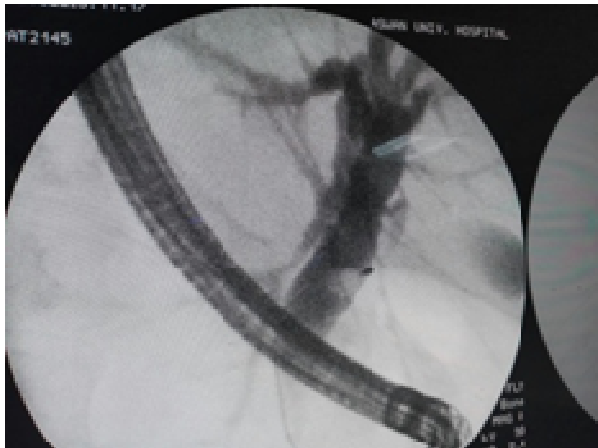


Fig. 1. Endoscopic retrograde cholangiogram showing dilated CBD with medium size stone. Removal of stone was achieved using the basket

Three patients had MRCP as their US examination showed biliary dilatation with normal laboratory level of bilirubin, and in all the three patients MRCP showed floating CBD stones. ERCP was performed at the endoscopy unit with the patient under total intravenous anesthesia in prone position, with 100% cannulation success rate and complete stone extraction in 39 (78.0 %) patients; 7patients (14.0%) revealed no stones. In 4 patients with failed stone extraction because of large stone, a plastic stent was inserted and patients were scheduled for CBD exploration within the next 6 weeks of the ERCP. ERCP was repeated in two cases for removal of plastic stents placed during previous procedures. Cholecystectomy was completed laparoscopically in 49patients. In one patient, laparoscopic cholecystectomy was started and during dissection the cystic duct was avulsed from its attachment near the CBD. We decided to perform an open exploration of the CBD with successful extraction of the stone. Cholecystectomy was completed with closure of the CBD over a T-tube. The postoperative course was smooth in 48 patients. Only two patients had complications in the form of biliary leak.



Figure .2. Laparoscopic cholecystectomy after ERCP shows pericholecystic adhesions

Group II (W&S) outcome

This group included 50 patients, 7 male and 43 female, with a mean age of 56.2years, Table 1. 30patients had CBD dilatation based on ultrasound (US) examination, with a mean bilirubin level of 4.8 mg/dl. Four patients had MRCP for similar reasons as in group 1. Computed tomography (CT) examination was performed for two patients to exclude neoplasia. ERCP was performed in the operating theatre with the patient under general anesthesia in prone position, with 100% cannulation success rate and complete stone extraction in 46 (92.0%)

patients; 4(8.0%) patients revealed no stones. As regards complications of ERCP, two patients developed acute post-ERCP pancreatitis, which completely resolved under conservative medical treatment. Therapeutic ERCP was repeated in three cases for treatment of recurrent CBD stones. Cholecystectomy was completed laparoscopically in 7 patients. Only two cases were converted to open cholecystectomy because of the intense adhesions. Only two patients had complications in the form of biliary leak from cystic duct stump and wound infection (Table 3).

DISCUSSION

In present study there were 17 patients(34%) of expectantly managed patients (50 patients) developed at least one recurrent biliary event after sphincterotomy during 2 years of follow up, compared with 2patients(4%) who underwent laparoscopic cholecystectomy(50 patients). A similar observation was reported in previous studies. Yasui T, et al study found that the absolute risk reduction of laparoscopic cholecystectomy is 96.0% (Yasui, 2012). In present study there were only two patients complained from pain after LC in group I but in group II (W&S) there were (22.0%) had pain, (6.0%) had cholecystitis, (2.0%) had cholangitis and (4.0%) had obstructive jaundice. This agree with (Sahoo, et al., 2017) which does not recommend a 'wait and watch' policy for choledocholithiasis; as 47% patients, managed conservatively, developed at least one recurrent biliary complication and only 37% needed cholecystectomy at a later date (Rasmiranjan Sahoo1, 2017).

Against this observation, the low recurrence rate (4.0%) of biliary-related events during follow-up after sphincterotomy, with gallbladder in situ, was reported in many retrospective studies with limited follow-up (Garcia-Alonso, 2015). Jian-Han Lai et al. (Jian-Han Lai, 2017) investigated the effect of an additional ES with cholecystectomy in preventing recurrent acute biliary pancreatitis "ABP" events. Their data showed a 0% rate for recurrent ABP events after cholecystectomy plus ES compared with a 19% rate for recurrent ABP events after cholecystectomy alone and 2% after ES alone. In present study there were no cases underwent cholecystectomy on demand in group I (LC) but there were 9 patients (18.0%) in group II (W&S) underwent cholecystectomy on demand with significance difference.

This agree with Boerma et al. study, in which open surgery (cholecystectomy and bile-duct exploration) with endoscopic sphincterotomy alone were compared, 20% of patients managed expectantly after sphincterotomy needed cholecystectomy during follow-up, and in another study, single-stage laparoscopic surgery (laparoscopic cholecystectomy and bile-duct exploration) was shown to be better than a two-stage procedure of endoscopic sphincterotomy and subsequent laparoscopic cholecystectomy, because of a shorter admission time (Djemila Boerma, 2002). Based on our results, it seems that the high cholecystectomy-on-demand rate of 18.0% (9/50) in our study could be related simply to the fact that all patients included had radiologically proven gallbladder stones, which is a suggested risk factor for recurrent symptoms. These observations would be consistent with previous studies (Nielsen, 2014). Also Boerma, et al.,(2002) reported cholecystectomy on demand in about 30% of uncomplicated cases. Major complications developed in one of 22 operated patients in the wait-and-see group (intra-abdominal abscess, 4.5%) and in three of 44 patients in the

laparoscopic group (all with intra-abdominal abscess, 6.8 %) (Djemila Boerma, 2002). Alternately, LC was advocated to follow ERCP in patients with choledocholithiasis to avoid the lingering morbidity and even mortality thereafter (Lau, 2006). In present study the mean operative time in the group I(LC) was 47.0 ± 11.4 min and in the group II(W&S) was 79.4 ± 16.8 min. The mean operative time in the group I was shorter than that of the group II, corroborating to another study (Lau, 2006). A randomized study by Boerma et al., (2002) showed that the "wait-and-see" policy was not advisable after ES in cases of combined cholecystocholedocholithiasis because of a high likelihood of a recurrent biliary symptoms and surgical conversion (Djemila Boerma, 2002) Keizman et al. found that the recurrence rate of symptomatic CBDS after endoscopic therapy was high (20%) in elderly patients⁽⁴⁾. However, elderly patients hesitate to undergo LC after ES because of the perceived higher risk for them or because they may be poor surgical candidates because concomitant chronic illness. Based on findings from 2 studies, some surgeons have proposed that patients with choledochocystolithiasis coming to ERCP should be given a chance with laparoscopic cholecystectomy after ES in the first instance, on the grounds that if they have poor surgical risk with significant comorbidity, they can be converted subsequently to wait-and-see policy after endoscopic sphincterotomy. To gain maximal benefit from cholecystectomy, surgery should be performed early (Phillips, 2012 and James, 2007). Earlier laparoscopic cholecystectomy was reported to improve outcomes after endoscopic sphincterotomy for choledochocystolithiasis. It is cost effective in developing countries (Hammarstrom, 1996). From present study early cholecystectomy after ES may prevent recurrent biliary complications, which are associated with increased postoperative morbidity and prolonged hospital stay. Moreover, the operating time and recurrence of stone was longer and more in patients who in group II (W&S), possibly due to scarring and fibrosis of the biliary tree and Calot's triangle, which may promote an error during dissection of the junction among cystic duct, common hepatic duct and CBD. As regard this study shows, a higher degree of complications was noted with group II (W&S).

Conclusion

Earlier laparoscopic cholecystectomy has been shown to improve outcomes after endoscopic sphincterotomy for choledochocystolithiasis. A wait-and-see policy after endoscopic sphincterotomy in combined choledochocystolithiasis cannot be recommended as standard treatment, since 34% of expectantly managed patients developed at least one recurrent biliary event and 18% needed cholecystectomy on demand. Based on findings from this study, we can conclude that in young and good-risk patients (good surgical risk patients without significant comorbidity) with concomitant bile duct stones and gallstones, laparoscopic cholecystectomy should be offered after endoscopic sphincterotomy and bile duct stone clearance.

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