Original Research Article

DOI: http://dx.doi.org/10.18203/2349-2902.isj20171140

Is it time to write obituary for open choledocholithotomy in the present era of endoscopic management? Outcome of surgery for failed endoscopic extraction, retrospective study

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Received: 29 November 2016 Revised: 10 March 2017 Accepted: 11 March 2017

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ABSTRACT

Background: Between 05 to 20 percent of patients undergoing cholecystectomy for gallstones, have choledocholithiasis. Treatment of the common bile duct (CBD) stones can be conducted as open cholecystectomy and open CBD exploration or laparoscopic cholecystectomy plus laparoscopic CBD exploration (LC + LCBDE) versus pre- or post-cholecystectomy endoscopic retrograde cholangiopancreatography (ERCP) in two stages, usually combined with either sphincterotomy or sphincteroplasty (papillary dilatation) for CBD clearance. The merits and demerits of individual techniques are yet to be settled.

Methods: We reviewed the outcome of patients operated at our centre after failed endoscopic clearance of CBD stones. Over a period of 03 years, total 2145 laparoscopic/open cholecystectomies were performed at our institute. In the same time period, 14 patients (06 males and 08 females) presented with choledocholithiasis after failed ERCP extraction (median age 59 years, range 29-62 years). All the patients had undergone ERCP and \pm sphincterotomy/sphincteroplasty with failed clearance. None of the patient had undergone a cholecystectomy previously.

Results: We performed open choledocholithotomy with T-tube drainage plus cholecystectomy in all the patients. There were no deaths and only one major complication. Surgery resulted in complete duct clearance in 93% of patients.

Conclusions: Open surgery can be performed safely and effectively in patients with retained bile duct stones and surgery can be offered as primary modality of treatment over combined endoscopic management after appropriated patient selection.

Keywords: CBD stones, Choledocholithiasis, Choledocholithotomy, ERCP

INTRODUCTION

The prevalence of choledocholithiasis has been estimated to be 05 to 20 percent of patients undergoing cholecystectomy. 1-4 Common bile duct (CBD) stones can be suspected pre-operatively by symptoms or signs of jaundice, pancreatitis, or cholangitis, or by derangement in liver function tests, or on imaging showing duct dilation or actual ductal stones. Treatment options include

open cholecystectomy with open CBD exploration or laparoscopic cholecystectomy plus laparoscopic CBD exploration (LC + LCBDE) versus pre- or post-cholecystectomy endoscopic retrograde cholangiopancreatography (ERCP) in two stages, usually combined with either sphincterotomy (commonest) or sphincteroplasty (papillary dilatation) for CBD clearance. The benefits and harms of the different approaches are not known.⁵ Endoscopic management (EM) being

considered is the treatment option of choice for choledocholithiasis, is associated with a 5-10% risk of complications.^{6,7}

Endoscopic sphincterotomy (ES) is possible in over 90% of patients with ductal stones, although the success rate of duct clearance is considerably lower.^{8,9} Failed ES is usually due to anatomical reasons such as periampullary diverticulae, whereas duct clearance rates are directly correlated with the size of the CBD stones.^{10,11} We have analyzed the outcome of patients undergoing open surgery after failed endoscopic clearance of CBD stones over a period of three years in our institute.

METHODS

Over a 3-year period from April 2013- March 2016; total laparoscopic/open cholecystectomies performed at our institute (Table 1). During the same period 14 patients (Males=06, Females=08) were referred to us with choledocholithiasis after failed EM of CBD stones. (Median age 59 years, range 27- 62 years). All patients had undergone **ERCP** and sphincterotomy/sphincteroplasty with failed **CBD** clearance. In seven patients, partial duct clearance was done and in remaining CBD could not be negotiated due to impacted stones or other technical difficulties. 12 patients had plastic stents inserted after failure of endoscopic clearance and in remaining two stents could not be negotiated. Two patients had undergone endoscopic management (EM) twice. 10 patients had stone size >15 mm in diameter and 04 had multiple densely packed stones. None of the patient has undergone a cholecystectomy previously. The presenting features of these patients was jaundice in 09 (64%), pain in 12 (85%), acute cholangitis in 5 (35.7%) and acute cholangitis with septic shock in 01patient (07%).

Table 1: Study statistics.

Study period	03 years (April 2013 – March 2016)
Total open choledocholithotomy	14 (Male-06, Female-08)
Total lap/open cholecystectomy	2145
Open choledocholithotomy incidence	0.65 % (14/2145)
Median age	59 years (27-62 years)
Median in patient stay	20 days (13-65 days)
Median post-op stay	12 days (07-49 days)
Clearance rate	93% (13/14)
Major post-op complication rate	14% (02/14)

RESULTS

All patients underwent open cholecystectomy and CBD exploration with removal of the retained stones. T-tube

was placed in all the patients. No patient underwent biliary-enteric anastomosis i.e. choledochojejunostomy or choledochoduodenostomy. There were no significant intra-operative complications. CBD stent was removed at the time of exploration. Two patients had postoperative complications. One patient had a retained stone on postoperative T-tube cholangiogram, which was removed successfully by a further EM. Second patient with empyema gallbladder in addition to choledocholithiasis at the time of surgery developed a sub hepatic abscess, which was managed by ultrasound guided percutaneous drainage. There were no deaths. The median total inpatient stay was 20 days (range 13-65 days) and the median postoperative stay was 12 days (range 07-49 days). Patient with empyema gall bladder had superficial surgical site infection, managed conservatively. Surgery resulted in complete duct clearance in 93% (13/14) of patients, one patient having a residual CBD stone discovered on postoperative T-tube cholangiography.

DISCUSSION

Choledocholithiasis can be suspected pre-operatively by symptoms or signs of jaundice, pancreatitis, or cholangitis, or by derangement in liver function tests, or on imaging showing duct dilation or actual ductal stones. Chronic obstruction can result in hepatic abscess, bile duct stricture, secondary biliary cirrhosis, and portal hypertension.^{8,10}

Our institute is a tertiary care institute in rural setup and major regional referral centre for hepatobiliary disorders. Although the surgical experience reported in this series included only 14 patients, this represented all surgical referrals over a 3-years period in a regional referral centre for hepatobiliary problems and reflects the fact that the majority of CBD stones are removed endoscopically. In these three years there were total 2145 laparoscopic/open cholecystectomies at our center. Of these 14 (0.65 percent) patients underwent CBD exploration for choledocholitiasis after failed EM. The incidence of patients undergoing surgery for retained CBD stones in this series (0.65%) is lower than that reported from some other centers (Vaira et al 3.5%, Neoptolemos et al 10.5%).^{9,12} This may be consequent to the nonavailability of EM at our centre and the suspected patients of choledocholithiasis being referred out for EM directly from peripheral hospitals. We have not included the patients who were treated primarily by EM.

Surgery resulted in complete duct clearance in 93% of patients, one patient having a residual CBD stone discovered on postoperative T-tube cholangiography, which was retrieved by EM before removal of T-tube. This complication could have been avoided by the routine use of choledochoscopy or intra-operative cholangiography. ¹³

The clearance rates are significantly better than those recently reported for extracorporeal or laser lithotripsy or with nasobiliary dissolution therapy. 14-16 A mechanical lithotripter may have reduced the number of patients requiring surgery, but the reported clearance rates with mechanical lithotripters vary widely from 25% to 100%. 17,18

LC + LCBDE offers the advantage of dealing with bile duct stones and gallbladder together, by a minimally invasive surgical procedure, during a single episode of hospitalization as well as anesthesia, and without the need for EM. However, there are only few centers performing LC+ LCBDE.

The study by Rogers et al, is the only trial that compared the quality of life (SF-36) and the Karnofsky performance score between the endoscopy and surgical groups, finding no significant difference between the two arms. ¹⁹ None of the other trials reported patient satisfaction or quality of life.

Postoperative pain scores were reported only by Bansal et al, using visual analogue scales and there was no significant difference between the LC + LCBDE versus the preoperative EM + LC groups. With participants in both the arms subjected to laparoscopic or open cholecystectomy, the pain scores might simply be a surrogate outcome, but it would be interesting to know the influence of an additional procedure i.e. EM, on patient satisfaction scores in future trials.

Although surgery is clearly more effective in dealing with retained ductal stones than its alternatives, it is generally considered to be associated with a higher morbidity and mortality.

Endoscopic intervention helps removal of stones from the duct so that surgical exploration of the bile duct can be avoided. When the duct is cleared by EM, the patient can then proceed to laparoscopic cholecystectomy. EM (either pre- or postoperatively) remains the preferred approach at most centers for managing patients with suspected choledocholithiasis. However, EM is associated with complications such as pancreatitis, hemorrhage, cholangitis, duodenal perforation (5% to 11%) and mortality of up to 1%. Failure rates of 5% to 10% are reported with EM. Also, when patients proceed to EM, a significant number of them may not have stones. ^{22,23}

The incidence of bile duct stones has previously been shown to rise markedly in the presence of acute cholangitis, the operative mortality rate without cholangitis being 1.2% compared with 11.9% in patients with cholangitis. ²⁴ The absence of mortality in the present series may well be related to the successful treatment of preoperative sepsis. While comparing the modalities of surgery alone or combined with EM, the effectiveness of treatment and the associated morbidity and mortality, consideration must also be given to the cost of treatment. An improved ability to select patients whose stones are

unlikely to be removed endoscopically would reduce this inpatient stay significantly. Stone size is well documented as an important factor and others need to be established.¹¹

The morbidity between surgical and endoscopic arm has been compared in 3 other trials in the literature in which the major complication rate was less in patients having surgical treatment: 7%, 8%, and 9% than in patients having EM: 8%, 10%, and 25%, respectively. 12,25,26 On the other hand, minor complications occurred less often in patients having EM, 6% and 10%, than in those having surgical treatment (15% for both). 25,26 In two trials overall morbidity was higher in patients having EM: 12% and 21%, than in patients having surgical treatment: 10% and 18%, respectively. 27,28

The hospital stay must be compared with that required for dissolution therapy, which often takes 1-2 weeks and leaves many patients requiring additional treatment, or the capital costs involved in establishing extracorporeal or laser lithotripsy for a small number of patients.²⁷ Endobiliary stenting is, perhaps, a more cost effective method of managing patients with retained CBD stones with either a further admission for attempted endoscopic duct clearance or leaving the endoprosthesis in situ.^{9,15,28}

Bertrand Suc et al in multicenter randomized trial concluded that the rate of second anesthesia for additional procedures and, consequently, the additional risks and costs are such that EM alone is insufficient and not warranted in patients with symptomatic choledocholithiasis who have not had cholecystectomies.²⁹ The only indication for initial EM would be a patient with previous cholecystectomy where in the risks related to leaving the gallbladder in place are eliminated. Surgical treatment is more advantageous than EM because the gallbladder can be removed (thus eliminating the risk of subsequent acute cholecystitis) and the CBD visualized directly by choledochoscopy. Routine combined endoscopic and surgical treatment cannot be the choice for CBD and gallbladder stones nowadays because of the increased risks and costs associated with more than one anesthesia and additional procedures.29

In a Cochrane review for surgical vs. endoscopic management of bile duct stones, Dasari et al concluded that open bile duct surgery seems superior to EM in achieving common bile duct stone clearance based on the evidence available from the early endoscopy era.⁵ There was no significant difference in the mortality and morbidity between laparoscopic bile duct clearance and the endoscopic options. There was no significant reduction in the number of retained stones and failure rates in the laparoscopy groups compared with the preoperative and intra-operative ERCP groups. There was no significant difference in the mortality, morbidity, retained stones, and failure rates between the single-stage laparoscopic bile duct clearance and two-stage endoscopic management.

There is an inclination of primary care providers in peripheral hospitals towards referring every patient of suspected or proven choledocholitiasis for EM as was evident by 0.65% incidence of CBD exploration in this study in major regional centre for hepatobiliary disorders. Like many other institutes in rural setup, the facilities for advanced laparoscopic surgeries are not yet available at our center. Endoscopy has its own limitation and complication and surgery is the final answer after failed EM. Advanced laparoscopic facilities are limited to major cities and the cost makes it less attractive for patients with poor resources. Open surgical exploration is a safe and effective treatment modality options for patients with cholelithiasis and choledocholithiasis and can be offered as one stage management after appropriated patient selection. A multicentre prospective randomized control trial will further corroborate the results of this study

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the

institutional ethics committee

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Cite this article as: Sharma R, Kumar V, Gupta N, Rana K, Dogra A, Nanda A. Is it time to write obituary for open choledocholithotomy in the present era of endoscopic management? Outcome of surgery for failed endoscopic extraction, retrospective study. Int Surg J 2017;4:1350-4.