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Laparoscopic common bile duct exploration; a preferential pathway for elderly patients

T.E. Platt[a,*], K. Smith[a], S. Sinha[a], M. Nixon[b], G. Srinivas[a], N. Johnson[a], S. Andrews[a]

[a] South Devon Upper GI Unit, Torbay Hospital, Torquay, Devon, UK
[b] Derriford Hospital, Plymouth, Devon, UK

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ABSTRACT

Background: Laparoscopic common bile duct exploration (LCBDE) has emerged as a recommended alternative to endoscopic retrograde cholangiopancreatography (ERCP) for the management of choledocholithiasis. However, its use in the elderly has been limited, and evidence of its safety and efficacy in these patients is yet to be established. This study describes our experience of LCBDE in elderly patients, analysing the safety and efficacy of this technique in comparison to younger patients.

Methods: All patients undergoing laparoscopic cholecystectomy (LC) with LCBDE for choledocholithiasis in our unit between January 2015 and January 2017 were included. Data pertaining to patient demographics, co-morbidities, investigations, operative technique and outcomes were analysed. Patients were divided into 2 groups based on age (Group A: < 65 years vs Group B: > / = 65 years) for comparative analysis.

Results: 124 patients (Group A: 65, Group B: 59) were included. Group B were more co-morbid and had a higher ASA grade than Group A. However, there was no significant difference between groups in rates of conversion to open or complications, including bile leak (3.1% vs 5.1%, p = 0.67), retained stone (4.6% vs 1.7%, p = 0.62), or complications according to Clavien-Dindo classification (p = 0.78). Re-intervention rates were also similar between groups (7.7% vs 3.4%, p = 0.44 and 3.1% vs 3.4%, p = 1.0 respectively), as was length of stay.

Conclusion: Despite higher frequency of comorbidities and ASA grade, LCBDE in elderly patients is safe and effective, and has similar outcomes to younger patients. Therefore elderly patients with choledocholithiasis should be offered LCBDE as an alternative to ERCP.

1. Introduction

10-15% of patients presenting with gallstone disease have synchronous common bile duct (CBD) stones [1–3]. Although small stones may pass spontaneously, they have the potential to cause significant complications such as jaundice, pancreatitis, cholangitis or hepatic abscesses. For these reasons intervention to remove even apparently incidental CBD stones is therefore recommended [4]. The traditional pathway for treating CBD stones in the elderly is via endoscopic retrograde cholangiopancreatography (ERCP) and subsequent interval completion laparoscopic cholecystectomy (LC) to prevent further passage of stones, if appropriate based on patient fitness for surgery. An alternative approach consisting of combined LC and intra-operative laparoscopic bile duct exploration (LCBDE) has been demonstrated to be safe and effective for removal of CBD stones [5,6]. Furthermore, complication rates and mortality are equivalent between one stage or two stage procedures, but the former results in shorter length of stay and is more cost effective [6–8]. There are few studies that have appraised this approach in elderly patients [9,10]. We investigate a comparison in outcomes for LC combined with LCBDE for elective and emergency patients in an elderly and non-elderly cohort of patients treated by our surgical unit.

2. Materials and methods

This study was approved by and registered with the Audit and Clinical Effectiveness review board of our institution and registered online (www.researchregistry.com). Study reporting was performed in line with the PROCESS criteria [11]. A prospectively maintained database was analysed to identify all patients undergoing LC with LCBDE between January 2015 and January 2017 at a single government funded health institution. Patient demographics including age, gender, ASA grade, co-morbidities, and indication for surgery were collected. Electronic patient records were examined to verify accuracy. Co-morbidities were recorded if they were considered to affect fitness for anaesthetic or intervention, and included hypertension, ischaemic heart

* Corresponding author. South Devon Upper GI Unit, Torbay Hospital, Lowes Bridge, Torquay, TQ2 7AA, UK.
E-mail address: timothyplatt@nhs.net (T.E. Platt).

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disease (angina, myocardial infarction, coronary artery bypass), atrial fibrillation, cardiac valve disease, cerebrovascular disease, peripheral vascular disease, asthma, chronic obstructive pulmonary disease, obstructive sleep apnoea, pulmonary embolus, chronic kidney disease, diabetes mellitus, alcoholic liver disease, immunosuppression, current cancer and neurological disorder significantly affecting mobility.

Patients were referred to the Upper GI unit via either an elective referral from primary care or other hospital based teams, or as an emergency admission. Pre-operative assessment included clinical history and examination, serum biochemistry and abdominal USS. Some patients, particularly if referred from other hospital based teams, had already undergone CBD imaging or intervention in the form of ERCP or MRCP. In our unit we do not routinely perform pre-operative CBD imaging, but rely on intra-operative laparoscopic ultrasound (LUS) or on-table cholangiography (OTC) to identify CBD stones. In some cases, pre-operative computed tomography (CT) scan is performed to rule out other pathology, such as pancreatic cancer or cholangiocarcinoma.

When CBD stones are identified on LUS/OTC, LCBDE is performed via the transcystic route (TC-) or choledochotomy (CD-). TC-LCBDE is generally preferred due to the lower morbidity compared to CD-LCBDE. The choice of procedure depends on the following criteria: 1) cystic duct (CD) of sufficient caliber to admit 3 mm choledochoscope, 2) small CBD stones which are possible to extract via the CD, 3) absence of hepatic duct stones. CD-LCBDE is performed if the CBD lumen is > 8 mm and contains large stones.

TC-LCBDE is performed via an incision in the cystic duct. A 3 mm choledochoscope *(Karl Storz, Tuttlingen, Germany)* is passed via the CD into the CBD. Stones are retrieved using a NCircle® tipless basket *(Cook Medical, IN, USA)* under direct vision. After removal of all stones the cystic duct is divided between laparoscopic clips.

CD-LCBDE is performed as follows. A vertical choledochotomy is made with a Berci knife and extended with laparoscopic scissors. 5 mm videoscope *(Karl Storz, Tuttlingen, Germany)* is used with NCircle® tipless or Gemini™ *(Boston Scientific, MA, USA)* retrieval baskets to remove stones. Choledochotomy is closed primarily with continuous 3-0 vicryl suture. Biliary decompression using a T-Tube is not routinely used, except in cases when impaired healing is felt likely, such as purulent cholangitis or patient immunosuppression, or following conversion to open for removal of a large, impacted CBD stone. After both TC-LCBDE and CD-LCBDE a passive drain is left in the supraduodenal space, and removed after 48 h s unless bile leak is evident. When the criteria for TC-LCBDE are not met and the CBD is inaccessible or insufficiently dilated for CD-LCBDE, LC is completed without LCBDE and ERCP is performed during the same admission.

Outcomes assessed included operative time, length of stay, complications and re-intervention rate. In particular, bile leak and retained stone rates were recorded. Bile leak was defined as persistent bile in the abdominal drain after 48 h s. Complications were graded according to Clavien-Dindo classification. Patients were divided into 2 groups for analysis: Group A consisted of patients under 65 years of age, while Group B contained patients aged 65 years or more. Statistical analysis was performed using Mann-Witney *U* test for non-parametric data, Students t-test for parametric data, and Fisher Exact test or Chi-squared test of independence for nominal data. A p value of < 0.05 regarded as significant. Passive follow-up was performed by reviewing hospital computer systems for post-operative clinical reviews and radiological or biochemical investigations.

3. Results

3.1. Demographics

124 patients undergoing LCBDE for CBD stones were identified. The median age was 63 years old, range 15–87. There were 65 patients in Group A, while Group B contained 59 patients. Comparison between these groups is demonstrated in Table 1. Overall, the male to female ratio was 1–1.8, and was not significantly different between groups A and B (1:2.5 vs 1:1.3, p = 0.076). The elderly group had significantly more comorbidities than the younger group ($p < 0.0001$), and higher ASA grade (p = 0.0012).

Table 1
Patients demographics and operative details. *Fisher's exact test, §Mann-Witney U test, +Chi-squared test of independence.

	Group A	Group B	Significance value	≥80 years old subgroup
n =	65	59	p = 0.063*	15
Median age	48 years	74 years		82 years
Male/Female	18/47	26/33		6/9
No of comorbidities				
0	44 (67.7%)	11 (18.6%)	*p < 0.00001*§	3 (20.0%)
1	14 (21.5%)	27 (45.8%)		4 (26.7%)
2	3 (4.6%)	12 (20.3%)		6 (40.0%)
3	2 (3.1%)	6 (10.2%)		0
4 or more	2 (3.1%)	3 (5.1%)		2 (13.3%)
ASA Grade				
I	18 (27.7%)	2 (3.4%)	*p=0.0008*§	0
II	41 (63.1%)	41 (69.5%)		6 (40.0%)
III	6 (9.2%)	16 (27.1%)		9 (60.0%)
Indication				
Biliary colic	28 (43.1%)	24 (40.7%)	p = 0.99+	8 (53.3%)
Cholecystitis	18 (27.7%)	18 (30.5%)		3 (20.0%)
Empyema	1 (1.5%)	1 (1.7%)		0
Cholangitis	7 (10.8%)	6 (10.2%)		0
Pancreatitis	11 (16.9%)	10 (16.9%)		4 (26.7%)
Presentation				
Elective	21 (32.3%)	20 (33.9%)	p = 1.0*	7 (46.7%)
Emergency	44 (67.7%)	39 (66.1%)		8 (53.3%)
Modality				
Lap	63 (96.9%)	54 (91.5%)	p = 0.25*	15 (100%)
Converted to open	2 (3.1%)	5 (8.5%)		0
Pre-op investigation				
Stones known pre op	14 (21.5%)	18 (30.5%)	p = 0.31*	10 (66.7%)
Stone not confirmed pre op	51 (78.5%)	41 (69.5%)		5 (33.3%)
Method of CBDE				
Transcystic	25 (38.5%)	19 (32.2%)	p = 0.57*	2 (13.3%)
Choledochotomy	40 (61.5%)	40 (68.8%)		13 (86.7%)
T-tube used	2 (3.1%)	8 (13.6%)	p = 0.046* or 0.087 (vs CD-LCBDE)*	0

3.2. Operative details

Indications for surgery included biliary colic, cholecystitis, gallbladder empyema, cholangitis and pancreatitis (Table 1). Overall, 41 (33.1%) were performed electively while 83 (66.9%) were performed in the CEPOD operating theatre during an emergency admission, though all procedures were performed during daylight hours. 32 (25.8%) cases were performed following pre-operative confirmation of CBD stones, while the remaining 92 (74.2%) were performed following intra-operative imaging (LUSS and/or OTC). CBD stones were identified upon exploration in all but 8 cases (6.4%). All 8 of these were performed via the *trans*-cystic route. In 7 of these cases, no CBD stones were seen on LUS and OTC, but the indication for LCBDE was a dilated CBD and lack of flow of contrast to the duodenum. Thus, CBD stones were seen on LUS/OTC in 117 patients, in whom stones were found on LCBDE in 116, giving a false positive rate of 0.9%.

There was no significant difference between the groups with respect to indication for surgery (p = 0.99), elective vs emergency split (p = 1.0), or whether CBD stones were identified pre-operatively or intra-operatively (p = 0.31). 117 cases were performed laparoscopically, while the conversion to open rate was 5.6% (7 cases). 5 of these were in the elderly group, which had a higher conversion-to-open

rate than the younger group (8.5% vs 3.1%), though this difference did not reach significance (p = 0.25). Overall, CBDE was performed via a transcystic route in 44 cases (35.5%), and via choledochotomy in the remaining 80 cases (64.5%), in which primary CBD closure was performed in 70 cases (87.5%), and 10 (12.5%) had a T-tube. Comparison according to age revealed a non-significant higher rate of choledochotomy in the elderly group compared to the younger group (68.8% vs 61.5%, p = 0.57). Overall T-Tube use was higher in the elderly group (p = 0.046), though this difference lost significance if only patients undergoing choledochotomy were considered (p = 0.087). Median operating time was 177 min, and was similar between Groups A and B (180 vs 162 min, p = 0.064).

3.3. Length of stay/Readmissions

Median post-operative length of stay following LCBDE overall was 3 days (0–52 days), and equivalent in both groups (p = 0.45). During the follow-up period, 11 (9%) patients required readmission to hospital for complications related to their procedure. Readmission rate was lower in Group B than Group A, though this difference was not statistically significant (5.1% vs 12.3%, p = 0.21). Follow-up data was available for median 146 days post op, with 94 patients (76%) having at least 6 weeks of follow-up.

3.4. Complications

Complications and comparisons between the younger and older groups are demonstrated Table 2. No patients in our study died. The bile leak rate was 4.0% (5 patients) and the retained stone rate was 3.2% (4 patients), and was similar between the groups. Complications classified according to Clavien-Dindo classification were as follows: Grade I: n = 1, Grade II: n = 9, Grade IIIa: n = 7, Grade 3 b: n = 4. Again, no significant differences were found in complication rates according to Clavien-Dindo classification (p = 0.78). Repeat interventions occurred in the form of ERCP (n = 7, 5.6%) for retained stone (n = 4) and bile leak (n = 3), or repeat laparoscopy (n = 4, 3.2%) for bile leak (n = 2), bleeding (n = 1), and interiorisation of drain (n = 1).

Table 2
Complications by age group. **Chi-squared test of independence, §Mann-Witney U test.*

	Group A	Group B	Significance value	≥80 years old subgroup
n=	65	59		15
Complications (C-D Grade)				
Grade I/II	5 (7.7%)	4 (6.8%)	p = 0.78 $^{+}$	1 (6.7%)
Grade IIIa	5 (7.7%)	2 (3.4%)		0
Grade IIIb	2 (3.1%)	2 (3.4%)		1 (6.7%)
Major complications				
Bile leak	2 (3.1%)	3 (5.1%)	p = 0.67*	1 (6.7%)
Retained stone	3 (4.6%)	1 (1.7%)	p = 0.62*	0
Other complications:				
Bleeding	1 (1.5%)	1 (1.7%)	p = 1.0*	0
Collection	3 (4.6%)	1 (1.7%)	p = 0.62*	0
Pneumonia	1 (1.5%)	2 (3.4%)	p = 0.60*	1 (6.7%)
Interiorisation of drain	1 (1.5%)	0	p = 1.0*	0
Acute kidney injury	1 (1.5%)	0	p = 1.0*	0
Total	**12 (18.5%)**	**8 (13.6%)**	**p=0.46***	**2 (13.3%)**
Intervention required for complication				
ERCP	5 (7.7%)	2 (3.4%)	p = 0.44*	0
Repeat laparoscopy	2 (3.1%)	2 (3.4%)	p = 1.0*	1 (6.7%)
Length of stay (median)	3 days	3 days	p = 0.45§	4 days
Readmissions	8 (12.3%)	3 (5.1%)	p = 0.21*	0

While there was a non-significant trend towards a higher post-operative ERCP rate in the younger group, there was no difference in re-laparoscopy rate.

3.5. Over 80's subgroup

Group B included 15 patients aged 80 years or older. The eldest patient was 90 years old and the median age was 82. Patient demographics are detailed in Table 1. Patients ≥80 years old had more comorbidities (p < 0.0001), had higher ASA grades (p < 0.0001) and were more likely to have CBD stones confirmed on pre-operative imaging (p = 0.00011) than patients under 80 years old. In this sub-group all procedures were completed laparoscopically. 1 patient (6.7%) suffered a complication in the form of a bile leak, requiring laparoscopic washout, and 1 further patient (6.7%) developed a pneumonia following surgery, which was treated with antibiotics (Table 2). There were no further complications in this sub-group, giving an overall complication rate in the ≥80s of 13.3%. There were no statistical differences in complications in the over 80s compared to under 80s, though the over 80's cohort was small.

4. Discussion

Laparoscopic bile duct exploration has been accepted as equivalent to ERCP for the treatment of CBD stones [12,13]. Despite this, utility of this technique in elderly patients has been somewhat more reserved with some authors recommending LCBDE as preferential over ERCP only in younger patients [14]. Others have recommended the single stage process for only patients with ASA grade I or II, while more comorbid patients are managed with ERCP and sphincterotomy [12]. This is particularly of significance as occurrence of choledocholithiasis during LC is higher in elderly patients, with an incidence of up to 60% [15–17]. Our study, however, demonstrates the safety and efficacy of LCBDE in elderly patients. We chose 65 years as the threshold of defining patients as elderly, in line with convention in the medical literature [9,18], though added a subgroup analysis of patients ≥80 years old. Outcomes in this subgroup appear to be equivalent to the rest of the study population, though statistical analysis was limited due to relatively low numbers. The main finding of our study was the equivalence of LCBDE in elderly patients compared to younger patients. Despite a significantly higher incidence of concurrent morbidities and higher ASA Grade in the elderly group, there was no difference in complications, re-interventions, length of stay or readmissions and this effect appeared to be maintained within the ≥80s subgroup. This is consistent with previous studies. Zhu et al. demonstrated similar outcomes in elderly patients undergoing transcystic LCBDE compared to younger patients [10], while Zheng et al. published similar findings following choledochotomy [19]. Furthermore, an assessment of risk factors for bile leak following choledochotomy found that while CBD diameter and inexperience of surgeon were risk factors for bile leak, patient age did not have an impact [20]. In line with this, we maintain the opinion that choledochotomy should only be performed with CBD diameter of more than 8 mm, and that age should not preclude elderly patients from LCBDE via choledochotomy.

Our study is unique in two ways. Firstly, to our knowledge, this is the first such study to include both elective and emergency cases of LCBDE in elderly patients. Overall 67% were performed as emergency procedures, and this split between elective and emergency cases was equivalent in both groups. In this study emergency cases were defined as those performed during an emergency admission. All were performed by surgeons with specialist expertise in LCBDE, and all during day hours. The safety of LCBDE in the emergency setting has been recently documented by Chan et al. though in their study there was a tendency away from emergency LCBDE in elderly patients [21]. Secondly, 73.2% of cases were performed following identification of choledocholithiasis on intra-operative imaging (LUS/OTC) only, with no preoperative CBD

stone confirmation. This lies in contrast to the practice of most units, in which patients undergo CBD stone confirmation by CT or MRCP prior to LCBDE [5,21–23]. Laparoscopic USS and OTC have high diagnostic accuracy in detection of CBD stones [24]. The advantage of intra-operative common bile duct imaging is that decisions regarding operative strategy are made on the basis of real-time investigations. Pre-operative imaging only indicates the presence or absence of common bile duct stones at the time of investigation, which may change in the interval leading to surgery.

These two distinguishing features represent the unselective approach of our unit to patients with gallstone disease and clinical features suggestive of choledocholithiasis. In our unit, preoperative bile duct imaging in the form of MRCP/ERCP/EUS is bypassed in preference for intra-operative imaging. Upon intra-operative demonstration of CBD stones, LCBDE is performed as needed. 1 patient in our study underwent negative LCBDE, and our false positive rate for intra-operative imaging was 0.9%.

The stone clearance rate in our study was 96.7%, and in the elderly cohort 98.3%, similar to previous studies. ERCP, on the other hand, has a success rate of up to 90%, with up to 25% of patients requiring more than 1 ERCP to achieve biliary clearance [4]. ERCP is recommended as a therapeutic intervention, and should not be used as a diagnostic tool [4]. Patients undergoing the two-stage process therefore, require pre-operative CBD stone confirmation with MRCP, EUS or CT scan. Consequently, a single stage approach, with intraoperative imaging, to manage elderly as well as younger patients with choledocholithisis reduces the number of investigations and procedures required. For patients admitted and treated emergently, this is also likely to reduce total hospital length of stay [7].

Costi et al. argued that, when feasible, LC should be performed following ERCP for choledocholithiasis in octogenarians to prevent recurrent complications of gallstones [25]. As backed up by our data and the results of others, we suggest that elderly patients, including octogenarians, who would be considered fit for LC, should also be considered suitable for LCBDE when indicated.

The main limitation of this study is that is an observational study in which the population was divided into cohorts based on age, and not in a case controlled manner. It is therefore subject to selection bias. Additionally, as the frequency of complications is low, the size of our study cohort may be too small to identify differences in complications between the groups, particularly in subgroup analysis of patients aged ≥ 80. Finally, while LCBDE appears to be as safe in elderly patients as in the young, further work, including randomized trials, needs to be conducted to show equivalence/improved outcomes compared to ERCP.

5. Conclusion

Laparoscopic bile duct exploration is gaining popularity in the surgical community as an alternative to ERCP for the treatment of common bile duct stones. While it's safety and efficacy is already established in young patients in the elective setting, this study adds to the increasing evidence pertaining to its safety in elderly patients, in both elective and emergency settings. In units that are able to offer LCBDE to patients with CBD stones, LCBDE should not be precluded in elderly patients considered fit for LC.

Ethical approval

None.

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Author contribution

Timothy Platt – Data collection, analysis, manuscript preparation, Kristy Smith – Data collection and analysis, Surajit Sinha – Data collection, Martha Nixon – study design, review of manuscript, Gandrapu Srinivas – Manuscript review, Surgeon, Nicholas Johnson – manuscript review, Surgeon, Stuart Andrews – Study design, Manuscript review, Surgeon.

Disclosure statement

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