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Original Paper

ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY VERSUS LAPAROSCOPIC TRANSCYSTIC BALLOON DILATATION OF PAPILLA VATERI IN PATIENTS WITH CHOLEDOCHOLITHIASIS

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*Two-step therapy, endoscopic retrograde cholangiopancreatography with papillotomy and stone evacuation from common bile duct (CBD), and laparoscopic cholecystectomy (ERCP/LC) is standard treatment of choledocholithiasis and acute cholecystitis in our hospital, Rīga East University Hospital Gaiļezers. The one-step method, LC with intraoperative transcystic balloon dilatation of the papilla Vateri and anterograde evacuation of gallstones to duodenum (BD/LC), has been introduced in our hospital. The aim of this study was to compare two-step and BD/LC methods and report the outcomes from hospital's clinical experience. A retrospective, comparative study was done from 01.2021 to 10.2023. Patients with acute calculous cholecystitis and choledocholithiasis with gallstone diameter in CBD cm, ASA score I-III were included. Gallstone's diameter and number, hospitalisation time, and success rate were analysed. A total of 95 patients were included in our study, of which 46 patients underwent BD/LC and in 49 patients ERCP/LC was used. Median diameter of gallstones in the CBD was 6.1 mm in BD/LC and 6.3 mm in the ERCP/LC group (*p *= 0.38). Median hospitalisation time for patients with single-step treatment was seven days, and two-step therapy — 14 days (*p *= 0.001). The complication rate in BD/LS was 4.34% but in ERCP/LC group — 10.2% after ERCP (*p *= 0.049). The success rate in BD/LC was 95.6% and in ERCP/LC group — 89.6% (*p *= 0.145). BD/LC is associated with a shorter hospitalisation time, similar success rate and lower complication rate compared with an ERCP/LC.*

Keywords: *gallstone disease, minimally invasive surgery, common bile duct exploration.*

INTRODUCTION

Choledocholithiasis, characterised by the presence of stones in the common bile duct, is a challenging clinical scenario often requiring intervention to prevent complications such as cholangitis and pancreatitis. Multiple approaches are used in the treatment of choledocholithiasis. The clinical guideline for gallstone disease, published in 2014 by the National Institute for Health and Care Excellence (NICE) suggested bile duct clearance and laparoscopic cholecystectomy to patients with symptomatic or asymptomatic common bile duct stones. Also, NICE recommended to clear the bile duct surgically at the time of laparoscopic cholecystectomy or with endoscopic retrograde cholangiopancreatography (ERCP) before or at the time of laparoscopic cholecystectomy (LC) (National Institute..., 2014). Laparoscopic transcystic balloon dilation of the papilla of Vateri with laparoscopic cholecystectomy, ERCP and

choledochoscopy with stone extraction in cases of choledocholithiasis are methods that are used in the treatment of choledocholithiasis (Plaudis *et al.*, 2016). These techniques offer distinct advantages and considerations, shaping the decision-making process in clinical practice. In Rīga East University Hospital Gaiļezers, all minimally invasive methods for CBD stone clearance are available — ERCP, choledochoscopy, and recently also transcystic balloon dilatation of papilla, but ERCP is still used more often.

Laparoscopic transcystic balloon dilatation of the papilla Vateri, performed during laparoscopic cholecystectomy, is a minimally invasive surgical technique. This technique involves the insertion of a balloon catheter through the cystic duct into the common bile duct, followed by inflation to dilate the papilla Vateri, facilitating stone passage into the duodenum (Bosley *et al.*, 2021). In contrast, ERCP is an endoscopic procedure involving the insertion of a flexible endoscope through the mouth into the duodenum to visualise the biliary tree and pancreatic duct. Stones in the common bile duct are extracted using specialised instruments, such as baskets or balloons, under direct endoscopic guidance (Mahalingam *et al.*, 2020).

Both laparoscopic transcystic balloon dilatation of the papilla Vateri and ERCP offer effective means of managing choledocholithiasis, but they differ in several key aspects. Laparoscopic transcystic balloon dilatation is performed concurrently with laparoscopic cholecystectomy, offering a single-step approach. This approach minimises the need for a separate endoscopic procedure and effectively prevents the risk of post-ERCP pancreatitis (Bosley *et al*., 2022). Additionally, the transcystic route may be preferable in patients with difficult biliary anatomy or small papillary orifices, where endoscopic access may be challenging (Testoni *et al*., 2016).

On the other hand, ERCP with stone extraction is a well-established endoscopic technique for managing choledocholithiasis, offering direct visualisation of the biliary tree and precise stone removal under endoscopic guidance. ERCP is particularly advantageous in cases where stone extraction is the primary objective (Chandrasekhara *et al*., 2017). However, ERCP is associated with risk of complications, including pancreatitis, bleeding, perforation, and infection, which may influence its appropriateness in certain patient populations (Manoharan *et al* 2019; Johnson *et al*, 2020). While the frequency of conducting an ERCP in individuals diagnosed with choledocholithiasis is on the rise, there remains uncertainty regarding whether single-step or two-step management offers superior outcomes for patients when both options are taken into account. The 2022 Danish national guidelines and the 2022 guidelines from the European Association of Endoscopic Surgery (EAES) advocate for a one-stage approach involving laparoscopic cholecystectomy and minimally invasive extraction of choledochal stones during the same procedure (Boni *et al*., 2022; Shabanzadeh *et al*., 2022). In contrast, international guidelines infrequently endorse intraoperative ERCP due to logistical challenges, likely stemming from the need for multi-specialty involvement (Rystedt *et al*., 2015; Georgiou *et al*., 2022). However, it is important to note that ERCP and transcystic stone extraction are not entirely interchangeable methods, particularly when dealing with large stones or stones situated above the bile duct's inflow from the gallbladder, as they may not be amenable to transcystic intervention (Strömberg *et al*., 2008).

As Rīga East University Hospital Gaiļezers employs various treatment options for choledocholithiasis and given the recent rise in annual laparoscopic transcystic duct exploration, it has become pertinent to compare these treatment methods with each other. This comparison is essential, especially considering the latest recommendations for choledocholithiasis treatment.

MATERIALS AND METHODS

A retrospective, comparative study was performed at Rīga East University Hospital Gaiļezers. Inclusion criteria were examination data from adult patients diagnosed with cholecysto-choledocholithiasis who underwent laparoscopic cholecystectomy (LC) and received either preoperative ERCP, postoperative ERCP or laparoscopic transcystic balloon dilatation of the papilla Vateri (BD) during LC and had choledocholithiasis confirmed on either intraoperative ultrasound examination (IOUS) or magnetic resonance cholangiopancreatography (MRCP) before the procedure, from 01.2021 to 10.2023. The patients with gallstones in gallbladder and choledocholithiasis with gallstone diameter in common bile duct (CBD) 1 centimeter or less, ASA score from I to III were included in study. Exclusion criteria were patients who received open cholecystectomy, had incomplete medical records or did not have choledocholithiasis identified on either ERCP, IOUS, or MRCP. We also excluded patients who underwent choledochoscopy and stone extraction during the LC.

Laparoscopic transcystic papillary balloon as a typical four-trocar technique for the LC is recommended. Trocars were positioned in the following way: 10 mm through the umbilical ring for the camera and three for the manipulation, one of them 10 mm at the epigastrium proprium and two — 5 mm to the right side.. A guide wire is brought down into the CBD through the additional small incision in right subcostal area using an introducer (6 French). The guide wire is carried down to the duodenum under X-ray control. The peripheral dilatation catheter (10×40 mm) is positioned in the middle of the sphincter Oddi, inflating the balloon with a mix of contrast and NaCl saline so it can be more easily visualised. The wire is then removed and thorough flushing with NaCl is done, and control is conducted with a new intraoperative cholangiography (IOC) to ensure that all the stones have gone. If not, then using a Fogarty catheter, the gallstones from CBD are pushed to dilatated papilla into the duodenum under fluoroscopic control. For double-checking, we use intraoperative laparoscopic ultrasonography (Atstupens *et al.*, 2020). Then, the Fogarty

catheter and introducer is removed, the cystic duct is closed with two clips and LC is continued.

All patients were divided into two groups. The first group underwent single-step (BD/LC) treatment, and the second group underwent two-step (ERCP/LC) therapy. Successful clearance of the common bile duct was defined as visualised clearance of the intra and extra hepatic bile duct on IOC, IOUS, or post-ERCP cholangiography without a need for subsequent common bile duct intervention. In cases where clearance of the common bile duct was not achieved, the initial intervention was considered unsuccessful. All including and excluding criteria are summarised in Figure 1. The following parameters were collected from the electronic medical records and compared between groups: gallstone diameter and number in CBD, hospitalisation time, lipase level after procedure, type of postoperative complications, and success rate.

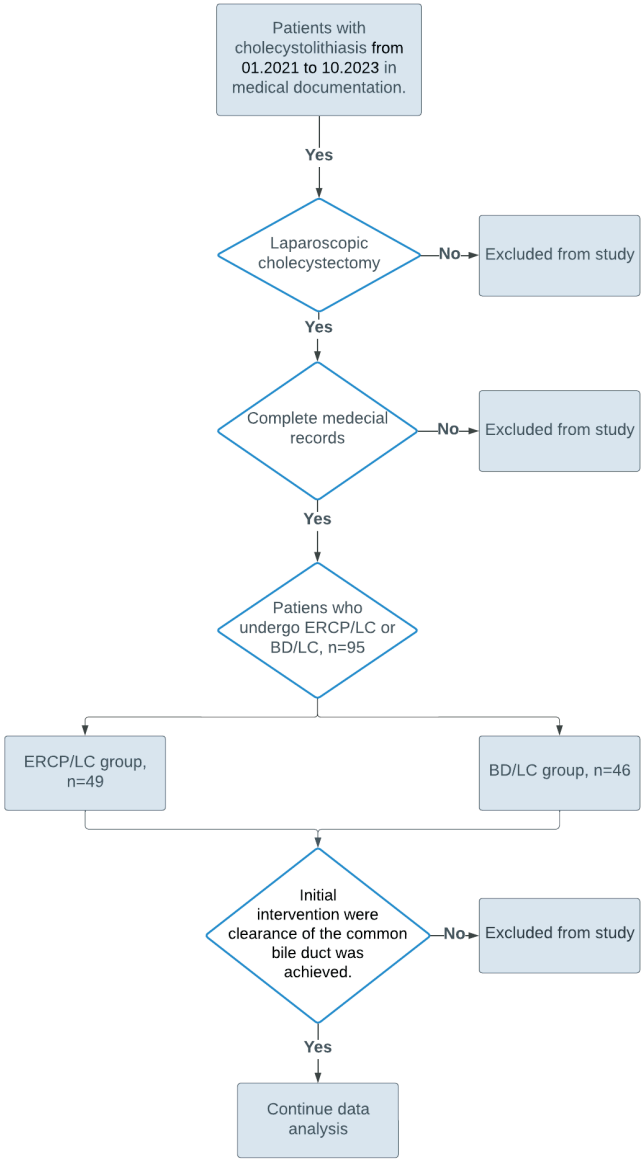

Fig. 1. Including criteria. ERCP, endoscopic retrograde cholangiopancreatography; BD, laparoscopic transcystic balloon dilatation of papilla Vateri; LC, laparoscopic cholecystectomy; n, number of patients.

Data were collected using Microsoft Office Excel (365) software and statistical analysis was performed using IBM SPSS Statistics. v. 23.0. Chicago. IL. USA. The Kolmogorov–Smirnov test was used to check if the data followed a normal pattern. Since a normal distribution was not detected, non-parametric methods were used for further statistical analysis of the data. We looked at the middle value (median) and the range between the middle 50% of the data (interquartile range, IQR). The Mann–Whitney U test was used for interval comparison of the data. p-values ≤ 0.001 were considered statistically significant.

RESULTS

Our study included a total of 95 patients, with 46 who underwent BD/LC treatment and 49 underwent ERCP/LC treatment. There were 21 males and 25 females in the BD/LC group and 28 males and 21 females in the ERCP/LC group. The median age in BD/LC group was 37 years (IQR 31–45 years) and in the ERCP/LC group — 41 years (IQR 34–49). The median number of gallstones in the CBD was two (IQR 1–2.75) in the BD/LC and two (IQR 1–3) in the ERCP/LC group, with a p-value of 0.071. In the BD/LC group median body mass index (BMI) was 29 kg/m^2 (IQR 24.75–36.5 kg/m^2) and in ERCP/LC group — 31 kg/m^2 (IQR 28.25–43.75 kg/m^2) (Table 1).

The median diameter of gallstones in the common bile duct was 6.1 mm (IQR 5.5–7 mm) for the BD/LC group and 6.3 mm (IQR 4.75–8 mm) for the ERCP/LC group, p-value = 0.38. The median lipase level in blood tests was 46 U/l (IQR 38.75–85.25 U/l) in the BD/LC group and 66 U/L (IQR 44.5–284.5 U/l) in the ERCP/LC group after ERCP procedure, p-value = 0.059. The median hospitalisation time was seven days (IQR 5 – 9l5 days) for single-step treatment and 14 days (IQR 10.25–19.5 days) for two-step therapy, with, p = 0.001. The complication rate was 4.34% (n = 2) in the BD/LC group and 10.2% (n = 5) in the ERCP/LC group after ERCP procedure, p = 0.049. In the BD/LC group, two patients (n = 2) experienced mild acute postoperative pancreatitis, while in the ERCP/LC group, four patients (n = 4) had moderate post-ERCP acute pancreatitis, and one patient (n = 1) had a duodenal perforation during the ERCP procedure (Table 2).

Table 1. Patient demographics

Data	ERCP/LC group	BD/LC group
Number of patients, n (%)	49 (51.5)	46 (48.5)
Males, n (%)	28 (57)	21 (45.6)
Females, n (%)	21 (43)	25 (54.4)
Age, years (IQR)	41 (34–49)	37 (31–45)
BMI, kg/m^2	31 (28.25–43.75)	29 (24.75–36.5)
Median number of gallstones in the CBD, n (IQR)	2 (1–2.75)	2 (1–3)

ERCP, endoscopic retrograde cholangiopancreatography; BD, laparoscopic transcystic balloon dilatation of papilla Vateri; LC, laparoscopic cholecystectomy; n, number; IQR, interquartile range; BMI; body mass index; %, per cent.

Table 2. Complications

	Mild acute postoperative pancreatitis	Moderate acute post-operative pancreatitis	Severe acute post-operative pancreatitis	Duodenal perforation	Bleeding	Infection
ERCP/LC group, n (%)	-	4 (8.16)	-	1 (2.04)	-	-
BD/LC group, n (%)	2 (4.34)	-	-	-	-	-

ERCP, endoscopic retrograde cholangiopancreatography; BD, laparoscopic transcystic balloon dilatation of papilla Vateri; LC, laparoscopic cholecystectomy; n, number; IQR, interquartile range; BMI; body mass index; %, per cent.

! NB in group ERCP/LC: complications after ERCP procedure.

The success rate was 95.6% (n = 44) in the single-step group and 89.6% (n = 39) in the two-step group, *p*-value = 0.145. All the results obtained and described above are summarised in Table 3 for a better overview of the material.

Table 3. Results

Data	ERCP/LC group	BD/LC group	*p*-value
Median diameter of gallstones in the common bile duct, mm (IQR)	6.3 (4.75-8)	6.1 (5.5-7)	0.38
Median lipase level in blood tests, U/L (IQR)	66 (44.5–284.5)	46 (38.75–85.25)	0.059
Median hospitalisation time, days (IQR)	14 (10.25–19.5)	7 (5–9.5)	0.001
Complication rate, n (%)	5 (10.2)	2 (4.34)	0.049
Success rate, n (%)	39(89.6)	44(95.6)	0.145

ERCP, endoscopic retrograde cholangiopancreatography; BD, laparoscopic transcystic balloon dilatation of papilla Vateri; LC, laparoscopic cholecystectomy; n, number; IQR, interquartile range; BMI; body mass index; U/l, units per litre; %, per cent; mm, millimetre

! NB p values ≤ 0.001 were considered statistically significant.

DISCUSSION

Choledocholithiasis poses a significant clinical challenge due to the potential for complications such as cholangitis, pancreatitis, and biliary sepsis. The optimal management strategy for choledocholithiasis remains a topic of debate, with single-step and two-step approaches being widely studied and compared in the literature.

Single-stage management typically involves laparoscopic cholecystectomy (LC) with simultaneous intraoperative common bile duct (CBD) exploration or laparoscopic transcystic duct exploration (LTDE). This approach offers several advantages, including the simultaneous resolution of both gallbladder disease and choledocholithiasis, reducing the need for multiple procedures and hospital admissions (Chen *et al*., 2014). In our hospital, intraoperative ultrasound examination of common bile duct during laparoscopic cholecystectomy is the method of choice for patients with suspected choledocholithiasis and in cases when choledocholithiasis identified intraoperative transcystic balloon dilatation of papillae Vateri is usually performed. Additionally, single-step management has been associated with shorter hospital stays, faster recovery times, and reduced healthcare costs, compared to two-step approaches (Li *et al*., 2020). Also, our results showed that there was a significant difference in hospitalisation time between the two groups, which indirectly may indicate that the financial costs for treating patients with a one-step method are much lower. However, to study this issue, further and more detailed studies of these two methods in our hospital are necessary.

Two-step management usually consists of preoperative or postoperative endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic stone extraction followed by LC. This approach allows for a staged and less invasive initial intervention with ERCP, potentially reducing the technical complexity and risk associated with CBD exploration during LC. Furthermore, two-step management allows for thorough preoperative evaluation of CBD anatomy and stone characteristics, facilitating appropriate planning and reducing the risk of intraoperative complications (Li *et al*., 2020; Patel *et al*., 2021). However, in the hospital Rīga East University Hospital Gaiļezers MRCP is usually performed to evaluate CBD anatomy and stone characteristics, before the ERCP procedure, since the size of the stone in common bile duct plays a big role in further decision-making about the treatment method for choledocholithiasis. Also, intraoperative ERCP is not performed in our hospital due to logistical challenges, and the heavy workload of endoscopic experts.

Numerous studies have compared the outcomes of single-step and two-step management strategies for choledocholithiasis. While some studies have reported similar complication rates, and overall success between the two approaches (Manivasagam, 2024), others have suggested better in terms of stone clearance, hospital stay and total operative time (Zhu *et al*., 2015). For example, a recent meta-analysis by Patel *et al*. (2021) found that single-step management was associated with lower rates of postoperative complications and readmissions compared to two-step management (Patel *et al*., 2021). Lu *et al*. (2012) in a meta-analysis concluded that single-step management is equivalent to two-step management, but requires fewer procedures (Lu *et al*., 2012). Also, our experience and research results showed a positive trend towards a decrease in the number and severity of complications after using a one-step method of treating choledocholithiasis. Moreover, we see that the number of hospitalisation days in patients who received the one-step treatment method is much lower than in patients who received ERCP procedure.

The choice between single-step and two-step management should be individualised based on patient factors, CBD stone characteristics, and institutional expertise. Factors such as the size and location of CBD stones, the presence of comorbidities, the surgeon's experience with CBD exploration, and the availability of endoscopic expertise should be carefully considered when determining the most appropriate management strategy for each patient.

Future research should focus on further elucidating the optimal management strategy for choledocholithiasis, taking into account advances in surgical techniques, endoscopic interventions, and imaging modalities. Additionally, studies evaluating long-term outcomes, including stone recurrence rates, quality of life measures, and healthcare resource utilisation, will provide valuable insights into the comparative effectiveness of single-step and two-step management approaches.

CONCLUSIONS

Management of choledocholithiasis remains a complex and evolving field, with single-step and two-step management strategies offering distinct advantages and considerations. Laparoscopic transcystic balloon dilatation of papilla Vateri in patients with choledocholithiasis is associated with a shorter hospitalisation time, similar success rate and lower complication rate, compared to ERCP/LC.

ETHICS

This article does not contain any studies involving human participants or animals performed by any of the authors. The study was approved by the Ethics Committee of Rīga East University Hospital (approved on 29.02.2024. Ethical code number 08-A/24).

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ENDOSKOPISKĀ RETROGRĀDĀ HOLANGIOPANKREATOGRĀFIJA PRET LAPAROSKOPISKU TRANSCISTISKU PAPILLAS VATERI BALONU DILATĀCIJU PACIENTIEM AR HOLEDOKOLITIĀZI

Rīgas Austrumu klīniskajā universitātes slimnīcā divetapu terapija ir standarta ārstēšanas taktika holedoholitiāzes gadījumā. Pirmajā posmā tiek veikta endoskopiskā retrogrāda holangiopankreatogrāfija ar papilotomiju un akmeņu evakuāciju no kopējā žultsvada (KŽ), bet otrajā posmā tiek veikta laparoskopiskā holecistektomija (ERHP/LS). Vienetapa metode — laparaskopiskā holecistektomija (LS) ar intraoperatīvu transcistisku papillas Vateri balona dilatāciju un anterogrādu akmeņu evakuāciju uz divpadsmitpirkstu zarnu (BD/LS) — tika izvērtēta Rīgas Austrumu klīniskajā universitātes slimnīcā "Gaiļezers". Šī pētījuma mērķis ir salīdzināt abas šīs metodes un ziņot par rezultātiem no mūsu klīniskās pieredzes. Retrospektīvs, salīdzinošs pētījums tika veikts pacientiem ar akūtu holecistītu un holedoholitiāzi, kuri tika ārstēti mūsu slimnīcā no 2021. g. janvāra līdz 2023. g. oktobrim. Pacienti, kuriem KŽ akmeņu diametrs bija 1 centimetru un ASA I–III, tika iekļauti mūsu pētījumā. Tika analizēts akmeņu diametrs un skaits KŽ, slimnīcā pavadītais laiks, pēcoperācijas komplikāciju veids un skaits. Kopumā pētījumā tika iekļauti 95 pacienti. No tiem 46 pacienti tika pakļauti BD/LS, bet 49 pacienti tika ārstēti ar ERHP/LS. KŽ konkrementa diametra mediana (Me) bija 6,1 mm BD/LC grupā un 6,3 mm ERCP/LC grupā, $p = 0.38$. Slimnīcā pavadītais laiks bija septiņas dienas BD/LS gadījumā, bet ERHP/LS gadījumā —14 dienas, $p = 0.001$. Komplikāciju biežums BD/LS bija 4,34%, bet ERHP/LS grupā — 10,2% pēc ERHP procedūras, $p = 0.049$. Veiksmīgu iznākumu rādītājs vienetapa ārstēšanas grupā bija 95,6%, bet divetapu ārstēšanas grupā 89,6%, $p = 0.145$. BD/LS ir saistīta ar īsāku slimnīcā pavadīto laiku, līdzīgu veiksmīga iznākuma rādītāju un zemāku komplikāciju biežumu salīdzinājumā ar ERHP/LS.