

# Single-stage approach for the management of choledocolithiasis with concomitant cholelithiasis. Implementation of a protocol in a secondary hospital

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## ABSTRACT

**Background:** Current evidence shows that single-stage treatment of concomitant choledocholithiasis and cholelithiasis is as effective and safe as two-stage treatment. However, several studies suggest that single-stage approach requires shorter hospitalization time and is more cost-effective than the two-stage approach, even though it requires considerable training. This study aimed to evaluate the implementation of a protocol for managing concomitant choledocholithiasis and cholelithiasis using single-stage treatment.

**Methods:** A prospective cohort study of patients diagnosed with cholelithiasis and choledocholithiasis who were treated with the single-stage treatment – transcystic instrumentation, choledocotomy or intraoperative endoscopic retrograde cholangiopancreatography (ERCP) – between September 2010 and June 2017 was assessed. The primary outcomes were complications, hospital stay, operative time and recurrence rate.

**Results:** 164 patients were enrolled. 141 (86%) were operated laparoscopically. Preoperatively diagnosed stones were not found by intraoperative imaging or disappeared after “flushing” in 38 patients (23.2%). Surgical approach was transcystic in 45 patients (27.41%), choledochotomy in 74 (45.1%), intraoperative ERCP in 4 (2.4%), and bilioenteric derivation in 3 (1.8%). Mean hospitalization stay was 4.4 days. Mean operative time was 166 min 27 patients (16.5%) had complications and 1 patient was exitus (0.6%). Recurrence rate was 1.2%.

**Conclusions:** Single-stage approach is a safe and effective management option for concomitant cholelithiasis and choledocolithiasis. Furthermore, a significant number of common bile duct stones pass spontaneously to duodenum or can benefit from a transcystic approach, with presumable low morbidity and cost-efficiency.

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## Introduction

Cholelithiasis or common bile duct stones (CBDS) are associated with a significant number of hospital admissions, readmissions, and complications. Cholangitis, acute pancreatitis, or obstructive jaundice secondary to the presence of lithiasis in the common bile duct (CBD) are the most common clinical presentations of CBDS. CBDS are also commonly diagnosed during routine pre-op radiology or biochemical work up of patients with symptomatic cholelithiasis and the CBDS incidence in these patients ranges from 5 to 33%.<sup>1–3</sup>

In patients diagnosed with CBDS and concomitant gallstones who also present with severe cholangitis or severe acute pancreatitis with progressive jaundice, urgent biliary drainage is indicated and definitive management of both the CBD stones and gallbladder can be deferred.<sup>4</sup> Biliary drainage is normally performed by endoscopic retrograde cholangiopancreatography (ERCP). However, percutaneous transhepatic cholangiography (PTC) with external biliary drainage is a useful option in emergency situations when urgent ERCP is not available or in cases of technical difficulty.<sup>1,2,5–8</sup>

For the remaining majority of patients, there is no international consensus on the optimal course of action. The various alternatives for these patients can be summarised into two categories: sequential (also called two-step or two-stage treatment) and simultaneous (also known as one-step, one-stage or single-stage treatment).<sup>5,9</sup>

The most widely performed procedure is the two-stage treatment. The two-stage treatment consists of conducting an ERCP first, with the aim of performing a sphincterotomy to facilitate stone extraction. This is generally followed by an interval laparoscopic cholecystectomy at a second stage. The two-stage treatment has the advantage of its technical simplicity, therefore it can be performed safely in most centers with available endoscopy. Nevertheless, there is a need for two invasive procedures with two separate admissions. Moreover, with the two-stage strategy, a significant number of patients will undergo unnecessary sphincterotomies, since 10–20% of CBDS will have passed spontaneously between the time of diagnostic imaging and the ERCP. Therefore some patients will be exposed to a potentially avoidable risk of morbidity and mortality associated with ERCP (5% and 1% respectively).<sup>5,10,11</sup> In addition, depending on the health care setting, the two procedures are often performed weeks apart. Therefore, there is a risk of recurrent CBDS before the interval cholecystectomy. Readmissions for biliary events are not uncommon.<sup>7</sup> Furthermore, papillotomies may cause a permanent dysfunction of sphincter of Oddi, allowing bile reflux. This has been associated in the long term with a high rate of bacteria, which is one of the important mechanisms of new biliary duct stone formation, ascending cholangitis, liver abscesses, and even some malignancies.<sup>12,13</sup>

An alternative strategy is the single-stage treatment. This has become feasible in the era of laparoscopic CBD exploration, which has become increasingly acceptable in the hands of experienced laparoscopic surgeons since it was first reported in 1991.<sup>14</sup> The single-stage treatment consists of exploration of the CBD associated to cholecystectomy. During

cholecystectomy, intra-operative cholangiography (IOC) or ultrasonography (IUS) is performed and CBDS are removed either using the transcystic approach, choledochotomy guided by choledochoscopy, or intraoperative ERCP with rendez-vous. Rendez-vous guided ERCP consists of introducing a transcystic catheter through the papilla, with the aim of facilitating papilla access to the endoscopist, minimizing this way the risk of cannulation failure and ERCP complications.<sup>1,2,11,15,16</sup>

The single-stage, when compared to the two-stage approach, has the advantage of treating the patient's biliary conditions in one admission and with a single procedure. In addition, the exploration of the CBD is carried on only in those cases where choledocholithiasis is confirmed at the moment of cholecystectomy, so unnecessary ERCPs are avoided.<sup>17–19</sup> The main disadvantages of the single-stage treatment are that it requires extra training and a longer operating time (in some cases), compared to a simple laparoscopic cholecystectomy. It also requires special equipment and occasional collaboration with an endoscopist which might not be available in all centres. More importantly, the surgeon has to consider the additional morbidity and mortality associated with choledochotomies (8% and 0.5%) or intraoperative ERCP (5% and 1%).<sup>1,15,20–22</sup>

Results from randomised controlled trials have found no statistically significant differences between the single and two-stage treatments regarding successful resolution of choledocholithiasis, morbidity or mortality. Several studies suggest greater cost-efficiency and shorter hospital stay in the single-stage treatment but further research is needed to confirm this cost benefit.<sup>1,3,10,12,13,15,22,23</sup> Therefore there remains considerable equipoise whether or not the single-stage operative procedure is preferable to, or non-inferior to the two-stage management for choledocholithiasis.

The objective of this study was to evaluate the results of a programme for the management of cholelithiasis with concomitant choledocholithiasis using the single-stage treatment strategy in a newly opened hospital.

## Methods and materials

A prospective study of consecutive patients diagnosed with gallbladder stones and CBDS after the implementation of a single-stage treatment protocol was conducted in our hospital centre in Barcelona, Spain (*Sant Joan Despí - Moisès Broggi Hospital. Consorci Sanitari Integral*). This was a new secondary hospital opened in 2010.

### Inclusion criteria

From September 2010 to June 2017, all consecutive patients with cholelithiasis and a radiological diagnosis of choledocholithiasis were enrolled. Magnetic resonance cholangiopancreatography (MRCP) was the standard imaging test to confirm CBDS. Only in presumably simpler cases, surgical treatment was indicated after CBDS confirmed on ultrasound (US). In all patients, intraoperative cholangiography (IOC) or intraoperative ultrasound (IUS) were performed to confirm the diagnosis of choledocholithiasis prior to extraction.

### Exclusion criteria

- Patients with surgical risk IV as defined by the American Society of Anesthesiologists (ASA).<sup>24</sup>
- Severe acute cholangitis
- Persisting or progressive jaundice.
- Severe acute pancreatitis associated to obstructive CBDS
- Emergency cholecystectomies for acute cholecystitis and jaundice with CBD exploration.

### Protocol for patient management

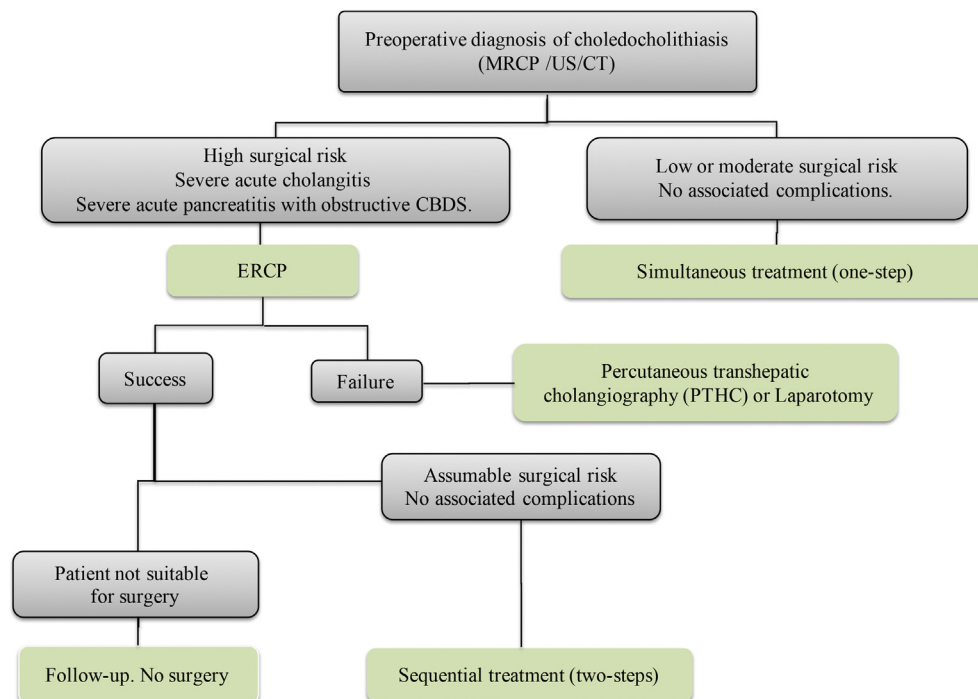
The protocol for proceedings at our centre for patients diagnosed with choledocholithiasis is summarised in Fig. 1. In low or moderate risk patients, without acute complications, single-stage treatment was attempted. In patients with persisting or progressive jaundice, impacted stones were suspected, therefore two-stage approach was performed in order to avoid conversion as laser lithotripsy was not available in our centre. Figure 2 outlines the flow of patients eligible for single-stage treatment.

1. Transcystic approach: If CBD was <7 mm, the cystic duct was short, relatively wide, not intricate, of right implantation, then a transcystic extraction was performed to remove persistent CBDS after flushing and administration of 1 mg of endovenous glucagon. In our centre the transcystic instrumentation was performed with Dormia baskets guided either by fluoroscopy or by IUS. If CBD was <7 mm and transcystic instrumentation was not feasible or failed, the endoscopist was contacted to perform an intraoperative ERCP with the aid of laparoscopically

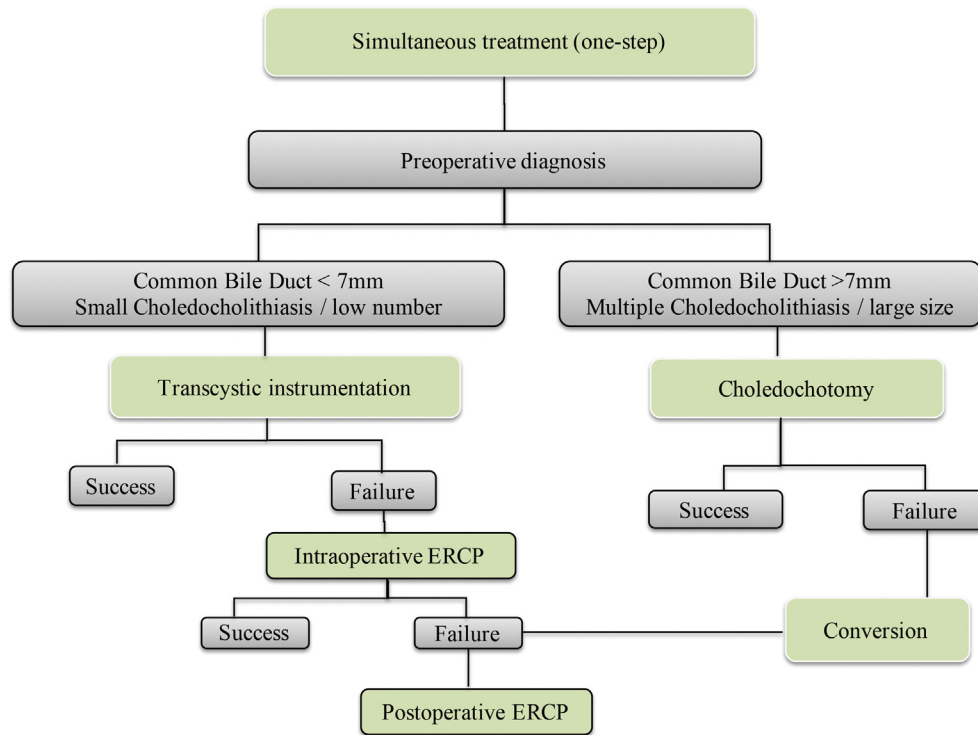
introduced rendez-vous wire. An experienced gastroenterologist was available to perform ERCP during the study period. If rendez-vous failed, a post-operative ERCP was performed the next day if the stone was not deemed to be impacted and if the CBD was narrow, in order to avoid a choledochotomy. Under these exceptional circumstances, a transcystic catheter was left in place in order to prevent postoperative complications.

2. Transcholedocal approach: In patients with a CBD dilatation >7 mm, multiple stones of large size, or non-favourable cystic duct, a laparoscopic choledochotomy was conducted. In this case, the guided extraction of the stones was performed through a flexible 5 mm choledochoscope, normally using Nitinol baskets. If this option failed, an open choledochotomy was conducted. Choledochorrhaphy (primary closure) was the first choice in all cases, however, a T tube drain was inserted when there was a risk of odditis as a result of blind instrumentation of the duct, cholangitis, or any circumstance such as uncertainty regarding duct clearance. After choledochal cleansing, a new IOC through the transcystic catheter was performed in order to rule out residual choledocholithiasis, to verify correct passing of the contrasting solution through the papilla, and the integrity of the choledochorrhaphy.
3. Conversion criteria: Laparoscopy was the standard approach, nevertheless conversion to open surgery was performed in the event of difficulties to complete the cholecystectomy or when removal of impacted stones found intraoperatively was not possible laparoscopically.

The primary outcomes of this study were morbidity, mortality, recurrence of CBDS, operative time, and hospitalisation



**Fig. 1 – Protocol for the treatment of cholelithiasis and concomitant choledocholithiasis.**



**Fig. 2 – Flow diagram for patients suitable for single-stage approach.**

length. Complications were assessed according to the Clavien-Dindo classification system.<sup>25</sup> Operative mortality was defined as deaths during hospital admission or within 30 days of the operation. We considered that there was a biliary fistula when drain output was >200 ml/day and was consistent with bilious fluid after the third postoperative day. All analyses were carried out using SPSS Statistics software package. Student T-test was used for continuous variables and Chi-square test was used for categorical data. A p value of <0.05 was considered significant.

## Results

### Patient demographics

During the study period, 164 patients were suitable for the single-stage treatment.

Mean age was 63 (ranging 20 to 91). 101 (61.5%) were female and 63 (38.5%) were male. Distribution of ASA grade was ASA I: 27 (16.5%), ASA II: 101 (61.6%) and ASA III: 36 (21.9%).

### Diagnosis

The most common symptom was jaundice, present in 118 patients (72%). Abdominal US was performed in 151 cases (92.1%). Among these, CBDS was demonstrated in 51 patients (33.8%). MRCP was performed in 141 patients (85.9%), with CBDS reported in 138 (98%). All patients had either MRCP or US CBDS confirmation. Endoscopic ultrasound was not used pre-operatively for any patients during the study period.

Intraoperative diagnosis was confirmed by performing IOC or IUS in all cases.

### Surgical treatment

Most cases (86%) were performed laparoscopically. However, conversion rate to open surgery was 14%. Reasons for conversion are listed in Table 1.

The different surgical techniques are summarised in Table 2. Transcystic removal of CBDS was successfully conducted in 45 patients (27.4%). Notably, in 38 patients (23.2%), stones previously diagnosed at MRCP were not found on intraoperative imaging or disappeared after “flushing” during IOC. Therefore, cases solved by either transcystic removal, “flushing” or in which CBDS had already passed spontaneously accounted for 83 patients (50.1%). In these patients, there was no need for

**Table 1 – Surgical approach.**

Approach	n (%)	Reason for approach
Laparoscopic	141 (86)	Protocol
Conversion	23 (14)	Bile duct injury
		Incisional hernia associated
		Previous ulcer surgery
		Impacted bile duct stone (n = 6)
		Atrophic and sclerotic gallbladder (n = 4)
		Cholecysto-colonic fistula
		Multiple choledochal stones (n = 5)
		Mirizzi type III (n = 3)
		Not resolution after rendez-vous

**Table 2 – Surgical technique.**

Type of surgical technique n (%)		
Cystic instrumentation 83 (50.1%)	Transcystic approach	
	45 (27.4%)	Spontaneous passing of stones or flushing
Common bile duct instrumentation 81 (49.9%)	38 (23.2%)	T Tube
	74 (45.1%)	42 (56.8%)
		Primary closure
		32 (43.2%)
	Intraoperative ERCP	
	4 (2.4%)	
	Bilioenteric derivation	
	3 (1.8%)	

either ERCP or choledochotomy. These patients underwent only a cystic instrumentation, such as during a standard cholecystectomy. We consider this group to have undergone a “cholecystectomy like” procedure. In the 81 patients who required choledochotomy, a primary closure was performed in 32 cases (43.2%), while T tube drainage was inserted in 42 (56.8%). The criteria to decide between primary closure or T tube drain were applied are outlined in the methods, however, during the early part of the study period, some additional T tube drains were placed due to the surgeon's personal choice. During the study period, 3 patients (1.8%) required biliary-enteric anastomosis (two choledoco-duodenostomies and one hepatico-jejuno-stomy). In two occasions, the indication was a dilated CBD with multiple impacted stones, while in another, the reason was a Mirizzi syndrome. Concerning the rendez-vous assisted ERCP, an expert endoscopist was available in all patients without CBD dilatation, however intraoperative ERCP was only required in 4 patients (2.4%).

### Postoperative data

Median operative time was 166 min and median hospital stay was 3 days. The overall complication rate was 16.2% but most complications were minor (grade I or II). Regarding major complications, 3 patients (1.8%) required reoperation. These were due to a bowel obstruction in the postoperative period, a persistent biliary fistula at the time of T tube removal and a mesenteric ischemia. There was one bile duct injury caused by perforation with a transcystic catheter at the junction of the cystic duct and bile duct. This was repaired intraoperatively but required conversion to open surgery. Post-operative bile leaks occurred in 7 patients (4.2%) but only two required reoperation or ERCP. One patient with obstructive sleep apnea required management in the intensive care unit for respiratory failure. There was one mortality, in the patient who developed mesenteric ischemia.

There were 2 cases of retained choledocholithiasis during follow up. In both cases there were limitations of intraoperative diagnosis. In one, intraoperative choledochoscopy was not performed due to choledochoscope failure. The second patient had a contrast allergy and transcystic instrumentation was US guided only. Both cases were treated with successfully with an ERCP. Complications are outlined in Table 3. There was a change in trend of the main variables

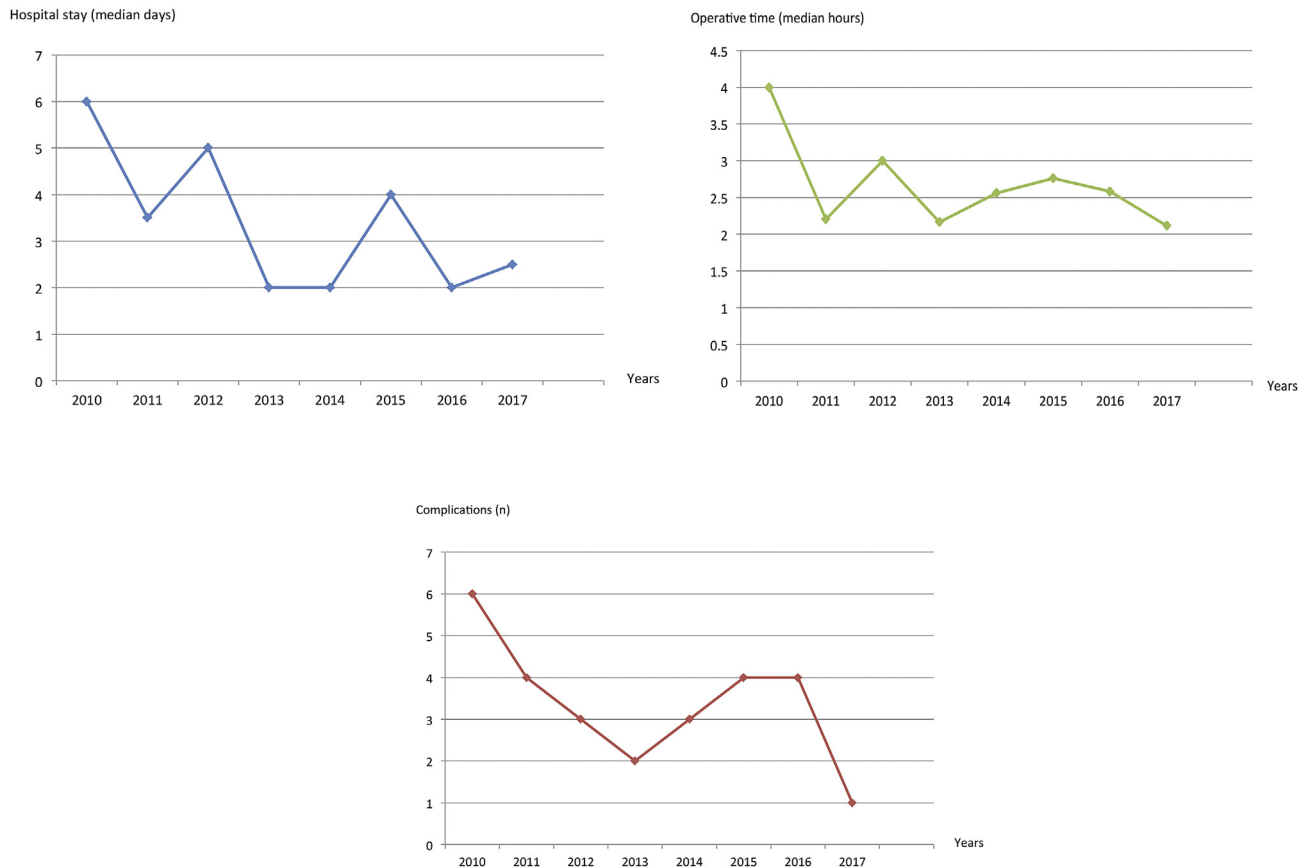
**Table 3 – Postoperative data.**

Operative time (min)	
Mean	166
Median	156
Range	52–408
Standard Deviation	76
Hospitalization Stay (days)	
Mean	4
Median	3
Range	1–28
Standard Deviation	4
Reoperation n (%)	3 (1.8)
Complications (Clavien) n (%)	
I	14 (8.5)
II	5 (3)
III	6 (3.7)
IV	1 (0.6)
V	1 (0.6)
	27 (16.5)
Recurrence of choledocholithiasis n (%)	2 (1.2)
Specific complications	
I	Wound infection n = 1 Skin haematoma n = 2 Urinary retention n = 2 Urinary tract infection n = 3 Mild bile leak n = 5 Jaundice n = 1
II	Tachycardia n = 1 Transitory cerebral accident n = 1 Myocardial infarction n = 1 Cholangitis n = 2
III	Small bowel obstruction n = 1 Bile duct injury n = 1 Severe bile leak n = 2 Recurrence of choledocholithiasis n = 2
IV	Respiratory failure n = 1
V	Massive intestinal ischemia n = 1

over the years. Overall, complications, operative time and hospital stay decreased during the span of time analysed (Fig. 3). In addition, the proportion of patients solved by cystic instrumentation compared to choledocotomies was inverted gradually (Fig. 4).

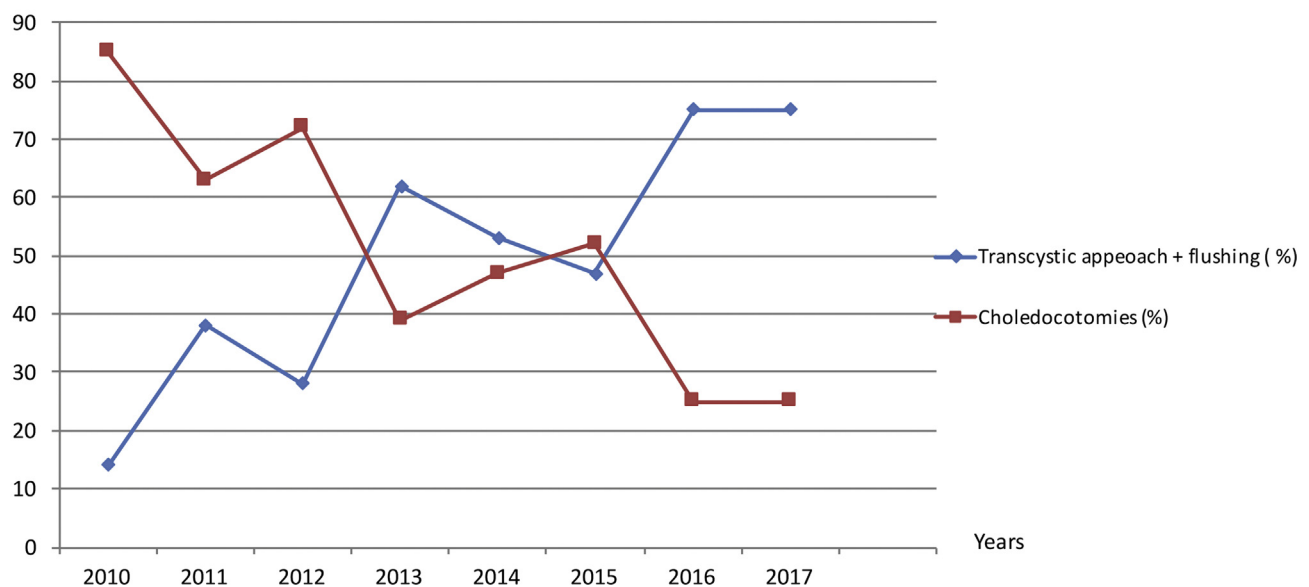
### Discussion

The ideal treatment for CBDS remains controversial. Several reviews conclude that there is no significant difference in the mortality, morbidity, retained stones, and failure rates between the single-stage and the two-stage management. Conversely, some studies have shown that the single-stage laparoscopic approach to choledocholithiasis associated to cholelithiasis might be more efficient, and that it avoids unnecessary procedures such as ERCP.<sup>1,2,5,26,27</sup> Our study shows that a implementation of a protocol based on the single-stage strategy is feasible in most patients. Moreover, in our experience, 50% of patients benefited from a transcystic instrumentation, a ‘cholecystectomy like’ operation without any additional morbidity compared to a standard laparoscopic cholecystectomy and with the added benefit of



**Fig. 3 – Evolution of main variables.**

#### % of surgical technique



**Fig. 4 – Evolution of surgical approach.**

avoiding potentially unnecessary ERCP in the two-stage approach.

Further randomised trials conducted with low risks of systematic and random errors are required to definitively

confirm or refute the present findings, as there is moderate heterogeneity among the existing studies. Moreover, further studies are needed to accurately evaluate clinically relevant outcomes such as procedure-specific morbidity,

additional procedures required to deal with the complications, hospital stay, total treatment cost and health economics, and, importantly, quality of life and patient satisfaction.

The main drawback of the single-stage approach is the additional technical requirements. It may involve extensive manipulation with instruments such as balloon dilators, guide wires, catheters, and baskets. There is a necessary learning curve, as surgical skills such as laparoscopic suturing of the CBD are necessary. With more refinement in equipment and technique, it is possible that one-stage approach may become the gold standard for concomitant gallstones and CBDS management. Certainly ERCP is irreplaceable in the setting of severe acute cholangitis, progressive jaundice or severe pancreatitis.<sup>1,2,5,7,13,28</sup> Therefore ERCP skills and close relationships with gastroenterologists must be encouraged. Pointing to the future, the advantages of single-stage management for patients with concomitant gallstones and CBDS should be considered when planning surgical training.

Overall, our results were similar to those reported in other series regarding complication rate, operative time, and hospital stay. Furthermore, there was a trend towards improvement in these key performance indicators over time. Conversely, the rate of retained stones in our experience, was slightly lower than published by other groups.<sup>2,13,28</sup> However, 3 mm choledochoscope for transcystic instrumentation and laser lithotripsy availability would likely decrease our rate of retained stones and conversions rate.

This improvement in operative time and in the rate of complications over the period analysed is likely due to the learning curve of the single-stage treatment by the surgical team. Some authors have assessed the learning curve for laparoscopic CBD explorations considering the necessary time to achieve standard values.<sup>29–31</sup> The reduction in the length of hospital stay could be explained by a gradual decrease in the number of complications as the learning curve progressed and by an increase in confidence regarding earlier removal or avoidance of drains.

One of the most important findings of our study is the number of unnecessary ERCP avoided in the single-stage approach. 50.1% of our patients were solved after flushing during IOC, by extraction through the cystic duct, or stones just passed spontaneously to the duodenum. These patients benefited from an operation that was not more complicated than a laparoscopic cholecystectomy. In addition, this “cholecystectomy like” patients avoided the short term complications of ERCP, such as pancreatitis, upper gastrointestinal bleeding or perforation, as well as the medium and long term potential consequences secondary to disruption of the sphincter of Oddi, such as cholangitis, recurrent CBDS or biliary malignancies.<sup>13</sup> The routine use of endoscopic ultrasound (EUS) immediately prior to ERCP would reduce non-therapeutic ERCP, however EUS is not available in many centres.

No clear guidelines for the indications of the transcystic approach versus choledochotomy are available. Transcystic technique has a success rate of 85–95%.<sup>32–34</sup> It has been stated by some authors that there are not relevant differences between transcystic or transcholedocal approach,<sup>5,35</sup> However, we agree with others who believe transcystic approach should be the primary strategy when feasible, as it is the least invasive,

has low morbidity rates and is very effective.<sup>32,36</sup> It is well known that transcystic instrumentation feasibility is clearly determined by the anatomy of the cystic duct (diameter, bifurcation angle of the cystic and hepatic ducts) and by the location, size and number of CBDS.<sup>9</sup> In spite of this, balloon dilatation, wider cysticotomies or transcystic choledochoscopy are some of the technical resources currently available which can increase the technical success in the setting of difficult anatomy. Throughout the study period, the proportion of cystic instrumentations increases, while the proportion of choledochotomies decreased. We believe this positively impacted on the improvements observed in terms of complications, operative time and hospital stay too.

As previously discussed, choledochoscopy is an indispensable tool as a guide for CBDS removal and to avoid residual lithiasis.<sup>5</sup> One of our recurrences occurred in a case where the choledochoscope was, damaged, so fluoroscopy guided removal was used as an alternative. IUS has been proved useful in some cases to guide the removal of stones in both transcystic or transcholedocal approach. However, it requires significant experience to assure stones clearance.<sup>34</sup> The second patient who recurred was likely due to a missed retained stone during IUS guided removal. Another necessary tool is the litotripter,<sup>5,34</sup> which we did not have available in our centre, fact which may have conditioned the conversion to laparotomy in patients with impacted stones in the papilla.

Regarding the traditional fear of CBD instrumentation, some of the complications after choledochotomies were associated with the use of T tubes (Kehr's drainage) or other types of biliary stenting, previously used systematically in some centres. T tubes were used aforesaid to decompress the biliary tree in the presence of postoperative swelling at the Ampulla of Vater and to provide easy percutaneous access for cholangiogram and extraction of retained stones. Nonetheless, recent evidence recommends primary closure after choledochotomy, in order to reduce the risk of T-tube-related complications, and also to facilitate early discharge, early return to normal activity, and less hospital expense.<sup>30,37,38</sup> As mentioned earlier, despite the fact that our protocol clearly defined the indications to place a T tube, some additional drains were placed due to surgeon's preconceptions mainly during the first period. These were commonly removed after 3 weeks. We had a severe complication after T tube removal (a bile leak), fortunately with no long-term consequences after reoperation.

Intraoperative ERCP is a safe and efficient treatment option for concomitant choledocolithiasis and cholelithiasis. The main drawback is that the necessary coordination and synchronisation of surgical and endoscopic teams is not always possible. Other inconveniences are technical, such as the subsequent difficulties of the cholecystectomy in relation to the air insufflated during ERCP, or the issues for the endoscopist due to the supine position.<sup>15,16,39–41</sup> In our centre's protocol, intraoperative ERCP was the alternative for those patients with narrow CBD where transcystic instrumentation had failed. An expert endoscopist was involved in the case beforehand and contacted when needed. This occurred rarely, though we believe this is a good available option in order to avoid postoperative ERCP.

One of the strengths of our study is that the analysis was carried out prospectively. Therefore, it gives information

about the implementation of such a technically complex protocol in a newly opened hospital. The main limitations of this study are that we did not compare the results with a two-stage group and that we did not assess costs, therefore we cannot draw strong conclusions regarding efficiency. Another limitation is due to the lack of laser lithotripsy and of a 3 mm choledoscope in our centre. These would probably increase the rate of transcystic instrumentations and decrease the conversion rate.<sup>42</sup>

## Conclusions

After the consolidation of our protocol, single-stage surgical approach of concomitant choledocholithiasis and cholelithiasis is safe. Furthermore, a significant number of patients may avoid an unnecessary preoperative ERCP. In our experience, half of the patients might undergo a “cholecystectomy like” procedure allowing the solution of both problems safely in a one-stage treatment.

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None to declare.

## Conflicts of interest

None to declare.

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