How to choose the most appropriate technique for the single-stage treatment of cholecysto-choledocolithiasis?

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Abstract

Background: We utilized transcystic clearance and intra-operative papillotomy through a rendezvous technique for the treatment of cholecysto-choledocolithiasis. The goal of this study was to evaluate the reliability of pre-operative parameters to address the most suitable surgical procedure.

Methods: A total of 180 patients affected by calculi of the gallbladder and bile duct underwent the single-stage treatment. According to several pre-operative parameters, 141 patients had to supposedly undergo transcystic clearance of the bile duct, while 39 patients had to be treated with the rendezvous technique. All patients were treated with the sequential procedure: first, we tried the transcystic procedure and, if there was a failure, we used a rendezvous technique. We prospectively analysed each group based on a series of variables such as sex, age, operative time, success rate of proposed treatment, conversion rate, post-operative complications and hospital stay.

Results: Transcystic clearance was successful in 134 out of 141 patients (95.0%), while 2 patients needed to undergo a laparo-endoscopy procedure (failure). Thirty-five out of 39 patients (89.7%) obtained common bile-duct (CBD) clearance through the rendezvous technique, while 1 patient obtained clean-up through the simple transcystic procedure (failure). Five out of 141 patients with transcystic clearance and 3 out of 39 patients with the rendezvous technique underwent laparotomy CBD clearance with conversion rates of 3.5% and 7.7%, respectively. Post-operative complications showed similar percentages for both procedures. However, the surgical time turned out to be longer for the rendezvous technique.

Conclusions: The one-stage procedure for the treatment of cholecysto-choledocolithiasis was possible in 94% of the cases utilizing a surgical technique selected according to the patient’s case history. The pre-operative parameters, such as jaundice, CBD diameters and stone diameters, have certified their reliability as good predictors of the most suitable procedure to follow.

Key words: Common bile-duct stone; transcystic laparoscopic bile-duct clearance; laparoscopic common bile-duct exploration; rendezvous; intra-operative endoscopic retrograde cholangiography
Introduction

Common bile-duct (CBD) stones emerge in 10%–15% of patients affected by gallbladder stones. Currently, there are many possible options to treat these cases: a single-step laparoscopic or endoscopic treatment, or a two-step treatment, in which an endoscopic papillotomy precedes a laparoscopic cholecystectomy [1]. Even though both methods are equivalent in terms of effectiveness, morbidity and mortality, the single-step treatment is better in terms of costs and patient compliance [2].

The one-stage approach is remarkably interesting because it is not standardized and could involve complex technical procedures, both manual and technological, that vary according to the chosen technique [3]. Three techniques can be used to obtain a complete clearance of the bili duct via a single-step laparoscopic approach: (i) a transcystic laparoscopic bile-duct clearance, (ii) a laparoscopic CBD exploration (LCBDE) and (iii) a rendezvous intra-operative endoscopic retrograde cholangiography (RV-IOERG).

The transcystic approach is the simpler and more utilized method, applicable in 60%–70% of cases [4]. However, LCBDE and RV-IOERG are preferred in cases of multiple stones with size ≥1 cm or when anatomical conditions are adverse [5]. Obviously, the degree of technical difficulty and the dedication of both the medical and radiological personnel vary according to the technique. A recent meta-analysis showed that not only had the rendezvous technique demonstrated having performed with a higher percentage of success, but it had also presented a lower likelihood of complications when compared to LCBDE [6]. The organizational aspect is the only downside of the rendezvous technique because the presence of the endoscopist in the operating room, not always easy to schedule, is required.

The goal of this paper is to identify, through an analysis of pre-operative clinical factors, the specific pathology of the patients in order to plan the most adequate laparoscopic treatment.

Methods

Between January 2010 and December 2017, 1818 patients affected by gallbladder stones were observed and 186 of them (10.2%) also presented bile-duct stones. Among these patients, 180 underwent the single-step treatment. The average age was 53 years (range, 32–77 years) and the distribution by sex was characterized by 83 females and 97 males. Out of six excluded patients, five had a clinical history of acute pancreatitis, four patients underwent pre-operative Endoscopic Retrograde CholangioPancreatography (ERCP) and subsequent cholecystectomy (two-step treatment) and two patients underwent only ERCP after pancreatitis resolution.

All the patients were pre-operatively studied through blood-chemical exams, abdominal ultrasound and, for the most part, with magnetic resonance cholangiography. The clear CBD stones diagnosis has been pre-operatively performed in 157 patients, whereas what was suspected in the pre-operative picture in the remaining 23 was intra-operatively confirmed.

Patients were divided into two subsets according to some parameters such as the degree of jaundice, the biliary tree and the stone diameters (Table 1). Following this classification, the patients were directed either to the group supposed to undergo transcystic treatment (n = 141) or to the group supposed to undergo the rendezvous treatment (n = 39). For every patient, we followed the flow chart (Figure 1), in which patients at the beginning of the treatment were included in the transcyctic treatment; for unsuccessful cases, a laparo-endoscopic treatment was performed. The patients were well informed about the two different modalities and were required to give informed consent prior to the surgery. In the transcyctic clearance, the Dormia basket and Fogarty catheter were utilized; for the most problematic cases, we verified the presence of the remaining stones with a choledochoscope. During the intra-operative papillotomy, we utilized a wire guide introduced through the cystic duct and collected by the endoscopist. At the beginning and at the end of surgery, patients were also subjected to intra-operative cholangiography (IOC) in order to verify the outcome of the clearance.

We prospectively analysed each group based on sex, age, surgical time, conversion rate, success rate of the proposed treatment, post-operative complications and hospital stay. The primary purpose was to show the successfulness of the proposed technique, while the secondary purpose was to demonstrate the effectiveness of the single-step treatment and the difference in lengths of hospital stay and post-operative complications between the two techniques.

Continuous variables were compared using the Mann–Whitney U test. Categorical variables were compared using the Fisher exact probability test or the chi-square test, when appropriate. Differences with a P-value of less than 0.05 were considered statistically significant.

Results

No mortality resulted from the surgery. The two groups were equivalent for age and gender (Table 2). The IOC confirmed the diagnosis of the bile-duct stone and the complete post-treatment clearance.

In the transcystic group (n = 141), transcystic laparoscopic bile-duct clearance was successful for 134 patients (95.0%), 2 patients needed to undergo a laparo-endoscopy (failure) and 5 patients underwent laparotomy with a conversion rate of 3.5%. The reasons for the unsuccessfulness of the remaining patients were, respectively, the number of stones for the first case (treated with a rendezvous technique) and an unfavourable cystic or extended inflammatory process in the other five for the second case. In the rendezvous group (n = 39), 35 patients (89.7%) received a complete clearance of the CBD with the rendezvous treatment and one patient with a transcystic treatment (failure); 3 patients (7.7%) presented an inflammatory local pathology typical of patients with ‘impacted’ stones, thus making a conversion to open surgery necessary (Table 3).

| Table 1. Pre-operative clinical factors and surgical approach |
|-------------------------------------------------------------|
| Treatment | Jaundice | CBD diameter | Stone diameter |
| Transcystic laparoscopic bile-duct clearance (n = 141) | ≤2 g/dL | ≤1 cm | ≤1 cm |
| Rendezvous intra-operative endoscopic retrograde cholangiography (n = 39) | >2 g/dL | >1 cm | >1 cm |

CBD, common bile duct.
Findings about post-operative complications showed similar percentages for both groups with the biliary leakage present in five patients in the transcystic group and in two patients in the rendezvous group (Table 4). These complications were treated with minimally invasive methods (eco-guide drainage or nasal biliary drainage). Furthermore, we only had one case of oedematous pancreatitis for patients who underwent an intra-operative papillotomy. Other secondary variables such as hospital stay and recurrence did not show statistically significant differences. However, operative time was longer in the rendezvous group, which resulted in a statistically significant difference with the transcystic group (Table 2). Moreover, the laparoscopic technique requires an average of 400 euros more than the transcystic technique.

### Discussion

Both gallbladder and bile-duct stones could be treated in different ways and the plausible one-step laparoscopic treatment helped to obtain results similar to those obtained with the regular treatment [7]. The one-step treatment, however, led to a reduction in expenses and better patient compliance; thus, it is indicated as the preferable one, when technically and medically possible [8].

There are different technical options available, amongst which we chose to utilize transcystic clearance or, in successful cases, rendezvous intra-operative endoscopic retrograde cholangiography. Therefore, we believe it is essential to suggest a

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**Table 2. Demographic and clinical variables**

| Variable                  | Transcystic group (n = 141) | Rendezvous group (n = 39) | P-value |
|---------------------------|-----------------------------|---------------------------|---------|
| Age, years                | 50.5 ± 19.2                 | 59.2 ± 16.8               | 0.218   |
| Males, n (%)              | 79 (56.0)                   | 18 (46.2)                 | 0.274   |
| Operative time, minutes   | 124.7 ± 52.7                | 207.3 ± 88.5              | <0.001  |
| Hospital stay, days       | 5.1 ± 3.4                   | 6.0 ± 7.2                 | 0.527   |
| Recurrence, n (%)         | 10 (7.1)                    | 0 (0.0)                   | 0.121   |

**Table 3. Success and conversion rate**

| Outcome                  | Transcystic group (n = 141) | Rendezvous group (n = 39) |
|--------------------------|-----------------------------|---------------------------|
| Success, n (%)           | 134 (95.0)                  | 35 (89.7)                 |
| Failure, n (%)           | 2 (1.4)                     | 1 (2.6)                   |
| --- Transcystic clearance | 5 (3.5)                     | 3 (7.7)                   |
| --- Rendezvous procedure  | 0 (0.0)                     | 0 (0.0)                   |

**Table 4. Post-operative complications**

| Complication          | Transcystic group (n = 141) | Rendezvous group (n = 39) |
|-----------------------|-----------------------------|---------------------------|
| Biliary leakages      | 5                           | 2                         |
| Wound infections      | 3                           | 0                         |
| Edematous pancreatitis| 0                           | 1                         |
| Incisional hernia     | 1                           | 0                         |
| Bleeding              | 1                           | 0                         |
| Pleural effusion      | 1                           | 0                         |
| Total, n (%)          | 11 (7.8)                    | 3 (7.7)                   |

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Regarding the unsuccessful cases, we rather prefer the rendezvous technique, which was more efficient compared to the sequential treatment due mainly to a reduction in complications and a higher percentage of success [10]. It is fundamental to clearly define the chosen treatment considering that the ‘rendezvous’ technique makes use of a guide wire, absent in simple endoscopic papillotomy. Intra-operative papillotomy requires a larger organizational effort, including the presence of an endoscopist who can perform endoscopy during surgery, which is the main reason why it is not so frequently used [11].

It would therefore be important to pre-operatively choose which technique would be utilized for each patient in order to establish whether a physician who can perform an endoscopy would be needed. We therefore set out a few simple and reutilizable parameters: the number of calculi, the CBD diameter and the serum bilirubin dosage to direct the patients towards the most suitable treatment. Most patients (n = 157) had a pre-operative diagnosis of bile-duct stones and the remaining ones (n = 23) underwent an IOC that we reserve for suspected cases. The application of an intra-operative routine cholangiography for every patient who undergoes a laparoscopic cholecystectomy cannot find indications, given that it does not reduce CBD injuries and that asymptomatic bile-duct calculi are rarely frequent [12].

Utilizing the pre-operative parameters, we divided the patients into two groups directing them to two different treatments. The main data showed an interesting numeric difference: 141 patients were recruited for the transcytic treatment, whereas 39 were recruited for the rendezvous treatment. This incongruence shows how bile-duct stones diagnosis complementary to the gallbladder has been previously performed and confirmed the main indication for transcytic clearance. After all, Vrako [13] showed that, in 90% of cases, the bile-duct stone diameter is no more than 1 mm larger than the cystic diameter.

Results confirmed our hypothesis: 94% of patients underwent the technique pre-operatively established. Particularly, in the transcytic group, transcytic clearance was not enough only for two patients (1.4%), while it registered a conversion rate equal to 3.5%. Possible causes for failure might derive from local inflammatory phenomena, anatomical variables or the number of present calculi [14]. Only one patient in the rendezvous group underwent a different treatment from the one previously established, whereas the conversion rate is bigger. Patients who need laparo-endoscopic treatment equally show a much more complex situation, mainly due to the number and disposition of the calculi; this phenomenon justifies a greater percentage of unsuccessful cases for the one-stage treatment. We believe that transcytic clearance could be recommended for CBD stones ≤1 cm and no more than 3; the laparo-endoscopic approach could be recommended for multiple CBD stones >1 cm or in adverse anatomical conditions.

Post-operative complications were limited and very similar in both groups. The biliary leakage slightly affected the outcome of the surgery and it had always been possible to treat these patients with minimally invasive treatments. Pancreatic complications were minimal in the rendezvous group (only one patient). This result depends, according to us, on the rendezvous treatment, which allowed an utterly safe papillotomy to be carried out. Other authors mention different results with a greater percentage of complications, even though they do not take into consideration rendezvous treatment cases, but solely those involving intra-operative papillotomy [15].

The surgery lasted longer for the rendezvous group, in line with the greater organizational and technical complexity of the treatment. At the end of this procedure, we performed an IOC in order to document the CBD clearance. Intra-operative echography was also a much more reliable and sensitive treatment even though it failed to gain momentum because of the high costs and long learning curve [16].

The low rate of recurrence demonstrates the effectiveness of these treatments for cholecysto-choledocolithiasis.

A limitation to our analysis is represented by our decision to not utilize laparoscopic cholecystectomy, which would have allowed us to evaluate cases of laparotomic conversion. We believe this technique to be extremely difficult, with post-operative complications likely to emerge [17]. Even though it has been demonstrated that the direct closure of the CBD is plausible [18], this cannot be considered a certainty, especially in the presence of a thin CBD. Moreover, in cases of impacted stones flogistic stenosis of the Vater’s papilla is often present and still requires a papillotomy [19].

The one-stage treatment of cholecysto-choledocolithiasis is preferable to sequential treatment [20]. The expanding skills in laparoscopic surgery have made it possible to treat gallbladder and bile-duct stones in a single step. In recent years, this method has attracted considerable attention. Also, the British Society of Gastroenterology has suggested the new approach to the surgical management of CBD stones [8]. There are many and different possible treatments that require several skills and specific indication according to the clinical history. Lack of a worldwide consensus on this clinical scenario may be the biggest impediment to establishing guidelines for managing this condition but, when it is possible, the one-stage approach is preferable [21, 22]. We have demonstrated that it is possible to address patients pre-operatively to direct them towards a specific treatment in order to obtain better technical and organizational management of the surgery and a more personalized approach to the patient’s disease.

Author’s contributions

Study conception and design: A.B.; acquisition of data: A.B., P.P., M.R.; analysis and interpretation of data: A.B., P.P., S.C., G.P., R.D.R.; drafting of the manuscript: A.B., P.P., G.B.; critical revision: A.B., G.B. All authors read and approved the final manuscript.

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Conflict of interest

All authors declare that they have no financial or personal relationship which could present a potential conflict of interest.

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