

# Direct Peroral Cholangioscopy in the Management of Difficult Biliary Stones: a New Tool to Confirm Common Bile Duct Clearance. Results of a Preliminary Study

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## ABSTRACT

**Background & Aims:** Endoscopic sphincterotomy (ES) with stone extraction is the standard treatment for choledocholithiasis. After stone retrieval, balloon-occluded cholangiography is generally performed to confirm bile duct clearance but can miss residual stones particularly in patients with residual small-sized stones, a large bile duct or pneumobilia. In addition, difficult common bile duct (CBD) stones requiring advanced endoscopic techniques for retrieval are a potential risk factor for choledocholithiasis recurrence.

**Methods:** We performed a retrospective evaluation of a prospectively maintained procedures database. From July 2016 to December 2017, all patients with difficult CBD stones who underwent endoscopic retrograde cholangiopancreatography (ERCP) with papillary balloon dilation-assisted stone retrieval and subsequent direct per-oral cholangioscopy (DPOC) using standard gastroscopes to confirm CBD clearance were analyzed.

**Results:** Thirty-six patients who underwent ERCP and DPOC were included. Technical success, defined as deep intubation of CBD with hepatic hilum visualization, was achieved in 31 of 36 patients (86%). During DPOC, residual CBD stones were visualized and removed in 7 of 31 patients (22.5%). After a mean of 241 ± 56 days of follow-up post-DPOC, no serious adverse events were reported, and there was no evidence or suspicion of recurrent choledocholithiasis.

**Conclusions:** Direct per-oral cholangioscopy immediately following difficult CBD stone removal was safe, feasible and accurate. In this setting, DPOC at the time of ERCP appears to be a very useful tool to achieve complete clearance of choledocholithiasis.

**Key words:** cholangioscopy – ERCP – difficult biliary stones – DPOC.

**Abbreviations:** CBD: common bile duct; DASE: dilation-assisted stone extraction; DPOC: direct per-oral cholangioscopy; EML: endoscopic mechanical lithotripsy; EPLBD: endoscopic papillary large-balloon dilation; ERCP: endoscopic retrograde cholangiopancreatography; ES: endoscopic sphincterotomy; IDUS: intraductal ultrasound.

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## INTRODUCTION

Endoscopic sphincterotomy (ES) with stone extraction is the recommended standard treatment for symptomatic choledocholithiasis [1]. However, in 10 to 15% of cases, common bile duct (CBD) stones are difficult to extract by standard endoscopic techniques and more advanced procedures to achieve complete stone clearance might be required [2-4].

Endoscopic papillary large-balloon dilation (EPLBD) with

or without ES has been widely considered as an effective and safe alternative technique along with endoscopic mechanical lithotripsy (EML) for the removal of difficult bile duct stones [5, 6]. A recent randomized multicenter study demonstrated that EPLBD was significantly superior to ES for retrieval of CBD stones ≥ 13mm in diameter, reducing the need for mechanical lithotripsy [7].

Furthermore, difficult bile duct stones are considered a risk factor for choledocholithiasis recurrence, recognized as a late adverse event after endoscopic retrograde cholangiopancreatography (ERCP) [8-10]. As a result, acute conditions such as cholangitis and biliary pancreatitis may occur and require repeated ERCP examination carrying the further risk of iatrogenic adverse events [11-14].

After stone retrieval, balloon-occluded cholangiography is generally performed to confirm bile duct clearance [15].

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However, in patients with residual small-sized stones, a large bile duct or pneumobilia, adequate bile duct evaluation may be challenging. Even if the stone extraction appears to be complete on the cholangiogram, residual stones may still remain in the CBD, potentially leading to further long-term symptoms and healthcare resource utilization [16]. Tsuchiya et al. [17] reported a 23.7% rate of residual CBD stones detected by intraductal ultrasound (IDUS) but not seen on cholangiography. However, the role of IDUS is limited due to probe availability, probe fragility and high procedure costs.

In recent years, there has been an increasing development of through-the-scope cholangioscopy techniques especially in the field of large stone management. These instruments are principally dedicated to the treatment of difficult biliary stones with laser or electrohydraulic lithotripsy, although other indications such as the confirmation of bile duct clearance at the end of the procedure have been also proposed [18]. Nevertheless, due to the high costs, these cholangioscopic procedures are usually performed only in specific scenarios, not solely for bile duct clearance confirmation. Direct peroral cholangioscopy (DPOC) refers to the use of standard upper endoscopes for the direct visualization of the biliary tract, usually after large ES or EPLBD [19, 20].

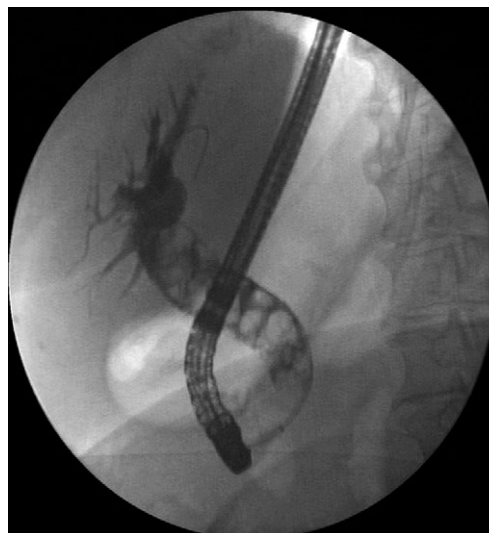
In this study, we aimed to evaluate the feasibility and safety of DPOC to confirm complete CBD clearance after dilation-assisted CBD stone extraction.

## METHODS

This was a retrospective evaluation of a prospectively maintained endoscopic procedure database. From July 2016 to December 2017, all patients with suggestive features of difficult biliary stones (both CBD dilated more than 12 mm and stone diameter larger than 10 mm) who underwent ERCP with dilation-assisted stone extraction (DASE) followed by DPOC were considered eligible for the study. Patients who were under the age of 18, pregnant, or critically ill with a pre-operative ASA IV score, as well as patients with concomitant cholecystitis or undergoing double anti-thrombotic therapy were excluded from the analysis. After confirmation of complete stones retrieval by a negative occlusive cholangiogram, a DPOC was performed using a standard forward-viewing gastroscope. The exact choice of gastroscope was at the discretion of the endoscopist.

### Endoscopic retrograde cholangiopancreatography

All ERCPs were performed using a duodenoscope (JF 160-V, Olympus, Tokyo, Japan; or ED-530XT, Fujifilm, Japan) under CO<sub>2</sub> insufflation. Deep sedation was conducted by an anesthetist-administered propofol-based sedation, with patients generally lying in left-lateral position. If performed, ES was achieved using a standard pull-type sphincterotome (Autotome or Ultratome; Boston Scientific Co. United States). Endoscopic papillary large-balloon dilation was carried out using a controlled radial expansion balloon (CRE, Boston Scientific Corp., Marlborough, United States). A contrast medium at a 1:1 dilution was generally used for cholangiography (Fig. 1). The equipment used to extract the CBD stones included a retrieval balloon catheter, a Dormia basket catheter, or a combination of



**Fig. 1.** Cholangiography: dilated common bile duct up to 20 mm and multiple (> 10) stones.

both. Mechanical lithotripsy was additionally performed when stone extraction proved to be increasingly difficult as a result of a large-sized CBD or in the case of disproportion between the stone diameter and bile duct caliber below. After stone extraction, balloon-occluded cholangiography was performed to check for complete clearance of the CBD stones. If any residual stones were observed, repeated endoscopic treatments were performed until the balloon-occluded cholangiogram was negative.

### Direct per-oral cholangioscopy

All of the DPOC procedures were carried out immediately after a negative balloon-occluded cholangiography during the same endoscopic session. Ultrastim (5.9 mm diameter, 2.0 mm working channel) or slim (8.5 mm diameter, 2.8 mm working channel) endoscopes (FujiFilm EG 530NW or EG 530FP), or standard gastroscopes (9.9 mm diameter, 2.8 mm working channel) (Olympus GIF-HQ190) were inserted via the per-oral route to directly access the bile duct, also under CO<sub>2</sub> insufflation.

Briefly, the endoscope was advanced through the mouth down to the second part of the duodenum. Then, at the endoscopist's discretion, the scope was turned into the orifice of the major papilla either directly or by means of a guidewire (Jagwire 0.035 inch-450 cm, Boston Scientific Co., United States) positioned deeply into the intrahepatic biliary tree. Then, the endoscope was further advanced into the bile duct as far as possible (Fig. 2, 3, 4). Neither balloon catheters, nor overtubes or other devices were used for this purpose. Technical success was defined as deep intubation of the CBD with hepatic hilum visualization. The DPOC time was defined as the interval between the endoscope inserting into the mouth of the patient up to the end of the procedure.

## RESULTS

### Patients

Thirty-six patients with difficult CBD stones undergoing both DASE and DPOC were included in this study (Table I).



**Fig. 2.** Fluoroscopic appearance of direct peroral cholangioscopy with the tip of endoscope inside the common bile duct (air cholangiography).



**Fig. 3.** Hepatic hilum visualization under direct peroral cholangioscopy.



**Fig. 4.** Stone fragment visualization in the distal common bile duct under direct peroral cholangioscopy.

The mean patient age was  $72.4 \pm 11.6$  years (range, 42-89 years) and 20 (55%) of the patients were female. Thirteen patients (36%) had a previous cholecystectomy. Twenty patients (55%) had an intact papilla (i.e. patients naïve to ERCP and ES), of whom two had a medical history of a subtotal gastrectomy with Billroth-II anastomosis and one had a peri-diverticular

position of the papilla. Of the remaining 16 patients, 10 had already undergone previous ERCPs and ES with or without attempted stone extraction, whilst the remaining 6 studied subjects had experienced an ERCP with failed cannulation in another center and, as such, were then referred to our institute.

**Table I.** Patient characteristics

Patients	n = 36
Age (years)	$72.4 \pm 11.6$ (range 42-89)
Gender, female n (%)	20 (55%)
ASA score	6 patients ASA 1 19 patients ASA 2 11 patients ASA 3
Intact papilla (patients naïve to ERCP)	20 patients
Peri-diverticular papilla	1 patient
Billroth-II gastrectomy	2 patients
Recurrent CBD stones	10 patients
Failed ERCP (referred from other center)	6 patients

CBD: common bile duct; ERCP: endoscopic retrograde cholangio-pancreatography.

### ERCP and DPOC

The results of the ERCP examinations are listed in Table II. Stone extraction was carried out by means of retrieval balloon catheter, Dormia basket catheter, or a combination of both. Mechanical lithotripsy was also performed in two cases. Mean procedural time (ERCP including DPOC) was  $51 \pm 14$  minutes.

**Table II.** Results of ERCP

Number of CBD stones	
1-2 stones	15 patients
3-5 stones	15 patients
more than 5 stones	6 patients
Maximum stone diameter (mean $\pm$ SD)	$12.9 \pm 3.4$ mm (range 10-20 mm)
Maximum CBD diameter CBD (mean $\pm$ SD)	$15.8 \pm 3.7$ mm (range 12-30 mm)
ES and/or EPLBD	
ES + EPLBD	30 patients
EPLBD alone	6 patients
Maximum balloon dilation (mean $\pm$ SD)	$13.4 \pm 2.1$ mm (range 10-18 mm)

CBD: common bile duct; ES: endoscopic sphincterotomy; EPLBD: endoscopic papillary large-balloon dilation

The DPOC results are shown in Table III. Technical success was achieved in 31 of 36 patients (86%). Guide-wire assisted intubation of CBD was performed in 20 cases (55%), while in the remaining 16 cases direct free-hand intubation was utilized. The slim endoscope was used in 15 patients, the ultra-slim endoscope was used in 12 patients and a standard gastroscope in the remaining 9 patients.

During DPOC, residual CBD stones were found in 7 of 31 patients (22.5%) in whom the hepatic bifurcation was reached. Mean residual stone diameter was  $6 \pm 1$  mm. In 4 patients, the residual stones were successfully extracted during per-oral cholangioscopy under direct endoscopic visualization using a



**Table III.** Results of direct per-oral cholangioscopy (DPOC)

Procedure time (mean $\pm$ SD)	6.3 $\pm$ 2.5 min (range, 3-15 min)
Guide-wire assisted intubation of CBD	20 patients (55 %)
Site reached	
Hilum or intrahepatic ducts	31 patients (86 %)
Distal CBD and not visualized hilum	3 patients (8 %)
Failed CBD intubation	2 patients (6 %)
Residual stones identified	7 patients (22.5 %)
Mean residual stone diameter	6 $\pm$ 1 mm
Residual stone(s) treatment	
DPOC	4 cases
Dormia basket	3 cases
Retrieval Roth-Net	1 case
Standard ERCP techniques	3 cases

CBD: common bile duct; DPOC: direct per-oral cholangioscopy.

basket catheter (in 3 cases) or a retrieval device (Roth-Net®, US Endoscopy) (in 1 case). In the remaining 3 patients, residual stones were removed by using a duodenoscope and standard ERCP devices after the cholangioscopy.

Mean DPOC procedure time was 6.3  $\pm$  2.5 min (range 3-15 min). No serious procedure-related adverse events (such as bleeding, pancreatitis, biliary tract infection or perforation) occurred.

Patients were followed up for a mean 241  $\pm$  56 days after the ERCP plus DPOC. At 3- and 6-months post-procedure, all subjects underwent outpatient biochemistry and abdominal ultrasound evaluation as well as a phone-call interview. During this follow-up, there were no patients with either evidence or suspicion of recurrent CBD stones.

## DISCUSSION

Endoscopic retrograde cholangiopancreatography has been widely accepted as an effective and minimally invasive treatment for CBD stones. Nevertheless, in clinical practice, acute cholangitis and pancreatitis due to recurrent choledocholithiasis occur frequently. Symptomatic recurrent CBD stones can occur in 4 to 24% of cases after successful endoscopic stone retrieval. Particularly in the case of multiple or large CBD stones, small stone fragments which are not detectable on the final cholangiogram can remain even after apparently complete endoscopic stone removal [21].

Hence, fluoroscopic confirmation of complete bile duct clearance after endoscopic treatment may be misleading. The most widely used technique is occlusion-balloon cholangiography, although different studies have reported that it is an imperfect tool in comparison with other modalities proposed to deal with this issue (i.e. mother-baby system cholangioscopy or IDUS) [16, 17].

In recent years, there has been increased development of cholangioscopy techniques, devices and applications. Huang et al. [19] reported 22.7% of patients having residual CBD stones revealed at DPOC performed by means of an ultra-slim scope, with an average stone diameter of 3-4 mm.

In this study, we reported the first retrospective analysis of DPOC performed by means of not only ultra-slim, but also slim and standard gastroscopes, in order to further evaluate

clearance of the lower biliary tract after ERCP for difficult stones. Our results showed a high CBD intubation rate of 94% (34 of 36 patients), with a technical success rate, defined as direct endoscopic hepatic hilum visualization, of 86% (31 of 36 patients).

In terms of the rate of unidentified residual stones, our results mirror those of previous studies [16, 17, 19]. Our rate of undetected residual CBD stones at occlusion-balloon cholangiography was 22.5%, with most residual stones/fragments being of small size, not exceeding 7 mm in diameter. It is unclear whether these small residual stones are of clinical significance; however, it is conceivable that these residual stones might not be excreted after the procedure and may be a nidus for stone recurrence and/or cause other long-term complications [22].

Meves et al. [23] firstly reported a large series of 100 patients in whom trans-nasal cholangioscopy was used for different diagnostic and therapeutic purposes (evaluation of indeterminate biliary strictures, confirmation of CBD stone clearance, tumor tissue ablation, etc.) using an ultra-slim gastroscope; the technical success rate was nearly 81%. Nevertheless, this study also clearly showed an important drawback of the technique: that access to the CBD is often limited and the evaluation of the intrahepatic ducts is feasible only in a minority of patients. In a recent study, Lenze et al. [24] reported the first clinical experience of DPOC with a new anchoring technique using the guide probe of Kautz. Biliary access and visualization of the target region were achieved in 18/20 procedures (90%). This and subsequent studies often reported the feasibility of direct cholangioscopy only by means of balloon-anchoring technique, overtube-assisted intubation of CBD, or dedicated double-bending tip endoscopes [25-28].

Direct per-oral cholangioscopy does not require anchoring or a dedicated cholangioscope, allowing cholangioscopy to be performed without additional costs or resources. In our study, we showed the safety and efficacy of this method performed with commonly available gastroscopes after EPLBD. Most importantly, we used a free-hand technique, without the need of specifically designed accessories to achieve CBD intubation.

Direct per-oral cholangioscopy performed with commonly available gastroscopes (ultra-slim, slim or standard endoscopes) has several advantages over the mother-baby endoscopic system. It indeed provides all the functionality of standard endoscopes enabling the extraction of residual CBD stones during the same endoscopic procedure under direct visualization. A basket catheter can pass through the 2-mm working channel of the ultra-slim endoscope to grasp residual stones. Also, a Roth-Net basket retrieval device can be used in the case of an extremely dilated CBD, through a standard 2.8 mm working channel of slim or standard endoscopes. Secondly, it displays superior imaging quality.

Another encouraging aspect of DPOC is its short procedural time. In our cohort, the mean employed time was 6.3  $\pm$  2.5 min (range 3-15 min), including the supplementary extraction procedures performed under direct endoscopic view. Considering that the overall mean procedural time was 51  $\pm$  14 minutes, additional DPOC examination increased it by only 10%. In our opinion, this is an acceptable additional time in the context of complex ERCP procedures in order to

better evaluate CBD clearance. Therefore, by directly checking and confirming the complete clearance of the CBD at the end of the ERCP, DPOC could allow significant total cost savings for both the procedure itself and potential avoidance of any future procedures or healthcare utilization due to retained CBD stones. However, we have to bear in mind that this technique should be considered as an advanced therapeutic biliary-pancreatic procedure. As in all other advanced procedures, it requires expertise and an adequate background.

In our series, no serious adverse events (such as bleeding, pancreatitis, biliary tract infection, or perforation) occurred either during the procedures or follow-up period. In addition, air embolism, a well-defined adverse event of cholangioscopy, was not observed [29].

Limitations of this study concern first of all its retrospective and non-randomized type alongside the relatively small number of patients enrolled. Therefore, it is reasonable to consider these results as a preliminary study. In addition to this, we arbitrarily considered DPOC as a procedure capable of ensuring 100% the presence or absence of stone residual, compared to the less performing gold-standard, such as the occlusion balloon cholangiogram. Finally, longer follow-up may also be required to ascertain that no patient in the DPOC group had recurrence of the stones.

## CONCLUSION

In the setting of difficult CBD stones, conventional ERCP with balloon-occluded cholangiography may not be the most reliable or satisfactory method for confirming complete bile duct clearance. Alternatively, DPOC using a standard endoscope appears to be a very useful and economical tool to not only, more confidently confirm the clearance of CBD stones, but also to immediately extract any identified residual stones/fragments. Our procedure data and relatively long recurrence-free follow-up period suggests that DPOC is feasible, efficient, accurate and safe in this subgroup of patients with difficult CBD stones. Further randomized-controlled studies addressing specific primary and secondary outcomes are eagerly warranted.

**Conflicts of interest:** None to declare

**Authors' contributions:** A.A. and A.R. conceived the study. A.A. performed the endoscopic examinations. F.A. and A.F. drafted the manuscript. E.T., L.M., R.M., S.C. F.D'A. followed up the patients. P.J.B checked English language. A.R. critically revised the manuscript. All authors approved the final version of the manuscript before submission.

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