

Retrospective Study

Efficacy and safety of endoscopic papillary balloon dilation for the removal of bile duct stones: Data from a “real-life” multicenter study on Dilation-Assisted Stone Extraction

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Abstract

AIM

To report data on Dilation-Assisted Stone Extraction (DASE) use in clinical practice and its efficacy and safety through three Italian referral centers for biliopancreatic diseases treatment.

METHODS

From January 2011 to December 2015 we collected data on 120 patients treated with DASE. Technical success was obtained when the endoscopist was able to place the balloon through the papilla inflating the balloon until the final diameter for an adequate time (at least 30 s). Clinical success was obtained after complete stone removal (no remaining stones were visible at the cholangiogram).

RESULTS

Forty-nine male (40.8%) and 71 female (59%) were enrolled. The mean age was 67.8 years \pm 15.7. The mean common bile duct (CBD) dilation was 19.2 mm

± 3.9 and the mean size of stones 15.8 ± 2.9 . DASE was applied as first approach in 38% (62% after initial failure of stones extraction). Technical and clinical success was of 91% and 87% respectively. In those in which DASE failed alternative treatment were adopted. After DASE 18% of patients experienced a complication (bleeding 9%, pancreatitis 8%, perforation 0.8%). At univariable analysis, elective endoscopic retrograde cholangiopancreatography ($P = 0.031$), DASE as first approach ($P = 0.032$), and cannulation of major papilla followed by guidewire insertion ($P = 0.004$) were related to low risk of complications. Pre-cut was related to an increased risk of complications ($P = 0.01$).

CONCLUSION

DASE allowed a higher first-session success rate and can be considered a valid alternative to endoscopic sphincterotomy not only for bigger CBD stones.

Key words: Endoscopic retrograde cholangiopancreatography; Dilation-Assisted Stone Extraction; Common bile duct stone; Endoscopic sphincterotomy; Endoscopic papillary balloon dilation

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Core tip: Endoscopic papillary large-balloon dilation after endoscopic sphincterotomy resulted effective for "difficult" common bile duct (CBD) stones treatment. This endoscopic technique has gradually spread to the current Dilation-Assisted Stone Extraction (DASE), in which balloon dilation was associated to a full or partial incision of the transverse fold, enhancing stones removal and reducing the risk of complications. Technical and clinical success was of 91% and 87% respectively; 18% of patients experienced a complication (bleeding 9%, pancreatitis 8%, perforation 0.8%). DASE allowed a higher first-session success rate and can be considered a valid alternative to endoscopic sphincterotomy not only for bigger stones of the CBD.

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INTRODUCTION

Endoscopic sphincterotomy (EST) during endoscopic retrograde cholangiopancreatography (ERCP) represents the standard endoscopic treatment for common bile duct (CBD) stones, present in up to 10% of patients who underwent cholecystectomy^[1]. EST was introduced in 1974^[2], and up to now is widely used in the current

clinical practice despite 5%-15% of all CBD stones are unable to be managed with EST alone (e.g., large CBD stones) increasing the number of complications as cholangitis and pancreatitis^[3]. In patients with large CBD stones, endoscopic mechanical lithotripsy (EML) using a mechanical lithotripter^[4], extra-corporeal shock wave lithotripsy or laser lithotripsy have proven useful to enhance stones removal^[5]. In 2003 some authors showed as endoscopic papillary large-balloon dilation (EPLBD) after EST resulted effective for "difficult" CBD stones (≥ 15 mm)^[6]. This "combined" endoscopic technique has gradually spread to the current Dilation-Assisted Stone Extraction (DASE) in which balloon dilation was associated to a full or partial incision of the transverse fold^[7,8], enhancing stones removal and reducing the risk of post-ERCP pancreatitis compared to EPLBD alone^[9,10]. This endoscopic approach can be applied safely for the treatment of CBD stones of all size as showed in a large randomized trial published in 2014 by Li *et al*^[8].

In the current study we reported "real-life" data on DASE use in clinical practice and its efficacy and safety through three Italian referral centers for biliopancreatic diseases treatment.

MATERIALS AND METHODS

Patients and study design

This retrospective study collected data from three referral centers for biliopancreatic diseases diagnosis and treatment [Gastroenterology and Endoscopy Unit, ARNAS Civico-Di Cristina-Benfratelli Hospital, Palermo; Endoscopy Unit, Policlinico G. Martino, Messina University, Messina; Endoscopy Unit, Amico Gaetano Fucito Hospital, Mercato San Severino (SA)].

All the included patients had either a single or more CBD stones documented through one or more abdominal imaging technique (ultrasound, computer tomography scan or magnetic resonance imaging). DASE was performed due to failure of the standard approach or as first approach due to the large size of the stones (≥ 12 mm).

Endoscopic technique

ERCP were performed by experienced endoscopists, and with patients under conscious or deep sedation according to the hospital guidelines of each center (short-acting benzodiazepine either alone or in combination with an opioid analgesic for conscious sedation, while propofol for deep sedation). Full blood count, biochemistry and coagulation parameters were obtained before the ERCP. Prior to the ERCP antimicrobial agent was administered in all patients to prevent post-procedural infection. ERCP was performed using a side-viewing endoscope (JF or TJF series scopes, Olympus Medical Systems, Co. Ltd, Tokyo, Japan). After selective cannulation, the CBD was imaged using diluted contrast medium injection and the endoscopist was able to evaluate the number and

the size of stones, and the diameter of the distal bile duct. In "naive" patients, EST was performed before attempting to remove the CBD stones. The breadth of the sphincterotomy incision was performed according to endoscopist evaluation, the limit of the transverse fold or the presence of ampullary/periampullary diverticulum. After EST, stones were removed with retrieval balloon catheter or Dormia basket according to the decision of each endoscopist. In those with stones removal failure, DASE was applied in order to reach or complete stones removal. DASE was performed using a balloon catheter (CRE Wireguided, Boston Scientific, Massachusetts, United States) passed over the guidewire and positioned across the main duodenal papilla. X-ray markers confirmed the correct placement of the balloon. The final diameter of the balloon was selected to correspond to the diameter of the distal bile duct. The balloon was gradually pressurized using diluted contrast medium injection through each diameter according to the corresponding atmosphere, reported by the manufacturer's instructions, and until waist disappearance. Final balloon dilation was maintained until 60 s thereafter. After that the balloon was gradually deflated and removed. Finally the stones were extracted using a retrieval balloon catheter or a Dormia basket. In patients with difficult-to-extract stones, the stones were removed after being crushed using EML. If the stones could not be removed a plastic stent insertion was performed and alternative approaches were planned (extra-corporeal shock wave lithotripsy, laser lithotripsy or surgical treatment).

Evaluation of efficacy and complications

To confirm the complete cleaning of the CBD each patient underwent contrast-enhanced imaging after occlusion with the retrieval balloon catheter. Technical success was obtained when the endoscopist was able to place the balloon through the papilla inflating the balloon until the final diameter for an adequate time (at least 30 s). Clinical success was obtained after complete stone removal (no remaining stones were visible at the cholangiogram).

All post-ERCP complications were recorded according to definitions standardized in the 1991 consensus conference. Post-ERCP pancreatitis were defined as clinical evidence of pancreatitis and elevation of pancreatic enzymes to three times the upper limit of normal 24 h after the procedure (mild if 2-3 d duration, moderate if 4-9 d, severe if longer than 10 d). Hemorrhage was considered only if there was clinical evidence of bleeding (melena or hematemesis), with an associated decrease in the hemoglobin concentration of at least 2 g/dL, the need for a blood transfusion or significant bleeding requiring endoscopic hemostasis. Cholangitis was recorded if there were symptoms as right upper quadrant abdominal tenderness, a temperature of 38 °C, and elevated liver enzyme levels. Perforation was recorded if evident during the ERCP or according to postoperative patient's symptoms combined with

abdominal radiography and/or abdominal computed tomography.

Statistical analysis

All data were collected by the three centers through an excel database. Each center filled out the own database according to a unique encoding of the variables so that to have uniform data for the final analysis. Data were analysed using the SPSS 15 (SPSS Inc., Chicago, IL, United States) software package. Continuous variables were summarized as mean (\pm SD) or median (range) according to their distribution. Categorical variables were summarized as frequency and percentage. Significant differences were calculated using a χ^2 test for categorical variables, and logistic regression for continuous variables. Differences were considered significant at a "P value" of less than 0.05. The variables that were significant on univariate analysis were evaluated in a subsequent multivariate model.

RESULTS

From January 2011 to December 2015, 1908 ERCP for CBD stones were performed in the three included referral centers. Finally we collected data on 120 patients treated with DASE (20% of all ERCP): 49 male (40.8%) and 71 female (59%), mean age of 67.8 years \pm 15.7. Patient characteristics are summarized in Table 1. There were no significant differences between the three enrolled centers and the baseline characteristics were well balanced. Indication for DASE was large stones in 69.2% (83/120 patients) and periampullary diverticulum in 30.8% (37/120 patients) as showed in Table 2. Almost all ERCP were performed electively and only 2.5% of those treated with DASE underwent rescue ERCP due to acute severe cholangitis. The majority of the treated patients underwent ERCP for the first time and only 1/4 of the patients presented an ampullary/periampullary diverticulum. The mean CBD dilation was 19.2 mm \pm 3.9 and the mean size of stones 15.8 \pm 2.9. In 87.5% of patients, CBD cannulation was made through cannulation of major papilla followed by guidewire insertion and contrast medium injection. After cholangiogram the endoscopists decided to perform DASE as first approach in 45 out of 120 patients (38%) while 62% of patients were treated after initial failure of stones extraction. The EST before DASE was "full length" in nearly half of patients, but as expected was much less common in those with ampullary/periampullary diverticulum (9/52 vs 43/52). After DASE technical success was of 91% with a significant rate of clinical success and stones extraction (87%). The mean size of the balloon dilation was 16.7 mm \pm 3.6. There were no differences between in retrieval balloon or Dormia basket using to achieve CBD clearance. In those in which DASE failed (16 patients), alternative treatment were adopted (mechanical lithotripsy in 12 patients, extra-corporeal shock wave lithotripsy in 3 patients, laser lithotripsy in one patient). Eighty-two

Table 1 Patients' characteristics

Gender (male/female), <i>n</i> (%)	49 (40.8)/71 (59)
Age (years), mean \pm SD	67.8 yr \pm 15.7
Patients at 1 st ERCP, <i>n</i> (%)	91 (75.8)
Patients previously treated with endoscopic sphincterotomy, <i>n</i> (%)	29 (24.2)
Ampullary/periampullary diverticulum, <i>n</i> (%)	37 (30.8)
Bile duct stones size (mm), mean \pm SD	15.8 \pm 2.9
Bile duct size (mm), mean \pm SD	19.2 \pm 3.9
Billroth I reconstruction, <i>n</i> (%)	3 (2.5)

patients were treated with pancreatic stent placement (12%) or with 100 mg indomethacin suppositories (57%) to reduce the risk of post-ERCP pancreatitis.

After DASE in less than ¼ of patients (18%) a complication was recorded. Bleeding and post-ERCP pancreatitis were the most common (9% and 8% respectively), while only in 1 patient a perforation was observed (he underwent DASE after CBD access made through cannulation of major papilla followed by guidewire insertion). The majority of complications occurred during the ERCP or within 24 h, and they were resolved conservatively (59%) or endoscopically (36%); only 1 patient underwent surgery due to post-procedural perforation. No adverse events related to the anesthetic technique were recorded (Table 3).

At univariable analysis, elective ERCP ($P = 0.031$, OR = 0.10; 95%CI: 0.009-1.21), DASE as first approach ($P = 0.032$, OR = 0.35; 95%CI: 0.136-1.11) and cannulation of major papilla followed by guidewire insertion ($P = 0.004$, OR = 0.21; 95%CI: 0.065-6.64), were related to low risk of complications. Pre-cut before DASE was related to an increased risk of complications ($P = 0.01$, OR = 5.11; 95%CI: 1.340-19.492). Indomethacin suppositories reduced the number of post-ERCP pancreatitis despite statistical significance was not reached ($P = 0.07$). Size of sphincterotomy incision, ampullary/periampullary diverticulum, balloon size, dilation time or devices for stones extraction resulted not related to complications. None of the significant variables resulted significant after multivariable analysis.

DISCUSSION

Our retrospective study showed as, in clinical practice of three referral centers for biliopancreatic diseases treatment, DASE was used in 20% of all ERCP for CBD stones removal. The efficacy and safety of this approach for difficult CBD stones were significant through the three participating centers.

Kawai *et al*^[2] have revolutionized the endoscopic approach of the CBD stones treatment with EST decreasing the need of surgery. Nevertheless 10%-15% of patients had "difficult" CBD stones and EST alone cannot be sufficient to remove the stones from the biliary tract. Difficulties can be related to the bile duct access (acute distal CBD angulation, sigmoid shaped CBD, periampullary diverticulum, CBD strictures Billroth

Table 2 Final results

Elective ERCP vs rescue ERCP, <i>n</i> (%)	117 (97.5) vs 3 (2.5)
Common bile duct cannulation technique, <i>n</i> (%)	
Cannulation of major papilla followed by contrast medium injection	5 (4.2)
Cannulation of major papilla followed by guidewire insertion	105 (87.5)
Pre-cut	10 (8.3)
Involuntary insertion of the guidewire into Wirsung, <i>n</i> (%)	25 (20.8)
Indication for DASE, <i>n</i> (%)	
Large stones	83 (69.2)
Periampullary diverticulum	37 (30.8)
DASE, <i>n</i> (%)	
As first approach	45 (38)
After stone extraction	75 (62)
Balloon size (mm), mean \pm SD	16.7 \pm 3.6
Dilation time (s), mean \pm SD	51 \pm 13.8
Sphincterotomy incision, <i>n</i> (%)	
Limited to one-third of the transverse fold	68 (56.7)
Full length of the transverse fold	52 (43.3)
Procedural success, <i>n</i> (%)	
Technical success	109 (90.8)
Clinical success	104 (86.7)
Stones extraction, <i>n</i> (%)	
Retrieval balloon	61 (51.8)
Dormia basket	59 (49.2)
Post-ERCP pancreatitis prophylaxis, <i>n</i> (%)	
None	38 (31.4)
Pancreatic plastic stent	14 (11.8)
Indometacin suppositories	68 (56.8)

ERCP: Endoscopic retrograde cholangiopancreatography; DASE: Dilation-Assisted Stone Extraction.

type I gastrectomy, Roux-en-Y-gastrojejunostomy), the size or number of stones, unusually shaped stones (barrel-shaped), impaction of stones, the location of the stones (intra hepatic, cystic duct), the Mirizzi syndrome^[3]. Staritz *et al*^[11] introduced endoscopic papillary balloon dilation as an alternative approach to EST but, despite the efficacy in CBD clearance, subsequent reports showed as this technique was related to the increased risk of severe pancreatitis (up to 15%) compared to sphincterotomy alone. In 2003 Ersoz *et al*^[6] introduced the combinations of EST and endoscopic papillary balloon dilation revolutionizing the treatment of CBD stones with successful clearance in up to 95% of patients with difficult stones. In the last years the use of EPLBD has evolved to the modern concept of DASE in which the use of this approach it is consolidated with the advantage to dilate both the papillary sphincter and distal bile duct, allowing for easy removal of the stones^[8]. In our retrospective series the technical success of DASE was more than 90% with a final successful clearance of the CBD near to 90%. These data are quite comparable to those from several studies compared EST alone with EST plus EPLBD (size of dilation was between 10 and 20 mm)^[7,12-15]. A systematic review and a recent meta-analysis^[16,17] showed, also, that the combined approach resulted effective and safe as EST alone but with a less needing in EML. Efficacy of DASE improved with increasing in stones size and resulted in low EML

Table 3 Complications after Dilation-Assisted Stone Extraction

Complications, <i>n</i> (%)	
No	98 (81.7)
Yes	22 (18.3)
Type of complications, <i>n</i> (%)	
Bleeding	11 (9.2)
Post-ERCP pancreatitis	10 (8.3)
Perforation	1 (0.8)
Timing of complications, <i>n</i> (%)	
Immediate	8 (6.7)
Within 24 h from the ERCP	11 (9.2)
After 24 h from the ERCP	3 (2.5)
Treatment of complications, <i>n</i> (%)	
Medical	13 (10.8)
Endoscopic	8 (6.7)
Surgical	1 (0.8)
Outcome of complications, <i>n</i> (%)	
Resolved	21 (17.5)
Unresolved (patient's exitus)	1 (0.8)

ERCP: Endoscopic retrograde cholangiopancreatography; DASE: Dilation-Assisted Stone Extraction.

needing, less procedure and fluoroscopy time compared to EST. In the current study only 10% of patients underwent EML due to DASE failure.

As showed in the results section DASE was used as first approach less frequently than as "second line" after stone extraction (38% vs 62%). This evidence is very interesting and it correspond to data reported by Li *et al*^[8] in which DASE was adopted not only for large stones but also for stones ≤ 12 mm difficult to remove at the first session.

In a large studied published in 1996^[18], the overall complications rate of EST was up to 10%: Pancreatitis 5.4% (0.4% severe), haemorrhage 2% (0.5% severe), cholangitis/cholecystitis 1% (0.1% severe), perforation 0.3%. Since its introduction in clinical practice, endoscopic papillary balloon dilation was categorized as one of the important causes of pancreatitis as showed by Disario *et al*^[10]. Nevertheless more recent studies disproved this evidence showing same rate of post-procedural pancreatitis comparing endoscopic papillary balloon dilation with EST^[19]. Some studies, also, reported that the risk of post-ERCP pancreatitis was related to the final diameter of the balloon with lower pancreatitis risk using a balloon ≥ 12 mm than those using a balloon ≤ 10 ^[20-23]. A randomized, controlled trial indicated that the pancreatitis risk for endoscopic papillary balloon dilation could be influenced by the dilation duration (a duration of 5 min is superior to the conventional 1-min duration)^[24]. Interestingly in this study the observed pancreatitis risk and efficacy of 5-min endoscopic papillary balloon dilation were comparable with those of EST, and the authors proposed the possible use of endoscopic papillary balloon dilation not only in selected patients (*e.g.*, patients with coagulopathy) but also in routinely treatment of CBD stones. Concerning other complications, DASE was not

related to an increased risk compared to EST alone^[8]. In Li's study ascending cholangitis was $< 1\%$ and the risk of perforation or bleeding were comparable in those treated with EST alone than in those treated with DASE. A recent meta-analysis by Xu *et al*^[25] confirmed a low rate of post-EPLBD bleeding compared to EST alone maybe because balloon compression of the sphincterotomy site during DASE can explain the low rate of bleeding.

In the current study the mean size of the balloon and the mean time of dilation were 16.7 mm and 51 s respectively with a final rate of post-ERCP pancreatitis or bleeding less than 9%. The majority of complications were immediate or early, and only 1 patient underwent surgery due to post-procedural perforation. No cholangitis/cholecystitis were recorded.

In our study elective ERCP, DASE as first approach and cannulation of major papilla followed by guidewire insertion, were related to low risk of complications. Pre-cut before DASE was related to an increased risk of complications. We can try to explain these findings: (1) patients treated electively are in better clinical condition compared to those treated as rescue therapy (*e.g.*, severe acute cholangitis increases the risk of bleeding); (2) DASE as first approach avoids "handling" of the CBD with retrieval balloon or Dormia basket reducing the risk of iatrogenic lesions or pancreatic injury; (3) cannulation of major papilla followed by guidewire insertion reduce the possibility of involuntary injection of contrast medium both in the Wirsung or submucosally in the papilla; and (4) pre-cut usually is reserved in those in which standard techniques of CBD cannulation failed so the risk of major papilla oedema or bleeding can increase.

No other variables were related to complications included ampullary/periapillary diverticulum confirming data reported in previous published studies^[26].

The main limit of the current study, despite the interesting findings, is due to the retrospective design that can affect final results. As well know retrospective studies are typically constructed to search records that have already been collected and some data can be missing. Retrospective database would probably be less accurate and consistent than that achieved with a prospective cohort study design. In multicenter retrospective studies, also, many different healthcare professionals are involved in patient care with different endoscopic skills that can affect the final analysis.

In conclusion, DASE allowed a higher first-session success rate and can be consider a valid alternative to EST not only for bigger CBD stones. In experienced hands DASE is a safe procedure with acceptable rate of complications. In clinical practice DASE should be reserved to patients with "difficult" CBD stones and/or in those after failure of CBD clearance with retrieval balloon or Dormia basket. In patients with high risk of post-ERCP complications DASE could be used as first approach instead to second-line option after failure of

CBD. Further well-designed study are needed to assess the routinely use of DASE for CBD stone ≤ 12 mm instead EST alone, and the advent of balloon-equipped sphincterotome could explore this aspect in the near future.

COMMENTS

Background

Endoscopic papillary large-balloon dilation after endoscopic sphincterotomy resulted effective for "difficult" common bile duct (CBD) stones treatment. This endoscopic technique has gradually spread to the current Dilation-Assisted Stone Extraction (DASE), in which balloon dilation was associated to a full or partial incision of the transverse fold, enhancing stones removal and reducing the risk of complications.

Research frontiers

In patients at risk for post-endoscopic retrograde cholangiopancreatography (ERCP) complication DASE could be used as first approach instead to second-line option after failure of CBD clearance with retrieval balloon or Dormia basket.

Innovations and breakthroughs

In this study DASE was useful to manage "difficult" CBD stones not only after failure of CBD clearance with retrieval balloon or Dormia basket but also as first approach in patients at risk for post-ERCP complication. After DASE in less than $\frac{1}{4}$ of patients a complication was recorded. The majority of complications occurred during the ERCP or within 24 h, and they were resolved conservatively or endoscopically in all patients but one (1 patient underwent surgery due to post-procedural perforation).

Applications

This study suggests that DASE allowed a higher first-session success rate and can be consider a valid alternative to EST not only for bigger CBD stones. DASE is a safe procedure in experienced hands.

Terminology

DASE: Dilation-Assisted Stone Extraction is a "combined" endoscopic technique in which balloon dilation was associated to a full or partial incision of the transverse fold after endoscopic sphincterotomy.

Peer-review

It is an interesting, well written manuscript from three referral centres including 120 patients with nice outcome. It gives a novel information as well as technical details.

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