Basket versus balloon extraction for choledocholithiasis : a single center prospective single-blind randomized study

K. Ekmektzoglou[1,2], P. Apostolopoulos[1], K. Dimopoulos[1], P. Tsibouris[1], C. Kalantzis[1], E. Vlachou[1], E. Kalafatis[1], G. Alexandrakis[1]

(1) Department of Gastroenterology, Army Share Fund Hospital (NIMTS), Athens, Greece ; (2) School of Medicine, European University Cyprus, Nicosia, Cyprus.

Abstract

***Background and study aims* : endoscopic retrograde cholangiopancreatography (ERCP) is essential when dealing in patients with choledocholithiasis. However, the proper extraction device selection is, often, a matter of the endoscopists' preference. We conducted a single center prospective randomized controlled study to access success rates for basket versus balloon catheters for small stones.**

***Patient and methods* : in our non-inferiority study, 180 patients with bile duct stones were randomized in a basket and a balloon catheter group. Inclusion criteria were fluoroscopically bile duct stones ≤10mm in diameter and a common bile duct diameter ≤15mm. The primary endpoint was the rate of complete bile duct clearance for each method. Secondary endpoints included time completed and amount of radiation dose recorded in each ERCP session, as well as any reported adverse events.**

***Results* : balloon was non-inferior to basket stone extraction (OR 3.35, 95% CI 1.12-10.05, p=0.031). Complete clearance was achieved in 69 out of 82 patients (84.1%) in the basket catheter group versus 79 out of 84 patients (94%) in the balloon catheter group (p=0.047) ; this seems to be especially true for patients with few stones and of small size (≤2 stones, p=0.043 and stone diameter ≤5mm, p=0.032). Complete stone clearance in the basket group patients took longer than that in the balloon group (4.52 and 4.06 min, respectively, p=0.015). Higher median radiation doses for stone clearance were recorded in the basket versus the balloon catheter group (1534.43 Gy versus 1245.45 Gy, p=0.023).**

***Conclusions* : our study showed that balloon was non-inferior to basket stone extraction.** (Acta gastroenterol. belg., **2020**, 83, **577-584**).

Key-words : ERCP, choledocholithiasis, balloon, basket, clearance.

Introduction

With common bile duct (CBD) stones being the most common imaging finding in patients with symptomatic cholelithiasis and acute biliary pancreatitis, both the American Society for Gastrointestinal Endoscopy (ASGE) and the European Society of Gastrointestinal Endoscopy (ESGE) have long ago set the standards of care for choledocholithiasis through published guidelines (1,2). Since the first reported endoscopic cannulation of the papilla of Vater in the late 1960s and the first described CBD stone extraction with endoscopic sphincterotomy in the mid-1970s (3,4), endoscopic retrograde cholangiopancreatography (ERCP) has become the *sine qua non* for treating choledocholithiasis (even in asymptomatic patients), with success rates around 90% (5).

However, the "*means to an end*" used during ERCP, that is the extraction devices used, are still in the hands of the endoscopist. In Europe, the ESGE guidelines propose no preference between basket and balloon catheters, while, on the other side of the Atlantic, the ASGE recommends balloon catheters as the first-line approach for safety reasons so as to avoid basket impaction (1,2). On the other hand, Japanese endoscopists seem to prefer a retrieval basket, possibly due to its better traction when compared to retrieval balloons (6,7).

With only two multicenter trials from Japan published comparing the efficacy between the aforementioned extraction devices for biliary duct stone removal and reporting contradicting findings (8,9), we conducted a single center prospective randomized controlled study to access success rates for basket versus balloon catheters for small stones (≤10mm) for the first time in Europe.

Methods

Settings

The study was conducted in the Department of Gastroenterology of the Army Share Fund Hospital (NIMTS) in Athens, Greece, over a 2-year span (from January 2016 to December 2017). Our Department is a high-volume ERCP referral center, with over 300 procedures performed in an annual basis. Written informed consent was obtained from all participants before enrollment. The study was approved by the Institutional Review Board of our Hospital (1078/2016), as it was found consistent with the Helsinki declaration.

Patients

Participants were patients with choledocholithiasis scheduled to undergo ERCP for therapeutic purposes. For the patients to be included in our study, previous imaging techniques (ultrasound and/or endoscopic ultrasound and/or computed tomography and/or magnetic resonance imaging) had to reveal bile duct stones not more than 10mm in diameter and a CBD diameter ≤15mm. Of

Correspondence to : Konstantinos Ekmektzoglou, 21 Nymphon Street, Gerakas 15344, Attica, Greece.
E-mail : ekmektzo@hotmail.com

Submission date : 25/11/2018
Acceptance date : 03/05/2020

course, both the CBD and stone diameter had to be verified during the ERCP cholangioscopy and compared with the endoscope shaft diameter (12.5mm) ; if CBD diameter was >16mm and CBD stone diameter ≥11mm, patients were excluded from the study.

Other exclusion criteria included i) age <18 years, ii) a history of previous endoscopic balloon dilation of the biliary sphincter or any previous ERCP attempt for stone extraction or any patient with previous endoscopic stent insertion, iii) intrahepatic stones, iv) severe coagulopathy (platelet count <50.000/mm^3 and/or international normalized ratio - INR - >1.5) or patients receiving anticoagulant therapy v) biliary stenosis, vi) previous gastrectomy (excluding Billroth-I reconstruction), vii) active severe pancreatitis or cholangitis (according to the revised Atlanta criteria and Tokyo guidelines, respectively) (10,11), viii) severe underlying medical condition that could exclude the patient from ERCP (severe cardiac or respiratory disease, Eastern Cooperative Oncology Group performance status ≥4, American Society of Anesthesiologists physical status ≥4, etc) (12).

Randomization

A web-based system was used for allocation and data collection. Patients were assigned to either a basket or balloon catheter before the start of the ERCP procedure (more specifically, after CBD cannulation and cholangiography) via computer-generated numbers using block randomization in a 1:1 ratio. A sealed envelope was handed out to the endoscopist, by a web technician with no participation in the study, allocating the patient to either one of two groups. The stratification was based on the CBD diameter (≤10m or 11-15mm), the diameter and number of bile duct stones (≤5mm or 6-10mm and ≤2 or 3-4 or ≥5, respectively), as depicted in the fluoroscopy procedural imaging findings. Patients were blinded to the respective catheter group ; investigators were not.

Equipment

Basket stone extraction was carried out with the basket catheter (FG-22Q-1 ; Olympus Corp, Tokyo). This basket catheter with a bullet-shaped distal tip which enables easy insertion in the CBD has an opening diameter of 22mm (Figure 1). This type of basket has four wires in its distal and proximal portion and is inserted in the CBD via the free-hand technique. This catheter has a lumen for contrast-material injection, allowing for visualization of residual stones during removal.

Balloon stone extraction was carried out with the balloon catheter (Multi-3V Plus ; Olympus Corp, Tokyo) (Figure 2). Each balloon can be easily adjusted to one of three sizes to suit the anatomical condition of each case (8.5, 11.5, and 15mm). This catheter is inserted in the CBD via the wire-guided technique and carries a contrast-injection hole above the balloon so as to perform balloon occlusion cholangiography (BOC).

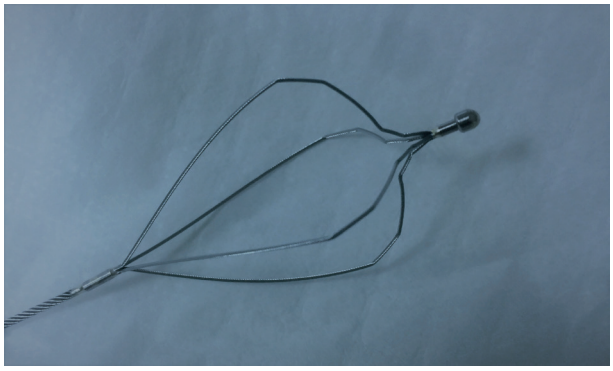

Figure 1. — The FG-22Q-1 basket catheter (Olympus Corp, Tokyo) used in our study.

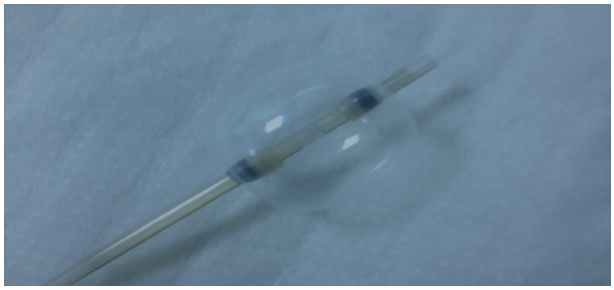

Figure 2. — The Multi-3V Plus balloon catheter (Olympus Corp, Tokyo) used in our study.

Procedure

All procedures were performed with the same oblique-angle duodenoscope (TJF-145 ; Olympus Corp, Tokyo) by two very experienced endoscopists (PA and GA), each with over 20 years of experience in ERCP. All patients were placed in the prone position ; conscious sedation was used. Afterwards, the CBD was cannulated via the wire-guided technique ; the guidewire used was the same every time (0.035 in ; Visiglide ; Olympus Corp, Tokyo). Slowly injected diluted iodinated contrast material was used so as to detect any filling defect (Ultravist 300 ; Bayer Hellas). Before any attempt for stone removal, an endoscopic sphincterotomy was performed using a wire-guided pull-type sphincterotome (CleverCut3V ; Olympus Corp, Tokyo) ; the incision length extended to (but not beyond) the upper limit of the papillary roof so as to allow the unobstructed passage of the sphincterotome while in its bowed configuration. Finally, biliary stone extraction took place.

When a stone extraction basket was used, both endoscopists made sure to advance the catheter into the CBD pass the most distal stone and thereafter push the basket out if the catheter. Under strict fluoroscopic guidance, the expanded basket was manipulated in a back-and-forth movement so as to capture the stone, which was removed without basket closure. Then the same process was repeated until complete stone clearance. For stones not caught with the aforementioned method, stone extraction was repeated with the basket in a partially

closed position with hand traction. After the removal of all stones, the presence of residual stones was detected with the aid of injecting contrast material through the basket ; when no filling defect was found (except for air bubbles), complete CBD clearance was achieved. Furthermore, since basket cholangiography is not considered the gold standard when performing cholangioscopy, BOC was performed in the end so as to assure complete stone clearance by not detecting filling defects (except for air bubbles) ; if residual choledocholithiasis was revealed, both endoscopists used the balloon catheter for complete stone removal.

As far as the balloon catheters are concerned, the process was identical to that of the basket catheter ; the balloon catheter was advanced into the CBD pass the most distal stone and, afterwards, inflated according to the CBD diameter. Under strict fluoroscopic guidance, the inflated balloon catheter was pulled from the CBD into the lumen of the duodenum clearing expelling stone/s in its path. The same process was repeated until complete stone clearance, which was confirmed by BOC. In the event of residual choledocholithiasis, both endoscopists used the basket extraction devise, as described above, until complete CBD stone clearance.

For both techniques, incomplete stone removal at the end of the procedure was managed with the insertion of a biliary plastic stent so as to avoid cholangitis and to allow the endoscopist to "buy time" by ensuring drainage so as to proceed with delayed stone removal, as biliary stones can become smaller, fragmented or, even, disappear (13).

Procedural findings

Both endoscopists recorded their findings during the ERCP procedure ; duodenal periampullary diverticula were reported, the ease of papillary cannulation, the use of precut sphincterotomy, needle-knife fistulotomy, transpancreatic biliary sphincterotomy, number of pancreatic guidewire-assisted biliary cannulations, prophylactic pancreatic stenting, endoscopic papillary balloon dilation, number of bile duct stones along with CBD diameter and the extraction method used, the cause of complete stone extraction failure, and the use of biliary stents. Difficult biliary cannulation was defined using the ESGE Clinical Guideline criteria for papillary cannulation and sphincterotomy techniques at ERCP (14). For the purposes of our study and so no to alter the incidence of adverse events, patients with difficult CBD cannulation, prophylactic pancreatic stenting and endoscopic papillary balloon dilation were, also, excluded from our study.

All ERCPs were timed ; the start time of the endoscopic procedure began from the beginning of the first stone extraction attempt. The stop watch was terminated with the end of the procedure, that is upon fluoroscopic confirmation of complete stone removal (via the basket or the balloon catheter or both) or upon BOC revealing residual stones (after failure to extract all stones with both catheters having been used). Last but not least, the amount of radiation dose used (as shown in the C-arm fluoroscope) was recorded in the same way as previously described for time.

Follow-up

All patients were monitored during their hospital stay after the ERCP, both clinically and through laboratory testing for 24 hours. They were discharged the following day provided that no adverse events were noted. If otherwise, patients were hospitalized until all adverse events had subsided and dealt sufficiently. Adverse events were defined according to the ASGE Standards of Practice Committee (15).

Endpoints

The primary endpoint of our study was the rate of complete bile duct clearance for each extraction method used (basket versus catheter). Secondary endpoints included time completed and the amount of radiation dose used in each ERCP session, as well as any reported adverse events.

Statistical analysis

In our study, the rate of complete stone extraction by balloon was assessed for non-inferiority to the basket catheter. For defining non-inferiority of the balloon compared to the basket, the lower 95% Confidence Interval (CI) of 0.9 for the Odds Ratio (OR) was chosen. The authors opted not to draft a superiority study, as the two previously pivotal Japanese studies comparing the efficacy between extraction devices for biliary duct stone removal reported contradicting findings, possibly due to major protocol differences.

A clinically significant difference for eradication between the two groups was decided to be 15%. In order to achieve 80% power for detecting this difference, along with an alpha level of 0.05 and an allocation ratio of 1:1, a needed sample of 180 patients was calculated (expected drop-out of 10%) ; the study was terminated when reaching this number of patients.

Both intention to treat (comparison of the treatment groups that included all patients as originally allocated after randomization) and per-protocol analysis (comparison of treatment groups that included only those patients who completed the treatment originally allocated) were performed so as to eliminate bias. Characteristics were compared using the Fisher's exact test and Mann-Whitney U test or Wilcoxon signed-rank test for baseline categorical and continuous variables, respectively. For variables with more than 2 values, the Kruskal-Wallis test was used to assess their distribution. Univariate analysis via the Fisher's exact test was used so as to evaluate the variables that were independently associated with complete clearance by either the basket or the balloon

catheter. As far as multivariate analysis was concerned, the difference of the observed complete clearance rates between the study groups were assessed with logistic regression analysis and the adjusted for baseline group differences OR ± 95% CI was produced. The level of significance was set at 0.05. Statistical analysis was carried out with the use of the SPSS statistics (version 17.0) software package (SPSS Inc, Chicago, IL).

Results

Patients allocated to groups and study flow

Out of the original 180 patients enrolled in the study and randomized in 2 groups (90 for the basket and 90 for the balloon catheter), 14 patients had to be excluded ; therefore, 82 patients were included to the basket catheter group and 84 to the balloon catheter group (Figure 3).

Patients' characteristics and data recorded during ERCP

Patients' characteristics are depicted in Table 1. No statistical significance was observed between the 2 groups. Table 2 shows the endoscopic, fluoroscopic and procedure-related data as recorded by the endoscopists during the ERCP.

Primary endpoint

Complete clearance was achieved in 69 out of 82 patients (84.1%) in the basket catheter group versus complete clearance in 79 out of 84 patients (94%) in the balloon catheter group (p=0.047). The causes for incomplete stone extraction as well as the next steps taken by our endoscopists so as deal with persistent choledocholithiasis, after both balloon and basket efforts (mechanical lithotripsy, plastic stent insertion), are depicted in Figure 3.

Given the clearance rate group differences with respect to stone number and size (Table 3), a logistic multivariate model controlling for these variables was made. The adjusted OR for the balloon compared to the basket catheter was 3.35 (95% CI 1.12-10.05, p=0.031), favoring balloon extraction (Figure 4). Stone number and size was not found to be statistically significant (OR 1.1, 95% CI 0.79-1.54, p=0.58 and OR 1.14 95%CI 0.92-1.41, p=0.22, respectively).

Secondary endpoints

Regarding time and radiation for each ERCP procedure, Table 4 depicts significant faster times and lower radiation doses in the balloon catheter allocated group (p<0.05). No statistically significant differences regarding adverse events between the two groups were shown ; 2 patients in each group exhibited post-ERCP pancreatitis (2.4% and 2.4%, respectively, p=1.00), with 2 patients in the group treated with the basket catheter and 3 in the group treated with the balloon catheter (2.4% and 3.6%, respectively, p=1.00) experiencing bleeding (Table 5).

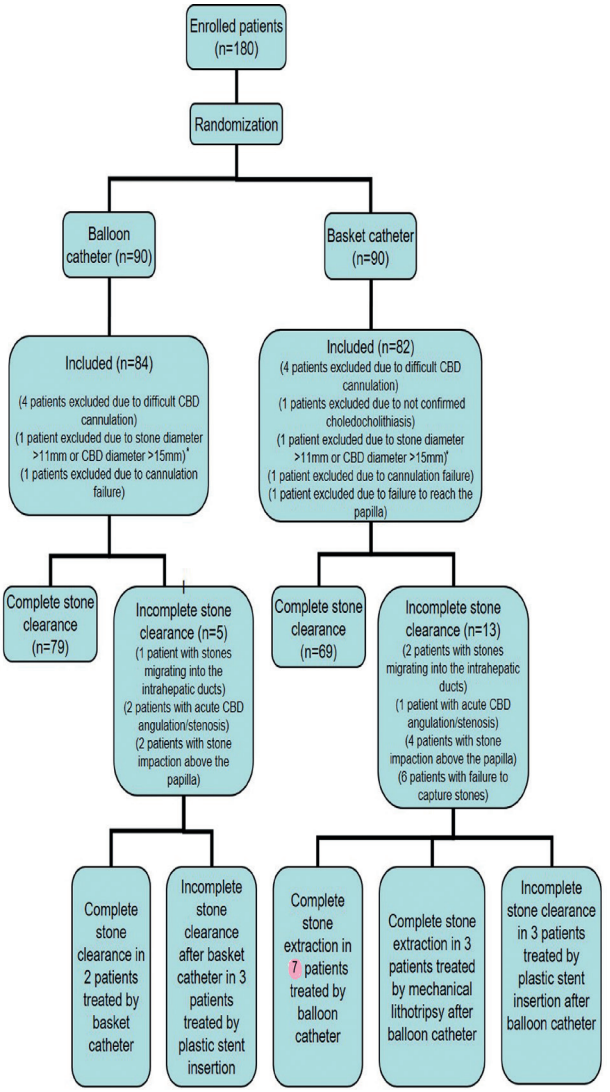

Figure 3. — Study protocol and flow chart.
* Treated with papillary balloon dilation

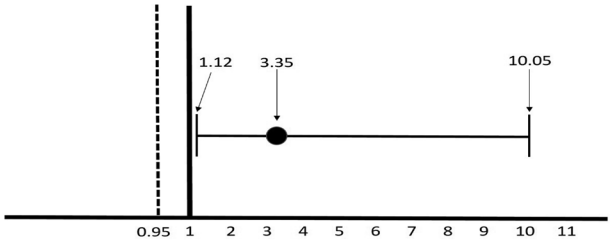

Figure 4. — The adjusted OR for the balloon clearance compared to the basket catheter.

Discussion

ERCP has become an integral part in the therapeutic armamentarium when dealing in patients with choledocholithiasis (16). With thousands of procedures being done annually (228,000 biliary endoscopies performed in

Table 1. — **Baseline characteristics of all patients who underwent ERCP basket or balloon stone extraction**

	Basket group (n=82)	Balloon group (n=84)	p-value
Male/female	43/39	40/44	0.534
Mean age ± SD (years)	62.3 ± 15.1	66.6 ± 13.11	0.497
Greeks/foreigners	62/20	55/29	0.176
ASA score			
I	42	48	0.778
II	30	28	0.893
III	10	8	0.903
Asymptomatic (%)	20 (24.4)	25 (29.8)	0.487
Cholangitis (%)	55 (67.1)	50 (59.5)	0.337
Pancreatitis (%)	7 (8.5)	9 (10.7)	0.793
Gallbladder status			
Post-cholecystectomy (%)	10 (12.2)	8 (9.5)	0.625
Chololithiasis (%)	43 (52.4)	45 (53.6)	1.00
Acalculus (%)	29 (35.4)	31 (36.9)	0.872
Pre-procedural imaging			
US (%)	22 (26.8)	22 (26.2)	1.00
EUS (%)	1 (1.2)	0 (0)	0.494
CT (%)	25 (30.5)	28 (33.3)	0.74
MRI/MRCP (%)	34 (41.5)	34 (40.5)	1.00

ASA : American Society of Anesthesiologists ; US : ultrasound ; EUS: endoscopic ultrasound ; CT : computed tomography ; MRI : magnetic resonance imaging ; MRCP : magnetic resonance cholangiopancreatography.

Table 2. — **Endoscopic, fluoroscopic and procedure-related data recorded during ERCP**

	Basket group (n=82) (%)	Balloon group (n=84) (%)	p-value
Peripappilary diverticula	26 (31.7)	30 (35.8)	0.624
Number of stones			
≤2	29 (35.4)	33 (39.3)	0.632
3-4	29 (35.4)	31 (36.9)	0.872
≥5	24 (29.2)	20 (23.8)	0.483
Median number of stones (range)	3 (1-7)	3 (1-7)	1.00
Stone diameter			
≤5mm	38 (46.3)	41 (48.8)	0.758
6-10mm	44 (53.7)	43 (51.2)	
Median stone diameter in mm (range)	6 (3-10)	6 (3-10)	1.00
CBD diameter			
≤10m	39 (47.6)	42 (50.0)	0.758
11-15mm	43 (52.4)	42 (50.0)	
Median CBD diameter in mm (range)	11 (7-15)	11 (7-15)	1.00
Precut sphincterotomy	2 (2.4)	0 (0)	0.242
Needle-knife fistulotomy	2 (2.4)	4 (4.8)	0.681
Transpancreatic biliary sphincterotomy	0 (0)	0 (0)	1.00
PGW-assisted biliary cannulation	0 (0)	0 (0)	1.00
Biliary stenting	3 (3.7)	3 (3.6)	1.00

CBD : common bile duct ; PGW : pancreatic guidewire.

Table 3. — **Complete stone clearance in the 2 groups**

	Basket group (n=82) (%)	Balloon group (n=84) (%)	p-value	Odds ratio
Overall	69/82 (84.1)	79/84 (94)	**0.047**	2.9768
Number of stones				
≤2	23/29 (79.3)	32/33 (97.0)	**0.043**	8.3478
3-4	24/29 (82.8)	29/31 (93.5)	0.247	3.0208
≥5	22/24 (91.7)	18/20 (90.0)	1.000	0.8182
Stone diameter				
≤5mm	28/38 (73.7)	38/41 (92.7)	**0.032**	0.2211
6-10mm	41/44 (93.2)	41/43 (95.3)	1.00	0.0667
CBD diameter				
≤10m	31/39 (79.4)	38/42 (90.5)	0.216	0.4079
11-15mm	38/43 (88.4)	41/42 (97.6)	0.202	0.1854

CBD : common bile duct.

Table 4. Time and radiation measured for each complete clearance by the assigned catheter

	Basket clearance 69/82 (84.1%)	Balloon clearance 79/84 (94%)	p-value
Median time (min) (range)	4.52 (3.33 - 3.75)	4.06 (1.52 - 7.26)	0.015
Median radiation (Gy) (range)	1534.43 (245.55 - 6824.44)	1245.45 (89.34 - 5634.34)	0.023

Table 5. — **Adverse events reported in the follow-up period**

	Basket group (n=82) (%)	Balloon group (n=84) (%)	p-value
Pancreatitis	2 (2.4)	2 (2.4)	1.00
Bleeding	2 (2.4)	3 (3.6)	1.00
Perforation	0 (0)	0 (0)	1.00
Cholangitis	0 (0)	0 (0)	1.00

the United States of America in 2009 and approximately 48,000 in the United Kingdom in 2007) (17,18), ERCP is the method of choice for bile duct stone extraction. However, when choosing the proper extraction device, data are inconsistent, with selection being, often, a matter of the endoscopists' preference. Both basket and balloon catheters have pros and cons. The first use a strong mechanical traction for stone extraction but can fail to catch small stones and are responsible for stone impaction. The latter may present a better option for small stones but can account for their migration in the intrahepatic bile duct or cystic duct or even their impaction in the corner pocket at the lower end of the CBD (1,2,6,7).

We conducted a single center prospective randomized study comparing success rates for basket versus balloon catheters for small stones (≤10mm) for the first time in Europe. Only two other recently published studies in Japan have raised the issue of catheter superiority (8,9). However, these are multicenter studies, with, as expected, contradicting findings.

Our study showed that balloon was non-inferior to basket stone extraction (OR 3.35, 95% CI 1.12-10.05, p=0.031). Complete clearance was achieved in 69 out of 82 patients (84.1%) in the basket catheter group versus complete clearance in 79 out of 84 patients (94%) in the balloon catheter group (p=0.047) ; these data could imply that complete stone clearance may be better when using a balloon than a basket catheter. This seems to be especially true for patients with few stones and of small size (≤2 stones, p=0.043 and stone diameter ≤5mm, p=0.032). Although the clearance rates reported in our study are in accordance with the study by Ishiwatari *et al*. (80.0% and 92.3% complete clearance for the basket and balloon catheters, respectively), where a balloon catheter was more likely to achieve complete endoscopic treatment over a basket catheter for extraction of stones ≤10mm, a fundamental difference has emerged ; contrary to us, Ishiwatari *et al*. recommended the balloon catheter as the first-line device in endoscopic treatment of patients with four or more bile duct stones (8). We cannot offer any valid explanation on this, even more so when their study has a major methodological bias with the sweep of a balloon catheter in the basket catheter group for duct clearance before performing a BOC (19). The study by Ozawa *et al*. revealed similar complete stone extraction rates and, therefore, similar efficacies within 10min only for the basket catheter (81.3%) ; lower rates (83.9%) were reported for the balloon catheter (9).

No easy explanation for these conflicting results can be adopted since each methodology used was different. Our study involved only a single institution, while the previous 2 were multicentered, providing a large bias when trying to interpret the endoscopists experience and preference of stone extraction method. To complicate matters even more, Ishiwatari *et al*. used trainees as well as expert endoscopists, while Ozawa *et al.* preferred to not mention anything about the endoscopists' experience and expertise (8,9). On the other hand, we preferred to perform all ERCP procedures by 2 very experienced endoscopists, therefore minimizing any methodological flaws. Besides, both our study and the study by Ishiwatari *et al*. used the same inclusion criteria as far as stone and CBD size were concerned ; the same is not true for the study by Ozawa *et al.* which included patients (even if they were few in numbers) with CBD diameter >15mm (8,9). Furthermore, Ishiwatari *et al*. included in their population patients who had had a previously performed ERCP alongside stent placement (with no attempt for stone extraction) when on anticoagulants or for those with severe cholangitis [8]. We decided to exclude patients with previous ERCP so as not to distort our clearance rates.

Even the randomization process was different between studies (8,9). While in both Japanese studies, patients were allocated to their groups according to the pre-procedural imaging criteria, our randomization was done only after fluoroscopic conformation of CBD size, stone number and size, thereby eliminating bias. We, as well as Ozawa *et al.* decided to use only one model for each basket or balloon catheter. On the contrary, Ishiwatari *et al*. opted for two models each for the balloon and basket catheters (8) ; even if the authors reported no significant difference in clearance rates between them, this, also, could alter data interpretation.

Our results, as expected, point out that a basket catheter with four wires may fail to catch stones that are either too small or too few ; it is these large spaces that are demarcated by the aforementioned wires that may allow stones of few mm in diameter or small in numbers to pass through. Maybe, a basket catheter with a different wire array could be more useful in these instances (20). We, also, reported that CBD size does not seem to affect, as

expected, stone clearance by either catheter, as both the balloon and the basket catheter have adjustable diameters (8.5 or 11.5 or 15mm and up to 22mm, respectively).

When considering stone impaction as a reason for incomplete clearance, both catheters in our study did not exhibit differences (2 patients with stones impacted in the balloon versus 4 patients in the basket catheter group). The same is true for stone migration in the intrahepatic bile ducts ; 1 patient with intrahepatic stone migration when treated with the balloon versus 2 patients when using the balloon catheter. Last but not least, in our study, no balloon catheter (when inflated), passed by smaller or larger stones without clearing them and leaving them behind in the CBD.

When the parameter of time was measured and compared between groups, our data showed that complete stone clearance in the basket group patients took longer than complete stone clearance in the balloon group (4.52 and 4.06 min, respectively, p=0.015). This is direct contrast with data reported by Ishiwatari *et al*. where complete clearance median times in one endoscopic session according to the type of extraction catheter and median times to complete clearance in one endoscopic session exhibited no statistically significant differences (8). Once again, the different aforementioned methodology used between studies prohibits us from making any associations between time and catheter type. Furthermore, our finding that stone clearance by a basket catheter is accompanied by statistically significant higher median radiation doses (for both the endoscopist and the patient) when compared to stone clearance by a balloon catheter (1534.43 Gy and 1245.45 Gy, respectively, p=0.023) seems to favor, once more the use of the balloon for choledocholithiasis.

Regarding adverse events, our study confirmed that both catheter types are relative safe with few adverse events and, most importantly, with no statistically significant differences between them. This is important, since our strict exclusion criteria (difficult CBD cannulation, prophylactic pancreatic stenting and endoscopic papillary balloon dilation) were in contrast with the ones used in the previously mentioned Japanese studies (8.9).

As mentioned earlier, our study revealed interesting findings that are not aligned with the 2 previous multicenter studies, differences partially attributed to the different protocols used. We strongly believe that our major strengths are the fact that all ERCPs were performed by 2 well experienced endoscopists and that our randomization was done only after fluoroscopic conformation of CBD size, stone number and size, thereby eliminating bias. However, our results maybe difficulty extrapolated to clinical practice as a single center experience can prevent further generalizability. Excluding patients with difficult cannulation and patients needing balloon dilation or placement of a prophylactic pancreatic stent creates a distance between the study's result and real life.

In conclusion, our study showed that balloon was non-inferior to basket stone extraction. Although premature to adopt in everyday clinical practice as our study was neither designed nor powered to do so, our data may indicate that it could be possible that complete stone clearance may be better when using a balloon over a basket catheter. Perhaps, new extraction devices, as novel retrieval baskets for small bile duct stones may help the endoscopist surpass this problem.

Taken economic cost as a noteworthy parameter, the endoscopist could choose a basket catheter (even a reusable one after sterilization) as the initial extraction device only for patents with certain bile duct stone size and diameter characteristics ; small stones that are few in number could first be treated with balloon catheters. This is important since cholangiography via the basket catheter is not sufficient to confirm duct clearance after extraction of multiple stones, as pointed out by Ishiwatari *et al* (8).

More prospective future studies with proper methodology will enhance our knowledge and provide us with more robust data regarding complete stone clearance and catheter type.

Conflicts of interest and source of funding

None declared.

References

1. MAPLE J.T., IKENBERRY S.O., ANDERSON M.A., APPALANENI V., DECKER G.A., EARLY D. The role of endoscopy in the management of choledocholithiasis. *Gastrointest. Endosc.,* 2011, **74** : 731-744.
2. WILLIAMS E.J., GREEN J., BECKINGHAM I., PARKS R., MARTIN D., LOMBARD M. *Gut* 2008, **57** : 1004-1021.
3. MCCUNE W.S., SHORB P.E., MOSCOVITZ H. Endoscopic cannulation of the ampulla of Vater : a preliminary report. *Ann. Surg*., 1968, **167** : 752-756.
4. DEMLING L., KOCH H., CLASSEN M., BELOHLAVEK D., SCHAFFNER O., SCHWAMBERGER K., *et al.* [Endoscopic papillotomy and removal of gall-stones : animal experiments and first clinical results (author's transl)]. *Dtsch. Med. Wochenschr.,* 1974, **99** : 2255-2257.
5. ADLER D.G., CONWAY J.D., FARRAYE F.A., KANTSEVOY S.V., KAUL V., KETHU S.R., *et al.* Biliary and pancreatic stone extraction devices. *Gastrointest. Endoscop.,* 2009, **70** : 603-609.
6. ITOI T., WANG H.P. Endoscopic management of bile duct stones. *Dig. Endosc*., 2010, **22** : S69-75.
7. BINMOELLER K.F., SCHAFER T.W. Endoscopic management of bile duct stones. *J. Clin. Gastroenterol.,* 2001, **32** : 106-118.
8. ISHIWATARI H., KAWAKAMI H., HISAI H., YANE K., ONODERA M., ETO K., *et al.* Balloon catheter versus basket catheter for endoscopic bile duct stone extraction : a multicenter randomized trial. *Endoscopy,* 2016, **48** : 350-357.
9. OZAWA N., YASUDA I., DOI S., IWASHITA T., SHIMIZU M., MUKAI T., *et al.* Prospective randomized study of endoscopic biliary stone extraction using either a basket or a balloon catheter : the BasketBall study. *J. Gastroenterol.,* 2017, **52** : 623-630.
10. BANKS P.A., BOLLEN T.L., DERVENIS C., GOOSZEN H.G., JOHNSON C.D., SARR M.G., *et al.* Classification of acute pancreatitis - 2012 : revision of Atlanta classification and definitions by international consensus. *Gut,* 2013, **62** : 102-111.
11. KIRIYAMA S., TAKADA T., STRASBERG S.M., SOLOMKIN J.S., MAYUMI T., PITT H.A., *et al.* TG13 guidelines for diagnosis and severity grading of acute cholangitis (with videos). *J. Hepatobiliary Pancreat. Sci*., 2013, **20** : 24-34.
12. ASA physical status classification system. Available from : https://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system

13. DUMONCEAU J.M., TRINGALI A., BLERO D., DEVIÈRE J., LAUGIERS R., HERESBACH D., *et al.* Biliary stenting : indications, choice of stents and results : European Society of Gastrointestinal Endoscopy (ESGE) clinical guideline. *Endoscopy,* 2012, **44** : 277-298.
14. TESTONI P.A., MARIANI A., AABAKEN L., ARVANITAKIS M., BORIES E., COSTAMAGNA G., *et al.* Papillary cannulation and sphincterotomy techniques at ERCP : European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline. *Endoscopy,* 2016, **48** : 657-683.
15. CHANDRASEKHARA V., KHASHAB M.A., MUTHUSAMY V.R., ACOSTA R.D., AGRAWAL D., BRUINING D.H., *et al.* Adverse events associated with ERCP. *Gastrointest. Endosc.,* 2017, **85** : 32-47.
16. YASUDA I., ITOI T. Recent advances in endoscopic management of difficult bile duct stones. *Dig. Endosc.,* 2013, **25** : 376-385.
17. PEERY A..F, DELLON E.S., LUND J., CROCKETT S.D., MCGOWAN C.E., BULSIEWICZ W.J., *et al.* Burden of gastrointestinal disease in the United States : 2012 update. *Gastroenterol.,* 2012, **143** : 1179-1187.
18. BAILLIE J., TESTONI P.A. Are we meeting the standards set for ERCP? *Gut,* 2007, **56** : 744-746.
19. KADAYIFCI A., SAVAS M.C. Do we overestimate the performance of the basket catheter for stone removal if the bile duct is swept with a balloon? *Endoscopy,* 2016, **48** : 867.
20. YASUDA I. Novel retrieval basket for small bile duct stones. *Dig. Endosc.,* 2015, **27** : 712.