

Endoscopic Treatment for Pancreatolithiasis with a Novel Nitinol Basket Catheter

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ABSTRACT

Objective Pancreatolithiasis is often treated by fragmentation of stones by extracorporeal shock wave lithotripsy, followed by additional endoscopic treatments, such as endoscopic pancreatic sphincterotomy. However, it is difficult to remove minute fragments or protein plugs using the conventional basket catheter. We recently used a newly developed nitinol basket catheter, for endoscopic removal of pancreatic stones. We report the results of our study on the usefulness of this catheter. **Patients and methods** The subjects were 8 patients with pancreatolithiasis treated by extracorporeal shock wave lithotripsy plus endoscopic treatment at our department between July 2014 and January 2015. There were 7 men and 1 woman, ranging in age from 26 to 86 years (median 46 years). Endoscopic removal of pancreatic stones using the nitinol basket catheter was performed a total of 15 times, and the insertability, success rate of pancreatic stone removal, complications, and pancreatic stone recurrence rate were examined. **Results** The nitinol basket catheter was easily inserted in 12 (80%) of the 15 sessions. In the remaining 3 sessions, it was difficult to insert the catheter because of narrowing of the main pancreatic duct in the pancreatic head, kinking of the pancreatic duct in the pancreatic head and body, and edema around the papilla present immediately after pancreatic sphincterotomy. The success rate of endoscopic removal of pancreatic stones was 87.5% (7/8 patients), 73% (11/15 sessions). As for complications, mild pancreatitis occurred in 1 session, and mild transient abdominal pain in 2; both complications resolved with conservative treatment. Recurrence of the pancreatolithiasis was found after 8 months in 1 (12.5%) of the 8 patients, who had narrowing of the main pancreatic duct in the pancreatic head. **Conclusion** The nitinol basket catheter is advantageous for the removal of small pancreatic stones and protein plugs, which are difficult to visualize by pancreatography, and may be useful for preventing recurrence of pancreatolithiasis.

INTRODUCTION

In the treatment of pancreatolithiasis, extracorporeal shock wave lithotripsy (ESWL) alone results in successful stone removal in only a half of all the patients [1, 2, 3].

Therefore, for the treatment of pancreatolithiasis, combined use of ESWL with endoscopic techniques for the removal of pancreatic stones is more effective than ESWL alone [4, 5]. Endoscopic treatments for pancreatolithiasis include EPST, endoscopic removal of pancreatic stones using a basket catheter, endoscopic pancreatic stenting, and endoscopic papillary balloon dilation. It has been reported that treatment using ESWL in combination with

the appropriate endoscopic procedure yields favorable results, with complete stone elimination rates of 76-100%, in comparison to treatment by ESWL alone [1, 2, 3, 6].

However, endoscopic removal of pancreatic stones is still challenging because there is no dedicated device for the narrow, irregular, and tortuous pancreatic duct. The problems with currently available basket catheters include their inability to be introduced to the targeted area, to expand in the narrow and tortuous pancreatic duct, and to catch, retrieve, or release stones, if needed. To overcome these hurdles, Sasahira *et al.* [7] developed a novel nitinol basket catheter dedicated to endotherapy for pancreatic duct stones.

Stone fragments can be minute, and it is sometimes difficult to capture and remove the fragments with the conventional basket catheter. In addition, protein plugs are soft and difficult to retrieve. Failure to remove small pancreatic stone fragments may lead to recurrence of pancreatolithiasis. We examined the usefulness of endoscopic removal of pancreatic stones using the newly developed nitinol basket catheter (NBC) with 72-wire mesh basket.

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Keywords Lithotripsy; Pancreatitis, Chronic

Abbreviations ESWL extracorporeal shock wave lithotripsy; NBC nitinol basket catheter

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PATIENTS AND METHODS

The subjects were 8 patients with pancreatolithiasis treated between July 2014 and January 2015. The patients comprised 7 men and 1 woman, ranging in age from 26 to 86 years (median 46 years). The chronic pancreatitis was alcoholic in 4 patients and idiopathic in the remaining 4 patients. The site of the pancreatolithiasis was the pancreatic head in 5 patients, the pancreatic head and body in 2 patients, and the accessory pancreatic duct in 1 patient. The stone was single in 1 patient and multiple in the remaining 7, the stone diameter was 4.8-15.3 mm (median 9.2 mm) in CT or ERCP, and the main pancreatic duct diameter was 5.2-9.2 mm (median 6.2 mm) (**Table 1**).

For endoscopic retrograde cholangiopancreatography (ERCP), the JF 260 V device (Olympus Medical, Tokyo, Japan) was used. The devices used for stone removal were an Olympus Flower basket (FG-V435P: 0.035-inch wire, guided by a guidewire, maximum outer diameter 2.9 mm at the insertion site, basket size 20 mm, 8-wire basket) and the novel nitinol basket catheter (Reforma®; Piolax Medical Devices Inc, Japan) (sheath outer diameter 7.4Fr, tapered end 5.7Fr, effective length 1900 mm, basket size 5 mm, fitted guidewire 0.025-inch, 72-wire basket). The flower basket has a single lumen, and the basket opens and shuts along the guidewire. On the other hand, the NBC has a double-lumen structure, composed of a lumen for the guidewire and another for the basket. The basket of the NBC, measuring 14 mm in its major axis, can be made to open after it protrudes from the catheter by manipulation at the hand level. The size of the basket can be adjusted (**Figure 1**).

For the treatment of pancreatolithiasis, ESWL and EPST were performed in all the patients. EPST was performed on the main papilla or the accessory papilla, or both. Thereafter, the pancreatic stones were removed using the NBC alone, or with the flower basket followed by insertion of the NBC.

For removal of a pancreatic stone with a basket catheter, the flower basket or NBC is inserted into the main pancreatic duct on the caudal side under the guidance of the

Table 1. Summary of 8 patients with pancreatolithiasis treated endoscopically with a newly developed basket catheter.

No. of patients	8
Age, median (range)	46 (26-86)
Etiology of pancreatitis	
Idiopathic	4
Alcoholic	4
Location of pancreatic stone	
Main PD (Head /Head-body)	7 (5/2)
Accessory PD	1
No of stones; single/multiple	1/7
Diameter of stone, median(range)	9.2 (4.8-15.3) mm
Diameter of PD, median(range)	6.2 (5.2-9.2) mm
PD pancreatic duct; No number	

guidewire, and the stone is held with the basket opened to a size comparable in diameter to the pancreatic duct; then, the stone is moved into the duodenum. The elimination of the pancreatic stones is confirmed by ERCP. Residual pancreatic stones were found in 6 patients after the initial attempt at endoscopic removal, and pancreatic stenting was performed in these patients. Thereafter, endoscopic removal of the pancreatic stones was performed 2-5 times (median 3 times) until complete elimination of the pancreatic stones was confirmed. The insertability of the NBC into the main pancreatic duct in the pancreatic tail, the success rate of pancreatic stone removal, the adverse events associated with the procedure, and the recurrence rate of pancreatolithiasis were examined in the subjects. The follow-up period was 6-20 months (median 14 months).

RESULTS

ESWL and endoscopic pancreatic sphincterotomy were performed in all 8 patients with pancreatolithiasis. Pancreatic sphincterotomy was performed on the main papilla in 6 patients, on the accessory papilla in 1, and on both the main and accessory papillae in 1. Four patients underwent endoscopic removal of the pancreatic stones after pancreatic stenting. Pancreatic stenting was performed to prevent acute pancreatitis in 2 patients. 2 patients performed pancreatic duct stenting as a mark to crush a stone in ESWL.

After the pancreatic stones were fragmented by ESWL, the fragments were removed endoscopically. The NBC was inserted in 15 sessions. For endoscopic removal of the pancreatic stones, the NBC alone was used in 10 sessions, and a combination of the flower basket and the NBC was used in 5 sessions. A pancreatic stent was placed temporarily in 4 patients to prevent the development of pancreatitis following endoscopic removal of the pancreatic stones. Pancreatic stones were eliminated by endoscopic removal of the pancreatic stones in 7 of the 8 patients, and spontaneously in the remaining 1 patient. Thus, complete removal of the pancreatic stones was achieved in all 8 patients (**Figure 2**).

The NBC was successfully inserted into the main pancreatic duct in the pancreatic tail in 12 (80%) of the 15 sessions. Insertion was difficult because of main pancreatic duct stenosis in 1 session, kinking of the main pancreatic duct in 1 session, and edema around the papilla in 1 session, in whom the initial insertion of the NBC immediately after the EPST was successful (**Figure 3**). In 2 of the 3 sessions with difficulty in inserting the NBC, a pancreatic stent was inserted, and subsequent retreatment with a flower basket catheter led to removal of all the pancreatic stones. Pancreatic stones were eliminated spontaneously in the remaining 1 patient.

Use of the NBC allowed successful retrieval of the pancreatic stones and protein plugs (**Figure 4**) in 11 (66.7%) of 15 sessions, 5 (62.5%) of the 8 patients, of the pancreatic stones alone in 1 session (6.7%), 1 patient

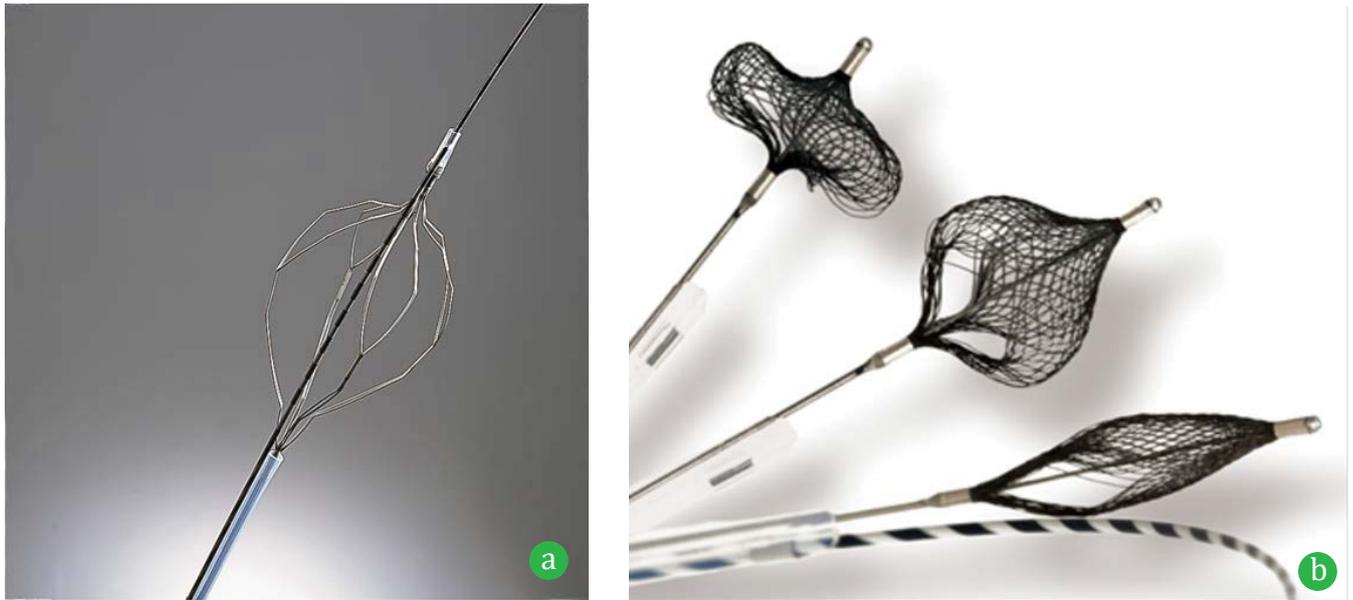


Figure 1. (a). Flower basket (FG-V435P: 0.035-inch wire, guided by a guidewire, maximum outer diameter 2.9 mm at the insertion site, basket size 20 mm, 8-wire basket), Olympus Devise. **(b).** the novel nitinol basket catheter (Reforma®; Piolax Medical Devices Inc, Japan: sheath outer diameter 7.4Fr, tapered end 5.7Fr, effective length 1900 mm, basket size 5 mm, fitted guidewire 0.025-inch, 72-wire basket), Piolax Medical Devices Inc B

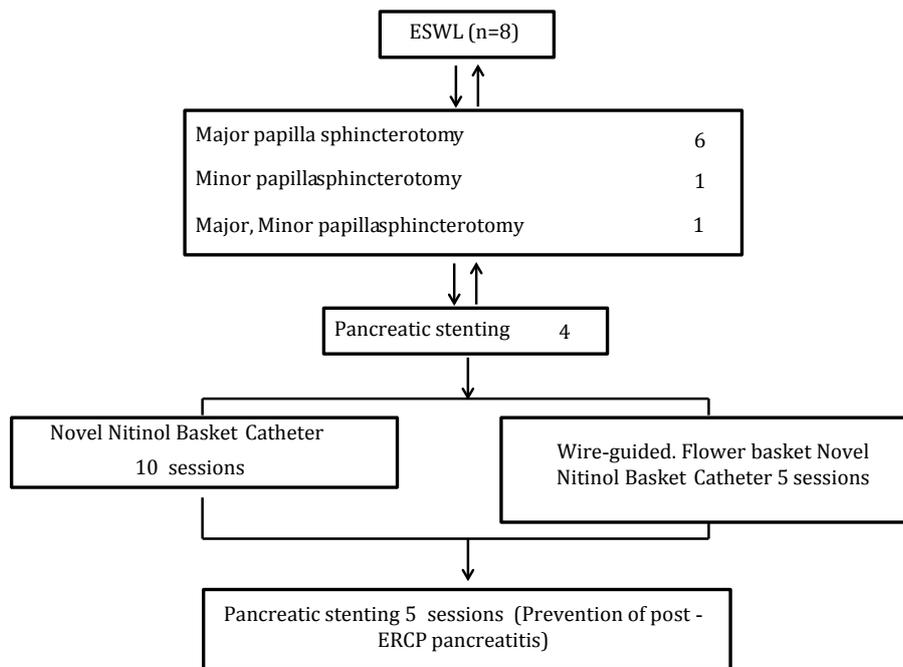


Figure 2. Clinical courses after treatment by novel nitinol basket catheter.

(12.5%), and of the protein plugs alone in 1 session (6.7%), 1 patient (12.5%). Therefore, endoscopic removal of pancreatic stones and protein plugs with the NBC was successful in 11(73%) of 15 sessions, 7 (87.5%) of the 8 patients (**Figure 5**). In the 1 case where removal was unsuccessful, the free stones moved from the pancreatic head to the tail, making them difficult to capture. Eventually, spontaneous elimination of the stones occurred in this case.

Adverse events associated with the removal of pancreatic stones using the NBC were found in 3 (20%) of the 15 sessions, 3 (37.5%) of the 8 patients, including mild pancreatitis following ERCP in 1 session and transient abdominal pain in 2 session; both of these adverse events resolved with conservative treatment (**Table 2**). Although

basket incarceration occurred in 1 session while removing pancreatic stones with a flower basket, implementation of ESWL after withdrawal of the endoscope resolved the incarceration, resulting in successful removal of the stones.

Recurrence of pancreatolithiasis occurred in 1 (12.5%) of the 8 patients during the follow-up period, about 8 months after the endoscopic treatment; this patient had stenosis of the main pancreatic duct in the pancreatic head.

DISCUSSION

Pancreatolithiasis is reported to recur at a frequency of 20-30% after these treatments [1, 6]. Continued drinking habit and stenosis of the main pancreatic duct have been cited as causative factors for the recurrence of pancreatolithiasis [8].



Figure 3. (a). The catheter was difficult to insert because of stenosis of the main pancreatic duct in the pancreatic head and body in 1 patient, even though the attempt was made after placement of a 5Fr pancreatic stent. **(b).** In another patient, catheter insertion was difficult because of kinking of the main pancreatic duct in the pancreatic head and body.

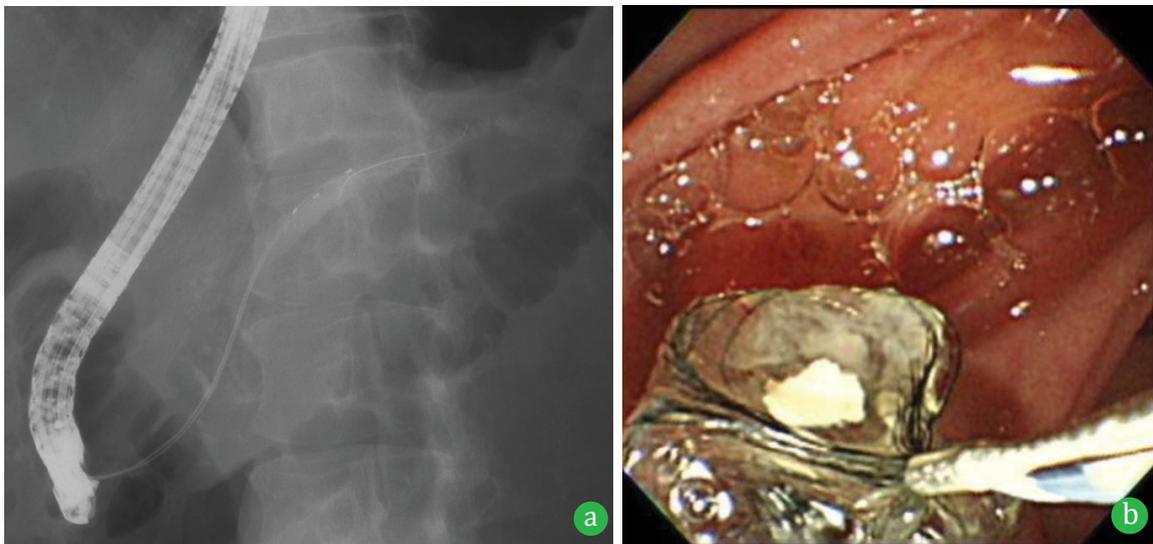


Figure 4. (a). The novel nitinol basket catheter was inserted into the main pancreatic duct in the pancreatic tail. **(b).** Using this new catheter, pancreatic stones and soft whitish protein plugs could be removed together.

On the other hand, early recurrence of pancreatolithiasis after endoscopic treatment can be attributed to the presence of residual stones, just like in the case of bile duct stones. Conventional basket catheters have a 4-wire or 8-wire basket with large gaps in the mesh. Therefore, there is the risk of small pancreatic stones passing through the mesh of the basket and remaining behind unremoved and causing recurrence of pancreatolithiasis. In addition, protein plugs are soft and difficult to hold and remove with a basket catheter. From this point of view, use of the NBC allows removal of small stone fragments and protein

plugs, and holds promise for preventing recurrence of pancreatolithiasis due to the presence of residual stones.

Adaptation of endoscopic techniques for the removal of pancreatic stones, the size of pancreatic stone has been reported to be limited to less than 5 mm [9]. The NBC has a fine, 72-wire mesh basket which is useful for capturing small stones measuring less than 5 mm in diameter. The gaps in the mesh are far smaller than those in an 8-wire basket. Therefore, soft protein plugs could also be removed in 75% (6/8) of the patients in this series. However, holding the basket in close contact with the duct could

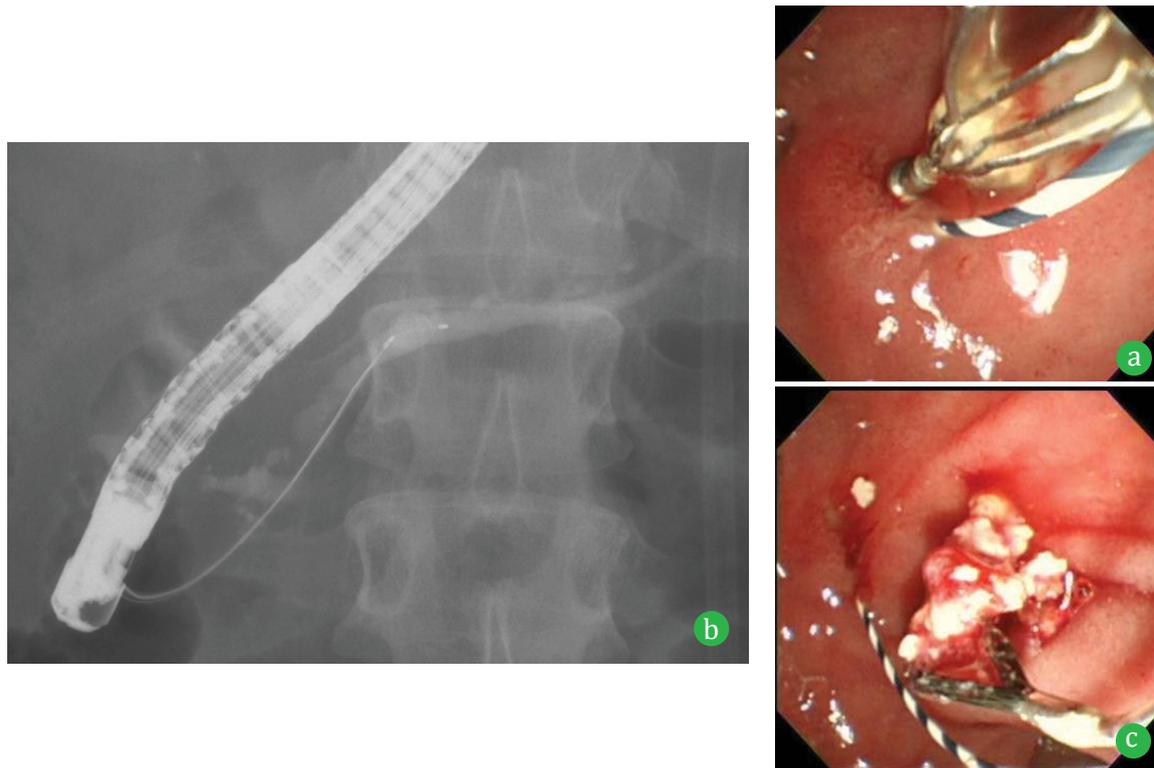


Figure 5. (a). Stones were removed with a flower basket. **(b).** Subsequently, Reforma was inserted into the main pancreatic duct on the caudal side, and then withdrawn. **(c).** Many small stones were removed with the novel nitinol basket catheter.

Table 2. Results of endoscopic treatment for pancreatolithiasis with a novel nitinol basket catheter (n=15 sessions).

Insertability	
successfull	12 (80%)
failure	3 (20%)
Effectiveness	
Removal rate	11 (73%)
pancreatic stone and protein plug	9
pancreatic stone alone	1
protein plug alone	1
Adverse events	
procedure-related adverse events	3 (20%)
transient abdominal pain	2
mild pancreatitis	1

be difficult in patients with 5 mm dilatation of the main pancreatic duct.

Therefore, a more efficient method seems to be to use the NBC to remove the small stones and protein plugs, followed by the use of the 8-wire mesh basket catheter to remove bigger stones.

As for the insertability, it was difficult to insert the NBC because of stenosis of the main pancreatic duct in 1 patient and kinking of the main pancreatic duct in another. In cases of stenosis of the main pancreatic duct, insertion and expansion of a pancreatic stent seems to enable insertion of the NBC and an 8-wire basket catheter. In our patient with kinking of the main pancreatic duct, an 8-wire basket could be inserted after stent placement, but insertion of the NBC was still difficult. This was probably because the NBC has a double-lumen structure. Therefore, it is necessary to use basket catheters properly, after taking into account the advantages and disadvantages of different types of catheters.

During endoscopic removal of pancreatic stones, it is most important to avoid basket incarceration, a complication that can occur from careless holding of a pancreatic stone. It is difficult to hold large pancreatic stones measuring 5 mm or more in diameter with the NBC because of its structure. The NBC is also designed to allow release of the stone that is held, and therefore is less likely to cause basket incarceration. Lack of any other serious complications in this patient series indicates the safety of this technique. Sasahira *et al.* [7] reported the same NBC to facilitate endoscopic removal of pancreatic stones. This study involved 10 patients with main pancreatic duct stones of 5 mm or less in the shorter diameter of the largest stone. In the first 5 cases, The NBC was used as salvage after stone extraction with a conventional basket catheter and retrieval balloon (salvage group). The NBC was easily introduced to the target stone in all patients. In the salvage group, additional stones were retrieved with the NBC in 3 of 5 patients. In the initial group, stone extraction by The NBC was successful, and no residual stones were extracted by additional balloon cleaning in any patients. Basket impaction or after-ERCP pancreatitis was not observed. They concluded that this new NBC helps the extraction of the small pancreatic stone.

Compared with their series, insertability and the removal rate of our study was the low rate than their results. We have observed a few patients of complication. We reported that recurrence rate was low. We considered that using a NBC might reduce the recurrence. However, this study is a small sample size without a control group, it is required a prospective study in large sample size.

CONCLUSIONS

The novel nitinol basket catheter is superior for removing small pancreatic stones and protein plugs which are difficult to visualize by pancreatography, and may be useful for preventing recurrence of pancreatolithiasis after endoscopic treatment.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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