





GASTROENTEROLOGY

Long-term outcome of endotherapy for pancreatic stones by using a dedicated pancreatic basket catheter

Tomotaka Saito,*  Yousuke Nakai,*[†]  Suguru Mizuno,* Hiroyuki Isayama,*[†]  Naoki Sasahira,*[‡]
Sachiko Kanai,* Kensaku Noguchi,* Tatsuya Sato,* Kazunaga Ishigaki,*  Ryunosuke Hakuta,*[†] Kei Saito,*
Tsuyoshi Hamada,* Naminatsu Takahara,* Hirofumi Kogure* and Kazuhiko Koike*

*Department of Gastroenterology, Graduate School of Medicine, The University of Tokyo, [†]Department of Endoscopy and Endoscopic Surgery, The University of Tokyo Hospital, [‡]Department of Gastroenterology, Graduate School of Medicine, Juntendo University, and [§]Department of Gastroenterology, Cancer Institute Hospital of Japanese Foundation of Cancer Research, Tokyo, Japan

Key words

calculi, chronic pancreatitis, endoscopic retrograde cholangiopancreatography, endoscopy, lithotripsy.

Accepted for publication 4 March 2021.

Correspondence

Dr Yousuke Nakai, Department of Endoscopy and Endoscopic Surgery, The University of Tokyo Hospital, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-8655, Japan.
Email: ynakai-ky@umin.ac.jp

Declaration of conflict of interest: The University of Tokyo and Piolax Medical Devices Inc conducted collaborate research between December 2007 and November 2009 to develop a dedicated pancreatic basket catheter. Y. N. received research grant from Piolax Medical Devices Inc.

Author contribution: T. Sai., Y. N., S. M., H. I., and N. S.: conception and design of the study, and analysis and interpretation of the data. T. Sai., Y. N., and S. M.: drafting of the article. S. K., K. N., T. Sa., K. I., R. H., K. S., T. H., N. T., H. K., and K. K.: critical revision of the article for important intellectual content. K. K.: study supervision. All authors: final approval of the article.

Introduction

Pancreatic stones in patients with chronic pancreatitis block the outflow of pancreatic juice and increase the ductal pressure, then lead to abdominal pain and acute exacerbation.^{1–6} Although endoscopic removal of pancreatic stones is less invasive treatment compared with surgical interventions,^{7,8} it is still technically challenging^{9–13} and the recurrence rate after endoscopic removal is reportedly as high as 20.9–45.0%.^{9,14,15} Introducing the therapeutic devices into the pancreatic duct (PD) is difficult due to the tortuous anatomy and the tight strictures,^{16,17} and the fragmented stones after extracorporeal shock wave lithotripsy (ESWL) are easily migrated into the dilated branch ducts. Small residual stones

that cannot be visualized on endoscopic retrograde pancreatography are considered to be one of the reasons for the high recurrence rate after endotherapy.¹⁸

To overcome the aforementioned difficulties in endotherapy for pancreatic stones, we previously reported usefulness of a novel basket catheter for pancreatic stones compared with conventional basket catheters in a pilot study.¹⁸ However, it is not elucidated whether reduction of residual stones by the use of this dedicated basket catheter would decrease the long-term recurrence of clinical symptoms due to pancreatic stones or not. In this study, we retrospectively compared the long-term outcomes of endotherapy for pancreatic stones with and without the use of this dedicated basket catheter.

Abstract

Background and Aim: Although endotherapy for pancreatic stones is less invasive compared with surgical interventions, its recurrence rate is high and residual pancreatic stones can be a cause of recurrence. We previously reported usefulness of a novel basket catheter with nitinol fine reticular structure for pancreatic stone retraction. In this retrospective study, we aimed to evaluate the long-term outcomes of endotherapy for pancreatic stones with and without the use of this dedicated basket catheter.

Methods: We retrospectively compared patients with symptomatic pancreatic stones who underwent the initial endotherapy between 2008 and 2019. The primary outcome was the symptomatic recurrence after complete stone clearance. Secondary outcomes were the rate of complete stone clearance, complications, risk factors for recurrences, and the treatment cost.

Results: A total of 101 patients who underwent endotherapy for pancreatic stones were analyzed: 41 patients by using the dedicated basket catheter and 60 patients by only the conventional devices. The complete stone clearance was achieved in 87.8% in the dedicated basket group and 88.3% in the conventional device group. Symptomatic recurrence was observed in 16.7% of the dedicated basket group and 47.2% of the conventional device group ($P < 0.01$). In the multivariate analysis, the use of the dedicated basket catheter was significantly associated with the reduced risk of symptomatic recurrence (hazard ratio, 0.40; 95% confidence interval, 0.15–0.92, $P = 0.031$). The complication rate and the cost were comparable between the two groups.

Conclusion: The use of this dedicated pancreatic basket catheter significantly reduced symptomatic recurrence after complete pancreatic stone removal.

Materials and methods

Study design and patients. This is a retrospective study comparing the dedicated basket catheter and the conventional devices for endotherapy of symptomatic pancreatic stones. Data on consecutive patients who underwent endotherapy for symptomatic pancreatic stones between 2008 and 2019 were extracted from our prospectively collected database at the University of Tokyo Hospital.

Patients with previous endoscopic or surgical pancreatic interventions, surgically altered anatomy, and those who underwent long-term stent placement for the treatment of the severe PD stricture were excluded from the analysis. The study was approved by the local ethical committee of the University of Tokyo (approval number: 2058).

A dedicated basket catheter. This dedicated basket catheter for pancreatic stones has fine reticular structures in the distal end to catch small fragmented stones, and the nitinol wires with adjustable basket length allow this basket to “reform” into an ideal shape by pulling the knob on the handle (Reforma; Piolax Medical Devices Inc, Kanagawa, Japan; Fig. 1). The outer sheath is 7.4 Fr at the maximum but is tapered to 5.7 Fr on the tip, and also, this basket has double lumens—one for the basket and the other for a 0.025-inch guidewire. Both characteristics help this basket introducing into the PD with the tortuous anatomy and the tight strictures.

Endotherapy for pancreatic stones. During endoscopic retrograde cholangiopancreatography (ERCP), pancreatic stones were extracted by using a retrieval balloon catheter (Extractor Pro; Boston Scientific Japan, Tokyo, Japan), a conventional basket catheter (Flower Basket V or Tetra Catch V; Olympus, Tokyo, Japan), and/or the dedicated basket catheter for pancreatic stones. The choice of the devices was at the discretion of attending physicians, but the dedicated basket catheter was mainly used as the first choice since its introduction in December 2010. In those cases with stones of 5 mm or less in the shorter diameter of the largest stone or fragmented stones, the dedicated basket or a balloon catheter was used. When the stones were relatively large (> 5 mm) and multiple, the dedicated basket was not used as a first device due to the risk of basket impaction.

Extracorporeal shock wave lithotripsy was combined with endotherapy in cases with stones larger than 8 mm or those impacted to the PD. ESWL was repeated until the stones were fragmented < 5 mm on X-ray. Electrohydraulic lithotripsy under peroral pancreatoscopy was considered when ESWL was ineffective.

For ampullary intervention before stone removal, pancreatic sphincterotomy or balloon dilation of the pancreatic orifice was performed at the discretion of the attending physician. In cases with PD stricture downstream the stone, the stricture was dilated with a 4- or 6-mm balloon dilation catheter. After endotherapy for pancreatic stones, a prophylactic pancreatic stent or a nasal pancreatic drainage tube was placed temporally for the prevention of post-ERCP pancreatitis (PEP). Cases with persistent PD stricture after balloon dilation underwent multiple plastic stents or covered metal stent placement¹⁹ and were excluded from the analysis as described earlier.

Outcomes. The primary outcome of this study was the symptomatic recurrence after complete stone clearance. Symptomatic recurrence included intolerable pain relapse, acute exacerbation, and de novo pseudocyst all due to the recurrent pancreatic stones. Acute exacerbation is defined as acute pancreatitis during the follow-up of chronic pancreatitis. The diagnosis of acute pancreatitis is based on “Japanese Guidelines for the Management of Acute Pancreatitis: Japanese Guidelines 2015.”²⁰ Complete stone removal was defined as no filling defects in the main PD on pancreatography with or without intraductal ultrasonography according to the previous reports.^{9,15,21–32} Complete stone removal of pancreatic stones was additionally confirmed by computed tomography (CT) scan within 3 months after ERCP. The secondary outcomes were the rate of complete stone clearance, treatment-related complications, risk factors for symptomatic recurrences, and the total cost of pancreatic stone treatment throughout the follow-up period.

Cost analysis. Cost analysis was conducted by calculating the procedure reimbursement and the cost of disposable accessories used for pancreatic stone treatment. Cost analysis included the cost for the initial pancreatic stone treatment and that for the recurrence treatment throughout the follow-up period. Reimbursement for procedures included the following: ERCP (\$2610) and ESWL (\$1780). Disposable accessories included the following: a dedicated basket catheter (\$540), a conventional basket catheter (\$370), a balloon catheter (\$350), a balloon dilation catheter (\$600), a sphincterotome (\$200), a pancreatic stent (\$250), a nasopancreatic catheter (\$67), a digital pancreatoscope (\$2780), and an electrohydraulic lithotripsy probe (\$460). The costs of other disposable accessories, such as guidewires and snares, were included in the reimbursement for procedures.

Statistical analysis. Categorical variables were described as numbers (%) and compared using the χ^2 test or Fisher’s exact test.

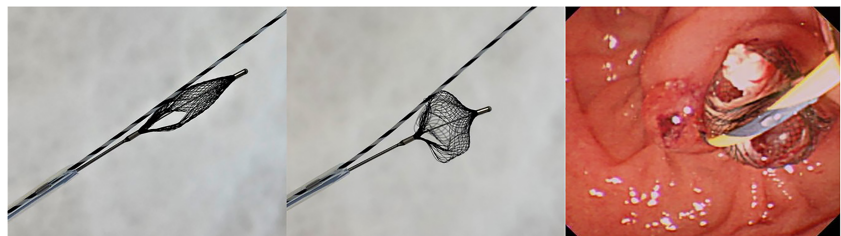


Figure 1 A dedicated basket catheter for pancreatic stones (Reforma; Piolax Medical Devices Inc).

Continuous variables were described as medians (ranges) or mean \pm standard deviation and compared using the Wilcoxon rank-sum test or Student's *t*-test. The cumulative incidence of symptomatic recurrence was calculated by the Kaplan–Meier method and compared by the log–rank test. The Cox proportional hazards regression model was used to estimate hazard ratios (HRs) and corresponding 95% confidence interval (CI) for symptomatic recurrence after complete stone clearance. Potential risk factors with $P < 0.2$ in univariable analyses were further analyzed in a multivariable model. A P value of < 0.05 was considered statistically significant in all analyses. JMP software (version 15.0; SAS International Inc., Cary, NC) was used for all statistical analyses. All P values were two-sided.

Results

During the study period of 11 years, 135 patients underwent the initial pancreatic stone treatment at our institute, and 34 patients were excluded from this analysis (Fig. 2). Forty-one patients underwent endotherapy by using the dedicated basket catheter (the dedicated basket group) and 60 patients by using only the conventional devices (the conventional device group). Complete stone clearance was achieved in 87.8% (36/41) in the dedicated basket group and 88.3% (53/60) in the conventional device group, respectively ($P = 0.936$). Complete stone clearance was also confirmed by CT scan in 62 cases within 3 months of stone clearance. Complete stone clearance was impossible due to the difficulty in the device insertion through torturous PD ($n = 8$) and the presence of pancreatic stones diffusely in the pancreas ($n = 4$).

Table 1 summarizes patients' characteristics and procedure details of the initial pancreatic stone treatment. There were no significant differences in the baseline characteristics between the two groups. The stones were located in the head of pancreas in more than 80% of both groups. Ten patients (24.4%) in the dedicated basket group used both the dedicated and conventional basket catheters. The mean numbers of sessions of ESWL (3.5 *vs* 4.1, $P = 0.307$), ERCP (1.1 *vs* 1.2, $P = 0.113$), and the mean ERCP

procedure time (78.5 min *vs* 84.1 min, $P = 0.688$) all for the initial pancreatic stone treatment were all comparable between the groups.

Treatment-related complications. Endoscopic retrograde cholangiopancreatography-related complications, ESWL-related complications, and all treatment-related complications during the initial pancreatic stone treatment were comparable between the two groups (Table 2). The rates of ERCP-related complications were 4.9% in the dedicated basket group and 11.7% in the conventional device group ($P = 0.589$). Mild PEP occurred in two of the dedicated basket group and five of the conventional device group. No moderate or severe PEP occurred in both groups. There was one basket impaction in one of the conventional device group. Pancreatitis was also the major complication after ESWL: 22.0% in the dedicated basket group and 16.7% in the conventional device group.

Symptomatic recurrence. The follow-up period was comparable between the groups (Table 2). Symptomatic recurrence after complete stone clearance was observed in 16.7% of the dedicated basket group and 47.2% of the conventional device group. Meanwhile, symptomatic recurrence rate was as high as 62.5% (60.0% in the dedicated basket group and 66.7% in the conventional device group) after incomplete stone clearance. The details of symptomatic recurrence after complete stone removal are described in Table 2. The cumulative incidences of symptomatic recurrence after complete stone clearance and incomplete stone clearance are shown in Figure 3. The cumulative symptomatic recurrence rate was 11.1%, 26.4%, and 33.3% at 2 years and 16.7%, 41.5%, and 41.7% at 5 years after complete stone removal by the dedicated basket catheter, complete stone removal by the conventional devices, and incomplete stone clearance, respectively.

In the multivariate analysis, the use of the dedicated basket catheter was significantly associated with the reduced risk of symptomatic recurrence after complete stone clearance (HR,

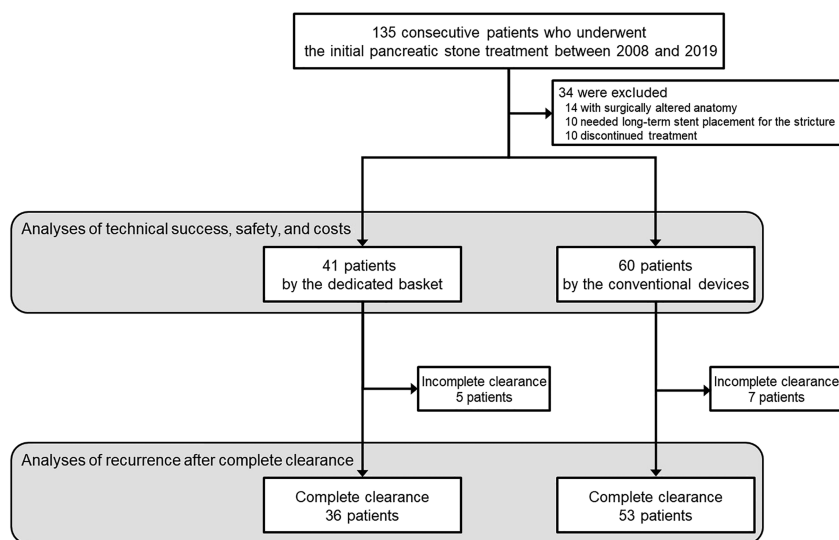


Figure 2 Flowchart of patients.

Table 1 Patients' characteristics and procedure details of the initial treatment

	The dedicated basket group (n = 41)	The conventional device group (n = 60)	P
Age, median (ranges), years	60 (28–84)	58 (27–90)	0.980
Sex			0.425
Male	31 (75.6%)	41 (68.3%)	
Female	10 (24.4%)	19 (31.7%)	
Etiology of chronic pancreatitis			0.921
Alcohol abuse	28 (68.3%)	41 (68.3%)	
Idiopathic	11 (26.8%)	17 (28.3%)	
Autoimmune pancreatitis	2 (4.9%)	2 (3.3%)	
Location of the stones			0.986
Head	34 (83.0%)	49 (81.7%)	
Body	5 (12.2%)	7 (11.7%)	
Tail	1 (2.4%)	2 (3.3%)	
Diffuse	1 (2.4%)	2 (3.3%)	
Number of the stones			0.147
Single	21 (52.8%)	22 (36.7%)	
Multiple	20 (47.2%)	38 (63.3%)	
The stone size at diagnosis, median (ranges), mm	10 (4–26)	10 (3–30)	0.616
The stone size at stone extraction, median (ranges), mm	3.8 (1–7)	4 (1–8)	0.927
Complete stone clearance	36 (87.8%)	53 (88.3%)	0.936
Ampullary intervention			0.054
Pancreatic sphincterotomy	15 (36.6%)	13 (21.7%)	
Balloon dilation of the pancreatic orifice	24 (58.5%)	36 (60.0%)	
None	2 (4.9%)	11 (18.3%)	
Balloon dilation for MPD stricture	7 (17.1%)	15 (25.0%)	0.338
Used devices [†]			
The dedicated basket	41 (100.0%)	0 (0.0%)	
The conventional basket	10 (24.4%)	29 (48.3%)	
Retrieval balloon	28 (68.3%)	60 (100.0%)	
Combination with POPS and EHL	1 (2.4%)	2 (3.3%)	0.796
Combination with ESWL	38 (92.7%)	52 (86.7%)	0.330
Number of ESWL sessions, mean ± SD	3.5 ± 2.2	4.1 ± 3.1	0.307
Number of ERCP sessions for extraction, mean ± SD	1.1 ± 0.3	1.2 ± 0.5	0.113
ERCP procedure time, mean ± SD, min	78.5 ± 59.6	84.1 ± 63.4	0.688

[†]Some patients used multiple devices.

Values are expressed as numbers (%) otherwise indicated.

EHL, electronic hydraulic lithotripsy; ERCP, endoscopic retrograde cholangiopancreatography; ESWL, extracorporeal shock wave lithotripsy; MPD, main pancreatic duct; POPS, peroral pancreatoscopy; SD, standard deviation.

0.40; 95% CI, 0.15–0.92, $P = 0.031$; Table 3). Multiple sessions for stone extraction of ERCP were also significantly associated with the reduced recurrence (HR, 0.26; 95% CI, 0.04–0.87, $P = 0.027$).

Cost analysis. The total cost of pancreatic stone treatment, which included the procedure reimbursement and the cost for the disposable accessories, was \$16 540 in the dedicated basket group and \$20 643 in the conventional device group ($P = 0.078$; Table 4). The procedure reimbursement was significantly lower in the dedicated basket group (\$14 152 vs \$17 899, $P = 0.046$), but the cost for disposable accessories was comparable (\$2388 vs \$2743, $P = 0.681$). The procedure reimbursement included the cost of all ERCPs (\$5729 vs \$8352, $P = 0.019$) and the cost of all ESWL (\$8422 vs \$9547, $P = 0.415$); both reflected total ERCP sessions (2.2 sessions vs 3.2 sessions) and ESWL sessions (4.7 sessions vs 5.4 sessions) throughout the follow-up period.

Discussion

In this retrospective study of endotherapy for symptomatic pancreatic stones, we demonstrated that this dedicated basket catheter did not increase the rate of complete stone clearance but significantly reduced symptomatic recurrence with an HR of 0.40 once complete stone clearance was obtained. As a result, the total cost tended to be reduced when the dedicated basket was used despite its relatively high cost.

The importance of complete stone clearance has been reported in endotherapy for pancreatic stones as Tadenuma *et al.* reported that incomplete stone removal was the significant risk factor for pain relapse.¹⁴ In our study cohort, the rate of symptomatic recurrence was as high as 62.5% after incomplete stone clearance as compared with 16.7% and 47.2% after complete clearance by the dedicated basket and the conventional devices, respectively. There are several technical difficulties to achieve complete stone removal during endotherapy for pancreatic stones.^{33,34} The PD is often tortuous and accompanied by the stricture in patients with chronic

Table 2 Treatment-related complications of the initial treatment and symptomatic recurrence after complete stone removal

	The dedicated basket group (n = 41)	The conventional device group (n = 60)	P
All complications [†]	11 (26.8%)	16 (26.7%)	0.986
ERCP-related complications	2 (4.9%)	7 (11.7%)	0.589
Pancreatitis (mild)	2	5	
Hemosuccus pancreaticus	0	1	
Basket impaction	0	1	
ESWL-related complications	9 (22.0%)	10 (16.7%)	0.357
Pancreatitis (mild/moderate)	6/2	6/3	
Pancreatic ductitis	1	1	
Complete stone clearance	36 (87.8%)	53 (88.3%)	0.936
Follow-up period, median (ranges), months [‡]	47 (10–111)	64 (1–133)	0.120
Symptomatic recurrence [‡]	6 (16.7%)	25 (47.2%)	0.002
Acute exacerbation	3	10	
Intolerable pain	3	10	
Pseudocyst	0	5	

[†]ERCP-related complication and ESWL-related complication overlapped in one patient in the conventional device group.

[‡]Data after complete stone clearance.

Values are expressed as numbers (%) otherwise indicated.

ERCP, endoscopic retrograde cholangiopancreatography; ESWL, extracorporeal shock wave lithotripsy.

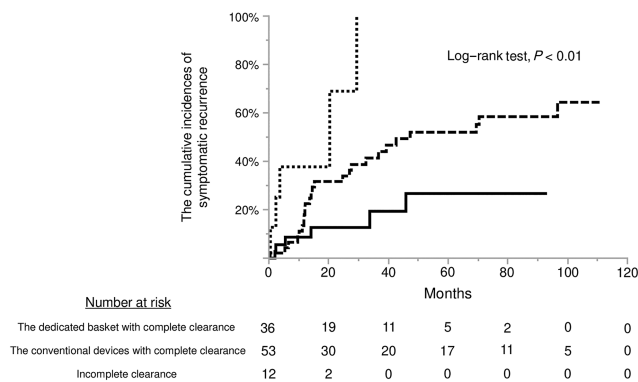


Figure 3 The cumulative incidence of symptomatic recurrence after incomplete stone clearance (.....), complete clearance by the dedicated basket catheter (—), and complete clearance by the conventional devices (---).

pancreatitis,^{16,19,35,36} which sometimes hinders the passage of stone extraction devices. Furthermore, small fragmented stones after ESWL can easily fall off from the basket or balloon catheter due to the tortuous PD with strictures.¹⁸ Moreover, small fractions can be easily escaped into the dilated side branches during balloon sweep. In our study cohort, the rate of complete stone removal was about 88% both in the dedicated basket group and in the conventional device group, and the reasons for incomplete stone removal were considered as anatomy associated rather than the device associated. Thus, there still needs improvement in the treatment strategy for those cases with difficult PD anatomy to further increase the complete stone clearance rate.

Among those with apparently complete stone clearance, however, there was a significant difference in the cumulative incidence of symptomatic recurrence between the dedicated basket group and the conventional device group with an HR of 0.40 in the multivariate analysis. Thus, even in cases with apparently complete

stone clearance on ERCP, there is a chance that residual small fragmented stones exist and can lead to the recurrent symptoms. Our pilot study¹⁸ supported this hypothesis because residual pancreatic stones were additionally extracted using this dedicated basket catheter in three out of five cases after stone clearance by conventional devices. Furthermore, the present long-term follow-up study revealed that the symptomatic recurrence rate was 16.7% in the dedicated basket group, which seemed to be lower than previously reported.^{9,14,15,37,38} However, a previous randomized controlled trial³⁸ did not demonstrate the superiority of endotherapy in addition to ESWL. Thus, it is still unclear whether endotherapy using the dedicated basket can lead to less symptomatic recurrence or not.

The number of ERCP sessions was another significant prognostic factor for symptomatic recurrence with an HR of 0.26 in cases who underwent multiple sessions of ERCP at the initial treatment. When endoscopic stone removal is finished within a single session, we suspect that residual fragmented stones might migrate into the side branch during endotherapy and lead to recurrent pancreatic stones later. Those migrated stones would fall into the main PD between ERCP sessions and can be readily removed in the next ERCP. During ERCP sessions, we inserted pancreatic stent or endoscopic nasopancreatic drainage to prevent pancreatitis or infection. Residual small fragmented stones would flow out to the duodenum through the stents or endoscopic nasopancreatic drainage tube. Thus, to achieve further complete stone clearance, multiple ERCP sessions might be necessary. Or the accurate diagnostic method of complete stone clearance can be an option such as peroral pancreatoscopy.^{39,40}

There is some concern about the cost by the use of the dedicated basket catheter because it is sometimes used in addition to the conventional basket and/or balloon catheters. As a matter of fact, however, the total cost of pancreatic stone treatment throughout the follow-up period was low in the dedicated basket group (\$16 540 vs \$20 643), though not statistically significant ($P = 0.078$). As symptomatic recurrence and subsequent ERCP sessions in the dedicated basket group were decreased, the total cost of procedure

Table 3 Univariable and multivariable analyses of risk factors for symptomatic recurrence after complete stone clearance

Characteristic	Event, <i>n</i> (%)	Hazard ratio			
		Univariable (95% CI)	<i>P</i>	Multivariable (95% CI)	<i>P</i>
Sex					
Male (<i>n</i> = 62)	21 (33.9%)	1 (referent)			
Female (<i>n</i> = 27)	10 (37.0%)	1.09 (0.49–2.26)	0.825		
Age at pancreatic stone treatment					
< 70 years (<i>n</i> = 66)	25 (37.9%)	1 (referent)		1 (referent)	
≥ 70 years (<i>n</i> = 23)	6 (26.1%)	0.54 (0.20–1.25)	0.157	0.70 (0.26–1.62)	0.425
Alcohol abuse					
No (<i>n</i> = 28)	9 (32.1%)	1 (referent)			
Yes (<i>n</i> = 61)	22 (36.1%)	1.14 (0.54–2.60)	0.747		
Stone located in the head					
No (<i>n</i> = 13)	5 (38.5%)	1 (referent)			
Yes (<i>n</i> = 76)	26 (34.2%)	0.83 (0.34–2.45)	0.703		
Diameter of the largest stone					
< 10 mm (<i>n</i> = 41)	11 (26.8%)	1 (referent)			
≥ 10 mm (<i>n</i> = 48)	20 (41.7%)	1.49 (0.73–3.24)	0.280		
Multiple stones					
No (<i>n</i> = 37)	12 (32.4%)	1 (referent)			
Yes (<i>n</i> = 52)	19 (36.5%)	1.18 (0.58–2.50)	0.655		
Combination with ESWL					
No (<i>n</i> = 10)	2 (20.0%)	1 (referent)			
Yes (<i>n</i> = 79)	29 (36.7%)	1.27 (0.38–7.90)	0.732		
Pancreatic sphincterotomy					
No (<i>n</i> = 67)	28 (41.8%)	1 (referent)			
Yes (<i>n</i> = 22)	3 (13.6%)	0.68 (0.16–1.97)	0.515		
Number of ERCP session					
1 (<i>n</i> = 77)	29 (37.7%)	1 (referent)		1 (referent)	
≥ 2 (<i>n</i> = 12)	2 (16.7%)	0.27 (0.04–0.89)	0.030	0.26 (0.04–0.87)	0.027
Use of the dedicated basket					
No (<i>n</i> = 53)	25 (47.2%)	1 (referent)		1 (referent)	
Yes (<i>n</i> = 36)	6 (16.7%)	0.42 (0.15–0.96)	0.040	0.40 (0.15–0.92)	0.031
Balloon dilation for MPD stricture					
No (<i>n</i> = 69)	22 (31.9%)	1 (referent)			
Yes (<i>n</i> = 20)	9 (45%)	1.22 (0.53–2.60)	0.619		

CI, confidence interval; ERCP, endoscopic retrograde cholangiopancreatography; ESWL, extracorporeal shock wave lithotripsy; MPD, main pancreatic duct.

Table 4 Cost analysis in US\$ for pancreatic stone treatment throughout the follow-up period

	The dedicated basket group (<i>n</i> =41)	The conventional device group (<i>n</i> =60)	<i>P</i>
Procedure reimbursement			
Total ERCP sessions, mean ± SD (ranges)	2.2 ± 1.6 (1–9)	3.2 ± 2.5 (1–13)	
Cost of total ERCP, mean ± SD (ranges), \$ [†]	5729 ± 4316 (2610–23490)	8352 ± 6557 (2610–33930)	0.019
Total ESWL sessions, mean ± SD (ranges)	4.7 ± 3.5 (0–19)	5.4 ± 3.9 (0–17)	
Cost of total ESWL, mean ± SD (ranges), \$ [†]	8422 ± 6319 (0–33820)	9547 ± 6871 (0–30260)	0.415
Total cost of procedure reimbursement, mean ± SD (ranges), \$	14152 ± 9012 (2610–44260)	17899 ± 10602 (2610–46390)	0.046
Device cost			
The total cost of disposable accessories, mean ± SD (ranges), \$	2388 ± 1578 (740–8462)	2743 ± 2454 (417–11282)	0.681
The total cost , mean ± SD (ranges), \$	16540 ± 9984 (4367–51532)	20643 ± 12347 (3210–54645)	0.078

[†]Cost for the initial pancreatic stone treatment and that for the recurrence treatment throughout the follow-up period.

ERCP, endoscopic retrograde cholangiopancreatography; ESWL, extracorporeal shock wave lithotripsy; SD, standard deviation.

reimbursement was significantly lower in the dedicated basket group compared with the conventional device group (\$14 152 vs \$17 899, *P* = 0.046). Thus, the dedicated basket catheter is cost-effective, too, when long-term outcomes are considered.

The retrospective nature and the limited sample size and events of this study are our study limitations. There were also non-significant differences in the follow-up period (47 and 64 months in the dedicated and conventional basket groups,

respectively) due to the timing of the introduction of the dedicated basket in our clinical practice. Patient allocation was not randomized, and the device selection was at the discretion of the physicians and affected by the chronological trend. We excluded patients who needed long-term stent placement for PD strictures because our study aim is to evaluate the effects of the dedicated basket on the symptomatic recurrence. However, concomitant PD strictures and pancreatic stones are common, and the role of the dedicated basket in this condition with pancreatic stents is mandatory. Furthermore, the conventional basket was used in 24.4% of the dedicated basket group because there is a risk of basket impaction if large and multiple pancreatic stones are grasped by the dedicated basket. Confirmation of complete stone removal is difficult in clinical practice. We hypothesized that small residual stone fragments, which cannot be detected by pancreatography or CT as defined in our study, might lead to symptomatic recurrence, but the more accurate diagnostic method for complete stone removal such as pancreatoscopy may be needed to confirm our hypothesis. Thus, the study results might be biased, and a further prospective study is warranted.

In conclusion, the dedicated pancreatic basket catheter significantly reduced symptomatic recurrence after complete pancreatic stone removal, and the reduced recurrence might result in the reduced cost of treatment.

References

- Hart PA, Conwell DL. Chronic pancreatitis: managing a difficult disease. *Am. J. Gastroenterol.* 2020; **115**: 49–55.
- Mullady DK, Yadav D, Amann ST *et al.* Type of pain, pain-associated complications, quality of life, disability and resource utilisation in chronic pancreatitis: a prospective cohort study. *Gut* 2011; **60**: 77–84.
- Kozarek RA, Brandabur JJ, Ball TJ *et al.* Clinical outcomes in patients who undergo extracorporeal shock wave lithotripsy for chronic calcific pancreatitis. *Gastrointest. Endosc.* 2002; **56**: 496–500.
- Brand B, Kahl M, Sidhu S *et al.* Prospective evaluation of morphology, function, and quality of life after extracorporeal shockwave lithotripsy and endoscopic treatment of chronic calcific pancreatitis. *Am. J. Gastroenterol.* 2000; **95**: 3428–38.
- Ohara H, Hoshino M, Hayakawa T *et al.* Single application extracorporeal shock wave lithotripsy is the first choice for patients with pancreatic duct stones. *Am. J. Gastroenterol.* 1996; **91**: 1388–94.
- Ito T, Ishiguro H, Ohara H *et al.* Evidence-based clinical practice guidelines for chronic pancreatitis 2015. *J. Gastroenterol.* 2016; **51**: 85–92.
- Inui K, Masamune A, Igarashi Y *et al.* Management of pancreatolithiasis: a nationwide survey in Japan. *Pancreas* 2018; **47**: 708–14.
- Dumoncau JM, Delhaye M, Tringali A *et al.* Endoscopic treatment of chronic pancreatitis: European Society of Gastrointestinal Endoscopy (ESGE) Guideline—updated August 2018. *Endoscopy* 2019; **51**: 179–93.
- Tandan M, Reddy DN, Talukdar R *et al.* Long-term clinical outcomes of extracorporeal shockwave lithotripsy in painful chronic calcific pancreatitis. *Gastrointest. Endosc.* 2013; **78**: 726–33.
- Inui K, Tazuma S, Yamaguchi T *et al.* Treatment of pancreatic stones with extracorporeal shock wave lithotripsy: results of a multicenter survey. *Pancreas* 2005; **30**: 26–30.
- Kwon CI, Gromski MA, Sherman S *et al.* Clinical response to dorsal duct drainage via the minor papilla in refractory obstructing chronic calcific pancreatitis. *Endoscopy* 2017; **49**: 371–7.
- Dite P, Ruzicka M, Zboril V, Novotny I. A prospective, randomized trial comparing endoscopic and surgical therapy for chronic pancreatitis. *Endoscopy* 2003; **35**: 553–8.
- Suzuki Y, Sugiyama M, Inui K *et al.* Management for pancreatolithiasis: a Japanese multicenter study. *Pancreas* 2013; **42**: 584–8.
- Tadenuma H, Ishihara T, Yamaguchi T *et al.* Long-term results of extracorporeal shockwave lithotripsy and endoscopic therapy for pancreatic stones. *Clin. Gastroenterol. Hepatol.* 2005; **3**: 1128–35.
- Adamek HE, Jakobs R, Buttman A, Adamek MU, Schneider AR, Riemann JF. Long term follow up of patients with chronic pancreatitis and pancreatic stones treated with extracorporeal shock wave lithotripsy. *Gut* 1999; **45**: 402–5.
- Costamagna G, Bulajic M, Tringali A *et al.* Multiple stenting of refractory pancreatic duct strictures in severe chronic pancreatitis: long-term results. *Endoscopy* 2006; **38**: 254–9.
- Oh D, Lee JH, Song TJ *et al.* Long-term outcomes of 6-mm diameter fully covered self-expandable metal stents in benign refractory pancreatic ductal stricture. *Dig. Endosc.* 2018; **30**: 508–15.
- Sasahira N, Isayama H, Tokyokawa Y *et al.* A novel basket catheter to facilitate endoscopic removal of pancreatic stones (with video). *Gastrointest. Endosc.* 2013; **78**: 925–9.
- Matsubara S, Sasahira N, Isayama H *et al.* Prospective pilot study of fully covered self-expandable metal stents for refractory benign pancreatic duct strictures: long-term outcomes. *Endosc. Int. Open* 2016; **4**: E1215–e22.
- Yokoe M, Takada T, Mayumi T *et al.* Japanese guidelines for the management of acute pancreatitis: Japanese Guidelines 2015. *J. Hepatobiliary Pancreat. Sci.* 2015; **22**: 405–32.
- Cahen DL, Gouma DJ, Nio Y *et al.* Endoscopic versus surgical drainage of the pancreatic duct in chronic pancreatitis. *N. Engl. J. Med.* 2007; **356**: 676–84.
- Saito T, Nakai Y, Mizuno S *et al.* A randomized-controlled trial of early endotherapy versus wait-and-see policy for mild symptomatic pancreatic stones in chronic pancreatitis. *Eur. J. Gastroenterol. Hepatol.* 2019; **31**: 979–84.
- Costamagna G, Gabbrielli A, Mutignani M *et al.* Extracorporeal shock wave lithotripsy of pancreatic stones in chronic pancreatitis: immediate and medium-term results. *Gastrointest. Endosc.* 1997; **46**: 231–6.
- Sauerbruch T, Holl J, Sackmann M, Paumgartner G. Extracorporeal lithotripsy of pancreatic stones in patients with chronic pancreatitis and pain: a prospective follow up study. *Gut* 1992; **33**: 969–72.
- Parsi MA, Stevens T, Lopez R, Vargo JJ. Extracorporeal shock wave lithotripsy for prevention of recurrent pancreatitis caused by obstructive pancreatic stones. *Pancreas* 2010; **39**: 153–5.
- Farnbacher MJ, Schoen C, Rabenstein T, Benninger J, Hahn EG, Schneider HT. Pancreatic duct stones in chronic pancreatitis: criteria for treatment intensity and success. *Gastrointest. Endosc.* 2002; **56**: 501–6.
- Maruyama M, Watanabe T, Kanai K *et al.* Extracorporeal shock wave lithotripsy treatment of pancreatic stones complicated with advanced stage autoimmune pancreatitis. *BMC Gastroenterol.* 2015; **15**: 28.
- van Huijgevoort NCM, Veld JV, Fockens P *et al.* Success of extracorporeal shock wave lithotripsy and ERCP in symptomatic pancreatic duct stones: a systematic review and meta-analysis. *Endosc. Int. Open* 2020; **8**: E1070–e85.
- Hu LH, Ye B, Yang YG *et al.* Extracorporeal shock wave lithotripsy for Chinese patients with pancreatic stones: a prospective study of 214 cases. *Pancreas* 2016; **45**: 298–305.
- Korpela T, Udd M, Tenca A *et al.* Long-term results of combined ESWL and ERCP treatment of chronic calcific pancreatitis. *Scand. J. Gastroenterol.* 2016; **51**: 866–71.
- Lapp RT, Wolf JS Jr, Faerber GJ *et al.* Duct diameter and size of stones predict successful extracorporeal shock wave lithotripsy and

- endoscopic clearance in patients with chronic pancreatitis and pancreaticolithiasis. *Pancreas* 2016; **45**: 1208–11.
- 32 Merrill JT, Mullady DK, Early DS, Azar RR, Edmundowicz SA, Jonnalagadda SS. Timing of endoscopy after extracorporeal shock wave lithotripsy for chronic pancreatitis. *Pancreas* 2011; **40**: 1087–90.
- 33 Delhaye M, Arvanitakis M, Verset G, Cremer M, Deviere J. Long-term clinical outcome after endoscopic pancreatic ductal drainage for patients with painful chronic pancreatitis. *Clin. Gastroenterol. Hepatol.* 2004; **2**: 1096–106.
- 34 Issa Y, Kempeneers MA, Bruno MJ *et al.* Effect of early surgery vs endoscopy-first approach on pain in patients with chronic pancreatitis: the ESCAPE randomized clinical trial. *JAMA* 2020; **323**: 237–47.
- 35 Sasahira N, Tada M, Isayama H *et al.* Outcomes after clearance of pancreatic stones with or without pancreatic stenting. *J. Gastroenterol.* 2007; **42**: 63–9.
- 36 Tringali A, Vadalà di Prampero SF, Landi R *et al.* Fully covered self-expandable metal stents to dilate persistent pancreatic strictures in chronic pancreatitis: long-term follow-up from a prospective study. *Gastrointest. Endosc.* 2018; **88**: 939–46.
- 37 Seven G, Schreiner MA, Ross AS *et al.* Long-term outcomes associated with pancreatic extracorporeal shock wave lithotripsy for chronic calcific pancreatitis. *Gastrointest. Endosc.* 2012; **75**: 997–1004 e1.
- 38 Dumonceau JM, Costamagna G, Tringali A *et al.* Treatment for painful calcified chronic pancreatitis: extracorporeal shock wave lithotripsy versus endoscopic treatment: a randomised controlled trial. *Gut* 2007; **56**: 545–52.
- 39 Attwell AR, Patel S, Kahaleh M, Raijman IL, Yen R, Shah RJ. ERCP with per-oral pancreatoscopy-guided laser lithotripsy for calcific chronic pancreatitis: a multicenter U.S. experience. *Gastrointest. Endosc.* 2015; **82**: 311–8.
- 40 Bekkali NL, Murray S, Johnson GJ *et al.* Pancreatoscopy-directed electrohydraulic lithotripsy for pancreatic ductal stones in painful chronic pancreatitis using SpyGlass. *Pancreas* 2017; **46**: 528–30.