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**Title:** Treatment outcomes, including risk factors of stone recurrence, for hepatolithiasis using balloon-assisted endoscopy in patients with hepaticojejunostomy (with video)

**Running Title:** Treatment outcomes using balloon-assisted endoscopy for hepatolithiasis

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YI, KM, and HK: conception and design of the research and writing the paper. KT, TT, AM, KAM, TY, YS, YF, DU, and SH: performing patient's treatment and critical revision of the article for important intellectual content. HO: final approval of the article. All authors read and approved the final manuscript.

**Conflict of interest**

All authors declare no conflicts of interest.

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**Abstract**

**Background and study aims**

Endoscopic treatment outcomes for hepatolithiasis in patients with altered anatomy is not well known. The aim of this study was to evaluate the treatment outcomes of hepatolithiasis in patients with hepaticojejunostomy (HJ) using short-type double-balloon endoscopy (sDBE) and to assess the risk factors for stone recurrence.

**Patients and methods**

This was a retrospective cohort study that consisted of 73 patients with hepatolithiasis who underwent bowel reconstruction with HJ at an academic center. Stone removal was performed using sDBE. After balloon-occluded cholangiography using sDBE, peroral direct cholangioscopy (PDCS) using ultraslim endoscopy was performed to check for residual stones, depending on the bowel reconstruction method. Recurrence was defined as the development of cholangitis from stones.

**Results**

The success rate of reaching the HJ site was 92% (67/73), and the complete stone removal rate was 93% (62/67) with multiple sessions (mean number 1.5±0.9). The occurrence rate of procedure-related adverse events was 6.8%. Among 58 patients evaluated for stone recurrence, 13 (22%) developed recurrence during a median follow-up period of 2.7 years (interquartile range: 1.5-4.8). Multivariate analyses determined that a stone diameter ≥8 mm

(odds ratio [OR], 5.57; 95% confidence interval [CI], 1.39-37.2; *P* = 0.013) and performing PDCS (OR, 0.16; 95% CI, 0.0084-0.90; *P* = 0.036) were significant factors for stone recurrence.

**Conclusions**

Endoscopic treatment using sDBE for hepatolithiasis was effective and safe. PDCS might reduce the rate of stone recurrence by detecting stones that are too small to confirm on fluoroscopic images.

**Key words**: Peroral direct cholangioscopy, Hepatolithiasis, Altered gastrointestinal anatomy, double-balloon endoscopy

## Introduction

Hepatolithiasis is a postoperative complication of hepaticojejunostomy (HJ), which is performed for various pancreatobiliary diseases. Hepatolithiasis can cause repeated episodes of cholangitis, liver abscess, liver cirrhosis, or liver atrophy. Complete stone removal and bile stasis elimination are therefore necessary and have commonly been achieved with a percutaneous approach [1].

Recently, balloon-assisted endoscopy for the treatment of biliary disease in patients with altered anatomy has been reported [2-5]. In particular, the usefulness of short-type double-balloon endoscopy (sDBE) has been demonstrated for various biliary interventions, such as dilation of biliary stricture, stent placement, and stone extraction [2-4]. This procedure has been gradually introduced for the treatment of hepatolithiasis in patients with HJ [2, 6, 7]. However, there have been only a few reports concerning this therapy, and the immediate and long-term treatment outcomes are unclear [2, 7]. Furthermore, the evaluation of the risk factors of stone recurrence after complete stone removal is not sufficient.

In the endoscopic diagnosis or therapeutic treatment using balloon-assisted endoscopy for patients with an altered GI anatomy, the efficacy of peroral direct cholangioscopy (PDCS), which involves replacing the balloon enteroscope with an ultraslim endoscope, has been described in some reports [7-10]. Overtube-assisted PDCS for bile duct stone treatment

allows for the detection of residual stones that can be subsequently removed using saline irrigation or a basket catheter [2, 7]. In the treatment of hepatolithiasis, residual stones are considered a risk factor for recurrent stones, so their removal by PDCS may reduce the risk of stone recurrence after endoscopic treatment.

In the present study, we evaluated the treatment outcomes of hepatolithiasis in patients with HJ using sDBE and to assess the risk factors for stone recurrence after complete stone removal.

## Patients and methods

*Patients*

The study flow chart is shown in Figure 1. We studied 73 consecutive patients with intrahepatic bile duct (IHBD) stones who underwent bowel reconstruction with HJ between January 2008 and December 2018 at Okayama University Hospital. Among them, 16 patients were included in our previous reports [2, 7]. The stones were diagnosed by abdominal ultrasonography (US), computed tomography (CT), or magnetic resonance cholangiopancreatography (MRCP) before the DBE procedure was performed.

This study was approved by the hospital's institutional review board (Approved number: 1804-028) for human research and was conducted in accordance with the Declaration of Helsinki.

*DBE procedure*

We conducted sDBE using an appropriate scope (EC-450BI5, EI-530B, or EI-580BT; Fujifilm, Tokyo, Japan) and a balloon overtube (outer diameter: 13.2 mm, inner diameter: 10.8 mm; total length: 1050 mm; TS-13140; Fujifilm). IHBD stone treatment was performed in three steps: (1) sDBE insertion into the HJ site; (2) IHBD contrast enhancement to confirm stones; and (3) stone extraction using a retrieval balloon catheter (Multi-3; Olympus Medical Systems, Tokyo, Japan, Tri-Ex Extraction Balloon; Cook Medical, Inc. NC, USA), a basket

catheter (8 wire type; Olympus, Memory Basket; Cook), and/or a mechanical lithotripter (ML) (Crusher Catheter; Xemex, Tokyo, Japan). Upon HJ anastomosis stricture identification, the anastomosis was dilated using a dilatation balloon catheter (Quantum Balloon Dilator; Cook or REN Balloon Dilator; Kaneka Medix, Osaka, Japan) before stone extraction. The balloon size was decided based on the diameter of the distal end of the bile duct (balloon size: 6, 8 or 10 mm). Following stone extraction, complete stone clearance was confirmed by balloon-occluded cholangiography.

When complete stone removal could not be achieved at the initial session, a plastic stent was placed for biliary drainage. Two to three months later, the sDBE procedure was performed again for stone removal. If severe stricture of the HJ site was noted after balloon dilation, plastic stents were placed. Three months later, we removed the plastic stents and evaluate the stricture of the HJ site. When the stricture was improved, we did not insert the stent and cleaned up the debris on IHBD using an extraction balloon. During DBE, carbon dioxide insufflation was performed.

The number and diameter of stones were confirmed via fluoroscopic images of cholangiography. The total procedure time was defined from the scope insertion to removal, including the scope insertion time. Adverse events were defined as those related to the procedure, according to the ASGE guideline [11].

*PDCS procedure (Video 1)*

After balloon-occluded cholangiography, the sDBE endoscope was exchanged for an ultraslim one (EG-530NW or EG-L580NW7; Fujifilm), leaving the balloon overtube in place with the balloon inflated. The ultraslim endoscope was introduced through the overtube at a point 90 to 100 cm from its tip and was advanced up to the HJ anastomosis and directly inserted into the IHBD, as described previously [7]. Residual stones were extracted using a 5-Fr basket catheter (Memory Basket; Cook), followed by suction after normal saline irrigation (Figure 2A, B). During the PDCS procedure, carbon dioxide insufflation was performed.

*Follow-up*

After discharge from the hospital, laboratory tests and US, CT, or MRCP were performed to check for stone recurrence every 6 to 12 months or whenever patients reported recurrence symptoms. Recurrence was defined as the development of cholangitis (upper abdominal pain, a leukocytosis-associated fever, and icterus) from IHBD stones. For the patients without stent placement, the recurrence-free duration was defined as the time from the date of discharge from the hospital to the detection of stones. For patients with stent placement, the duration was defined as the time from the day of a stent-free condition to the detection of stones.

*Statistical analyses*

Continuous data are presented as the median and interquartile ranges (IQR). Continuous variables were compared using the Mann–Whitney U-test. The frequency distribution was compared using Fisher's exact or $\chi^2$ tests. The cumulative probability of stone recurrence-free was assessed using the Kaplan–Meier method and compared using log-rank tests. A multivariate analysis was performed using a Cox proportional hazard model to analyze the risk factors for stone recurrence, and significant variables in the univariate analysis (P values < 0.2) were selected for inclusion in the multivariate analysis. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated. P values < 0.05 were considered statistically significant. All analyses were performed using the JMP Pro 13 software program (SAS Institute, Cary, NC, USA).

## Results

*Patient characteristics and study flow*

The characteristics of 73 patients in whom DBE was attempted are shown in Table 1. The patients' median age was 70 (61-76) years old, and 41 (56%) were male. Bowel reconstruction methods were Child in 46 (63%), Rou-en-Y in 22 (30%), and others (not the Child or Rou-en-Y method) in 5 (7%).

The study flow chart is shown in Fig 1. Of the 73 patients, the HJ site could not be reached using sDBE in 6, and all of these patients underwent percutaneous trans-hepatic drainage (PTBD) for stone removal. Thus, 67 patients were analyzed for endoscopic treatment. The success rate of reaching the HJ site was 92% (67/73). Regarding the bowel reconstruction method, the success rate of the Child method was 100% (46/46), that of the Roux-en-Y method was 77% (17/22), and that of other methods was 80% (4/5). The median time to reach the HJ site was 14 (IQR: 9-27) minutes.

*Treatment results of DBE procedure*

The cholangiography findings and therapeutic procedures with sDBE are shown in Table 2. The maximum stone diameter was 8 mm (IQR: 5-10), and the median number of stones was 3 (IQR: 1-5). The concomitant HJ anastomotic stricture in 50 (71%) patients was dilated using a dilation balloon. ML was used to crush stones in 23 (34%) patients. PDCS was

performed for 21 (31%) patients to check for residual stones after stone removal (20 patients underwent bowel reconstruction via the Child method, 1 patient underwent reconstruction via another method). Among these patients, residual stones were detected in 9 (43%), and all had their stones successfully removed with a 5-Fr basket (4 or 8 wire type) and saline irrigation. Twenty-five patients underwent plastic stent placement after the procedure (10 patients for stones, 15 patients for stricture). The rate of complete stone removal at the initial session was 73% (49/67), and the rate increased to 93% (62/67) with additional sessions (mean number of sessions: 1.5±0.9). The median procedure time at the initial session was 70 minutes (IQR: 54-98). Regarding the reconstruction method, the rate of complete stone removal in patients who underwent Roux-en-Y reconstruction tended to be lower than that with the Child method (59% vs. 76%, $p$=0.18) (Table 3).

*Adverse events*

The occurrence of procedure-related adverse events was 6.8% (5/73). During the procedures, bile duct end laceration caused by balloon dilation in 1 (1.4%) patient was managed conservatively, including ENBD and antibiotics administration. After the procedures, mild cholangitis was observed in 4 (5.5%) patients and was managed by antibiotics administration.

*Stone recurrence and risk factors for recurrent after complete stone removal*

Of the 67 patients who underwent successful stone removal, 9 were excluded from the analysis of stone recurrence after stone removal (incomplete stone removal: 5, repeated stent placement for HJ stricture: 2, lost to follow up >3 months). Thus, 58 patients were ultimately analyzed for recurrence after complete stone removal (Fig. 1).

During the median follow-up of 2.7 years (IQR: 1.5-4.8), 13 patients (22%) developed stone recurrence. The overall probability of a recurrence-free status at 1, 3, and 5 years was 91%, 80%, and 75%, respectively (Fig. 3). The median time to stone recurrence was 1.4 years (IQR: 0.3-2.7). For the analysis of stone recurrence, bowel reconstruction with the Roux-en-Y method, a stone diameter ≥8 mm, and performing PDCS were potential risk factors for stone recurrence ($P < 0.2$) in the univariate analyses. Multivariate analyses determined that a stone diameter ≥8 mm (OR, 5.57; 95% CI, 1.39-37.2; $P = 0.013$) and performing PDCS (OR, 0.16; 95% CI, 0.0084-0.90; $P = 0.036$) were significant factors for recurrence after complete stone removal (Table 4).

Figure 4 shows the Kaplan-Meier analysis for the probability of a recurrence-free status in patients with risk factors. The patients with a stone diameter ≥8 mm showed a significantly shorter time to recurrence than those with a stone diameter <8 mm ($P$=0.013, log-rank test) (Fig. 4A). Patients who underwent PDCS showed a significantly lower recurrence rate than those without PDCS ($P$=0.044, log-rank test) (Fig. 4B). All patients with stone recurrence were successfully treated with sDBE.

**Discussion**

To our knowledge, this is the first report on the evaluation of the rate of stone recurrence and risk factors for recurrence after removal of hepatolithiasis using sDBE in patients with HJ.

For a normal anatomy, suggested predictors of bile duct stone recurrence after endoscopic extraction include a dilated bile duct, large stones, multiple stones, using ML, and periampullary diverticulum [12-17]. Two main causes of stone recurrence have been proposed in previous reports: including residual stones after stone removal, which can be inferred from multiple stones and using ML, and the congestion of bile juice, which can be inferred from a dilated bile duct and periampullary diverticulum. In the present study, performing PDCS reduced the risk of stone recurrence. PDCS was performed for 21 (31%) patients to check for residual stones after stone removal. Stones were detected in 9 (43%) patients, and all cases were successfully managed by removing the stones with a basket and/or saline irrigation. After complete stone removal, only 1 patient who underwent PDCS developed stone recurrence at 24 months. In contrast, of the 13 patients with stone recurrence, 5 (38%) developed recurrence within 1 year, and none of them underwent PDCS.

Regarding the means for assessing complete stone clearance, balloon-occluded cholangiography by fluoroscopy in patients with HJ anastomosis carries a risk of overlooking stone fragments by disturbing the pneumobilia with a wide-open anastomosis. This situation is similar to stone extraction in conventional endoscopic retrograde

cholangiopancreatography, with approximately 24%-28.3% of patients retaining stones even after complete stone removal [18,19]. PDCS was able to detect small or muddy stones that could not be detected on fluoroscopic images, which might have prevented early stone recurrence. PDCS may thus be a promising procedure for ensuring the optimal treatment, complete stone clearance, and maintenance of stone clearance.

While using ML for large stones is reportedly a risk factor for stone recurrence due to small stones remaining after stone crushing [14], it was not found to be a risk factor for stone recurrence in the present study. One reason for this discrepant finding is considered to be because IHBD stones with HJ anastomosis were usually muddy or soft stones composed of bilirubin that were easily crushed even when using a balloon catheter for large stone removal. Both ML and a balloon catheter carry a risk of small stones remaining after completion of the procedure, so the presence of large stones might only indicate stone recurrence in patients with HJ anastomosis.

Regarding the condition of the bile duct, congestion with bile juice is suggested to eb a risk factor for recurrence [13, 16, 17]. In our study, when the HJ site showed severe stricture, plastic stents were placed until the stricture improved. Although congestion with bile juice and stone recurrence were suggested to be strongly related in previous reports [13, 16, 17], it was difficult to evaluate the relationships between these two factors in this study, as all of the included patients with HJ stricture had been treated before follow-up for stone

recurrence. However, of the 13 patients who developed stone recurrence, 5 (38%) developed recurrence of HJ stricture at the same time, indicating that stone recurrence and anastomotic stricture were closely related.

The rate of complete stone removal by sDBE at the initial session was 73% (49/67), and that rate increased to 93% (62/67) with additional sessions (mean number of sessions: 1.5±0.9). While the rate at the initial session was not very high, the final rate of complete stone removal was relatively good. Generally, stone removal using DBE in patients with altered GI anatomy is more difficult than that in patients with normal anatomy. One reason for this is considered to be the insufficiency of maneuverable devices to remove IHBD stones via DBE (scope channel diameter: EC-450BI5 or EI-530B, 2.8 mm; EI-580BT, 3.2 mm). However, when we selected PTCS for stone removal, at least two procedure sessions were needed for stone removal (first step: insert the biliary tube via the percutaneous trans-hepatic route and dilate the fistula, second step: insert the cholangioscope via the trans-hepatic route). In our previous reports on treatment methods (PTCS vs. sDBE) for IHBD stones with an HJ anatomy, the median hospitalization period for complete stone clearance was significantly shorter with sDBE than with PTCS (10 vs. 35 days. $p<0.001$), and the median numbers of procedure sessions were 1 (IQR: 1-2) and 5 (IQR: 4-6), respectively [2]. Development of adequate equipment for stone removal is required.

The rate of adverse events with endoscopic procedures using a balloon enteroscope

for pancreaticobiliary disease is reportedly low (5%-10.6%); these events include bleeding, retroperitoneal air, pancreatitis, and perforation [2, 4, 20]. In our study, 5 patients (7.5%) developed adverse events, including mild cholangitis and laceration of the bile duct end. The laceration of the bile duct end was caused by excessive balloon dilation to a size larger than the IHBD end diameter. Although no serious complications have been reported for PDCS using an ultraslim endoscope [7-10], there is still a risk of air embolism, cholangitis, or bile duct laceration. Careful endoscope manipulation and appropriate carbon dioxide insufflation during the procedures are necessary.

During a median follow-up of 2.7 years (IQR: 1.5-4.8), 13 patients (22%) developed stone recurrence. The overall probability of a recurrence-free status at 1, 3, and 5 years was 91%, 80%, and 75%, respectively. Although there have been no other reports on the long-term outcomes of endoscopic treatment of hepatolithiasis in patients with HJ anastomosis, the recurrence rates of bilioenteric stricture or hepatolithiasis after percutaneous treatment were reported to be 14%-30% with a median follow-up of 28-65 months [21-23]. The recurrence rate after percutaneous or sDBE treatment seems to be almost the same. Endoscopic treatment using sDBE is less invasive than percutaneous treatment.

Several limitations associated with the present study warrant mention. First, this work was a retrospective, single-center study. Second, PDCS was unable to be performed in patients with Roux-en Y. The length of the ultraslim endoscope was 1300 mm, making it

difficult to use for long-afferent or efferent loop bowel reconstruction. Third, counting the number of stones was sometimes difficult due to pneumobilia. Therefore, the number of stones may have been slightly off. Prospective multicenter studies involving a larger population are warranted.

In conclusion, we evaluated the treatment outcomes of hepatolithiasis in patients with HJ using sDBE and risk factors for recurrence after complete stone removal. Endoscopic treatment using sDBE was effective and safe. Large stones were found to be a risk factor for recurrence after complete removal. PDCS might reduce the risk of stone recurrence by detecting small stones that cannot be confirmed on fluoroscopic images.

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Table 1. Patient characteristics (n=73)

| Parameter | Number |
|---|---|
| Age, median (IQR), years | 70 (61–76) |
| Sex, male, *n* (%) | 41 (56) |
| Primary disease for surgery, *n* (%) | |
| Pancreatic neoplasm[a] | 31 (42) |
| Biliary cancer | 13 (18) |
| Gastroduodenal neoplasm[b] | 7 (10) |
| Congenital biliary dilation | 9 (12) |
| Hepatolithiasis | 2 (3) |
| Liver failure requiring liver transplantation | 2 (3) |
| Others | 9 (12) |
| Bowel reconstruction methods, *n* (%) | |
| Child | 46 (63) |
| Roux-en-Y | 22 (30) |
| Others | 5 (7) |

IQR: interquartile range, Ph: pancreatic head, Pb: pancreatic body, Pt: pancreatic tail,

[a] including pancreatic cancer, intraductal papillary mucinous neoplasm, pancreatic neuroendocrine tumor

[b] including gastric cancer, duodenal cancer, gastrointestinal stromal tumor

Table 2. Treatment results of DBE-ERC (n=67)

| Parameter | Number |
|---|---|
| Maximum size of stone (IQR), mm | 8 (5-10) |
| Number of stones (IQR) | 3 (1-5) |
| Concomitant HJ anastomotic stricture, *n* (%) | 50 (71) |
| Using ML for stone removal, *n* (%) | 23 (34) |
| Performing PDCS to check for residual stones, *n* (%) | 21 (31) |
| Confirming and removing residual stones, *n* (%) | 9 (43) |
| Placement of plastic stent | |
| for stone/ for stricture | 10 / 15 |

DBE-ERC: double-balloon enteroscopy-assisted endoscopic retrograde cholangiography

IQR: interquartile range, HJ: hepaticojejunostomy, ML: mechanical lithotripter

PDCS: peroral direct cholangioscopy

Table 3. Rate of complete stone removal (n=67)

| Parameter | Initial session, (*n*)% | Additional session*, (*n*)% |
|---|---|---|
| Overall | 73 (49/67) | 93 (62/67) |
| According to reconstruction methods | | |
| Child | 76 (35/46) | 98 (45/46) |
| Roux-en-Y | 59 (10/17) | 76 (13/17) |
| Others | 100 (4/4) | - |

* mean number of sessions: 1.5±0.9 (standard deviation)

Table 4. Cox proportional hazard model analysis for stone recurrence after complete stone removal

| | Recurrence | | Univariable analysis | | Multivariable analysis | |
|---|---|---|---|---|---|---|
| Variable | + | - | OR (95% CI) | *P* value | OR (95% CI) | *P* value |
| Age, ≥70 yr | 5 | 26 | 0.53 (0.16-1.58) | 0.25 | | |
| Gender, female | 4 | 20 | 0.67 (0.18-2.09) | 0.5 | | |
| Reconstruction method, Roux-en-Y | 5 | 6 | 2.64 (0.84-7.93) | 0.11 | 1.02 (0.29-3.36) | 0.98 |
| HJ stricture at initial procedure, yes | 10 | 37 | 0.94 (0.28–4.24) | 0.93 | | |
| Maximum size of stone, ≥8mm | 11 | 22 | 5.56 (1.48-36.0) | 0.009 | 5.57 (1.39-37.2) | 0.013 |
| No. of stone, ≥ 4 | 6 | 18 | 1.61 (0.51-4.91) | 0.4 | | |
| Stone removal with initial procedure, success | 9 | 35 | 0.68 (0.22–2.54) | 0.54 | | |
| Using ML for stone removal | 4 | 14 | 1.44 (0.38-4.52) | 0.56 | | |
| Performed PDCS | 1 | 20 | 0.16 (0.0088-0.82) | 0.024 | 0.16 (0.0084–0.90) | 0.036 |

OR: odds ratio, CI: confidence interval, ML: mechanical lithotripter, PDCS: peroral direct cholangioscopy

**Figure legends**

Figure 1.

The flowchart of this study.

Figure 2.

A: Peroral direct cholangioscopy using an ultraslim endoscope in a patient with hepaticojejunostomy. The tip of the ultraslim endoscope is advanced into the intrahepatic bile duct.

B: Endoscopic imaging showed residual bile duct stones which were removed using a 5-Fr basket catheter.

Figure 3.

Kaplan-Meier curves showing the probability of being stone-free after complete stone removal.

Figure 4.

A: Kaplan-Meier curves showing the probability of being stone-free after complete stone removal in patients who had a stone diameter ≤8 mm.

B: Kaplan-Meier curves showing the probability of being stone-free after complete stone

removal in patients with or without PDCS.

PDCS: peroral direct cholangioscopy.

**VIDEO LEGEND**

The DBE scope was exchanged for an ultraslim endoscope, leaving the overtube with its balloon inflated. The ultraslim endoscope was advanced through the balloon overtube up to the hepaticojejunostomy anastomosis and directly inserted into the intrahepatic bile duct. Residual stones were detected and extracted using a 5-Fr basket catheter and suction after normal saline irrigation