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INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

Percutaneous cholecystoduodenal stent as a definite treatment for acute cholecystitis in elderly or comorbid patients: a bicentric retrospective study

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PURPOSE

To investigate the safety and efficacy of percutaneous cholecystoduodenal stent (CDS) placement to prevent recurrence of acute cholecystitis in patients who were unfit for cholecystectomy.

METHODS

Between April 2016 and January 2022, 46 patients [median age (range) = 81 (37–99) years; men = 15] with acute cholecystitis who were unfit for surgery underwent percutaneous cholecystostomy followed by a CDS placement in two institutions. Plastic stents of three different materials were used [polyethylene, polyurethane (PU), and polycarbonate (PCB)-based PU]. Clinical outcomes, including technical and clinical success rates and early (<30 days) and delayed adverse events, were retrospectively assessed by stent type.

RESULTS

CDS placement was technically successful in 39 patients. Clinical success, defined as cholecystostomy catheter removal, was achieved in 35 of 39 patients. Immediate complications, such as acute pancreatitis and peritonitis, occurred in two patients. Two patients experienced recurrent cholecystitis during a 113-day follow-up (range, 3–1,723). Three-stent groups had significantly different delayed complications on Fisher's exact test ($P = 0.021$). The Bonferroni post-hoc analysis showed the PCB-PU group tended to have fewer complications than the PU group ($P = 0.060$).

CONCLUSION

CDS placement is applicable in treating acute cholecystitis patients who were initially unfit for surgery, but further investigation is needed. Although it was not statistically significant, a PCB-PU stent can be suitable for this use because it tends to have fewer delayed complications and is equipped with a drawstring and side holes.

KEYWORDS

Biliary system, catheter, gallbladder, percutaneous, stent

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The standard treatment of acute cholecystitis, laparoscopic cholecystectomy, carries risks of general anesthesia and surgery.[1-3] Due to those risks, surgeons often hesitate to perform this surgery on elderly or comorbid patients. Percutaneous cholecystostomy does not require general anesthesia and is known to be safe, so it is usually implemented as a bridge to surgery or definite treatment in elderly and comorbid patients.[1,4] However, maintaining the external drainage catheter can cause adverse events (AEs), including dislocation, bile leakage, or infection, and substantially impair the patient's quality of life. Patients treated only by temporary cholecystostomy and antibiotics for acute cholecystitis experienced a 1-year and 3-year recurrence of acute cholecystitis of 35% and 46%, respectively.[2] For these patients, cholecystoduodenal or cystic duct stent (CDS) can be a beneficial alternative treatment. Only one previous clinical study of 33 patients and several case reports have been

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published on percutaneous CDS placement; thus, this topic requires more extensive clinical studies.[2,5-9] Furthermore, no dedicated devices are available for this procedure, and the most appropriate type of stent is unknown. Additionally, recent literature on endoscopic CDS supports the efficacy of CDS.[10] Technical success rates were reported to be high in both percutaneous (91%) and endoscopic (6%4–100%) approaches and had significant clinical success rates (>80%).[2,9-13] This study aims to investigate the safety and efficacy of percutaneous CDS placement for patients with acute cholecystitis who are unfit for cholecystectomy and to assess its clinical outcomes.

Methods

Patients

The Institutional Review Board of Incheon St. Mary Hospital (approval no: OC21RADI0153) and the Institutional Review Board of Chung-Ang University H.C.S. Hyundae Hospital (approval no: BI0-IRB 2021-006) approved this retrospective study. Due to its retrospective nature, the requirement of informed consent was waived. Between April 2016 and January 2022, patients that presented with acute cholecystitis and were ineligible for surgery were candidates for the placement of a CDS. Medical records and radiological images of these patients were retrospectively reviewed. All patients were diagnosed with acute cholecystitis based on right upper abdominal tenderness, laboratory findings, and imaging studies, including ultrasonography or computed tomography, and were treated with percutaneous cholecystostomy.[14] Several days after improving the acute inflammatory condition, a surgeon and an anesthesiologist assessed the patient's surgical eligibility. Patients who did not qualify for surgery were referred to interventional radiology for CDS placement. Indications for CDS placement included patients who were elderly (>80 years old), at high risk for general anesthesia due to comorbidity, or had a poor performance status (Eastern Cooperative Oncology Group III or IV). Patients younger than 19 years old were not considered for this study. Immediate postprocedural AEs (<30 days) were evaluated using the Cardiovascular and Interventional Radiology Society of Europe (CIRSE) classification system.[15] Delayed AEs were recorded regarding stent fracture, dislocation, and recurrent cholecystitis.

Procedure

Three dedicated interventional radiologists conducted the procedure (with 3, 8, and 10 years of experience, respectively). The placement of CDS was performed under conscious sedation with fentanyl (1 μg/kg) and midazolam (0.05 mg/kg). After subcutaneous injection of 2% lidocaine at the cholecystostomy site, the cholecystostomy catheter was exchanged with an 8 Fr vascular sheath with a tip marker (Super Sheath R/O, Boston Scientific, Marlborough, MA or Brite Tip sheath, Cordis, Miami Lakes, FL). Cystic duct cannulation was attempted with appropriate-shaped catheters, including 4 or 5 Fr Cobra (Cook, Bloomington, IN), 5 Fr Kumpe (Cook), or Davis (Jungsung Medical, Seoul, Korea) with 0.035- or 0.032-inch regular guidewires (Terumo, Tokyo, Japan). After cannulating the cystic duct with a guidewire up to the jejunum, 5 to 8 Fr plastic stents were placed over the guidewire (Figure 1). Pushers enclosed in a ureteral double-J set were used to insert the stent into the gallbladder. Initially, 11 patients underwent placement of a polyethylene stent, which was not equipped with a drawstring. However, the rest of the patients underwent placement of a double-J ureteral stent fitted with a drawstring. The double-J catheter shape and location were adjusted with drawstrings. A 10.2 Fr cholecystostomy catheter was immediately placed over the wire used for the stent placement to assist with procedure-associated symptom relief and prevent recurrent cholecystitis due to stent malfunction. After several days without clinical symptoms of fever or pain, a capping test and transcatheter cholecystography were performed to evaluate stent patency. In the case of a negative capping test and confirmed stent patency, the temporary catheter was removed, and the patient was discharged from the hospital. Outpatient clinic follow-ups were recommended for patients every six months or after any unexpected events. Regular stent exchanges or surgery were not considered unless there was any event of recurrent cholecystitis.

Main points

- Cholecystoduodenal stents (CDS) were successfully placed in 39 of 46 patients, and external drainage catheters were successfully removed in 35 of 39 patients.
- Immediate complications presented as recurrent cholecystitis occurred in two patients during a 113-day follow-up (range, 3–1,723).
- A polycarbonate-based polyurethane stent seems more suitable for this use.
- CDS placement could be a safe and effective treatment for preventing recurrent cholecystitis in surgically ineligible patients.

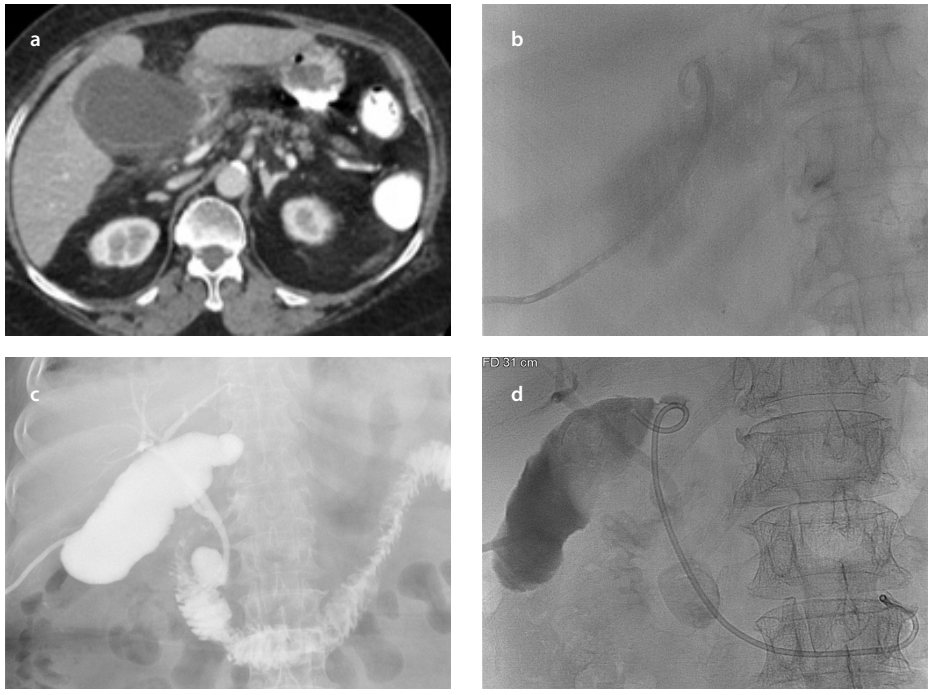

Figure 1. Successful cholecystoduodenal stent placement. **(a)** An 80-year-old woman with type 2 diabetes mellitus and atrial fibrillation presented with right upper abdominal pain. Computed tomography shows a distended gallbladder with mural wall thickening, suggestive of acute cholecystitis. **(b)** A percutaneous cholecystostomy catheter that was placed via transperitoneal access under ultrasonography and fluoroscopy guidance. **(c)** A transcatheter cholecystography showing patent cystic duct and duodenal diverticulum 17 days after cholecystostomy. **(d)** After cannulation of the cystic duct with a 5 Fr catheter and a 0.035-inch guidewire, a polyethylene stent (7 Fr, 12 cm) was placed over the guidewire.

Materials and types of stents

During the first two years, patients were treated with a 7 Fr, 12–15 cm polyethylene stent (double-J and single-J, Zimmon, Cook, Bloomington, IN) traditionally used for endoscopic insertion. The polyethylene stent was not equipped with a drawstring or side holes. A single-J stent, usually used for pancreatic duct stents and with side holes, was subsequently utilized for the above papilla placement in two patients. During the next two years, patients were treated with a polyurethane (PU) double-J (5–8 Fr, 20–30 cm, Endo-Sof, Cook, Bloomington, IN) catheter for a ureteral stent, which had a drawstring and multiple side holes. While using the PU stent, a high incidence of stent fracture and dislocation was noticed. Therefore, both institutions used polycarbonate (PCB)-based PU stents (6–8 Fr, 14 cm Inlay Optima, BD, Franklin Lakes, NJ) for the rest of the duration. A photograph of the three stents is presented in Figure 2. Depending on the situation, the stent size and length were decided at the operators' discretion.

Statistical analysis

Normality was tested with the Shapiro–Wilk test. The differences in AE rates between the three stent groups (polyethylene, PU, and PCB-PU) were compared using Fisher's exact test. Post-hoc tests between groups were performed by implementing Bonferroni's methods. Statistical analysis and adjustment of *P* values for multiple comparisons were conducted with R software (version 4.0.3, The R Foundation for Statistical Computing, Vienna, Austria; RVAideMemoire Package). Two-tailed *P* values of less than 0.050 were considered statistically significant. Subgroup analysis on technical success and AEs in transhepatic and transperitoneal access groups was performed using chi-square or Fisher's exact test.

Results

During the six-year study period, 46 patients underwent an attempt to place a CDS via percutaneous access in two hospitals (41 patients at Incheon St. Mary's Hospital and 5 patients at Chung-Ang University H.C.S. Hyundae Hospital). Polyethylene stents were attempted in 11 patients with double-J (n = 9) or single-J (n = 2) stents. PU double-J stents were attempted in 14 patients, and PCB-PU stents were attempted in 21 patients. Collectively, 39 patients successfully received CDS (Figure 3). Clinical success, defined as removing the cholecystostomy catheter, was achieved in 35 of 39 patients. The median periods from percutaneous cholecystostomy to CDS and from CDS to cholecystostomy catheter removal were 16 (0–794) and 5 (0–41) days, respectively. Percutaneous catheters were kept in seven technically unsuccessful patients and four clinically unsuccessful patients. Furthermore, one of seven technically unsuccessful patients underwent cholecystectomy during the follow-up period. The patients' characteristics are presented in Table 1.

The detailed causes of clinical failures included: contrast medium obstruction during transcatheter cholecystography in two patients (Figure 4), pancreatitis leading to stent removal in one patient, and advanced protrusion of the single-J stent against the duodenal wall in one patient initially intended to be placed above the papilla. In the patient with the protruding stent, concerns of a duodenal ulcer formation by the abutting stent tip resulted in stent removal. An immediate postprocedural AE occurred in 16 patients, including 14 minor (CIRSE classification I and II) and 2 major (CIRSE classification III) AEs. The most common AE was abdominal pain (n = 8), followed by fever (n = 4) and vomiting (n = 2). All patients with minor AEs were treated with conservative management and recovered without sequelae. Major AEs were present in one patient with pancreatitis and another patient with biloma and peritonitis. The patient with pancreatitis was treated with stent removal and conservative management and recovered. The patient with biloma underwent percutaneous drainage and recovered. During the follow-up period (median, 113 days; range, 3–1,737), the most common delayed AEs were stent dislocation (n = 7) and fracture (n = 7, Figure 5), followed by recurrent cholecystitis (n = 2). Twelve patients died of their disease progression, and 34 patients were still alive at the time of the last evaluation. Clinical outcomes are displayed in Table 2. Delayed AEs occurred differently in the three stent groups (*P* = 0.021). However, subsequent post-hoc analysis showed no significant difference in the groups with the Bonferroni method (polyethylene vs. PU: *P* = 0.117; polyethylene vs.

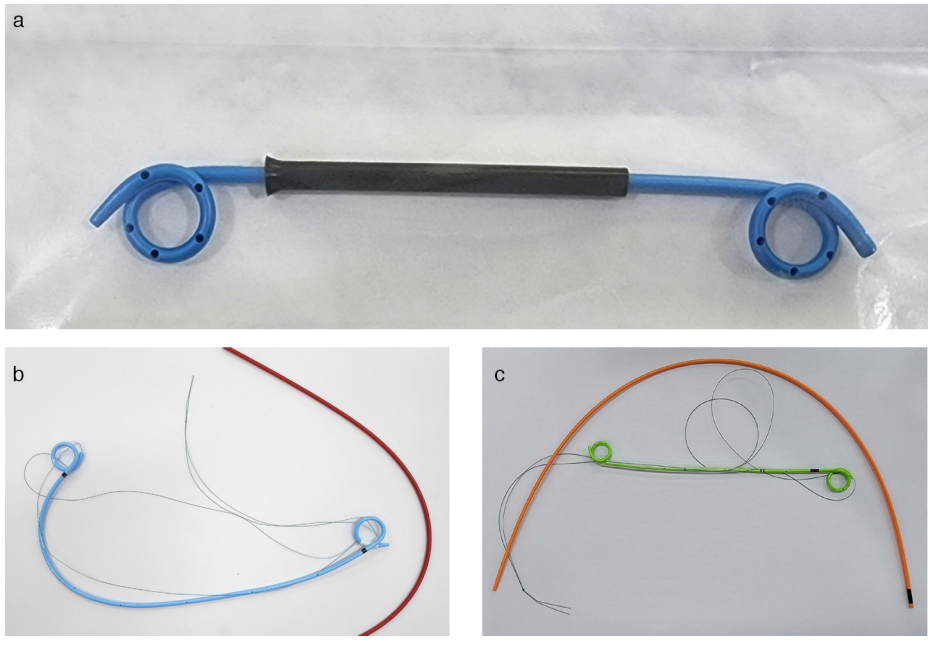

Figure 2. Photographs of three double-J stents. **(a)** Polyethylene stent (Zimmon, Cook, 7 Fr, 7 cm). **(b)** Polyurethane (Endo-Sof, Cook, 8 Fr, 26 cm) with pusher. **(c)** Polycarbonate-based polyurethane (Inlay Optima, Bard, 6 Fr, 14 cm) with pusher.

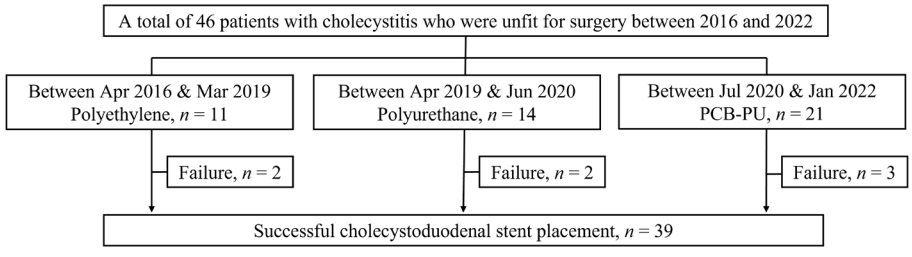

Figure 3. Flow chart of patient selection. PCB-PU, polycarbonate-based polyurethane

PCB-PU: $P > 0.999$; PU vs. PCB-PU: $P = 0.060$). The subgroup analysis showed no significant differences in the technical success rate (transhepatic and transperitoneal access: 15/19 vs. 24/27, $P = 0.424$) and AEs rates (5/19 vs. 12/27, $P = 0.215$) in transhepatic and transperitoneal access groups.

Discussion

This bicentric retrospective study successfully placed CDSs in 85% of the patients. Major AEs occurred in 5% of technically successful patients, and all patients recovered without operative treatment. Recurrent cholecystitis occurred in 6% of clinically successful patients after a median follow-up of 113 days. The three-catheter groups seemed to experience different delayed AEs ($P = 0.021$), although a post-hoc analysis could not reveal the differences.

Patients with an increased perioperative risk often require a permanent cholecystostomy catheter to avoid recurrent cholecystitis.[2] Patients with a long-term catheter can be afflicted by insertion site discomfort, local infection, and recurrent cholecystitis due to occlusion and may require routine catheter replacements. Furthermore, the catheter can frequently dislocate from the gallbladder and necessitate reinsertion.[16] Patients with a non-independent lifestyle could be more vulnerable to sepsis secondary to recurrent cholecystitis. Hersey et al.[2] reported on the safety and efficacy of CDS placement with 33 patients in 2015. Additionally, several cases have been published.[2,17] This present study is in concurrence with the previous study and demonstrated similar outcomes regarding clinical success rate and complications.[2] Major AEs, such as pancreatitis and peritonitis, occurred in two patients. The presumed cause of pancreatitis was either mechanical trauma during the procedure or an anomalous pancreaticobiliary ductal union. Peritonitis was caused by bile leakage during the stent insertion process. The patient underwent CDS placement 10 days after a cholecystostomy. Tract maturation over 2–3 weeks post-cholecystostomy might prevent bile peritonitis.[18]

Due to the lack of a dedicated stent for this purpose, polyethylene stents were initially adopted. These stents are typically used for endoscopic insertion and resist peristalsis and bile. However, polyethylene stents have a smaller inner lumen diameter than PU stents and are not equipped with side holes, pushers, or a drawstring. The next type used was the double-J ureteral stent made of PU. Although they were used off-label, they provided a larger inner diameter than the polyethylene stent and had side holes, pushers, and a drawstring. However, the double-J PU stents frequently fractured and dislocated during follow-up. Finally, PCB-PU stents were introduced to provide the benefit of a ureteral stent and resistance to peristalsis and bile. The PCB-PU stents seemed more suitable for this usage than other ureteral stents.

Although transhepatic access can be advantageous regarding tract maturation, the transperitoneal route was preferred in this study because it provides a favorable angle for cystic duct cannulation. Transhepatic access often formed an acute angle between the cholecystostomy tract direction and gallbladder axis and the angle made it difficult to cannulate the cystic duct. Transperitoneal

Table 1. Characteristics of patients who underwent percutaneous cholecystoduodenal stent placement as a treatment of acute cholecystitis

Characteristics	Value[a]
Total number of patients	46
Age (y)	81 (37–99)
Sex (M:F)	15:31
Predisposing condition	
Cerebral injury/dementia	23 (50)
Cardiac disease	6 (13)
Old age (>80 y)	6 (13)
Hepatic/renal disease	5 (11)
Malignancy	5 (11)
Other medical condition[b]	1 (2)
ECOG	
1	12 (26)
2	10 (22)
3	12 (26)
4	12 (26)
Charlson comorbidity index	6 (4–10)
ASA score	
2	28 (61)
3	18 (39)
Access	
Transhepatic	19 (41)
Transperitoneal	27 (59)
Time interval from cholecystostomy to stent, d	16 (0–794)
Follow-up period, months	4 (0–57)

[a]Data are presented as numbers with percentages in parentheses or medians with ranges in parentheses; [b]myasthenia gravis. ASA, American Society of Anesthesia; ECOG, Eastern Cooperative Oncology Group; M, male; F, female.

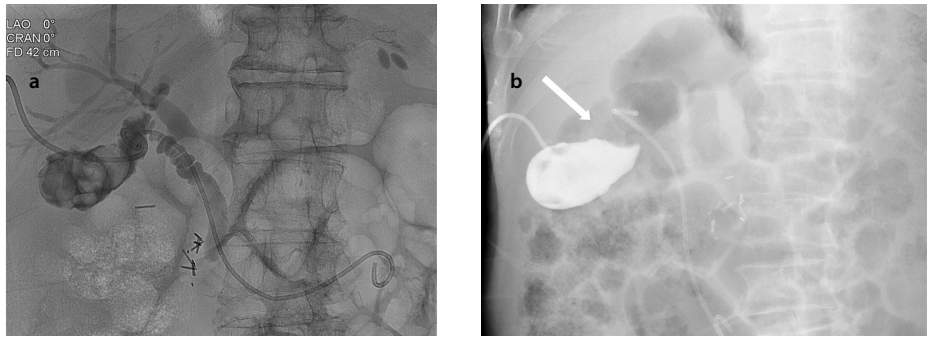

Figure 4. A case of clinical failure. **(a)** An 82-year-old man with gastric cancer and chronic kidney disease successfully underwent cholecystoduodenal stent (polyurethane, 7 Fr 12 cm). **(b)** Follow-up transcatheter cholecystography showing obstruction at the infundibulum by gallstone (arrow); the patient had abdominal pain. The patient was discharged from the hospital with a percutaneous cholecystostomy catheter.

Table 2. Comparison of outcomes for cholecystoduodenal stent placement in patients with acute cholecystitis by stent type

	Total	Polyethylene	Polyurethane	PCB-PU
Number of patients	46	11	14	21
Technical success	39	11	12	16
Clinical success	35	7	12	16
Immediate AE (<30 d)				
Minor	14	6	3	5
Major	2	1[a]	1[b]	0
Delayed AE				
Dislocation	7	3	2	2
Fracture of stent	7	0	7	0
Recurrent cholecystitis	2	0	0	2
Total	16	3	9	4

[a]One patient with pancreatitis; [b]one patient with biloma and peritonitis. AE, adverse event; PCB-PU, polycarbonate-based polyurethane.

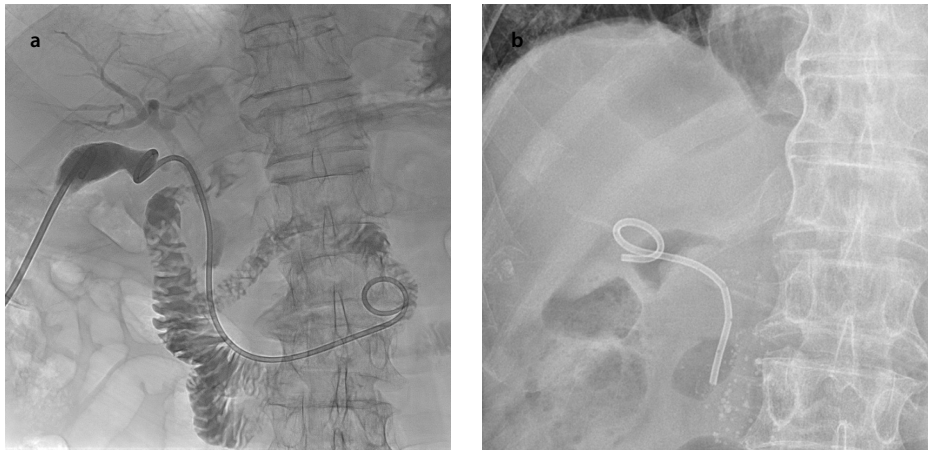

Figure 5. A case of delayed stent fracture. **(a)** A 66-year-old woman with a history of traumatic subdural hematoma received a cholecystoduodenal stent (polyurethane, 6 Fr 20 cm). **(b)** A plain radiograph at a regular 26-month follow-up of stenting showing a stent fracture; however, the patient had no associated symptoms.

access could have a higher risk of AEs such as bile peritonitis. However, rates of technical success (P = 0.424) and AEs (P = 0.215) were not significantly different in transhepatic and transperitoneal access groups. In patients with stent fractures, no fracture-associated symptoms were observed. Stent fractures occurred in the second portion of the duodenum, the stent's most angulated and hinged portion. The fractured distal portion of the stent passed through bowel movement, and proximal portions effectively functioned after the fracture.

Limitations of this study include an indication bias due to its retrospective nature, although we conducted the procedure consecutively. Additionally, the numbers in each patient group were small. Another limitation of this study is that it could be controversial whether side holes and a drawstring in stents help preserve patency and stent placement. The placement of CDS could be beneficial for surgically inapplicable patients. However, cholecystectomy remains a more reliable treatment of cholecystitis for any surgically eligible patients. Therefore, indications for CDS and surgical qualification should be carefully evaluated during the initial and follow-up treatment.

In conclusion, the use of CDSs could be applicable but still needs further investigation in treatment algorithms of acute cholecystitis patients who were initially ineligible for surgery. Although it was not statistically significant, a PCB-PU stent could be suitable for this indication because it tends to have fewer delayed complications and is equipped with a drawstring and side holes.

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Conflict of interest disclosure

The authors declared no conflicts of interest.

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