

Endoscopic transpapillary gallbladder stenting for acute cholecystitis

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Background

Cholecystectomy is the treatment of choice for acute cholecystitis. However, the mortality rate of emergency cholecystectomy in high-risk patients with severe comorbidities remains unsatisfactory. Endoscopic transpapillary gallbladder stenting (ETGBS) has emerged as a useful interventional endoscopic technique for the management of acute cholecystitis.

Aim

The purpose of this research was to assess the safety and effectiveness of ETGBS in the treatment of acute cholecystitis in elderly individuals who were not good candidates for surgery.

Patients and methods

We studied 35 elderly patients, 60 years of age or older, receiving treatment at Aswan University Hospital's surgery department for acute cholecystitis. Every patient had ETGBS, involving the insertion of a 7-Fr stent into the gallbladder. If ETGBS was unsuccessful, percutaneous transhepatic gallbladder drainage was carried out. The effectiveness of ETGBS was the primary outcome measure in this investigation.

Results

ETGBS was successful in 30 (85%) individuals with acute cholecystitis. 8.57% (3/35) of the cases had early adverse events (AEs). Three patients had endoscopic sphincterotomy hemorrhage, one had minor pancreatitis, and one patient experienced obstructive jaundice as early AEs. There were 8.57% (3/35) late AEs. Late AEs included cholangitis in one patient and cholecystitis recurrence in two others. Percutaneous transhepatic gallbladder drainage was used for the five individuals in whom ETGBS failed.

Conclusion

ETGBS appears to be a successful treatment for elderly patients with acute cholecystitis who are unsuitable for surgery.

Keywords:

acute cholecystitis, endoscopic transpapillary gallbladder stenting, percutaneous transhepatic gallbladder drainage

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Introduction

Cholecystectomy is the standard treatment for acute cholecystitis [1,2]. However, in high-risk patients with severe comorbidities such as acute cardiac disease, liver cirrhosis, or considerable medical sickness, the mortality rate of emergency cholecystectomy (about 30%) remains poor [3]. Thus, high-risk individuals are treated with percutaneous transhepatic gallbladder drainage (PTGBD) or percutaneous transhepatic gallbladder aspiration (PTGBA) as a temporary therapy for gallbladder decompression [4–7]. But occasionally, conditions like severe thrombocytopenia, severe coagulopathy, anatomically inaccessible lesions, or the existence of ascites make PTGBA/D procedures inappropriate [8]. Endoscopic transpapillary gallbladder stenting (ETGBS) has recently emerged as an important tool in interventional endoscopy for the treatment of acute cholecystitis, for which emergency cholecystectomy and PTGBD are considered high-risk procedures

[8–12]. This will allow for the correction of defective physiologic parameters while saving the definitive surgery after these have been solved. In patients who are not good surgical candidates, ETGBS may be a feasible long-term management option for symptomatic cholecystolithiasis in addition to being an effective treatment for acute cholecystitis [1,3,13]. The following positive impacts are the causes of the positive ETGBS findings. First, gallstone impaction or migration into the cystic duct is prevented with stents. Second, because bile may flow around clogged stents, they may still offer gallbladder drainage. Third, because the stent straightens the cystic conduit, bile flow may improve. In contrast, the transpapillary method of ETGBS carries a slight risk

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of associated pancreatitis, and conservative treatment can occasionally effectively treat acute cholecystitis without the need for further intervention.

As a result, high-risk patients who are not good candidates for an urgent cholecystectomy require an efficient long-term treatment plan to manage acute cholecystitis. Nonetheless, only a small number of studies have offered thorough long-term ETGBS follow-up study. More research is needed to determine the reasons underlying the excellent patency findings.

Patients and methods

Between March 2023 and October 2023, 35 patients received ETGBS for acute cholecystitis at Aswan University Hospital's department of surgery (19 males and 16 females). The significant risk of coagulopathy, poor physical status, and advanced age of all the patients rendered them unsuitable for an emergency cholecystectomy.

These criteria were used to identify high-risk individuals with acute cholecystitis: (1) individuals with serious health problems that increase the risk of postoperative morbidity and mortality, such as cirrhosis, brain disease, cardiopulmonary disease, cancer, or other serious disorders, (2) patients with a severe bleeding disorder, (3) individuals whose gallbladder is inaccessible or who have anatomical anomalies, (4) individuals with significant ascites, as this is a known contraindication to percutaneous treatment.

The following criteria were used to diagnose acute cholecystitis: (1) the existence of manifestations, (2) abnormalities in laboratory results (white blood cell count and C-reactive protein), and (3) an imaging examinations revealed a dilated gallbladder, thicker gallbladder wall, and pericholecystic fluid (transabdominal ultrasonography and computed tomography). The Tokyo Guidelines (TG) grading system was used to determine the severity of acute cholecystitis.

Technical success of ETGBS was defined as the stent tip remaining in the gallbladder, clinical success was defined as an improving in laboratory test results and clinical complaints within 3 days following Endoscopic transpapillary gallbladder stenting (EGBS). After EGBS, adverse events (AEs) were classified as early if they happened within seven days and late if they happened at least eight days later.

Distal migration of the stent was defined by us to include not only the migration of the stent to the intestine or outside the body, but also the stent tip slipping out of the gallbladder in considerable portions.

Monthly reviews of US and laboratory results, along with an assessment of symptoms, were conducted for ETGBS patients until they died or the termination of the study period.

The patients (or a family member in the case of a brain infarction or dementia patient) provided written informed consent, and the ethics committee of the Aswan University faculty of medicine authorized this study. We have permission to publish all of the content in this article, including the personal data in the tables.

Using a video duodenoscope, endoscopic retrograde cholangiography (ERC) was carried out. Using an over-the-wire endoscopic retrograde cholangiopancreatography (ERCP) cannula and a 0.018, 0.025, or 0.035 inch guidewire, the bile and cystic ducts were cannulated. The guidewire was inserted into the GB via the cannula and progressed retrogradely. A 7Fr stent (10 or 15 cm) was inserted into the GB over this wire.

ETGBS technique

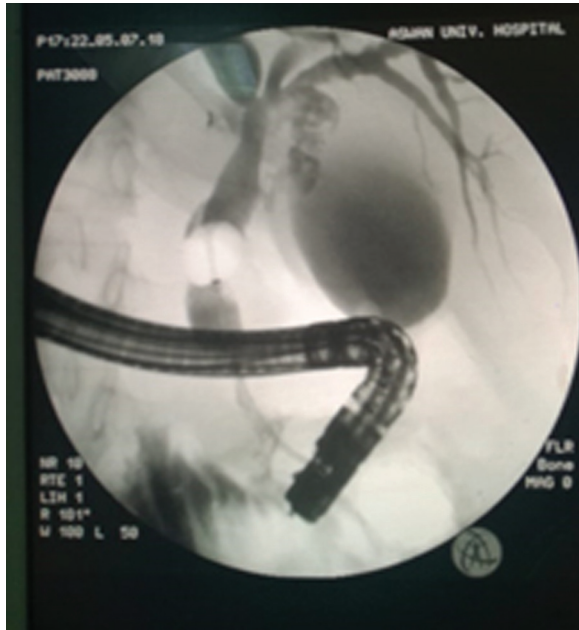
Using a video duodenoscope, ERC was carried out (Fig. 1). Sometime, the opacification of cystic duct and GB needing an occlusion balloon (Fig. 2). Following

Figure 1



Cholangiogram demonstrating opacification of cystic duct.

Figure 2



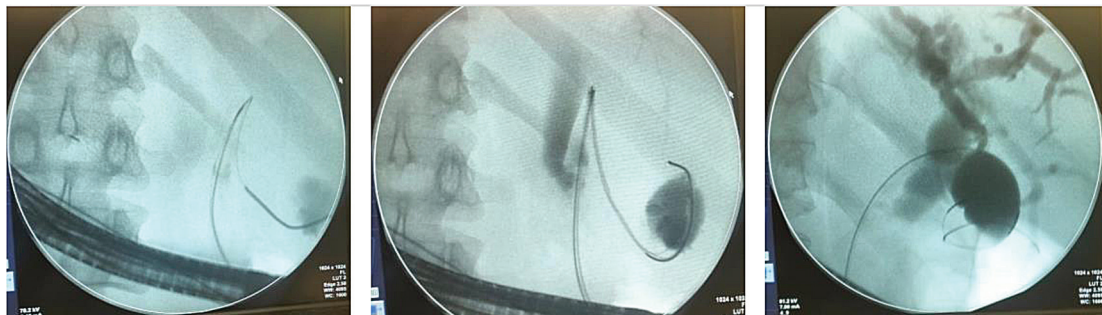
Opacification of cystic duct and gallbladder needing an occlusion balloon.

Figure 3



A hydrophilic guidewire introduced into the cystic duct.

Figure 4



Advancement of guidewire from the cystic duct to the gallbladder (Guidewire coiled into gallbladder).

bile duct cannulation, a hydrophilic GW was introduced into the cystic duct (Fig. 3) and inserted into the GB (Fig. 4). Next, we inserted a 7-Fr tapered catheter with side holes into the gallbladder over the GW, suctioned the bile, and subsequently irrigated the GB with saline (Fig. 5). Finally, we inserted a 7-Fr plastic stent into the GB (Fig. 6).

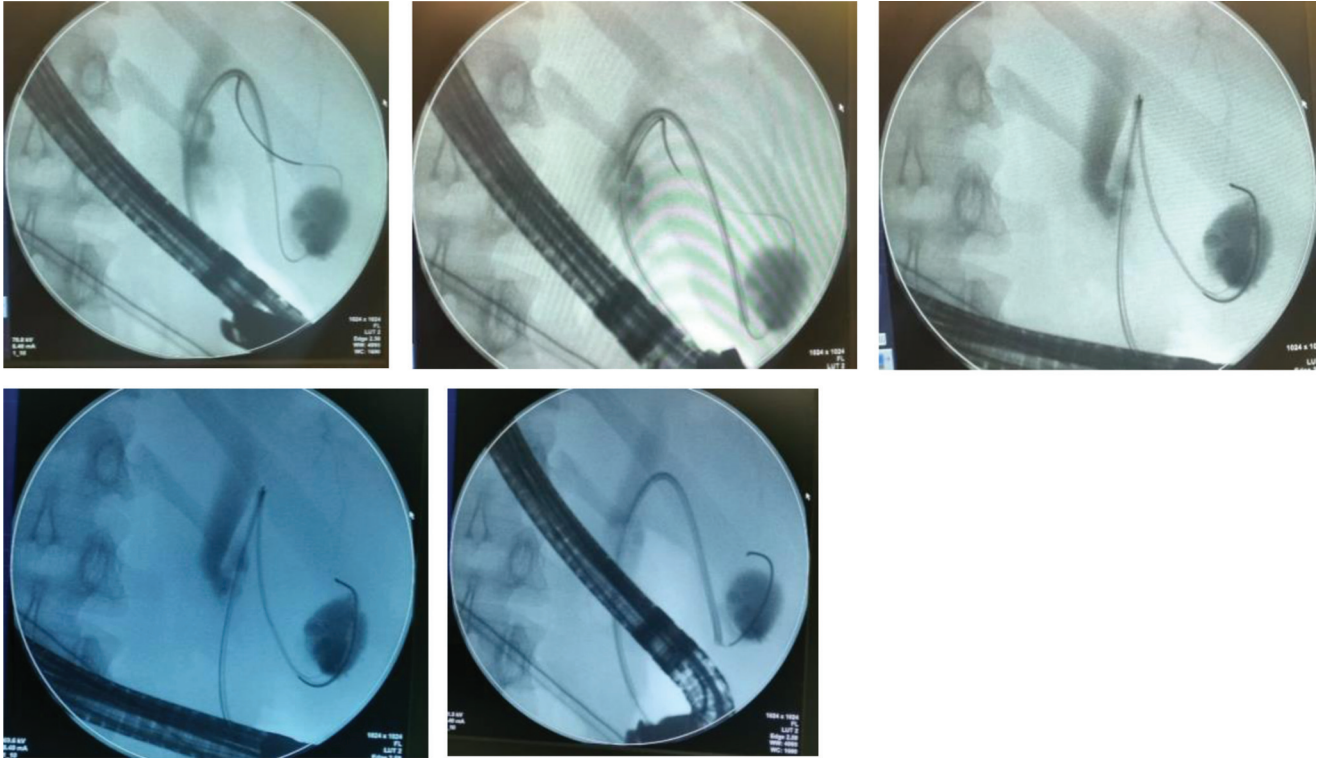
Results

Table 1 displays the features of the 35 individuals. Thirty-five patients who had acute cholecystitis and were not good candidates for cholecystectomy underwent emergency ETGBS. The success rate of ETGBS was 85% in 30 patients, and the procedure took 29.8 ± 12.1 min (mean \pm SD). For all 30 patients, clinical success was attained in less than three days.

Within a week, everyone discharged from the hospital. We gave all 30 patients antibiotics for 3 days following ETGBS. Out of the 30 patients, 21 were monitored without surgery because of their poor general state, and five received cholecystectomy within 2 months following ETGBS. Four individuals died from nonbiliary disorders, including malignant lymphoma (3 months after ETGBS), respiratory failure (2 weeks after ETGBS), heart failure (1 month after ETGBS), and bile duct cancer (2 months after ETGBS).

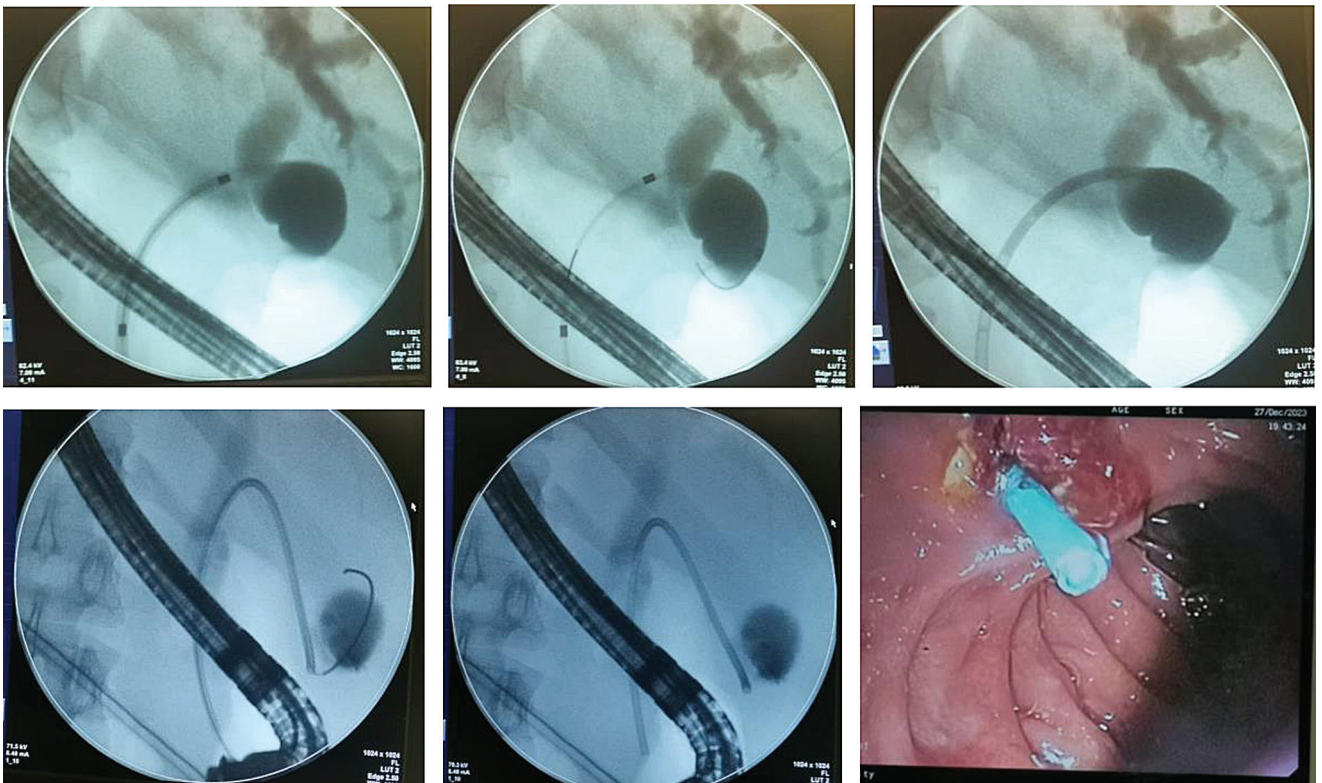
Out of 35 patients, five patients had a failed ETGS due to significant kinking of the cystic duct ($n=2$), full blockage of the cystic duct by stones ($n=2$), or adhesions in the cystic duct ($n=1$). Three of the five patients in whom ETGS failed underwent PTGBD, and two of them underwent repeat PTGBA. Two of

Figure 5



A catheter inserted into the cystic duct and gallbladder over the GW, suctioned the bile, and subsequently irrigated the gallbladder with saline.

Figure 6



Placement of the transpapillary gallbladder plastic stent. The stent extending from the duodenum into the gallbladder.

Table 1 Characteristics of patients

Characteristics	Value
Number of patients	35
Age (median (range))	74 (60-85)
Sex	
Male	19
Female	16
Comorbidities	
-Benign	
1- Poor cerebral condition	4
2- Poor cardiovascular condition	4
3- Poor cerebral and cardiovascular condition	3
4- Poor pulmonary function	2
5- Poor liver function	3
6- Poor renal function	5
7- Cholelithiasis	7
8- Portal hypertension	2
9- Multiorgan failure	1
-Malignant	
1- Bile duct cancer	1
2- Pancreatic cancer	1
3- colon cancer	1
4- Lymphoma	1
Severity grading of acute cholecystitis	
1- I	3
2- II	20
3- III	12

the three patients who received PTGBD underwent cholecystectomy within 2 months, while one died after 1 month due to respiratory failure. Due to their poor overall state, the two patients who received recurrent PTGBA were monitored but did not undergo surgery.

Table 2 presents the specifics of the AEs. There were 8.57% early AEs (3/35). Early AEs included cholestatic jaundice in one patient, endoscopic sphincterotomy (EST) hemorrhage in another, and mild pancreatitis in one patient. Stasis at the papilla resulting from stent implantation without EST induced cholestatic jaundice, further EST improved the condition. All early AEs were alleviated by

Table 2 Outcome and adverse events

Number of patients	35
Technical success	30/35 (85.7%)
Clinical success	30/30 (100%)
Adverse events	
-Early (≤ 7 days) (%)	3(8.57%)
Pancreatitis	1
Bleeding	1
Obstructive jaundice	1
-Delay (> 7 days) (%)	3(8.57%)
Cholangitis	1
Cholecystitis	2
- Total (%)	6(17%)
Follow-up period (days)	180

conservative therapy or endoscopic procedures. During the monitoring period, the rate of late AEs was 8.57% (3/35). One late AE had cholangitis, while two had cholecystitis recurrences. One patient's cholecystitis recurrence was caused by stent migration. The overall rate of early and late AEs was 17% (6/35).

Discussion

Cholecystectomy is the treatment of choice for acute cholecystitis [14,15]. However, in very unwell elderly patients, the mortality rate of emergency cycholecystectomy might reach 30% [16,17]. A number of authors who shared their positive experiences with the percutaneous transhepatic technique brought attention to PTGBD or PTGBA for these unsatisfactory surgical candidates [4-7]. Nonetheless, patients who are unable to tolerate the percutaneous transhepatic route occasionally present (for example, due to anticoagulant/antiplatelet therapy, gallbladder malposition, or disseminated intravascular coagulation). The benefits of PTGBD or PTGBA must be carefully balanced against the risks of biliary leak and the morbidity of intra-abdominal hemorrhage. As a result, ETGBS has been described as a feasible alternative to PTGBD or PTGBA [8,18-20].

Although ETGBS is an alternate procedure when emergency cholecystectomy and PTGBD are considered high risk, it is not without technical challenges [8-12]. The claimed technical success percentage over the past 10 years ranges from 64 to 96%. The intricacy of putting the guide wire into the gallbladder contributes to the technical difficulty of ETGBS. Severe inflammatory strictures, duct tortuosity, impacted stones obstructing the gallbladder's neck, and a cystic duct outlet not showing up on the cholangiogram are some of the reasons that can cause failure [21-29].

The technical success percentage of ETGBS (85.7%) in our investigation was comparable with earlier researches. In smaller series, Feretis *et al.* [18], Toyota *et al.* [19], Kjaer *et al.* [20], and Itoi *et al.* [8] reported 89% (16/18), 82% (18/22), 70.6% (24/34), and 83.7% (38/43) of ETGBS success rates. All 30 (100%) patients with acute cholecystitis in our study experienced clinical success with ETGBS. Five cases occurred where we were unable to implant a stent in the GB due to 2 cases of severe kinking of the cystic duct, one case of cystic duct adhesion, and two cases of cystic duct obstruction by stones.

Additionally, since purulent debris, sludge, or gallstones accumulate and obstruct efficient drainage, the clinical success rate with ETGBS has been observed to be about 10% lower than the technical success rates [30–32]. Clinical success rates in this study were 100% for cases where ETGBS was technically successful, which is quite favorable. This positive result was probably caused by the gallbladder being irrigated with saline through a catheter and viscous bile being suctioned out before the stent was implanted.

Research on ETGBS has demonstrated a positive clinical result up to three years following stent implantation, negating the necessity for stent replacement on a regular basis [1,33]. At least 80% of the 20 patients undergoing ETGBS maintain stent patency without needing stent exchange for at least 2 years, according to a prospective follow-up study conducted by Lee *et al.* [3]. We conducted ETGBS on 30 elderly individuals in the current series. Consequently, during the course of their survival or follow-up period, 28 (93.3%) patients did not experience a cholecystitis recurrence. After three months of follow-up, there were no late problems in 27 patients. Explaining the ETGBS procedure's success is necessary. The primary cause of acute cholecystitis is unquestionably cystic duct blockage by stone. By filling the cystic duct's lumen and avoiding stone impaction, stents are believed to offer protection against recurrent cholecystitis [13]. Additionally, it has been proposed that stents may continue to drain the bile duct even in the event of stent obstruction by means of a 'wicking' process, in which bile flows around the stents [13]. It is also possible that the stent will stop bile from flowing into the cystic duct from the common hepatic duct.

The rate of early AEs in our series was 8.57% (3/35). One patient experienced mild pancreatitis, another experienced EST hemorrhage, and a third patient experienced obstructive jaundice as early AEs. Nonetheless, even if ETGBS is therefore generally safe, post-ERCP pancreatitis must be avoided with caution. Because of defective coagulation, EST is frequently not possible in patients receiving ETGBS; yet, stent implantation without EST may result in bile outflow obstruction at the papilla. One case of obstructive jaundice due to cholestasis at the papilla was included in our investigation. This is believed to be the result of stent placement without EST, and improvement was shown with additional EST. Conservative treatment or endoscopic procedures improved all of the early AEs.

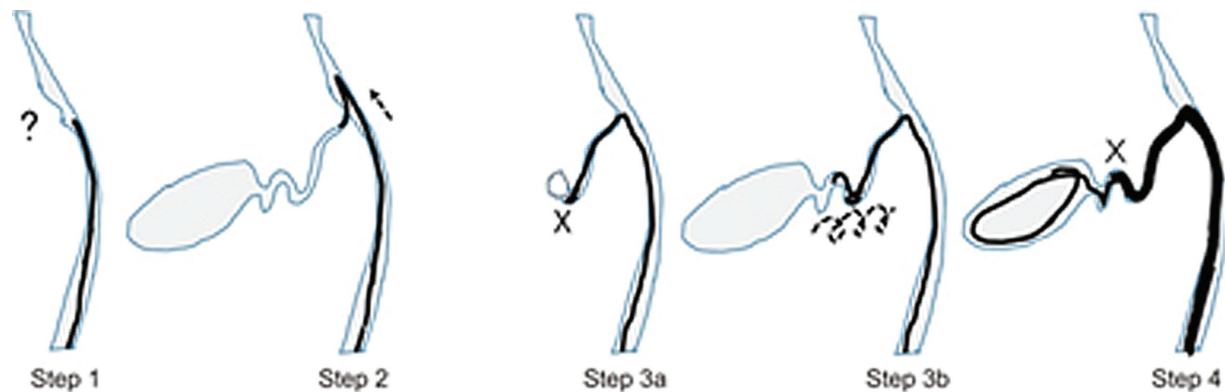
GB perforation happened in 2% of patients who had this method of therapy, according to Pannala *et al.* [34]. There have been reports of additional AEs, such as stent migration and cholangitis. According to Lee *et al.* [3], two patients experienced spontaneous distal migration seven months following ETGBS with EST, while one patient who received ETGBS without EST experienced choledocholithiasis-related cholangitis 19 months following the treatment. One patient in our study experienced spontaneous stent distal migration 1 month following ETGBS.

Of the participants in our study, only three experienced late problems. A patient experienced a recurrence bout of cholecystitis 2 months following ETGBS as a result of stent blockage. We believed that the stent's insertion without using saline to flush the GB of any sludge was most likely the reason for the occlusion that happened after 2 months. Since we repeatedly cleaned the GB with 20 ml of sterile saline after ETGBS was conducted, we did not experience recurring cholecystitis caused by stent occlusion after that. After 1 month of ETGBS, a second patient experienced a recurrence episode of cholecystitis as a result of the stent migrating distally due to significant intestinal peristalsis. Consequently, since the previous stent had only reached the gallbladder's neck, we placed the new one all the way to the fundus. This could help to explain why, while performing ETGBS, the gallbladder must be thoroughly cleaned multiple times with sterile saline and have a stent inserted all the way to the fundus in order to prevent stent migration and occlusion. A cholangitis without cholecystitis necessitated the removal of the stent in one patient 3.5 months following ETGBS. Since the patient was on antiplatelet therapy, EST was not performed, which may have resulted in insufficient flow in the common bile duct, which was the primary cause of cholangitis. If it is feasible, we advise executing EST; if not, we advise opening the stent side holes to provide sufficient flow in the common bile duct following ETGBS.

The study's technical success rate of 85.7% for ETGBS may support its continued clinical application for older individuals with acute cholecystitis who are not good candidates for surgery. We believe that patients with acute cholecystitis, for whom the transhepatic route is not appropriate, are the best candidates for ETGBS.

Our study is limited by the small populations studied and the omission of patients with acalculous cholecystitis. The Mutignani M *et al.* study reported no statistical significance in the success rate of ETGBS

Figure 7



Four-Step Classification: classification based on the steps of Endoscopic transpapillary gallbladder stenting. The Endoscopic transpapillary gallbladder stenting procedure is classified according to the steps at which failure can occur, as follows; step 0, step 1, step 2, step 3a, step 3b, and step 4.

between those presented with calculous cholecystitis versus those with noncalculous type [35].

Michihiro Yoshida and colleagues [36] divided the ETGBD procedure into sequential phases to detect when the ETGBD failed and was abandoned, as follows: step 0, inability to cannulate the common bile duct (CBD); step 1, inability to locate the opening of the cystic duct; step 2, due to an unsuitable angle, the guidewire was unable to proceed over the cystic duct; step 3a, guidewire entry to the GB is unsuccessful because of a cystic duct blockage. (inflammation, malignancy, or impaction of stones); step 3b, guidewire entry to the GB is unsuccessful because of many tortuosities; and step 4, inability to put the stent or drainage tube into the GB. (Fig. 7) [36].

ETGBD, endoscopic transpapillary gallbladder drainage; CD, cystic duct; GW, guidewire; GB, gallbladder [36].

Conclusion

ETGBD appears to be a successful treatment for elderly patients with acute cholecystitis who are unsuitable for surgery, but only as a temporary measure.

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Conflicts of interest

Disclosure: the authors report no conflict of interest in the materials or methods used in this study or the findings specified in this paper.

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