

Endoscopic ultrasound-guided transmural stenting for gallbladder drainage in high-risk patients with acute cholecystitis: a systematic review and pooled analysis

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Abstract

Background Endoscopic ultrasound-guided transmural stenting for gallbladder drainage is an emerging alternative for the treatment of acute cholecystitis in high-risk surgical patients. A variety of stents have been described, including plastic stents, self-expandable metal stents (SEMSs), and lumen-apposing metal stents (LAMSs). LAMSs represent the only specifically designed stent for transmural gallbladder drainage. A systematic review was performed to evaluate the feasibility and efficacy of EUS-guided drainage (EUS-GBD) in acute cholecystitis using different types of stents.

Methods A computer-assisted literature search up to September 2015 was performed using two electronic databases, MEDLINE and EMBASE. Search terms included MeSH and non-MeSH terms relating to acute cholecystitis, gallbladder drainage, endoscopic gallbladder

drainage, endoscopic ultrasound gallbladder drainage, alone or in combination. Additional articles were retrieved by hand-searching from references of relevant studies. Pooled technical success, clinical success, and adverse event rates were calculated.

Results Twenty-one studies met the inclusion criteria, and the eligible cases were 166. The overall technical success rate, clinical success rate, and frequency of adverse events were 95.8, 93.4, and 12.0 %, respectively. The technical success rate was 100 % using plastic stents, 98.6 % using SEMSs, and 91.5 % using LAMSs. The clinical success rate was 100, 94.4, and 90.1 % after the deployment of plastic stents, SEMSs, and LAMSs, respectively. The frequency of adverse events was 18.2 % using plastic stents, 12.3 % using SEMSs, and 9.9 % using LAMSs.

Conclusions Among the different drainage approaches in the non-surgical management of acute cholecystitis, EUS-guided transmural stenting for gallbladder drainage appears to be feasible, safe, and effective. LAMSs seem to have high potentials in terms of efficacy and safety, although further prospective studies are needed.

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Acute cholecystitis is a frequent event in clinical practice, and urgent or emergent surgery represents the standard approach. Conservative treatment is the choice in poor surgical candidates; however, in such patients a delay in surgery is associated with increased risk of sepsis and mortality [1]. Non-surgical drainage is an alternative option that can be used either as a bridge for subsequent surgery or as a definitive treatment in patients who remain unfit for

surgery. Therapeutic non-surgical approaches include percutaneous cholecystostomy, transpapillary drainage of the gallbladder, and EUS-guided transmural gallbladder stent placement [2].

Percutaneous cholecystostomy (PC), including percutaneous transhepatic gallbladder drainage (PTGBD) and aspiration (PTGBA), is the most established and performed technique. This approach has shown to resolve acute cholecystitis in approximately 90 % of patients and to be particularly useful for patients who cannot undergo a surgical intervention [3]. PC allows source control of infection, while bile samples can be obtained for microbiological analysis and culture sensitivity [4]. US is the modality of choice for image-guided PC as it is a relatively simple technique and can be used in bedridden patients. However, adverse events may occur in up to a quarter of patients undergoing PC with biliary peritonitis, bleeding, pneumothorax, and complications derived from premature tube removal being the most frequent and most dreadful. Moreover, cholecystostomy tubes are uncomfortable and have a negative impact on quality of life [5].

Endoscopic transpapillary gallbladder drainage (ETGBD) represents an alternative to percutaneous cholecystostomy with the placement of either a nasogallbladder drainage (ENGBD) tube or a double-pigtail stent (EGBS) as an internal drainage during ERCP. ETGBD can be performed in patients with advanced liver disease, ascites, or coagulopathy. Disadvantages of this approach include technical difficulty of the selective cystic duct cannulation, risk of post-ERCP pancreatitis, and increased risk of clogging of smaller (e.g., 7 Fr) stents [1].

Concomitantly to the progress on EUS-guided drainage of extraluminal collections (e.g., abscesses, pancreatic pseudocysts), a rapid evolution of endoscopic transmural access to the gallbladder has occurred. Transmural EUS-guided gallbladder drainage (EUS-GBD), firstly described in 2007 [6], has been recently reported as the most viable alternative to percutaneous cholecystostomy. The gallbladder is usually apposed to the gastrointestinal tract and imaged under EUS from the distal gastric antrum or the duodenal bulb with a therapeutic linear array echoendoscope. Then a needle is introduced into the gallbladder and a guidewire positioned, which allows the insertion of a nasogallbladder tube or internal stent.

A variety of plastic stents (straight, single, and double pigtail) and self-expandable metal stents (SEMSs) have been used during EUS-GBD with similar treatment outcomes. However, plastic and SEMSs are tubular stents not specifically designed for EUS-guided gallbladder drainage procedures, with bile leakage, stent occlusion, and migration as possible adverse events. In order to overcome these limitations, modified stents with flared ends and lumen-apposing metal stents (LAMSs) have been introduced [7].

Based on the present data, it remains unclear which type of stent may be more appropriate for the EUS-guided treatment of acute cholecystitis. To our knowledge, there is no published analysis comparing the efficacy of different types of stents for the transmural EUS-guided gallbladder drainage. In this study, we conducted a systematic review of the literature and compared the efficacy of plastic stents, SEMSs, and LAMSs in high-risk patients with acute cholecystitis.

Materials and methods

Search strategy and study selection

A comprehensive computer-assisted literature search of articles published up to September 2015 was conducted from 2 computerized databases, MEDLINE and EMBASE. Search terms included MeSH and non-MeSH terms relating to acute cholecystitis, gallbladder drainage, endoscopic gallbladder drainage, endoscopic ultrasound gallbladder drainage, alone or in combination. Additional articles were retrieved by hand-searching through references of relevant studies. Only publications in English were included. Initial screening, in order to remove duplicated and non-relevant articles, was undertaken by two independent authors (AB and FV). Predefined criteria were used to determine eligibility for inclusion. Any disagreement was settled by a third author (AR). We included studies of any design on EUS-guided gallbladder drainage techniques in patients with acute cholecystitis who required gallbladder decompression and were unfit for surgery as a consequence of their advanced age or underlying diseases (high surgical risk). Acute cholecystitis was defined by clinical, laboratory, and imaging findings [2]. We then selected only cases where EUS-GBD was performed by transmural stenting as a temporary or definite non-surgical measure. Since in our analysis we focused on internal transmural gallbladder drainage, studies or cases where EUS-GBD was performed by nasobiliary drainage were excluded. Cases of gallbladder decompression for malignant obstruction were excluded. Data on stent type and access route to the gallbladder were also collected.

Data were extracted in a Microsoft Excel database that included predefined field selected in order to record all the relevant aspects of the studies included in the analysis. Copies of all articles identified as potentially relevant were obtained and authors contacted as necessary.

Outcome measures

We evaluated technical success, clinical success, adverse events, and mortality rate for each type of stent. The

following definitions were applied: (1) Technical success of EUS-guided gallbladder drainage was defined as successful stent deployment between the duodenum or the stomach and the gallbladder; technical success rate was calculated according to an intention-to-treat analysis; (2) clinical success was defined as resolution of acute cholecystitis [2]; clinical success rate was calculated according to an intention-to-treat analysis; (3) adverse events were classified according to ASGE guidelines and divided as procedural (within 2 weeks) or late (≥ 2 weeks after stent placement) [8]; and (4) procedure-related mortality was defined as mortality related to the procedure within 30 days from stent deployment. Outcome measures were also evaluated after excluding data from case reports and case series with only two patients.

Statistical methods

Since randomized controlled trials on this topic were missing and the design of the published studies was mixed, we were unable to perform a formal meta-analysis. Data for EUS-guided gallbladder drainage using plastic stents, SEMs, and LAMSs were analyzed, and the outcome measures were estimated by pooling the raw counts from each study. Therefore, pooled rates and their 95 % confidence intervals should be taken as descriptive only. We calculated an exact binomial 95 % confidence interval (CI) for each rate. Differences between groups were compared using Chi-squared tests, and two-sided p values < 0.05 were defined as statistically significant.

Results

The results of the search strategy have been summarized in Fig. 1. Twenty-one studies met the inclusion criteria. Supplementary Table S1 shows the characteristics of the studies included, and Appendix 1 the search algorithms used. Eight (38 %) were case reports, and only two studies had a prospective design. A total of 166 cases were analyzed, most of them derived from retrospective studies (108/166, 65 %). Overall technical and clinical success rates were 95.8 % (159/166) and 93.4 % (155/166), respectively; the frequency of non-fatal adverse events was 12.0 % (20/166). There was no procedure-related mortality. Data on the choice of approach to access the gallbladder were available from 151 cases with a transgastric approach used in 65 patients (43 %) and a transduodenal route in 86 patients (57 %).

EUS-GBD using plastic stents was reported in 1 small prospective study (8 cases), 1 retrospective study, 3 case series with less than 5 patients, and 3 case reports with a total of 22 cases. EUS-guided transmural gallbladder

stenting with SEMs was reported in 5 studies with a total of 85 cases. However, since 15 patients prospectively studied by Jang et al. [9] were included in a subsequent retrospective study [10], we decided to remove these cases from our analysis. There were 9 studies (4 case reports on only one patient) describing the feasibility and safety of LAMSs for EUS-GBD in acute cholecystitis, with a combined total of 71 patients.

EUS-guided transmural gallbladder drainage by plastic stents

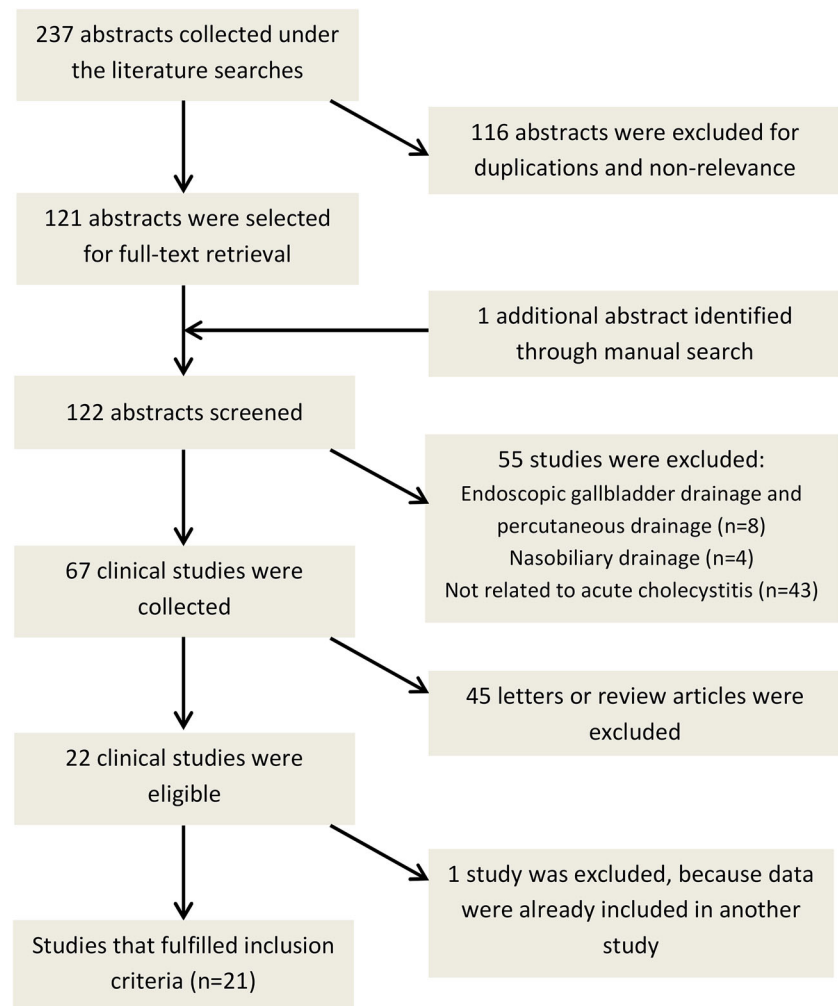
The reported results are shown in Table 1. The pooled technical and clinical success rate using plastic stents in 22 cases was 100 % (95 % CI, 0.846–1). The frequency of adverse events ranged from 0 to 37.5 %, with a pooled adverse event frequency of 18.2 % (4/22). The reported adverse events included 3 procedural adverse events (pneumoperitoneum, bile leakage, and bile peritonitis) and 1 late adverse event (stent migration) (Table 4). When we analyzed data after excluding case reports and case series with only 2 patients, we obtained the same rates for the outcome measures considered.

EUS-guided transmural gallbladder drainage by SEMs

Outcomes obtained using SEMs are reported in Table 2. The pooled technical and clinical success rates were 98.6 % (95 % CI, 0.926–1) and 94.4 % (95 % CI, 0.866–0.985), respectively. A fully covered SEM (CSEM) was placed in 10 patients (13.6 %), whereas 63 patients (86.4 %) underwent a partially covered SEM (PCSEM) placement. Clinical success rate was significantly greater for PCSEM compared to CSEM (98 vs 70 %, $p < 0.001$). The frequency of adverse events ranged from 0 to 33.3 %, with a pooled adverse event rate of 12.3 % (9/73). Adverse events occurred more commonly in the CSEM group although the difference did not reach statistical significance (33.3 vs 11.2 %, $p = 0.34$). Procedural adverse events included pneumoperitoneum and duodenal perforation; late adverse events were stent migration and worsening of cholecystitis due to stent occlusion (Table 4). After excluding case reports outcome measures showed a similar pattern (Table 2).

EUS-guided transmural gallbladder by LAMS

Table 3 summarizes the reported outcomes of EUS-GBD using LAMS. The pooled technical and clinical success rates were 91.5 % (95 % CI, 0.825–0.968) and 90.1 % (95 % CI, 0.807–0.959), respectively. The frequency of adverse events ranged from 0 to 15.4 %, with a pooled

Fig. 1 Flow diagram on the literature search

adverse event frequency of 9.9 % (7/71). Only procedural adverse events were reported, including abdominal pain, bleeding, infections, and fever. Equally to SEMS, when case reports were excluded from the analysis, technical success, clinical success, and adverse event rate did not differ significantly and showed a similar trend.

Discussion

EUS-guided transmural gallbladder drainage has recently emerged as an alternative to percutaneous cholecystostomy in high-risk patients with acute cholecystitis. Both EUS transmural nasogallbladder drainage and gallbladder stenting have been shown to be comparable to PTGBD with feasibility and clinical success in more than 95 % of cases [5, 7]. In this review, we focused on EUS-GBD by transmural stenting, and indeed, our results confirmed the technical feasibility and the efficacy of this approach (95.8 and 93.4 %, respectively). Nasobiliary drainage has been

proposed as a bridge to surgery in some patients: It allows the decompression of the gallbladder from the infected fluid and to rinse the gallbladder with sterile saline [10, 11]. However, tube dislodgment and patient discomfort represent main disadvantages [7].

Although transmural endoluminal stenting has the important advantage of avoiding external drainage, serious procedure-related complications such as bile leakage and stent migration have been reported. A variety of stents have been used in order to overcome these limitations. However, no comparative studies exist and it is unclear from the current literature whether the clinical success and frequency of adverse events depend on the type of stent (Table 4).

The results from our systematic review show that outcome measures are remarkably high and comparable among the different types of stents considered. Pooled technical success rates for plastic stents, SEMSs, and LAMSs were 100, 98.6, and 91.5 %, respectively. Similarly, pooled clinical success rates were more than 90 % for

Table 1 Outcomes of EUS-GBD by plastic stents

Author (year)	Design	No. of cases	Mean age	Technical success, no. (%)	Clinical success, no. (%)	Procedural AEs, no. (%)	Late AEs, no. (%)	Total AEs, no. (%)	Mean follow-up (days)	Transgastric/duodenal
Baron et al. [6]	CR	1	74	1 (100)	1 (100)	0	0	0	77	0–1
Kwan et al. [11]	CS	3	48	3 (100)	3 (100)	1 (33.3)	0	1 (33.3)	42	1–2
Kamata et al. [17]	CR	1	71	1 (100)	1 (100)	0	0	0	183	1–0
Takasawa et al. [24]	CR	1	71	1 (100)	1 (100)	0	0	0	N/A	1–0
Subtil et al. [25]	CS	4	N/A	4 (100)	4 (100)	0	0	0	365	N/A
Song et al. [26]	P	8	71.4	8 (100)	8 (100)	2 (25)	1 (12.5)	3 (37.5)	186 (median)	1–7
Itoi et al. [27]	CS	2	N/A	2 (100)	2 (100)	0	0	0	137	1–1
Attasaranya et al. [28]	R	2	N/A	2 (100)	2 (100)	0	0	0	102	N/A
Total, no (%), 95 % CI)		22		22/22 (100 %, 0.85–1)	22/22 (100 %, 0.85–1)	3/22 (13.6 %)	1/22 (4.5 %)	4/22 (18.2 %, 0.05–0.4)		5–10
Total excluding CRs and CS [24]		17		17/17 (100 %, 0.80–1)	17/17 (100 %, 0.80–1)	3/17	1/17	4/17 (23.5 %, 0.06–0.49)		2–8

CR case report, CS case series, P prospective, R retrospective, AEs adverse events, N/A not applicable

all types of stents (100, 95.5, and 90.1 % for plastic stents, SEMS, and LAMS, respectively).

The 100 % technical and clinical success rate reported for plastic stents is probably an overestimation, since data are available only from case reports and small case series including only two patients, which are commonly subject to publication bias. Moreover, the majority of these studies focused on immediate technical feasibility and reported only short-term outcomes. Although the analysis of case reports performed is inherently limited and difficult to generalize, the use of plastic stents has been largely abandoned in recent years and therefore it is unlikely that other studies on EUS-GBD using this type of stent will be published. In contrast, reports and studies on the feasibility and efficacy of EUS-GBD with SEMS have been increasingly published [9, 10, 12–14]. In our study, the use of SEMSs demonstrated pooled rates of technical success and clinical efficacy of more than 90 %. Furthermore, excellent long-term outcomes of EUS-GBD with SEMSs have been shown in a retrospective study with no recurrence of cholecystitis in 96.4 % of cases and a reintervention rate of 3.6 % during a median follow-up of 275 days [10].

Potential advantages of metal stents over plastic stents are larger caliber, adjustable deployment, and the immediate sealing of the transmural fistulous tract after stent

expansion [7, 10]. However, high risk of stent migration is an important limitation of SEMS when they are used for transmural drainage, especially for CSEMS. In order to avoid this complication, modified covered SEMSs have been developed by enlarging and bending the flared ends (BONA-AL stent, Standard Sci-Tech, Seoul, Korea; NAGI stent Taewoong, Seoul, Korea). PCSEMSs have been also introduced (BONA-AL stent, Standard Sci-Tech, Seoul, Korea). The uncovered flared ends have been shown to prevent stent migration by tissue ingrowth. Indeed, although CSEMSs were used in relatively few patients, in our analysis the clinical success rate was higher with PCSEMS compared to CSEMS. However, drawbacks of PCSEMS are that uncovered ends can potentially cause mucosal injury, bleeding, and stent embedding [15]. LAMSs (AXIOS, Boston Scientific Corp Natick, MA, USA) are fully covered self-expandable metal stents with bilateral flanges specifically designed for EUS-guided, transenteric drainage of pseudocyst, or non-adherent fluid collection. The design of these stents should provide a robust lumen anchorage, overcoming the limitations of tubular stents [16]. Furthermore, the large diameter of LAMSs (10 and 15 mm) may allow access to the gallbladder with a slim endoscope with the purpose of removing stones [14, 17, 18] or taking biopsies [19]. In our

Table 2 Outcomes of EUS-GBD by SEMS

Author (year)	Design	No. of cases	Mean age	Technical success, no. (%)	Clinical success, no. (%)	Procedural AEs, no. (%)	Late AEs, no. (%)	Total AEs, no. (%)	Mean follow-up (days)	Transgastric/duodenal
Widmer et al. [12]	CS	3	N/A	3 (100)	2 (66.7)	0	0	0	152	3–0
Ogura et al. [13]	CR	1	71	1 (100)	1 (100)	0	0	0	183	0–1
Choi et al. [10]	R	63	N/A	62 (98.4)	62 (98.4)	3 (4.8)	4 (6.3)	7 (11.2)	275 (median)	33–30
Kedia P et al. [14]	R	6	N/A	6 (100)	4 (66.7)	1 (16.7)	1 (16.7)	2 (33.3)	264	0–6
Total, no. (%), 95 % CI)		73		72/73 (98.6 %, 0.93–1)	69/73 (94.5 %, 0.87–0.98)	4/73 (5.5 %)	5/73 (6.8 %)	9/73 (12.3 %, 0.06–0.22)		36–37
Total excluding case reports		72		71/72 (98.6 %, 0.92–1)	68/72 (94.4 %, 0.86–0.98)	4/72 (5.6 %)	5/72 (6.9 %)	9/72 (12.5 %, 0.05–0.22)		36–36

CR case report, CS case series, R retrospective, AEs adverse events, N/A not applicable

analysis, LAMS placement was technically successful in 91.5 % of patients and clinical success was achieved in 90.1 %.

The trend toward a reduced technical and clinical success of LAMSs compared to SEMSs could be attributed to the learning curve associated with placement of this new system. Common intraprocedural failures are related to difficult insertion or uncontrolled stent release; successful management by an additional insertion of a second SEMS in order to ensure a proper drainage and positioning has been described with clinical success [18, 20, 21]. LAMS deployment is a two-step procedure with exchange of the access device with the stent delivery catheter over the guidewire. Recently, a novel cautery-tipped stent delivery system has been introduced (Hot AXIOS, Boston Scientific Corp Natick, MA, USA); this new system allows single-step gallbladder stenting without prior needle puncture or guidewire insertion [22] reducing the risk of technical problems. Another advantage of this single-step delivery system is that the procedure can be effectively performed at bedside without X-ray guidance [23].

According to our literature review, the incidence of procedure-related adverse events of EUS-guided transmural drainage is relatively low (12.0 %). Metal stents showed advantages over plastic stents as they were associated with a decreased risk of bile leakage and stent occlusion. When the two types of SEMS used for EUS-GBD were compared, adverse events rate did not differ significantly between CSEMS and PCSEMS, although there was a trend in favor of PCSEMS. However, one potential drawback is represented by fact that most of the patients treated with SEMS come from a single study using PCSEMS and data, particularly on the adverse events rate, should be interpreted cautiously.

The introduction of new devices and techniques appears to reduce complication rates. LAMSs have a dedicated design for transmural drainage making the procedure faster and more effective, with an overall procedural adverse event rate of 9.9 %. However, LAMS deployment is challenging even in expert hands and the learning curve is an important issue to be considered.

In EUS-GBD, the gallbladder can be accessed by either a transduodenal or transgastric approach, and in our analysis, these different routes were similarly used when the whole population was considered. Unfortunately, because of a lack of detailed information on individual cases in most of the studies, no enough data were available to evaluate the efficacy and safety between these two approaches.

Our review has several limitations. First, we acknowledge a publication bias derived from the inclusion of case reports. However, results obtained after excluding case reports and small case series did not differ significantly, showing a similar trend. Second, plastic stents have been

Table 3 Outcomes of EUS-GBD by LAMS

Author (year)	Design	No. of cases	Mean age	Technical success, no. (%)	Clinical success, no. (%)	Procedural AEs, no. (%)	Late AEs, no. (%)	Total AEs, no. (%)	Mean follow-up (days)	Transgastric/duodenal
Itoi et al. [29]	R	5	54	5 (100)	5 (100)	0	0	0	152	1–4
De la Serna-Higuera et al. [18]	R	13	79.9	11 (84.6)	11 (84.6)	2 (15.4)	0	2 (15.4)	101	10–3
Turner et al. [30]	CR	1	81	1 (100)	1 (100)	0	0	0	N/A	0–1
Monkemuller et al. [31]	CR	1	86	1 (100)	1 (100)	0	0	0	N/A	1–0
Teoh et al. [22]	CR	1	85	1 (100)	1 (100)	0	0	0	90	0–1
Moon et al. [19]	R	7	N/A	7 (100)	7 (100)	0	0	0	152	N/A
Teoh et al. [32]	CR	1	87	1 (100)	1 (100)	0	0	0	90	N/A
Walter et al. [20]	P	30	85	27 (90)	26 (86.7)	4 (13.3)	0	4 (13.3)	298	11–19
Irani et al. [21]	R	12	74 (median)	11 (91.7)	11 (91.7)	1 (8.3)	0	1 (8.3)	365	1–11
Total, no. (%), 95 % CI)		71		68/71 (91.5 %, 0.83–0.97)	64/71 (90.1 %, 0.80–0.95)	7/71 (9.9 %)	0/71	7/71 (9.9 %, 0.04–0.19)		24–39
Total excluding case reports		67		61/67 (91.0 %, 0.81–0.97)	60/67 (89.6 %, 0.80–0.96)	7/67 (10.4 %)	0/67	7/67 (10.4 %, 0.04–0.20)		23–37

CR case report, CS case series, R retrospective, P prospective, AEs adverse events, N/A not applicable

Table 4 Procedural and late adverse events

Adverse events	Plastic stents	SEMSs	LAMSs
Pneumoperitoneum	1	2	–
Bile peritonitis	1	–	–
Bile leakage	1	–	–
Stent migration	1	3	–
Duodenal perforation	–	1	–
Worsening of cholecystitis due to stent occlusion	–	3	–
Right abdomen pain	–	–	1
Infections	–	–	2
Bleeding	–	–	3
<i>Hematochezia</i>			
<i>Melena/Hemobilia</i>			
Fever	–	–	1
Total	4/22 (18.2 %)	9/73 (12.3 %)	7/71 (9.9 %)

recently replaced in favor of SEMS, and theoretically, their inclusion in our analysis could be questionable. However, EUS-GBD for the treatment of acute cholecystitis has rapidly evolved in the last decade and plastic stents represent the main type used in the early experience of this procedure. Third, prospective long-term procedural outcomes are available only from a limited number of studies. Fourth, since methods and devices for EUS-GBD are not yet standardized and considerable heterogeneity exists among patients from different studies, no comparative analysis can be performed. Mixed design of the studies and the lack of randomized, controlled trials prevented performance of a formal meta-analysis.

In conclusion, EUS-guided transmural gallbladder drainage is emerging as an attractive alternative to PTGBD for the management of acute cholecystitis in surgical high-risk patients. A recognized advantage is the avoidance of external drainage, and rates of technical and clinical success appear to be similar. Appropriate stent selection is crucial, and the new generation of dedicated devices has the potential for further improve the feasibility and safety. Comparative controlled studies are required to confirm these results in terms of long-term outcomes and cost-effectiveness.

Compliance with ethical standards

Disclosures Dr. Khashab is a consultant for Boston Scientific and Xlumen. Dr. Repici is a consultant for Boston Scientific. Drs. Anderloni, Buda, Vieceli, Hassan have no conflicts of interest or financial ties to disclose.

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