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Review Article

Recent development of endoscopic ultrasound-guided gallbladder drainage

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ABSTRACT

Endoscopic ultrasonography-guided gallbladder drainage (EUS-GBD) has emerged as a promising alternative treatment to high-risk patients suffering from acute cholecystitis and are unfit for surgery. EUS-GBD has similar rates of technical and clinical success compared to other alternative treatments, but the procedure has been shown to reduce adverse event rates and the need for repeated interventions. This review aims to provide a summary of the recent development in the EUS-GBD technique with various devices employed in the procedure.

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Keywords: Acute cholecystitis; Endoscopic ultrasonography-guided gallbladder drainage; Malignant biliary obstruction; Percutaneous cholecystostomy

Introduction

Laparoscopic cholecystectomy (LC) is the treatment of choice for patients suffering from acute cholecystitis (AC). In patients that are at very high risk for cholecystectomy, temporary drainage of the gallbladder may be required.¹ Conventionally, the gallbladder could be drained by two approaches, namely, percutaneous transhepatic gallbladder drainage (PT-GBD) and endoscopic transpapillary gallbladder drainage (ET-GBD).^{1,2} PT-GBD is associated with several short and long term issues including dysfunctional cholecystostomy tube (46%) and recurrence of AC (41%) requiring repeated interventions (28%).^{3,4} Meanwhile, ET-GBD is associated with a lower success rate when compared to PT-GBD but avoids the presence of an external tube.² Thus, an alternative approach of draining the gallbladder with higher technical success and lower adverse events rate is required.

Since 2007, endoscopic ultrasonography-guided gallbladder drainage (EUS-GBD) has emerged as the third alternative for draining the gallbladder in AC. EUS-GBD has been reported to be more advantageous than PT-GBD with reduced adverse events, number of re-interventions, hospital stay, postprocedural pain scores and fewer unplanned admissions whilst the clinical and technical success rates are comparable.^{5,6} In 2018, the revised

Tokyo Guideline has included EUS-GBD as one of the treatment modalities for non-surgical management of AC.¹ Moreover, there are some variations in the technique of EUS-GBD to incorporate different types of puncture routes, stents and stent delivery systems. In this review, we describe the latest techniques and advancements of EUS-GBD.

Indications

There are several potential indications for EUS-GBD. Firstly, EUS-GBD could be offered as an option for gallbladder drainage in elderly patients suffering from AC that are at very high risk for cholecystectomy.⁷ Secondly, EUS-GBD could be used to convert long-term cholecystostomy to internal drainage.^{8,9} Finally, EUS-GBD could be used for drainage of the biliary tract for malignant biliary obstruction after failed endoscopic retrograde cholangiopancreatography (ERCP) and EUS-guided biliary drainage.^{10,11}

Choice of Stents

The stenting device used in the first few pioneering studies were nasobiliary drainage tubes or plastic stents.^{12,13} However, the use these stents do not impart lumen to lumen adherence for

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maintenance of tight organ anastomosis and may risk leakage of intestinal contents. Thereafter, the use of fully covered self-expandable metal stent (cSEMS) were described. cSEMS are more advantageous over plastic stents as they provide better sealing of the fistula tract between gallbladder wall and the gastrointestinal lumen and hence may reduce the risk of leak.¹⁴ However, placement of cSEMS requires progressive dilation of the fistula tract and this could lead to longer procedure time and risk leakage of gastrointestinal contents or air to the peritoneal cavity during exchange of instruments. Furthermore, stent migration and stent impingement onto adjacent organs could occur with the use of cSEMS.¹⁵ Hence, further improvement of the stenting device is required.

Recently, lumen-apposing metal stent (LAMS) has been developed for EUS-GBD. The design rationale of LAMS is to generate adequate lumen apposing force to anastomose two non-adherent organs and to prevent stent migration.¹⁶ Currently, there is no consensus on what properties LAMS should constitute but these stents share several similarities in design. The stents are composed of braided nitinol covered entirely with silicone and have bilateral flanges to prevent migration, they are short in length but have a large lumen diameter. In an *ex-vivo* study, it was noted that LAMS with different design characteristics exhibit different lumen apposing force and LAMS with higher lumen apposing forces should be used for EUS-GBD. Furthermore, a delivery system equipped with a cautery tip has been developed.¹⁷ The device allows direct puncture and delivery of the stent, permitting single step placement of the LAMS and avoidance of multiple device exchanges.

Technique of EUS-GBD

EUS-GBD can be performed by the conventional technique or direct puncture with a cautery enhanced delivery system. Regardless of the technique, the endoscopist also needs to decide on the site of puncture. The gallbladder can be drained from the distal gastric antrum and the duodenum.¹⁸ Depending on the puncture site, the access site at the gallbladder will vary. The gallbladder is generally accessed at the neck or infundibulum through punctures from duodenum. Meanwhile, the gallbladder is accessed at the fundus or body through puncture at the distal gastric antrum.¹⁹ In general, the neck or body of the gallbladder is chosen as the optimal target for puncture under the guidance of EUS.¹⁰ The factors affecting the selection of puncture site involve presence of vessels between the gastric or duodenal wall and the gallbladder wall, presence of duodenal stenosis and the distance between the gastric or duodenal wall to the gallbladder wall. However, it should be noted that transgastric punctures may increase the risk of stent migration or even dislocation as stomach is relatively more mobile.¹⁹ Stent migration could result in bile leakage into the peritoneal space, which may lead to bile peritonitis.¹⁰ Furthermore, there may be a risk of food impaction in the gallbladder and also the risk of buried stent syndrome. However, Teoh et al⁵ has reported that both antral and duodenal puncture routes share similar clinical and technical success rate and risk of adverse events. Nevertheless, it is the author's preference to drain the gallbladder from the duodenum.

Conventional Technique

A number of devices are required for accessing the gallbladder from the gastrointestinal tract and dilating the fistula tract. These include a 19-gauge fine-needle aspiration needle, 6-Fr cystotome,

Fig. 1. Endoscopic ultrasound examination showed distended gallbladder with sludge and stones compatible with acute cholecystitis.

needle-knife and a 4 mm dilating balloon. The gallbladder is first punctured with a 19-gauge needle, bile is then aspirated out to confirm that the needle is in gallbladder and to obtain sample for bacterial culture to identify the appropriate antibiotic therapy.²⁰ Contrast injection is generally not required as presence of bile aspirate indicates that the needle is in proper position. A guidewire is then inserted through the needle to the gallbladder and is allowed to coil within for the track dilation and stent insertion later. Common choices of guidewire include 0.035-inch, 450 cm-long guidewire (Jagwire; Boston Scientific, Marlborough, MA, USA) or 0.025-inch guidewire (Visiglide; Olympus, Tokyo, Japan). After the insertion of guidewire, a dilator is required for fistula dilation and these can be cautery or non-cautery dilators.^{21,22} For cautery dilators, a 6Fr cystotome or needle-knife can be used. The cystotome is generally preferred as it provides a radial cautery on the guidewire to create the fistula. Afterwards, the track is further dilated by non-cautery dilators. A 6Fr-7Fr-9Fr Biliary dilation catheter or balloon dilator (4 mm) are the commonly employed devices.²² Thereafter, the stent is inserted into the gallbladder and deployed between the gallbladder and gastrointestinal lumen. Depending on the type of stent that is being used, the method of deployment may vary. For LAMS, the distal flange is usually deployed under EUS guidance, followed by intra-channel deployment of the proximal flange and pushing the stent out of the endoscope channel under endoscopic guidance.

Direct Puncture with Cautery Enhanced Delivery system and LAMS

Recently, EUS-GBD with a cautery-tipped stent delivery system (HOT AXIOS; Boston Scientific) and (SPAXUS; Taewoong Medical, Gimpo, Korea) that allows the insertion of a lumen-apposing stent without the need of a dilation device has been described.¹⁷ The distal tip of this stent delivery system was modified to incorporate a cautery tip for direct puncture and eliminates the need of a multi-stepped fistula track dilation. Thereafter, the stent is deployed as described above (Fig. 1–5). According to a multi-centered retrospective study, this one-step system has proven to reduce the procedural time significantly which can in theory reduce the risk of fluid leakage and adverse events compared with the conventional technique (3.1 vs 7.7 minutes, $P = 0.041$).²³

Fig. 2. Direct puncture with a cautery enhanced delivery system.

Fig. 3. Opening of the distal flange under endoscopic ultrasound guidance.

Fig. 4. The distal flange of the stent opened as seen under X-ray.

Fig. 5. Endoscopic appearance of a completely opened stent.

However, in another retrospective study comparing the hot and cold AXIOS system (Boston Scientific), both devices showed similar technical and clinical success rates and overall adverse event rates.⁵ Studies that reported on outcome of HOT AXIOS (Boston Scientific) for EUS-GBD is shown in Table 1^{5,6,20,21,23–31} and the reported technical and clinical success rates ranged between 90.0%–98.7% and 86.7%–96.0%, respectively. On the other hand, the cautery tipped delivery system is also reported for another LAMS, SPAXUS (Taewoong Medical). The SPAXUS stent is advantageous in that it can be recaptured if technical difficulties are encountered. In addition, SPAXUS is up to 2 cm in length which can be applied to patients whose distance between gallbladder and the gastrointestinal tract is longer.

Outcomes of EUS-GBD

EUS-GBD vs percutaneous gallbladder drainage

PT-GBD is recommended method for draining the gallbladder in patients that are at very high risk for cholecystectomy and suffering from AC.¹ PT-GBD is associated with risk of adverse events such as blockade, dislodgement, skin infections and recurrent AC resulting in the need of repeated interventions. With the development of EUS-GBD, multiple studies compared the efficacy of EUS-

GBD and PT-GBD as summarized in Table 2.^{5–7,21,25,29}

When comparing EUS-GBD and PT-GBD, most clinical studies demonstrated similar rates of technical (95%–100% vs 96.6%–100%) and clinical success (86.7%–100% vs 86%–100%, respectively). Whilst EUS-GBD has been shown to be associated with significantly lower rate of adverse events than PT-GBD (13.0%–32.2% vs 39.5%–77.5%, $P < 0.05$). In the latest randomized study, EUS-GBD was shown to significantly reduce 1 year adverse events (10 [25.6%] vs 31 [77.5%], $P < 0.001$), 30-day adverse events (5 [12.8%] vs 19 [47.5%], $P = 0.010$), re-interventions after 30 days (1/39 [2.6%] vs 12/40 [30%], $P = 0.001$), number of unplanned readmissions (6/39 [15.4%] vs 20/40 [50.0%], $P = 0.002$) and recurrent cholecystitis (1/39 [2.6%] vs 8/40 [20.0%], $P = 0.029$). Postprocedural pain scores and analgesic requirements were also less ($P = 0.034$). The predictor to recurrent AC was the performance of PT-GBD (odds ratio, 5.63; 95% confidence interval, 1.20–53.90; $P = 0.027$).⁷ Thus, EUS-GBD could be considered as a promising alternative to replace PT-GBD as the first line of alternative treatment although further research is still needed.

Table 1 Summary of Recent Publications on Endoscopic Ultrasonography-Guided Gallbladder Drainage

Author	Year	Stent	No. of patients	Technical success	Clinical success	Adverse event	Repeat intervention
Jang et al ²⁹	2012	Nasobiliary drainage tube	30	29 (96.7)	29 (96.7)	2 (6.7)	Not accessed
Choi et al ³⁰	2014	DONA-AL	63	62 (98.4)	62 (98.4)	3 (4.8)	2 (2.6)
Kedia et al ⁶	2015	Nasobiliary drainage tube	30	30 (100)	26 (86.7)	4 (13.3)	4 (13.3)
Walter et al ³¹	2016	Hot AXIOS	30	27 (90.0)	26 (86.7)	4 (13.3)	Not assessed
Kahaleh et al ²⁴	2016	cSEMS/AXIOS	35	32 (91.4)	31 (88.6)	8 (22.9)	Not assessed
Teoh et al ⁵	2017	Hot AXIOS	59	57 (96.6)	53 (89.8)	19 (32.2)	1 (1.7)
Irani et al ²⁵	2017	Cold AXIOS/Hot AXIOS	45	44 (97.8)	43 (95.6)	5 (11.1)	11 (24.4)
Dollhopf et al ²³	2017	Hot AXIOS	75	74 (98.7)	72 (95.9)	8 (10.7)	Not assessed
Teoh et al ²⁶	2018	SPAXUS	17	15 (88.2)	16 (94.1)	0 (0)	Not assessed
Tyberg et al ²¹	2018	AXIOS	42	40 (95.2)	40 (95.2)	9 (21.4)	4 (9.52)
Minaga et al ²⁷	2019	cSEMS/BONA-AL/plastic stent	21	19 (90.5)	17 (89.5)	3 (15.8)	0 (0)
James and Baron ²⁰	2019	AXIOS	15	14 (93.3)	14 (93.3)	2 (13.3)	Not assessed
Cho et al ²⁸	2020	BONA-AL/SPAXUS	71	69 (97.2)	69 (97.2)	6 (8.5)	Not assessed

Values are presented as number (%).

Table 2 Summary of Recent Publications Comparing the Outcomes between EUS-GBD and PT-GBD

Author	Year	No. of patients	Technical success		Clinical success		Adverse event		Repeat intervention	
			EUS-GBD	PT-GBD	EUS-GBD	PT-GBD	EUS-GBD	PT-GBD	EUS-GBD	PT-GBD
Jang et al ²⁹	2012	59	96.7 ($P = 0.001$)	96.6 ($P = 0.001$)	96.7 ($P = 0.0001$)	93.1 ($P = 0.0001$)	6.7 ($P = 0.492$)	3.4 ($P = 0.492$)	NA	NA
Kedia et al ⁶	2015	73	100 ($P = 0.58$)	97.6 ($P = 0.58$)	86.7 ($P = 0.08$)	97.6 ($P = 0.08$)	13.3 ($P = 0.013$)	39.5 ($P = 0.013$)	NA	NA
Teoh et al ⁵	2017	118	96.6 ($P = 0.15$)	100 ($P = 0.15$)	89.8 ($P = 0.30$)	94.9 ($P = 0.30$)	32.2 ($P < 0.001$)	74.6 ($P < 0.001$)	1.7 ($P = 0.13$)	27.1 ($P = 0.13$)
Irani et al ²⁵	2017	90	97.8 ($P = 0.98$)	100 ($P = 0.98$)	95.6 ($P = 0.12$)	91.1 ($P = 0.12$)	17.8 ($P = 0.07$)	31.1 ($P = 0.07$)	24.4 ($P = 0.001$)	24.9 ($P = 0.001$)
Tyberg et al ²¹	2018	155	95.2 ($P = 0.179$)	99.1 ($P = 0.179$)	95.2 ($P = 0.157$)	85.8 ($P = 0.157$)	16.7 ($P = 0.613$)	18.6 ($P = 0.613$)	24 ($P = 0.037$)	10 ($P = 0.0$)
Teoh et al ⁷	2020	80	97.4 ($P = 0.494$)	100 ($P = 0.494$)	92.3 ($P = 1$)	92.5 ($P = 1$)	25.6 ($P < 0.001$)	77.5 ($P < 0.001$)	2.6 ($P = 0.002$)	50 ($P = 0.002$)

Values are presented as percentage (%).

EUS-GBD, endoscopic ultrasonography-guided gallbladder drainage; PT-GBD, percutaneous transhepatic gallbladder drainage; NA, not assessed.

EUS-GBD vs ET-GBD

The technique of ET-GBD requires expert endoscopy skills to insert the guidewire and stent through the curved and thin cystic duct. In a retrospective cohort study of 78 patients comparing the efficacy of EUS-GBD against ET-GBD, EUS-GBD has been found to have significantly higher clinical success rate than ET-GBD (95% vs 76.3%, $P < 0.05$).³² The rate of recurrent cholecystitis has also been reduced significantly by EUS-GBD in comparison with ET-GBD (2.6% vs 18.8%, $P = 0.023$).³² Similar results were also reported by meta-analysis where EUS-GBD was found to be associated with higher technical and clinical success rate (pooled odd ratio: 5.22 & 4.16, respectively; $P < 0.05$) as well as lower rate of recurrent cholecystitis (pooled odd ratio, 0.33; $P = 0.01$) whilst there were no difference in overall adverse events rates.³³ Meanwhile, a retrospective study of 172 patients suggests that the rate of procedure-related adverse event is significantly lower in EUS-GBD (7.1%) group than ET-GBD (19.3%).³⁴ These results all established the superiority of EUS-GBD over ET-GBD for managements of high-risk non-surgical candidates.

EUS-GBD vs ET-GBD vs PT-GBD

In an international multicentered retrospective study of 372 patients comparing the outcomes of the three procedure, EUS-GBD and PT-GBD have a significantly higher technical (94% vs 98% vs 88%) and clinical success rate (90% vs 97% vs 80%) than ET-GBD.³⁵ EUS-GBD was also associated with less frequent late-term adverse events than the other two procedures (1.9% vs PT-GBD 19.8% vs ET-GBD 4.8%, $P < 0.001$) while the three procedures share similar rates of post-procedural adverse event. Moreover, the mean hospital stay was significantly reduced with EUS-GBD compared with PT-GBD and ET-GBD (EUS-GBD vs PT-GBD vs ET-GBD = 16 vs 19 vs 18; $P = 0.01$).

The efficacies between the three procedures have also been studied by a number of meta-analysis studies, Mohan et al³⁶ summarized the results of 15,131 patients and the analysis showed that EUS-GBD is superior to ET-GBD while inferior to PT-GBD in terms of technical success rates while EUS-GBD is superior to both procedures in terms of clinical success rates.³⁷ The complication rates have been found to be similar between the three procedures,

complications include pancreatitis, bleeding, perforation and stent migrations, to name a few. The results of a network ranking meta-analysis agree with Mohan et al's results³⁶ on technical (EUS-GBD vs PT-GBD vs ET-GBD = 2.00 vs 1.02 vs 2.98) and clinical success rates (EUS-GBD vs PT-GBD vs ET-GBD = 1.48 vs 1.55 vs 2.98).³⁷ Furthermore, this network meta-analysis has shown that the EUS-GBD has the lowest risk of recurrent cholecystitis, which is in line with the aforementioned studies. In addition, EUS-GBD has a lower risk of repeated intervention and readmission compared with PT-GBD while having a higher rate of such risks compared to ET-GBD. Interestingly, EUS-GBD has the highest risk of overall mortality among the three procedures (EUS-GBD vs PT-GBD vs ET-GBD = 2.62 vs 2.09 vs 1.29) despite homogeneity among the pooled groups. The results of Mohan et al's meta-analysis³⁶ also show similar results. Nonetheless, the results could be affected by numerous factors, for example, EUS-GBD has been employed with high-risk patients whose conditions have been worse. Hence, further research could be directed to evaluate the mortality rates between procedures and derive guidelines to reduce post-procedural mortalities.

EUS-GBD vs laparoscopic cholecystectomy

EUS-GBD is currently indicated for patients at very high-risk for LC. Whether the approach is suitable for surgically fit patients is to be confirmed. A propensity score analysis matching patients for age, sex, and age-adjusted Charlson score compared the 1-year outcomes of EUS-GBD with LC.³⁸ The technical success rates (100% vs 100%), clinical success rates (93.3% vs 100%, $P = 1$), lengths of hospital stay (6.8 [8.1] vs 5.5 [2.7] days, $P = 1$), 30-day adverse events (4 [13.3%] vs 4 [13.3%], $P = 1$) and mortality rates (2 [6.7%] vs 0 [0%], $P = 0.492$) were similar. The rates of recurrent biliary events (3 [10%] vs 3 [10%], $P = 0.784$), reinterventions (4 [13.3%] vs 3 [10%], $P = 1$) and unplanned readmissions (3 [10%] vs 3 [10%], $P = 0.784$) in 1-year were also similar. These results indicate that EUS-GBD may potentially be an alternative to LC in a selective group of surgically fit patients.

In conclusion, EUS-GBD has been shown to be an effective means of achieving gallbladder drainage with superior efficacy to PT-GBD and ET-GBD in patients deemed at high-risk for LC. The procedure also creates portal for removing gallstones resulting in low rates of recurrent AC. Further studies are required to assess if the procedure is suitable in a selected group of surgically fit patients.

Conflicts of Interest

Professor Anthony Y.B. Teoh is a consultant for Boston Scientific, Cook, Taewoong and Microtech Medical Corporations.

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