Interventional procedure overview of endoscopic ultrasound-guided gallbladder drainage for acute cholecystitis when surgery is not an option

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Table 1 Abbreviations

Abbreviation	Definition
ASA	American Society of Anesthesiology
ATSEMS	Anti-migrating tubular self-expandable metal stents
CI	Confidence interval
ERCP	Endoscopic retrograde cholangiopancreatography
ETP-GBD	Endoscopic transpapillary gallbladder drainage
EUS-GBD	Endoscopic ultrasound-guided gallbladder drainage
IQR	Interquartile range
LAMS	Lumen-apposing metal stents
LC	Laparoscopic cholecystectomy
OR	Odds ratio
PT-GBD	Percutaneous gallbladder drainage
RR	Relative risk
SEMS	Self-expandable metal stent
SD	Standard deviation

Indications and current treatment

Acute cholecystitis is inflammation of the gallbladder. The most common cause of acute cholecystitis is gallstones (calculous cholecystitis) blocking the duct that drains the gallbladder (cystic duct). This means bile cannot drain from the gallbladder, causing pain, nausea, vomiting and fever.

Acalculous cholecystitis is a less common, but usually more serious, cause of acute cholecystitis. It usually develops as a complication of a serious illness, infection or injury that damages the gallbladder. It can be caused by accidental damage to the gallbladder during major surgery, serious injuries or burns, sepsis, severe malnutrition, or HIV or AIDS.

Initial treatment usually involves fasting, pain relief, and antibiotics if there is an infection. The gallbladder can be surgically removed (open or laparoscopic cholecystectomy) to prevent acute cholecystitis re-occurring, and to reduce the risk of developing complications, such as gangrenous cholecystitis and peritonitis.

People who cannot have surgery may be able to have percutaneous cholecystostomy. This involves inserting a drainage catheter in the gallbladder through a small entry hole made in the abdominal wall. Endoscopic transpapillary

gallbladder drainage is a less common alternative. It involves inserting a plastic stent through the ampulla and cystic duct into the gallbladder endoscopically.

What the procedure involves

Endoscopic ultrasound-guided gallbladder drainage for acute cholecystitis is typically done under sedation or general anaesthesia using a specialist endoscope with an ultrasound probe and fluoroscopic guidance. Imaging is used before the procedure to determine its feasibility. An anastomotic tract is created into the gallbladder through either the wall of the antrum of the stomach (cholecystogastrostomy) or the wall of the duodenum (cholecystoduodenostomy). A stent is inserted to establish biliary drainage into the gut and relieve the gallbladder obstruction. Occasionally, the anastomotic tract may be created between the gallbladder and jejunum (cholecystojejunostomy) if the anatomy has been altered by previous surgery.

Different technologies are used to create the anastomotic tract and deploy the stent, and stents can be made of different materials. Single-step devices allow for single-step delivery of the stent without the need to change instruments for track dilation. Multistep devices need track dilation with a cystotome and a biliary balloon.

The aim is to drain bile from the gallbladder and avoid the need for emergency cholecystectomy, particularly in people for whom surgery poses a high risk.

Outcome measures

The main outcomes included technical success (generally defined as the ability to access and drain the gallbladder by placement of a drainage tube or stent with immediate drainage of bile), clinical success (defined as resolution of clinical symptoms or improvement in biochemical parameters) and recurrence of cholecystitis. Other outcomes included reintervention rates, hospital readmissions and adverse events.

Evidence summary

Population and studies description

This interventional procedures overview is based on more than 15,000 patients from 4 systematic reviews (Fabbri 2022, Mohan 2020, Podboy 2021, Hemerly 2023), 1 randomised controlled trial (Teoh 2020), 3 non-randomised comparative studies (Siddiqui 2019, Teoh 2021, Cho 2022), 1 registry (Teoh 2019), 1 case series (Torres Yuste 2019) and 2 case reports (Kim 2019, Koutlas 2023). About 1,000 patients had the procedure. There was some overlap in patients between

the studies and overlap in papers between the systematic reviews. Some of the studies summarised separately were also included in at least 1 of the reviews. The randomised controlled trial by Teoh et al. (2020) and the registry study by Teoh et al. (2017) were included in the systematic reviews by Podboy et al. (2021), Fabbri et al. (2022) and Hemerly et al. (2023). The non-randomised comparative study by Siddiqui et al. (2019) was included in Podboy et al. (2021) and Hemerly et al. (2023) and Teoh et al. (2021) was also included in Podboy et al. (2021).

This is a rapid review of the literature, and a flow chart of the complete selection process is shown in <u>figure 1</u>. This overview presents 12 studies as the key evidence in <u>table 2</u> and <u>table 3</u>, and lists 73 other relevant studies in <u>table 5</u>. Because of the large body of evidence, case series with 10 or fewer patients have been excluded.

Of the 72 studies included in the systematic review by Mohan et al. (2020). 7 were prospective and the rest were retrospective. Based on the Newcastle-Ottawa scale for cohort studies to assess bias, 37 studies were considered to be high quality, 33 studies were of medium quality, and 2 studies were considered to be of low quality. Of the 27 studies in Fabbri et al. (2022), 6 were prospective (including 1 randomised controlled trial) and the rest were retrospective. The authors described the overall quality of the included studies as sufficient. The only randomised controlled trial was at low risk of bias. Of the observational studies, 7 were high quality and the remaining studies were at high risk of bias. No study was at very high risk of bias. Of the 10 studies included in Podboy et al. (2021), 2 were randomised controlled trials and 8 were retrospective case cohort studies (1 matched 1:1 and 1 propensity score matched). The overall quality of evidence was evaluated using the Grading of Recommendations Assessment Development and Evaluation method. Of the retrospective studies, all 8 were considered very low quality, with studies lacking randomisation and allocation concealment. For the 2 randomised controlled trials, the level of evidence was considered moderate to low. The systematic review by Hemerly et al. (2023) included 2 randomised controlled trials, 6 retrospective cohort studies and 3 published abstracts from a gastroenterology annual scientific meeting. The risk of bias in the included studies was moderate.

The studies included patients from Hong Kong, US, Denmark, Spain, Korea, China, Australia, India, Thailand and Singapore. In the review by Podboy et al. (2021), the median follow up was 212.5 days for patients who had EUS-GBD. The longest median follow up was 24.4 months, but this was a retrospective case series with only 22 patients (Torres Yuste 2019).

All studies included patients with acute cholecystitis for whom cholecystectomy was a high risk. The mean or median age ranged from 63 to 88 years. In the systematic review by Fabbri et al. (2022), 33% of patients had an underlying cancer.

Most of the comparative studies compared EUS-GBD with PT-GBD or ETP-GBD, but 1 compared it with LC (Teoh 2021).

<u>Table 2</u> presents study details.

Figure 1 Flow chart of study selection

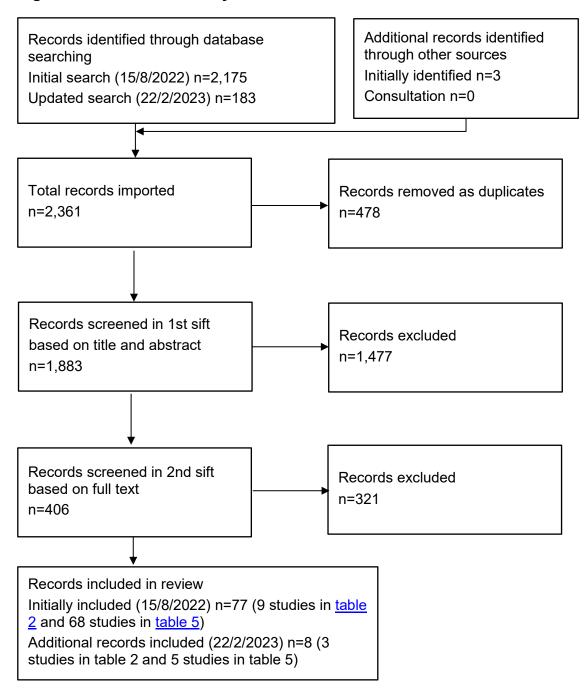


Table 2 Study details

Study no.	First author, date country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
1	Fabbri C, 2022 Country not reported for individual studies	n=1,004 (56.3% male; 95% CI 51.3% to 61.2%)	Weighted mean 74 years (95% CI 71.9 to 76.1)	Systematic review and meta-analysis (27 studies); patients were enrolled between February 2009 and February 2020.	A study population which included patients treated with transmural EUS-GBD through metal stents for acute cholecystitis; an almost complete description of the baseline patients' clinical features analysed; and a complete description of technical and clinical success rates, together with the description of post-procedural adverse events.	Transmural EUS-GBD; 64% of procedures used a duodenal approach (n=699). Number of stents used: 654 LAMS, 205 ATSEMS, 145 SEMS or metal stent	Not reported
2	Mohan B, 2020 Country not reported for individual studies	n=15,131 (61% male)	The mean or median age ranged from 65 years to 85 years.	Systematic review and comparative meta-analysis (72 studies)	Studies that evaluated EUS-GBD, ETP-GBD, and PT-GBD in patients with acute cholecystitis who were considered high risk for immediate cholecystectomy because of age or	EUS-GBD (n=557), ETP- GBD (n=1,223) or PT-GBD (n=13,351).	Not reported

Study no.	First author, date country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
					underlying chronic disease processes such as malignancy were included. Exclusion criteria: studies on gallbladder drainage for malignant stricture of the bile ducts, studies with a		
					sample size of fewer than 10 patients, studies conducted in a paediatric population (age less than 18 years), and studies not published in the English language.		
3	Podboy A, 2021 Country not reported for individual studies	n=1,267 EUS-GBD 51% male PT-GBD 58% male ETP-GBD 67% male	Median 71.0 years (range 62 to 82.7) for EUS- GBD, 74.7 years (range 60.4 to 81.2) for PT- GBD and 64.1 years (range 60 to	Systematic review and network meta- analysis (10 studies)	Comparative studies assessing the efficacy of either of 2 or all modalities (PT-GBD, EUS-GBD, and ETP-GBD) used for treating acute cholecystitis in patients at high risk for cholecystectomy. Studies were included if they reported all 3 primary outcomes of	EUS-GBD (n=472), PT-GBD (n=493) and ETP-GBD (n=302). Wide variations in anatomic puncture location, stent size, and stent type were noted within the included studies.	Median 212.5 days for EUS- GBD, 177.5 days for PT-GBD, and 150 days for ETP-GBD

Study no.	First author, date country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
			77.9) for ETP- GBD		interest: (1) technical success, defined as the ability to access and drain the gallbladder by placement of a drainage tube or stent with immediate drainage of bile; (2) clinical success, defined as resolution of clinical symptoms or improvement in biochemical parameters; and (3) postprocedure adverse events.		
4	Hemerly M, 2023 Included studies took place in Europe, Asia and US	n=1,155 58% male (484/840)	Not reported	Systematic review and meta-analysis (11 studies)	Comparative studies evaluating both endoscopic and interventional radiology techniques (EUS-GBD versus PT-GBD) for the treatment of patients with acute cholecystitis who are suboptimal candidates for surgery were included. All relevant published abstracts	EUS-GBD (n=470), PT-GBD (n=685)	Range 6 days to 450 days (EUS- GBD), 36 days to 834 days (PT-GBD)

Study no.	First author, date country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
					and full-text manuscripts, regardless of language and year of publication, were included.		
5	Teoh A, 2020 Hong Kong	n=79 (42:37)	Mean 81.9 years (EUS- GBD); 79.8 years (percutaneous)	Randomised controlled trial	Consecutive patients aged 18 or over with grade 2 or 3 acute calculous cholecystitis, at very high risk for cholecystectomy. Patients were deemed very high risk if they satisfied 1 or more of the following criteria: Age 80 or above, American Society of Anesthesiology grade 3 or above, age adjusted Charlson Comorbidity Index above 5 or Karnofsky score less than 50.	EUS-GBD using LAMS (n=39) versus PT-GBD (n=40)	1 year
6	Siddiqui A, 2019 US, Denmark	n=372 (233:139)	Mean 63 years	Non- randomised comparative study (retrospective)	Patients with acute cholecystitis who were not candidates for cholecystectomy. Only patients with at least	EUS-GBD using LAMS (n=102), PT-GBD (n=146), ETP-GBD (n=124)	Median 3 months (range 3 to 9)

Study no.	First author, date country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
					3 months follow up were included.		
7	Cho S, 2022 South Korea	n=182 EUS-GBD 47% male PT-GBD 62% male; p=0.045	Median 73 years (EUS-GBD), 71 years (PT- GBD)	Non- randomised comparative study (retrospective)	Acute cholecystitis, high surgical risk (class 3 or 4 on the American Society of Anesthesiologists Physical Status classification system), or advanced malignancy, and age 20 years or older.	EUS-GBD using an antimigrating tubular SEMS (n=75), PT-GBD (n=107; long term outcomes for ex situ [n=84] or in situ [n=17])	Median 677 days (EUS- GBD), 344 days (PT- GBD); p=0.07
8	Teoh A, 2021 Hong Kong	n=60 (35:25)	Mean 78 years (EUS-GBD); 76.4 years (LC)	Non-randomised comparative study (propensity score analysis of a retrospective database)	Patients with acute cholecystitis who had EUS-GBD or LC as a definitive management. In the EUS-GBD group, patients were at very high risk for cholecystectomy, satisfying 1 or more of the following criteria: age 80 years or above, ASA grade 3 or above, age adjusted Charlson comorbidity index more than 5, Karnofsky score less	EUS-GBD within 6 to 8 hours of diagnosis (n=30) or LC within 24 hours of diagnosis (n=30). Device used for EUS-GBD: LAMS (AXIOS, Boston Scientific, US). An additional double-pigtail plastic stent was inserted through the LAMS if there was concern that	Mean 571.9 days (EUS- GBD); 264.4 days (LC), p=0.002

Study no.	First author, date country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
					than 50. Elderly patients who refused surgery were also included. In the LC group, patients were surgically fit and presented with fewer than 7 days of pain.	the gallstones could block the stent.	
9	Teoh A, 2019 Hong Kong, Spain, Denmark, US, Korea, China, Australia, India, Thailand, Singapore	n=379 (199:180)	Mean 73.6 years	Registry (international retrospective)	Consecutive patients who had EUS-GBD planned and attempted for symptomatic gallstones, acute cholecystitis or conversion of percutaneous cholecystostomy were included. Cholecystectomy was considered to be unsuitable if patients satisfied 1 or more of the following criteria: Age 80 years or above, ASA grade 3 or above, age adjusted Charlson score 4 or	EUS-GBD using a variety of LAMS and stents with antimigration designs. Singlestep (including the HOT AXIOS stent, Boston Scientific) and multi-step (including the SPAXUS stent, Taewoong Medical, Korea; the BONA-AL stent, Standard Sci Tech Inc., Korea; and the Microtech stent, Nan Jing Co. Ltd.,	Mean 433.6 days

Study no.	First author, date country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
					higher or Karnofsky score less than 50.	China) devices were used.	
10	Torres Yuste, 2019 Spain	n=22 (14: 8)	Median 88.3 years (IQR 82.6 to 92.7 years)	Case series (retrospective)	Patients who had EUS-GBD for acute cholecystitis. Cholecystectomy was dismissed in all cases because of the patients' advanced age and poor physical status (class 3 or higher on the ASA Physical Status classification). None of the patients improved after 24 to 72 hours of conservative management with intravenous antibiotics, fluid replacement and bowel rest. Patients with a stent indwell time less than 12 months were excluded.	EUS-GBD using LAMS. The deployment technique depended on the type of stent used. With a conventional LAMS (AXIOS, Boston Scientific) serial dilation with cystotome followed by a biliary balloon was done before insertion of the stent under EUS and fluoroscopic guidance. In case of an electrocautery-enhanced (hot) LAMS (AXIOS, Boston Scientific) the stent was deployed directly	Median 24.4 months (IQR (18.2 to 42.4 months)

Study no.	First author, date country	Patients (male: female)	Age	Study design	Inclusion criteria	Intervention	Follow up
						over the guidewire.	
11	Kim J, 2019 US	n=2 (0: 2)	80 and 86 years	Case reports	Patients with severe retrograde reflux of gastric contents into the gallbladder after EUS-GBD.	EUS-GBD	Not reported
12	Koutlas N, 2023	n=1 male	50 years	Case report	Patient with cholecystocolonic fistula after EUS-GBD for stump cholecystitis.	EUS-GBD with LAMS	3 months

Table 3 Study outcomes

First author, date	Efficacy outcomes	Safety outcomes
Fabbri C, 2022	Pooled results (27 studies, n=1,004 unless stated otherwise)	Pooled results (27 studies, n=1,004)
2022	 Technical success=98.0% (95% CI 96.3 to 99.3%; I²=23.6%) Per-procedure clinical success=98.8% (95% CI 97.2 to 99.8%; I²=29.4%) 	Procedure-related adverse events=14.8% (95% CI 8.8 to 21.8%; I²=82.4%) • Stent malfunction or dislodgment=3.5% (95% CI 0.1 to 6.7%; I²=64.5%) • Procedure-related mortality=0.1% (95% CI 0.0 to 0.1%; I²=0%)
	 Overall clinical success=95.4% (95% CI 92.8 to 97.5%; I²=35.3%) Cholecystitis recurrence=3.4% (95% CI 1.6 to 5.7%; 21 studies, n=965, I²=32.3%) 	0.1%; I ² =0%) • 30-day all-cause mortality=2.9% (95% CI 0.5 to 6.6%; I ² =74.1%)

First author, date	Efficacy outcomes	Safety outcomes
	Hospital stay (days)=8.0 (95% CI 6.4 to 9.6; 11 studies, n=687, I²=91.3%) Technical success increased when studies reported an experience proxied to more than 10 cases per year (OR 2.84; 95% CI 1.06 to 7.59). The overall clinical success improved when the experience proxied more than 10 cases per year (OR 3.85; 95% CI 1.46 to 10.15). In addition, the use of anti-migrating devices (LAMs or ATSEMs) improved this outcome (OR 2.33; 95% CI 1.16 to 4.68). Multivariable meta-regression identified both as independent modifiers of the overall clinical success. The OR for experience was 3.52 (95% CI 1.33 to	 Bile leak or peritonitis=1.5% (95% CI 0.1 to 3.9%; I²=59.5%) Bleeding=0.3% (95% CI 0.1 to 1.2%; I²=10.3%) Pneumoperitoneum=0.5% (95% CI 0.0 to 0.6%, I²=0%) Adverse events reduced when the experience proxied to more than 10 cases per year (OR 0.35; 95% CI 0.19 to 0.65). The use of anti-migrating devices also reduced adverse events (OR 0.30; 95% CI 0.17 to 0.52). Multivariable meta-regression identified the use of anti-migrating devices (OR 0.36; 95% CI 0.14 to 0.98) as the only modifier of procedure-related adverse events. After meta-regression, the residual I² was still substantial (67.8%, Egger's test: p=0.145).
	9.33) and that of anti-migrating devices was 2.16 (95% CI 1.07 to 4.36). After meta-regression, the residual I ² was 0% (Egger's test: p=0.147).	
Mohan B,	Pooled rates of technical success	Pooled rates of adverse events
2020	• EUS-GBD=95.3% (95% CI 92.8 to 96.9, I ² =0%; 14 studies, 557 patients)	• EUS-GBD=12.4% (95% CI 6.9 to 21.1, I ² =6%; 13 studies, 546 patients)
	• ETP-GBD=83% (95% CI 80.1 to 85.5, I ² =29%; 21 studies, 851 patients)	• ETP-GBD=9.6% (95% CI 5.9 to 15.3, I ² =27%; 21 studies, 1,209 patients)
	 PT-GBD=98.7% (95% CI 98.0 to 99.1, I²=0%; 33 studies, 2,203 patients) p=0.001 for EUS-GBD versus ETP-GBD and PT-GBD 	• PT-GBD=15.1% (95% CI 11.1 to 20.3, I ² =95%; 39 studies, 11,997 patients) p=0.32 for EUS-GBD versus ETP-GBD and p=0.56 for
	Pooled rates of clinical success	EUS-GBD versus PT-GBD

First author, date	Efficacy outcomes	Safety outcomes
	 EUS-GBD=96.7% (95% CI 94.0 to 98.2, I²=0%; 14 studies, 557 patients) ETP-GBD=88.1% (95% CI 83.6 to 91.4, I²=50%; 22 studies, 1,223 patients) PT-GBD=89.3% (95% CI 86.6 to 91.5, I²=84%; 38 studies, 11,800 patients) p=0.001 for EUS-GBD versus ETP-GBD and PT-GBD Pooled rates of recurrence EUS-GBD=4.2% (95% CI 2.4 to 7.4, I²=0%; 14 studies, 557 patients) ETP-GBD=4.6% (95% CI 2.8 to 7.4, I²=53%; 22 studies, 1,223 patients) PT-GBD=10.8% (95% CI 8.3 to 13.9, I²=76%; 37 studies, 3,677 patients) p=0.99 for EUS-GBD versus ETP-GBD and p=0.001 for EUS-GBD versus PT-GBD 	 Pooled rates of bleeding EUS-GBD=4.3% (95% CI 2.7 to 6.8, I²=0%; 13 studies, 546 patients), p=0.02 ETP-GBD=1.9% (95% CI 1.1 to 3.1, I²=0%; 21 studies, 1,209 patients) PT-GBD=2% (95% CI 1.5 to 2.7, I²=0%; 37 studies, 3,597 patients) Pooled rates of perforation EUS-GBD=3.7% (95% CI 2.3 to 6, I²=0%); 13 studies, 546 patients), p=0.04 ETP-GBD=2% (95% CI 1.2 to 3.2, I²=0%; 21 studies, 1,209 patients) PT-GBD=2% (95% CI 1.4 to 2.9, I²=0%; 36 studies, 3,524 patients) Pooled rates of bile leak or bile peritonitis EUS-GBD=2.9% (95% CI 1.6 to 5.1, I²=0%; 13 studies, 546 patients) ETP-GBD=1.4% (95% CI 0.8 to 2.5, I²=0%); 21 studies, 1,209 patients) PT-GBD=2.7% (95% CI 2.1 to 3.5, I²=0%; 37 studies, 3,597 patients) Pooled rates of pancreatitis EUS-GBD=1.4% (95% CI 0.7 to 3.1, I²=0%; 13 studies, 546 patients) EUS-GBD=5.1% (95% CI 3.5 to 7.3, I²=17%; 21 studies, 1,209 patients), p=0.003

First author, date	Efficacy outcomes	Safety outcomes
		PT-GBD=1.1% (95% Cl 0.7 to 1.7, l²=0%; 36 studies, 3,524 patients) Pooled rates of stent occlusion
		 EUS-GBD= 2.6% (95% CI 1.2 to 5.6, I²=0%; 12 studies, 506 patients)
		 ETP-GBD=1.8% (95% CI 0.9 to 3.6, I²=0%; 20 studies, 1,171 patients)
		 PT-GBD=1.8% (95% CI 1.1 to 2.8, I²=56%; 36 studies, 3,524 patients) Pooled rates of stent migration
		 EUS-GBD=2.7% (95% CI 1.3 to 5.4, I²=0%; 13 studies, 546 patients)
		• ETP-GBD=2.2% (95% CI 1.2 to 3.9, I ² =0%; 20 studies, 1,171 patients)
		 PT-GBD=7.4% (95% CI 5.5 to 10, I²=79; 38 studies, 3,977 patients), p=0.01 Pooled rates of mortality
		• EUS-GBD=26% (95% CI 16.7 to 38.1, I ² =86%); 9 studies, 398 patients), p=0.001
		• ETP-GBD= 16.6% (95% CI 10.5 to 25.2, I ² =77%; 13 studies, 884 patients)
		• PT-GBD=11.2% (95% CI 8.7 to 14.1, I ² =83%; 37 studies, 3,597 patients)
Podboy A, 2021	Technical success – network meta-analysis:	Adverse events – network meta-analysis:

First author, date	Efficacy outcomes	Safety outcomes
	PT-GBD vs EUS-GBD, RR=1.04 (95% CI 1.01 to 1.09, 7 studies, 782 patients)	PT-GBD vs EUS-GBD, RR=1.02 (95% CI 0.42 to 1.91; 6 studies, 702 patients)
	 ETP-GBD vs EUS-GBD, RR= 0.81 (95% CI 0.43 to 0.99, 3 studies, 589 patients) 	 ETP-GBD vs EUS-GBD, RR=1.16 (95% CI 0.42 to 2.38; 3 studies, 498 patients)
	• ETP-GBD vs PT-GBD, RR=0.78 (95% CI 0.42 to 0.96; 1 study, 270 patients)	 ETP-GBD vs PT-GBD, RR=1.26 (95% CI 0.41 to 3.06; 2 studies, 341 patients)
	There was no statistically significant heterogeneity between the pooled studies.	There was statistically significant heterogeneity between the pooled studies comparing EUS-GBD and PT-GBD
	On the network ranking estimate PT-GBD was noted to be ranked most likely to result in technical success followed by EUS-GBD and ETP-GBD (EUS-GBD vs	(p=0.013, I ² =65.3%) but not for the remaining pooled categories. The network ranking estimate was lowest for PT-GBD
	PT-GBD vs ETP-GBD: 2.00 vs 1.02 vs 2.98). Clinical success – network meta-analysis:	followed by EUS-GBD (EUS-GBD vs PT-GBD vs ETP- GBD: 1.96 vs 1.88 vs 2.16), although there was wide
	 PT-GBD vs EUS-GBD, RR=0.99 (95% CI 0.87 to 	variability.
	1.05, I ² =40.3%; 7 studies, 778 patients)	Unplanned admissions – network meta-analysis:
	• ETP-GBD vs EUS-GBD, RR=0.75 (95% CI 0.38 to 0.97, I2=; 4 studies, 402 patients)	 PT-GBD vs EUS-GBD, RR=4.54 (95% CI 1.52 to 8.92; 4 studies, 658 patients)
	• ETP-GBD vs PT-GBD, RR=0.76 (95% CI 0.40 to 0.98; 1 study, 71 patients)	 ETP-GBD vs EUS-GBD, RR=1.32 (95% CI 0.06 to 5.83; 1 study, 226 patients)
	There was no statistically significant heterogeneity between the pooled studies.	 ETP-GBD vs PT-GBD, RR=0.31 (95% CI 0.02 to 1.31; 1 study, 270 patients)
	The network ranking estimates closely preferred EUS-GBD over PT-GBD and ETP-GBD (EUS-GBD vs PT-	There was statistically significant heterogeneity between EUS-GBD and PT-GBD (p=0.029, I ² =66.9%).
	GBD vs ETPGBD:1.48 vs 1.55 vs 2.98).	The network rating preferred ETP-GBD over other
	Recurrent cholecystitis – network meta-analysis:	modalities (EUS-GBD vs PT-GBD vs ETP-GBD: 1.582 vs 2.944 vs 1.474).
		Disease-specific mortality – network meta-analysis:

First author, date	Efficacy outcomes	Safety outcomes
	PT-GBD vs EUS-GBD, RR=1.96 (95% CI 0.75 to 4.09; 6 studies, 708 patients)	PT-GBD vs EUS-GBD, RR=0.83 (95% CI 0.19 to 1.81; 3 studies, 287 patients)
	• ETP-GBD vs EUS-GBD, RR=3.72 (95% CI 1.39 to 7.54; 3 studies, 443 patients)	 ETP-GBD vs EUS-GBD, RR=0.47 (95% CI 0.03 to 1.80; 1 study, 71 patients)
	• ETP-GBD vs PT-GBD, RR=2.20 (95% CI 0.66 to 5.37; 1 study, 270 patients)	 ETP-GBD vs PT-GBD, RR=0.81 (0.04 to 3.93; 0 studies, 0 patients)
	There was no statistically significant heterogeneity between the pooled studies.	There was no statistically significant heterogeneity between the pooled studies.
	Ranking estimates preferred EUS-GBD over other modalities (EUS-GBD vs PT-GBD vs ETP-GBD: 1.089 vs 2.02 vs 2.891).	Ranking estimate EUS-GBD vs PT-GBD vs ETP-GBD: 2.62 vs 2.09 vs 1.29.
	Need for reintervention – network meta-analysis:	
	 PT-GBD vs EUS-GBD, RR=3.07 (95% CI 1.52 to 2.94; 4 studies, 394 patients) 	
	• ETP-GBD vs EUS-GBD, RR=0.77 (95% CI 0.23 to 0.68; 2 studies, 216 patients)	
	• ETP-GBD vs PT-GBD, RR=0.26 (95% CI 0.08 to 0.23; 1 study, 270 patients)	
	There was no statistically significant heterogeneity between the pooled studies.	
	Ranking estimates preferred ETP-GBD (EUS-GBD vs PT-GBD vs ETP-GBD: 1.81 vs 2.99 vs 1.199).	
Hemerly M, 2023	EUS-GBD compared with PT-GBD	EUS-GBD compared with PT-GBD
	Technical success (10 studies):	Adverse events (10 studies):
	• EUS-GBD=96.5%	• EUS-GBD=17.9%

First author, date	Efficacy outcomes	Safety outcomes
	• PT-GBD=98.6%, risk difference=-0.02 (95% CI -0.04 to 0.00; I ² =0%; p=0.05)	PT-GBD=33.9%, risk difference=-0.14 (95% CI -0.29 to 0.01; I²=90%; p=0.07)
	According to GRADE, the quality of evidence was high.	According to GRADE, the quality of evidence was very low.
	Clinical success (10 studies):	Hospital readmission (5 studies):
	• EUS-GBD=93.5%	• EUS-GBD=9.7%
	• PT-GBD=91.9%, risk difference=0.02 (95% CI -0.03 to 0.07; I ² =63%; p=0.38)	• PT-GBD=31.6%, risk difference=-0.21 (95% CI -0.44 to 0.02; I ² =93%; p=0.08)
	According to GRADE, the quality of evidence was moderate.	According to GRADE, the quality of evidence was very low.
	Recurrent cholecystitis (8 studies):	
	• EUS-GBD=4.2%	Subgroup analysis: EUS-GBD with cautery-enhanced
	• PT-GBD=7.6%, risk difference= -0.03 (95% CI -0.07 to -0.00; I ² =36%; p=0.04)	LAMS compared with PT-GBD (n=647)
	According to GRADE, this outcome was supported by	Adverse events (5 studies):
	high quality evidence.	EUS-GBD with LAMS=19%
	Reintervention (6 studies):	• PT-GBD=45.2%, risk difference=-0.33 (95% CI -0.52
	• EUS-GBD=3.4%	to -0.14; I ² =88%; p=0.0006) The number needed to harm was 3.85.
	• PT-GBD=33.8%, risk difference= -0.34	
	(95% CI -0.69 to 0.01; I ² =99%; p=0.05)	According to GRADE, the quality of evidence was moderate.
	According to GRADE, the quality of evidence was low.	Hospital readmission (3 studies):
	Subgroup analysis: EUS-GBD with	• EUS-GBD with LAMS=7.3%
	cautery-enhanced LAMS compared with PT-GBD (n=647)	 PT-GBD=37.1%, risk difference=-0.36 (95% CI -0.70 to -0.03; I²=95%; p=0.03)

First author, date	Efficacy outcomes	Safety outcomes
	Technical success (4 studies):	According to GRADE, the quality of evidence was
	EUS-GBD with LAMS=95.9%	moderate.
	• PT-GBD=99.6%, risk difference=-0.03 (95% CI -0.06 to 0.01; I ² =0%; p=0.1)	
	According to GRADE, the quality of evidence was high.	
	Clinical success (4 studies):	
	EUS-GBD with LAMS=91%	
	• PT-GBD=94.8%, risk difference=0.04 (95% CI -0.08 to 0.01; I ² =0%; p=0.1)	
	According to GRADE, the quality of evidence was high.	
	Recurrent cholecystitis (4 studies):	
	EUS-GBD with LAMS=2%	
	• PT-GBD=6.8%, risk difference= -0.05 (95% CI -0.09 to -0.02; I ² =63%; p=0.02)	
	According to GRADE, this outcome was supported by high quality evidence.	
	Reintervention (4 studies):	
	EUS-GBD with LAMS=1.7%	
	• PT-GBD=34.8%, risk difference= -0.35 (95% CI -0.8 to 0.1; I ² =99%; p=0.13)	
	According to GRADE, the quality of evidence was moderate.	
Teoh A, 2020	Technical success:	30-day adverse events (p=0.001):

First author, date	Efficacy outcomes	Safety outcomes
	 EUS-GBD=97.4% (38/39) PT-GBD=100% (40/40), p=0.494 Clinical success: EUS-GBD=92.3% (36/39) PT-GBD=92.5% (37/40), p=1.00 Analgesic requirements (total paracetamol in mg); mean (SD) EUS-GBD=3,345 (5,663) PT-GBD=5,165 (5,068), p=0.034 Recurrent acute cholecystitis at 1 year: EUS-GBD=2.6% (1/39) PT-GBD=20% (8/40), p=0.029 Reinterventions after 30 days: EUS-GBD=2.6% (1/39) PT-GBD=30% (12/40), p=0.001 	 EUS-GBD=12.8% (5/39); blocked stent (n=2), perforation (n=1), atrial fibrillation (n=1), pneumonia (n=3) PT-GBD=47.5% (19/40); tube dislodgement (n=15), multiorgan failure (n=3), pericholecystic collection (n=1), acute myocardial infarction (n=1), atrial fibrillation (n=1), pneumonia (n=1), bleeding (n=1), decompensated liver cirrhosis (n=1), urinary tract infection (n=1) 30-day mortality (p=1): EUS-GBD=7.7% (3/39) PT-GBD=10% (4/40) Adverse events at 1 year (including recurrent acute cholecystitis), p<0.001: EUS-GBD=25.6% (10/39); 5 within 30 days listed above plus 1 recurrent acute cholecystitis, 1 blocked stent or tube and 3 common bile duct stones needing ERCP PT-GBD=77.5% (31/40); 19 within 30 days listed above plus 8 recurrent acute cholecystitis, 18 tube dislodgement, 2 blocked stent or tube and 1 common bile duct stones needing ERCP Unplanned admissions (p=0.002): EUS-GBD=15.4% (6/39) PT-GBD=50% (20/40)
Siddiqui A, 2019	Technical success:	Total procedural adverse events (p=0.07):

First author, date	Efficacy outcomes	Safety outcomes
	 EUS-GBD=94% (96/102) PT-GBD=98% (143/146) ETP-GBD=88% (109/124), p=0.003 Clinical success: EUS-GBD=90% (92/102) PT-GBD=97% (141/146) ETP-GBD=80% (99/124), p<0.001 After controlling for age, gender, pathology, number of sessions, and technical success, only the number of sessions variable (1 or more than 1 session) was a statistically significant predictor of clinical resolution (OR=0.036, 95% CI 0.004 to 0. 353, p=0.0043). Need for additional surgical intervention: EUS-GBD=0% (0/102) PT-GBD=49.7% (73/146) ETP-GBD=11.4% (14/124), p<0.001 	 EUS-GBD=11.8% (12/102); 2 perforation, 5 self-limited bleeding, 1 infection, 2 bile leaks, 2 self-limited abdominal pain needing observation PT-GBD=4.1% (6/146); 3 self-limited bleeding, 1 infection, 2 bile leaks ETP-GBD=7.2% (9/124); 2 self-limited bleeding, 3 pancreatitis, 4 self-limited abdominal pain needing observation There was no statistically significant difference in the severity of procedural adverse events between the 3 groups (p=0.85). Patients with calculous pathology were 2 times more likely to have an adverse event (OR=1.9, 95% CI 1.04 to 3.57, p=0.04), and patients who had more than 1 procedure session were almost 3 times more likely to have an adverse event (OR=2.7, 95% CI 1.23 to 6.07, p=0.0138).
	Surgical removal of the gallbladder was eventually needed in 24% of patients either for recurrent acute cholecystitis not amenable to non-surgical therapy or when the patient had improved medically. The timing of surgery was between 1 and 4 months after the index intervention. In patients that did not need a cholecystectomy, those	 Long-term (3 to 9 month follow up) adverse events (p<0.001): EUS-GBD=1.9% (2/102); 1 catheter or stent dislodgment, 1 infection PT-GBD=19.8% (29/146); 11 catheter or stent dislodgment, 2 pain, 4 catheter or stent occlusion, 5 cellulitis, 5 infection, 2 abscess

First author, date	Efficacy outcomes	Safety outcomes
	that had ETP-GBD had a statistically significantly lower clinical success (78%) for resolution of acute cholecystitis compared to those that had PT-GBD (94%) or EUS-GBD with LAMS (92%); p=0.002.	 ETP-GBD=4.8% (6/124); 2 catheter or stent dislodgment, 4 catheter or stent occlusion Unplanned hospital admissions (p<0.001): EUS-GBD=4% (4/102) PT-GBD=19.8% (29/146) ETP-GBD=3.2% (4/124)
Cho S, 2022	Technical success:	 Early adverse events: EUS-GBD=5.5% (4/73); 1 leakage, 1 migration, 2 pneumoperitoneum PT-GBD=18.9% (20/106); 3 bleeding, 8 migration, 3 leakage,5 occlusion, 1 infection p=0.01 Late adverse events (excluding recurrence of cholecystitis) EUS-GBD=6.0% (4/67); all asymptomatic PT-GBD in situ=11.8% (2/17); 1 tube site infection, 1 asymptomatic

First author, date	Efficacy outcomes	Safety outcomes
	Comparison of EUS-GBD with PT-GBD ex situ	
	Crude recurrence of cholecystitis:	
	• EUS-GBD=6.0% (4/67)	
	• PT-GBD ex situ=9.6% (8/83), p=0.422	
	Cumulative rate of cholecystitis at 2-year follow up:	
	• EUS-GBD=4.1%	
	• PT-GBD ex situ=9.1%, p=0.426	
	PT-GBD in situ was a statistically significant predictor of recurrent cholecystitis (hazard ratio 14.6; 95% CI 2.9 to 72.8).	
Teoh A, 2021	Technical success:	30-day adverse events:
	• EUS-GBD=100% (30/30)	EUS-GBD=13.3% (4/30); 2 patients died (described)
	• LC=100% (30/30)	below), 1 patient had upper gastrointestinal bleeding needing endoscopic haemostasis, and 1 had a
	Clinical success:	blocked stent because of gallstones needing
	• EUS-GBD=93.3% (28/30)	endoscopic insertion of an additional double-pigtail
	• LC=100% (30/30)	stent through the LAMS.
	Mean length of hospital stay (SD):	LC=13.3% (4/30); 1 patient had intraabdominal adjusting pageting parentages 4 had
	• EUS-GBD=6.8 (8.1)	collections needing percutaneous drainage, 1 had multiorgan failure, 1 had upper gastrointestinal
	• LC=5.5 (2.7)	bleeding needing endoscopic haemostasis, and 1
	Recurrent cholecystitis:	patient had a chest infection.
	• EUS-GBD=3.3% (1/30)	30-day mortality:

First author, date	Efficacy outcomes	Safety outcomes
	 LC=0% (0/30) Recurrent biliary events: EUS-GBD=10.0% (3/30) LC=10.0% (3/30) All were because of the presence of common bile duct stones, which were not suspected on preprocedural imaging. These events all resulted in unplanned admissions, and the stones were removed by ERCP. Reinterventions: EUS-GBD=13.3% (4/30) LC=10.0% (3/30) 	 EUS-GBD=6.7% (2/30); 1 aspiration pneumonia and 1 uncontrolled sepsis LC=0% (0/30) Unplanned readmissions: EUS-GBD=10.0% (3/30) LC=10.0% (3/30)
Teoh A, 2019	Technical success=95.3% of patients Clinical success=90.8% of patients Recurrent cholecystitis=2.4% (9/379) Unplanned procedural events=9.2% of patients (defined as any deviations of the procedure from the planned procedural steps) Endoscopists who had done fewer than 25 of the procedures had significantly more procedures that were longer than 30 minutes (p=0.006), more unplanned procedural events (p=0.012) and more 30-day adverse events (p=0.031).	30-day adverse event rate=15.3% (58/379) 30-day mortality rate=9.2% Procedure-related adverse events, n=20 • Stent obstruction, n=3 • Stent migration, n=3 • Bile leak, n=3 • Duodenal perforation, n=2 • Pneumoperitoneum, n=2 • Gastric outlet obstruction from stent, n=1 • Bleeding from puncture site, n=1 • Infected abdominal collection, n=1 • Bleeding in gallbladder, n=1

First author, date	Efficacy outcomes	Safety outcomes
		 Bleeding from cystic artery, n=1 Infected ascites, n=1
		In multivariate analyses, clinical failure (p=0.014; RR 8.69, 95% CI 1.56 to 48.47) and procedure done by endoscopist with experience of fewer than 25 procedures (p=0.002; RR 4.68, 95%CI 1.79 to 12.26) were statistically significant predictors of 30-day adverse events. The only statistically significant predictor of 30-day mortality was the presence of 30-day adverse event (p<0.001; RR 103, 95% CI 11.24 to 944.04).
Torres Yuste, 2019	Gallstone-related hospital admissions during follow up=4.5% (1/22) During follow up 12 patients (54.5%) visited the emergency room 34 times with a median of 1 visit per patient (IQR 0 to 3; range 0 to 7). There were 36 hospital admissions during follow up, with a median of 1 admission per patient (IQR 0 to 3; range 0 to 9). 63.6% (14/22) of patients died during follow up: 1 of them of pancreatic cancer progression, while the rest died from non-biliary causes. Long-term endoscopic follow up was available in 3 patients: 1 patient had a patent stent at 31 months, 1 patient had an obstructed stent because of overgrowth at 42 months after stent deployment and 1 patient had buried-stent syndrome but with a patent fistula at 51 months follow up.	There were no LAMS-related adverse events after the first year of follow up.

First author, date	Efficacy outcomes	Safety outcomes
Kim J, 2019	Both procedures were successful initially.	Patient 1: frail 86-year-old with end-stage renal disease on haemodialysis, diabetes mellitus, hypertension, congestive heart failure, obstructive apnoea, and coronary artery disease who had had coronary artery stenting. She was admitted weeks after EUS-GBD with intractable right upper quadrant pain. A CT scan confirmed gastric reflux into the gallbladder. This was eventually managed with repeat endoscopic drainage on an outpatient basis, though the patient did have another hospitalisation for severe antibiotic-associated colitis. Patient 2: an 80-year-old woman with diabetes mellitus, hypertension, coronary artery disease, and hypothyroidism who developed a stent occlusion with recurrent cholecystitis needing a repeat endoscopic procedure, an infected biloma needing an intraperitoneal drain, and, ultimately, extraluminal free air. The patient eventually had an open cholecystectomy, partial liver resection, gastric antrectomy, and Billroth II gastrojejunostomy.
Koutlas N, 2023	CT scan confirmed appropriate positioning of the LAMS and plastic double pigtail stent with new pneumobilia the day after the procedure. Abdominal pain had resolved 2 weeks after the procedure.	Cholecystocolonic fistula The patient presented with diarrhoea 2 weeks after EUS-GBD. Upper endoscopy and cholecystoscopy revealed a cholecystocolonic fistula. The LAMS and double pigtail stent were removed and the cholecystogastric tract was closed with clips. At 3-month follow-up, the symptoms had resolved.

Procedure technique

Most of the procedures were done using LAMS. In the systematic review of 27 studies by Fabbri et al. (2022), 64% of procedures used a duodenal approach and LAMS were the most common type of stent used (n=654). Details of procedure technique were not reported in the systematic review by Podboy et al. (2021) but the authors noted there were wide variations in anatomic puncture location, stent size and stent type within the included studies.

Efficacy

Technical success

Technical success of EUS-GBD was reported in 8 studies and ranged from 95% to 100%. In the systematic review of 27 studies on EUS-GBD (n=1,004), the pooled rate of technical success was 98% (95% CI 96% to 99%, I²=24%; Fabbri 2022). In the systematic review of 72 studies comparing EUS-GBD, ETP-GBD and PT-GBD, the pooled rates of technical success were 95% for EUS-GBD (95% CI 93% to 97%, I²=0%; 14 studies, n=557), 83% for ETP-GBD (95% CI 80% to 86%, I²=29%; 21 studies, n=851) and 99% for PT-GBD (95% CI 98% to 99%, I²=0%; 33 studies, n=2,203; Mohan 2020). In the network meta-analysis of 10 comparative studies, PT-GBD was ranked most likely to result in technical success, followed by EUS-GBD and ETP-GBD (Podboy 2021). In the systematic review of 10 studies comparing EUS-GBD and PT-GBD, technical success rates were 97% and 99%, respectively (p=0.05, I²=0%, 10 studies; Hemerly 2023).

In the randomised controlled trial of 79 patients, technical success was 97% (38/39) for EUS-GBD and 100% (40/40) for PT-GBD (p=0.494, Teoh 2020). In the non-randomised comparative study of 372 patients, technical success was 94% (96/102) for EUS-GBD, 98% (143/146) for PT-GBD and 88% (109/124) for ETP-GBD (p=0.003; Siddiqui 2019). In the non-randomised comparative study of 182 patients, technical success was 97% (73/75) for EUS-GBD and 99% (106/107) for PT-GBD (p=0.570; Cho 2022). In the non-randomised comparative study of 60 patients, technical success was 100% (30/30) for both EUS-GBD and LC (Teoh 2021). In the registry study of 379 patients, technical success was 95% (Teoh 2019).

Clinical success

Clinical success of EUS-GBD was reported in 8 studies and ranged from 90% to 97%. In the systematic review of 27 studies on EUS-GBD (n=1,004), the pooled rate of overall clinical success was 95% (95% CI 93% to 98%, I²=35%; Fabbri 2022). In the systematic review of 72 studies, the pooled rates of clinical success were 97% for EUS-GBD (95% CI 94% to 98%, I²=0%; 14 studies, n=557), 88% for ETP-GBD (95% CI 84% to 91%, I²=50%; 22 studies, n=1,223) and 89% for PT-GBD (95% CI 87% to 92%, I²=84%; 38 studies, n=11,800; Mohan 2020). In

the network meta-analysis of 10 comparative studies, the network ranking estimates closely preferred EUS-GBD for clinical success over PT-GBD and ETP-GBD (Podboy 2021). In the systematic review of 10 studies, clinical success was 94% for EUS-GBD and 92% for PT-GBD (10 studies, I²=63%, p=0.38; Hemerly 2023).

In the randomised controlled trial of 79 patients, clinical success was 92% (36/39) for EUS-GBD and 93% (37/40) for PT-GBD at 1 year follow up (p=1.00, Teoh 2020). In the non-randomised comparative study of 372 patients, clinical success was 90% (92/102) for EUS-GBD, 97% (141/146) for PT-GBD and 80% (99/124) for ETP-GBD (p<0.001) with a median follow up of 3 months (Siddiqui 2019). In the non-randomised comparative study of 182 patients, clinical success was 96% (72/75) for EUS-GBD and 95% (102/107) for PT-GBD (p=0.999; Cho 2022). In the non-randomised comparative study of 60 patients, clinical success was 93% (28/30) for EUS-GBD and 100% (30/30) for LC, with mean follow-up periods of 572 days and 264 days respectively (p=0.002; Teoh 2021). In the registry study of 379 patients with a mean follow up of 434 days, clinical success was 91% (Teoh 2019).

In the case series of 22 patients with a median follow up of 24 months, long-term endoscopic follow up was available for 3 patients (Torres Yuste 2019). Of these 3 patients, 1 had a patent stent at 31 months, 1 had an obstructed stent because of overgrowth at 42 months after stent deployment and 1 had buried-stent syndrome but with a patent fistula at 51 months follow up.

Recurrence of cholecystitis

Recurrence rates after EUS-GBD were reported in 7 studies and ranged from 2% to 6%. In the systematic review of 27 studies on EUS-GBD (n=1,004), the pooled recurrence rate was 3% (95% CI 2% to 6%, I²=32%; 21 studies, n=965; Fabbri 2022). In the systematic review of 72 studies, the pooled recurrence rates were 4% for EUS-GBD (95% CI 2% to 7%, I²=0%; 14 studies, n=557), 5% for ETP-GBD (95% CI 3% to 7%, I²=53%; 22 studies, n=1,223) and 11% for PT-GBD (95% CI 8% to 14%, I²=76%; 37 studies, n=3,677; Mohan 2020). In the network meta-analysis of 10 comparative studies, the network ranking estimates for recurrence rates preferred EUS-GBD over PT-GBD and ETP-GBD (Podboy 2021). In the systematic review of 10 studies, the recurrence rate was 4% for EUS-GBD and 8% for PT-GBD (8 studies, I²=36%, p=0.04; Hemerly 2023).

In the randomised controlled trial of 79 patients, the rate of recurrence was 3% (1/39) for EUS-GBD and 20% (8/40) for PT-GBD at 1 year follow up (p=0.029, Teoh 2020). In the non-randomised comparative study of 60 patients, the rate of recurrence was 3% (1/30) for EUS-GBD and 0% (0/30) for LC, with mean follow up periods of 572 days and 264 days respectively (Teoh 2021). In the non-randomised comparative study of 182 patients, late recurrence of cholecystitis was reported in 6% (4/67) of patients who had EUS-GBD and 24% (4/17) of

patients who had PT-GBD in which the tube was left in place, with median follow ups of 677 days and 344 days respectively (p=0.049). For patients who had PT-GBD in which the tube was removed, the rate of recurrence was 10% (8/83) (p=0.42 compared with EUS-GBD, Cho 2022). In the registry study of 379 patients with a mean follow up of 434 days, the rate of recurrence was 2% (9/379; Teoh 2019).

Recurrence of biliary events

In the randomised controlled trial of 79 patients, common bile duct stones needing ERCP was reported in 8% (3/39) of patients who had EUS-GBD and 3% (1/40) of patients who had PT-GBD at 1 year follow up (Teoh 2020). In the non-randomised comparative study of 60 patients, recurrent biliary events were reported for 10% (3/30) of patients both in the EUS-GBD and the LC group, with mean follow-up periods of 572 days and 264 days respectively (Teoh 2021). In the case series of 22 patients, there was 1 gallstone-related hospital admission during follow up (median 24 months, Torres Yuste 2019).

Reintervention

The rate of reinterventions was reported in 5 studies. In the systematic review of 10 studies, the reintervention rate was 3% after EUS-GBD and 34% after PT-GBD (6 studies, I²=99%, p=0.05, Hemerly 2023). In the non-randomised comparative study of 372 patients, a need for additional surgical intervention was reported for 0% (0/102) of patients who had EUS-GBD, 50% (73/146) of patients who had PT-GBD and 11% (14/124) of patients who had ETP-GBD (p<0.001) with a median follow up of 3 months (Siddiqui 2019). In the non-randomised comparative study of 182 patients, the reintervention rate was 6% (4/67) after EUS-GBD and 47% (8/17) for patients who had PT-GBD in which the tube was left in place, with median follow ups of 677 days and 344 days respectively (p=0.001; Cho 2022).

In the randomised controlled trial of 79 patients, reinterventions after 30 days were reported for 3% (1/39) of patients who had EUS-GBD and 30% (12/40) of patients who had PT-GBD (p=0.001, Teoh 2020). In the non-randomised comparative study of 60 patients, the reintervention rate was 13% (4/30) for EUS-GBD and 10% (3/30) for LC, with mean follow-up periods of 572 days and 264 days respectively (Teoh 2021).

Hospital admissions

The rate of unplanned hospital admissions after the procedure was reported in 4 studies. In the systematic review of 10 studies, the rate of hospital readmissions was 10% after EUS-GBD and 32% after PT-GBD (5 studies, I^2 =93%, p=0.08; Hemerly 2023). In the randomised controlled trial of 79 patients, the rate of unplanned hospital admissions was 15% (6/39) for patients who had

EUS-GBD and 50% (20/40) for patients who had PT-GBD (p=0.002, Teoh 2020). In the non-randomised comparative study of 372 patients, the rate of unplanned hospital admissions was 4% (4/102) for patients who had EUS-GBD, 20% (29/146) for patients who had PT-GBD and 3% (4/124) for patients who had ETP-GBD (p<0.001) with a median follow up of 3 months (Siddiqui 2019). In the non-randomised comparative study of 60 patients, the rate of unplanned readmissions was 10% (3/30) for EUS-GBD and 10% (3/30) for LC, with mean follow-up periods of 572 days and 264 days respectively (Teoh 2021).

Safety

Mortality

Mortality was reported in 5 studies. In the systematic review of 27 studies on EUS-GBD (n=1,004), the pooled procedure-related mortality was less than 1% (95% CI 0% to 0.1%, I^2 =0%) and 30-day all-cause mortality was 3% (95% CI 0.5% to 7%, I^2 =74%; Fabbri 2022). In the systematic review of 72 studies, the pooled mortality rates were 26% for EUS-GBD (95% CI 17% to 38%, I^2 =86%; 9 studies, n=398), 17% for ETP-GBD (95% CI 11% to 25%, I^2 =77%; 13 studies, n=884) and 11% for PT-GBD (95% CI 9% to 14%, I^2 =83%; 37 studies, n=3,597; Mohan 2020).

In the randomised controlled trial of 79 patients, 30-day mortality was 8% (3/39) for EUS-GBD and 10% (4/40) of patients who had PT-GBD (p=1, Teoh 2020). In the non-randomised comparative study of 60 patients, the 30-day mortality was 7% (2/30) for EUS-GBD and 0% (0/30) for LC (Teoh 2021). In the registry study of 379 patients, 30-day mortality was 9% (Teoh 2019).

Stent malfunction, dislodgment or migration

Stent malfunction, dislodgment or migration was reported in 5 studies. In the systematic review of 27 studies on EUS-GBD (n=1,004), the pooled rate of stent malfunction of dislodgment was 4% (95% CI 0.1% to 7%, I²=64.5%; Fabbri 2022). In the systematic review of 72 studies, the pooled rates of stent migration were 3% for EUS-GBD (95% CI 1% to 5%, I²=0%; 13 studies, n=546), 2% for ETP-GBD (95% CI 1% to 4%, I²=0%; 20 studies, n=1,171) and 7% for PT-GBD (95% CI 6% to 10%, I²=79%; 38 studies, n=3,997; Mohan 2020).

Catheter or stent dislodgment during follow up were reported in 1% (1/102) of patients who had EUS-GBD, 8% (11/146) of patients who had PT-GBD and 2% (2/124) of patients who had ETP-GBD in the non-randomised comparative study of 372 patients (Siddiqui 2019). Early stent migration was reported in 1% (1/73) of patients after EUS-GBD and 8% (8/106) of patients after PT-GBD in the non-randomised comparative study of 182 patients (Cho 2022). Stent migration was reported in 1% (3/379) of patients and gastric outlet obstruction from the stent was reported in 1 patient in the registry study of 379 patients (Teoh 2019).

Stent occlusion

Stent occlusion was reported in 5 studies. In the systematic review of 72 studies, the pooled rates of stent occlusion were 3% for EUS-GBD (95% CI 1% to 6%, I^2 =0%; 12 studies, n=506), 2% for ETP-GBD (95% CI 1% to 4%, I^2 =0%; 20 studies, n=1,171) and 2% for PT-GBD (95% CI 1% to 3%, I^2 =56%; 36 studies, n=3,524; Mohan 2020).

A blocked stent within 30 days was reported in 5% (2/39) of patients who had EUS-GBD in the randomised controlled trial of 79 patients. At 1 year, a blocked stent was reported in 1 additional patient who had EUS-GBD and 5% (2/40) of patients who had PT-GBD (Teoh 2020). Catheter or stent occlusion during follow up were reported in 0% (0/102) of patients who had EUS-GBD, 3% (4/146) of patients who had PT-GBD and 3% (4/124) of patients who had ETP-GBD in the non-randomised comparative study of 372 patients (Siddiqui 2019). A blocked stent because of gallstones was reported in 1 patient who had EUS-GBD in the non-randomised comparative study of 60 patients (Teoh 2021). Stent obstruction was reported in 1% (3/379) of patients in the registry study of 379 patients (Teoh 2019). An obstructed stent because of overgrowth at 42 months after stent deployment was reported in 1 patient in the case series of 22 patients (Torres Yuste 2019).

Bile leak or peritonitis

Bile leak or peritonitis was reported in 5 studies. In the systematic review of 27 studies on EUS-GBD (n=1,004), the pooled rate of bile leak or peritonitis was 2% (95% CI 0.1% to 4%, I^2 =59.5%; Fabbri 2022). In the systematic review of 72 studies, the pooled rates of bile leak or bile peritonitis were 3% for EUS-GBD (95% CI 2% to 5%, I^2 =0%; 13 studies, n=546), 1% for ETP-GBD (95% CI 1% to 3%, I^2 =0%; 21 studies, n=1,209) and 3% for PT-GBD (95% CI 2% to 4%, I^2 =0%; 37 studies, n=3,597; Mohan 2020).

Procedural bile leaks were reported in 2% (2/102) of patients who had EUS-GBD and 1% (2/146) of patients who had PT-GBD in the non-randomised comparative study of 372 patients (Siddiqui 2019). Bile leak was reported in 1% (3/379) of patients in the registry study of 379 patients (Teoh 2019). Leakage was reported as an early adverse event in 1% (1/73) of patients after EUS-GBD and 3% (3/106) of patients after PT-GBD in the non-randomised comparative study of 182 patients (Cho 2022).

Bleeding

Bleeding was reported in 5 studies. In the systematic review of 27 studies on EUS-GBD (n=1,004), the pooled rate of bleeding was <1% (95% CI 0.1% to 1%, I^2 =10.3%; Fabbri 2022). In the systematic review of 72 studies, the pooled rates of bleeding were 4% for EUS-GBD (95% CI 3% to 7%, I^2 =0%; 13 studies,

n=546), 2% for ETP-GBD (95% CI 1% to 3%, I²=0%; 21 studies, n=1,209) and 2% for PT-GBD (95% CI 2% to 3%, I²=0%; 37 studies, n=3,597; Mohan 2020).

Procedural self-limited bleeding was reported in 5% (5/102) of patients who had EUS-GBD, 2% (3/146) of patients who had PT-GBD and 2% (2/124) of patients in the non-randomised comparative study of 372 patients (Siddiqui 2019). Upper gastrointestinal bleeding needing endoscopic haemostasis was reported in 1 patient who had EUS-GBD and 1 patient who had LC in the non-randomised comparative study of 60 patients (Teoh 2021).

Bleeding from the puncture site, bleeding in the gallbladder and bleeding from the cystic artery were each reported in 1 patient in the registry study of 379 patients (Teoh 2019).

Perforation

Perforation was reported as an adverse event in 4 studies. In the systematic review of 72 studies, the pooled rates of perforation were 4% for EUS-GBD (95% CI 2% to 6%, I²=0%; 13 studies, n=546), 2% for ETP-GBD (95% CI 1% to 3%, I²=0%; 21 studies, n=1,209) and 2% for PT-GBD (95% CI 1% to 3%, I²=0%; 36 studies, n=3,524; Mohan 2020).

Perforation was reported in 1 patient who had EUS-GBD in the randomised controlled trial of 79 patients (Teoh 2020). Perforation was reported in 2% (2/102) of patients who had EUS-GBD in the non-randomised comparative study of 372 patients (Siddiqui 2019). Duodenal perforation was reported in less than 1% (2/379) of patients in the registry study of 379 patients (Teoh 2019).

Pneumoperitoneum

Pneumoperitoneum was reported in 3 studies. In the systematic review of 27 studies on EUS-GBD (n=1,004), the pooled rate of pneumoperitoneum was less than 1% (95% CI 0% to 1%, I²=0%; Fabbri 2022). Pneumoperitoneum was reported in less than 1% (2/379) of patients in the registry study of 379 patients (Teoh 2019). Pneumoperitoneum was reported as an early adverse event in 3% (2/73) of patients after EUS-GBD and none of the patients after PT-GBD in the non-randomised comparative study of 182 patients (Cho 2022).

Pancreatitis

In the systematic review of 72 studies, the pooled rates of pancreatitis were 1% for EUS-GBD (95% CI 1% to 3%, I^2 =0%; 13 studies, n=546), 5% for ETP-GBD (95% CI 4% to 7%, I^2 =17%; 21 studies, n=1,209) and 1% for PT-GBD (95% CI 1% to 2%, I^2 =0%; 36 studies, n=3,524; Mohan 2020).

Infection

Periprocedural infection was reported in 1 patient who had EUS-GBD and 1 who had PT-GBD in the non-randomised comparative study of 372 patients (Siddiqui 2019). In the same study, infection during the follow-up period (3 to 9 months) was reported in 1% (1/102) of patients who had EUS-GBD and 3% (5/146) of patients who had PT-GBD. Infected abdominal collection and infected ascites were each reported in 1 patient in the registry study of 379 patients (Teoh 2019).

Other

Gastric reflux into the gallbladder after EUS-GBD was described in 2 patients as case reports (Kim 2019). In 1 patient, this was managed with repeat endoscopic drainage. The other patient eventually had an open cholecystectomy, partial liver resection, gastric antrectomy and Billroth 2 gastrojejunostomy. Another case report described a cholecystocolonic fistula after EUS-GBD for stump cholecystitis. This was successfully treated endoscopically (Koutlas 2023).

Anecdotal and theoretical adverse events

Expert advice was sought from consultants who have been nominated or ratified by their professional Society or Royal College. They were asked if they knew of any other adverse events for this procedure that they had heard about (anecdotal), which were not reported in the literature. They were also asked if they thought there were other adverse events that might possibly occur, even if they have never happened (theoretical).

They did not list any anecdotal adverse events.

They listed the following theoretical adverse events:

- One theoretical adverse event is around eventual progression to surgery. This
 technique has been used to 'bridge' a patient to surgery, but the effect of these
 stents on eventual surgery is not clear.
- The procedure involves creating a connection between the gallbladder and stomach or duodenum (a cholecystoduodenal fistula). This would likely lead to more adhesions around the gallbladder and the bowel and makes any future surgical cholecystectomy or other abdominal surgery technically more difficult. The potential risk of complications from future abdominal operation could be higher than for percutaneous cholecystostomy.

Three professional expert questionnaires for this procedure were submitted. Find full details of what the professional experts said about the procedure in the specialist advice questionnaires for this procedure.

Validity and generalisability

- Two randomised controlled trials on EUS-GBD for acute cholecystitis were identified, the most recent of which is included in the key evidence tables and the other (Jang 2012) is included in table 5. Most of the evidence is from retrospective observational studies.
- There was evidence from Europe, North America, Asia and Australasia, but no studies based in the UK were identified for inclusion in the key evidence.
- Most of the procedures were done by experienced endoscopists in tertiary referral centres. One study reported that unplanned procedural events were statistically significantly more common when the procedure was done by endoscopists with experience of fewer than 25 procedures (p=0.033; Teoh 2019).
- In the systematic review by Fabbri et al. (2022), 8 of the 27 studies reported
 10 or more cases per year per centre.
- None of the studies reported quality of life outcomes.
- The longest mean or median follow up was 24 months, but this was in a small retrospective case series with only 22 patients (Torres Yuste 2019).
- There were variations in technique and stents used within and between studies. In 1 systematic review and meta-analysis, the use of anti-migrating devices was shown to reduce the rate of procedure-related adverse events and increase the overall clinical success (Fabbri 2022).
- In 1 systematic review and meta-analysis, the pooled mortality rate was higher for EUS-GBD than for ETP-GBD and PT-GBD. This result should be interpreted with caution because there was considerable heterogeneity and not all studies reported mortality data. The authors suggested that a possible explanation for the higher all-cause mortality was that most of the EUS-GBD

studies were done in patients for whom the overall survival was low to begin with and the studies adequately followed up their patients to report a mortality event, unlike the ETP-GBD and PT-GBD studies (Mohan 2020).

- In the non-randomised study comparing EUS-GBD with LC, the follow-up period was statistically significantly longer in the EUS-GBD group (Teoh 2021).
- None of the papers included in tables 2 and 3 reported that the study was funded by a company. Declarations of interest were reported by at least 1 author in most of the papers.
- Ongoing trial:
 - Efficacy and Safety of Lumen Apposing Metal Stents: a Retrospective
 Multicentre Study (NCT03903523); Italy; observational cohort study; n=500;
 estimated end date December 2023

Existing assessments of this procedure

A guideline on the use of therapeutic endoscopic ultrasound-guided procedures was published by the ESGE in 2022 (van der Merwe 2022). The ESGE made the following recommendation regarding EUS-GBD:

 'ESGE recommends that, in patients at high surgical risk, EUS-guided gallbladder drainage (GBD) should be favored over percutaneous gallbladder drainage where both techniques are available, owing to the lower rates of adverse events and need for re-interventions in EUS-GBD (Strong recommendation, high quality of evidence)'.

The Tokyo Guidelines 2018 (Mori 2017) include the following recommendation:

 'We recommend PT-GBD as a standard drainage method for surgically high-risk patients with acute cholecystitis. (Recommendation 1, level B).
 However, ETP-GBD or EUS-GBD could be considered in high-volume institutes when performed by skilled endoscopists. (Level B)'

Related NICE guidance

Interventional procedures

- NICE's interventional procedures guidance 720 (2022) on <u>percutaneous</u> insertion of a cystic duct stent after cholecystostomy for acute calculous <u>cholecystitis</u> (Recommendation: special arrangements)
- NICE's interventional procedures guidance 508 (2014) on <u>single-incision</u>
 <u>laparoscopic cholecystectomy</u> (Recommendation: normal [now known as standard] arrangements)

NICE guidelines

 NICE clinical guideline 188 (2014) on <u>gallstone disease: diagnosis and</u> <u>management</u>

Professional societies

- · Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland
- British Society of Gastroenterology
- · British Society of Interventional Radiology
- Royal College of Radiologists.

Evidence from patients and patient organisations

NICE received 2 completed questionnaires from patients who had the procedure (or their carers).

Patients' views on the procedure were consistent with the published evidence and the opinions of the professional experts.

Company engagement

NICE asked companies who manufacture a device potentially relevant to this procedure for information on it. NICE received 1 completed submission. This was

considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

References

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- 5. Teoh AYB, Kitano M, Itoi T et al. (2020) Endosonography-guided gallbladder drainage versus percutaneous cholecystostomy in very high-risk surgical patients with acute cholecystitis: an international randomised multicentre controlled superiority trial (DRAC 1). Gut 69: 1085–91
- 6. Siddiqui A, Kunda R, Tyberg Amy et al. (2019) Three-way comparative study of endoscopic ultrasound-guided transmural gallbladder drainage using lumen-apposing metal stents versus endoscopic transpapillary drainage versus percutaneous cholecystostomy for gallbladder drainage in high-risk surgical patients with acute cholecystitis: clinical outcomes and success in an International, Multicenter Study. Surgical Endoscopy 33: 1260–70
- 7. Cho SH, Oh D, Song TJ et al. (2022) Long-term outcomes of endoscopic ultrasound-guided gallbladder drainage versus in situ or ex situ percutaneous gallbladder drainage in real-world practice. Digestive Endoscopy https://doi.org/10.1111/den.14485
- 8. Teoh AYB, Leung CH, Tam PTH et al. (2021) EUS-guided gallbladder drainage versus laparoscopic cholecystectomy for acute cholecystitis: a propensity score analysis with 1-year follow-up data. Gastrointestinal Endoscopy 93: 577–83

- 9. Teoh AY, Perez-Miranda M, Kunda R et al. (2019) Outcomes of an international multicenter registry on EUS-guided gallbladder drainage in patients at high risk for cholecystectomy. Endoscopy International Open 7: e964–e973
- Torres Yuste R, García-Alonsoa FJ, Sánchez-Ocanaa R et al. (2019) Safety and clinical outcomes of endoscopic ultrasound-guided gallbladder drainage with lumen-apposing metal stents in patients with dwell time over one year. Annals of Gastroenterology 32: 514–21
- Kim JJ, Hiotis SP, Sur MD (2019) Gastric Reflux Into the Gallbladder After EUS-guided Stenting—Letter to the Editor Regarding "EUS-guided Versus Percutaneous Gallbladder Drainage: Isn't It Time to Convert?" Journal of Clinical Gastroenterology 53: 392–3
- Koutlas NJ, Pawa R (2023) Cholecystocolonic fistula following endoscopic ultrasound-guided gallbladder drainage for stump cholecystitis. Clinical Journal of Gastroenterology 16: 116–120
- 13. van der Merwe SW, Van Wanrooij RLJ, Bronswijk M et al. (2022)
 Therapeutic endoscopic ultrasound: European Society of Gastrointestinal
 Endoscopy (ESGE) Guideline. Endoscopy 54: 185–205
- 14. Mori Y, Itoi T, Baron TH et al. (2017) Tokyo Guidelines 2018: management strategies for gallbladder drainage in patients with acute cholecystitis (with videos). Journal of Hepato-Biliary-Pancreatic Sciences 25: 87–95

Methods

NICE identified studies and reviews relevant to endoscopic ultrasound-guided gallbladder drainage for acute cholecystitis from the medical literature. The following databases were searched between the date they started to 22 February 2023: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the internet were also searched (see the <u>literature search strategy</u>). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following inclusion criteria were applied to the abstracts identified by the literature search.

 Publication type: clinical studies were included with emphasis on identifying good quality studies. Abstracts were excluded if they did not report clinical IP overview: Endoscopic ultrasound-guided gallbladder drainage for acute cholecystitis when surgery is not an option outcomes. Reviews, editorials, and laboratory or animal studies, were also excluded and so were conference abstracts, because of the difficulty of appraising study methodology, unless they reported specific adverse events that not available in the published literature.

- Patients with acute cholecystitis for whom surgery was not an option.
- Intervention or test: endoscopic ultrasound-guided gallbladder drainage
- Outcome: articles were retrieved if the abstract contained information relevant to the safety, efficacy, or both.

If selection criteria could not be determined from the abstracts the full paper was retrieved.

Potentially relevant studies not included in the main evidence summary are listed in the section on <u>other relevant studies</u>.

Find out more about how NICE selects the evidence for the committee.

Table 4 literature search strategy

Databases	Date searched	Version/files
MEDLINE (Ovid)	22/02/2023	1946 to February 21 2023
MEDLINE In-Process (Ovid)	22/02/2023	1946 to February 21 2023
MEDLINE Epubs ahead of print (Ovid)	22/02/2023	February 21 2023
EMBASE (Ovid)	22/02/2023	1974 to 2023 February 21
EMBASE Conference (Ovid)	22/02/2023	1974 to 2023 February 21
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	22/02/2023	1974 to 2023 February 21
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	22/02/2023	1974 to 2023 February 21
International HTA database (INAHTA)	22/02/2023	

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

MEDLINE search strategy

1 exp Cholecystitis/

- 2 cholecystitis.tw.
- 3 ((gallbladder* or gall bladder*) adj4 (inflam* or empyema or infect* or irritat*)).tw.
- 4 biliary tract/ or bile ducts/ or cystic duct/ or gallbladder/
- 5 (obstruct* or block* or stenos* or stoppage* or narrow* or imped*).tw.
- 6 4 and 5
- 7 ((Biliary or "Bile duct*" or gallbladder* or gall bladder* or "cystic duct*") adj4 (obstruct* or block* or stenos* or stoppage* or narrow* or imped*)).tw.
- 8 1 or 2 or 3 or 6 or 7
- 9 gallbladder/ and drainage/
- 10 Endoscopes/ or Endoscopy/ or Endoscopy, Digestive System/
- 11 Stents/
- 12 Ultrasonography, Interventional/
- 13 Endosonography/
- 14 (12 or 13) and 9
- 15 (10 or 11) and 9
- 16 (Endoscop* adj4 ultraso* adj4 guid* adj4 (cholecystoduodenostom* or cholecystogastrostom* or cholecystojejunostom*)).tw.
- 17 (Endoscop* adj4 ultraso* adj4 guid* adj4 (Biliary or "Bile duct*" or gallbladder or gall bladder or "cystic duct*") adj4 drain*).tw.
- 18 (EUS-guid* adj4 (cholecystoduodenostom* or cholecystogastrostom* or cholecystojejunostom*)).tw.
- 19 (EUS-guid* adj4 (Biliary or "Bile duct*" or gallbladder or gall bladder or "cystic duct*") adj4 drain*).tw. 220 (EUS-GBD or EUSGBD).tw.
- 21 "lumen-apposing metal stent*".tw.
- 22 LAMS.tw.
- 23 or/14-22
- 24 8 and 23
- 25 "Electrocautery-Enhanced Delivery System".tw.
- 26 "GORE VIABIL Biliary Endoprosthesis".tw.
- 27 "Short Wire Biliary Endoprosthesis".tw.
- 28 ("hot axios*" or axios*).tw.
- 29 or/24-28
- 30 animals/ not humans/
- 31 29 not 30

Other relevant studies

Other potentially relevant studies to the IP overview that were not included in the main evidence summary (<u>table 2</u> and <u>table 3</u>) are listed in table 5 below.

Case series with 10 or fewer patients have been excluded.

Table 5 additional studies identified

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Ahmed O, Rogers AC, Bolger JC et al. (2018) Meta-analysis of outcomes of endoscopic ultrasound-guided gallbladder drainage versus percutaneous cholecystostomy for the management of acute cholecystitis. Surgical Endoscopy 32: 1627–35	Systematic review and meta- analysis n=495 (5 studies)	Acute cholecystoenterostomy is a promising alternative to percutaneous cholecystostomy in high-risk patients with acute cholecystitis, with equivalent success rates, improved pain scores and lower reintervention rates, without the morbidities associated with external drainage.	A more recent systematic review and meta-analysis is included.
Ahmed O, Ogura T, Eldahrouty A et al. (2018) Endoscopic ultrasound- guided gallbladder drainage: Results of long- term follow-up. Saudi Journal of Gastroenterology 24: 183–88	Case series n=13 Follow up: median 240 days	The rates of technical success, functional success, and adverse events were 100%, 92% and 8%, respectively. Recurrence of cholecystitis was observed in 1 patient (8%).	Studies with more patients or longer follow up are included.
Anderloni A, Buda A, Vieceli F et al. (2016) Endoscopic ultrasound- guided transmural stenting for gallbladder drainage in high-risk patients with acute	Systematic review n=166 (21 studies)	Endoscopic ultrasound- guided transmural stenting for gallbladder drainage appears to be feasible, safe, and effective. LAMSs seem to have high potential in	A more recent systematic review and meta-analysis is included.

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
cholecystitis: a systematic review and pooled analysis. Surgical Endoscopy 30: 5200–8		terms of efficacy and safety, although further prospective studies are needed.	
Auriemma F, Fugazza A, Colombo M et al. (2022) Safety issues in endoscopy ultrasound-guided interventions using lumen apposing metal stents. Minerva Gastroenterol (Torino). 68:177-185	Review	Early recognition and management of adverse events associated with LAMS is critical to improve outcomes.	Only cites 3 studies on EUS- GBD, all of which are included in the overview.
Chan SM, Teoh AYB, Yip HC et al. (2017) Feasibility of per-oral cholecystoscopy and advanced gallbladder interventions after EUS-guided gallbladder stenting (with video). Gastrointestinal Endoscopy 85: 1225–32	Cohort study n=25	The recent development of EUS-GBD with a lumenapposing stent has made endoscopic assessment and advanced gallbladder interventions via the stent possible. Per-oral cholecystoscopy and advanced gallbladder interventions were feasible and safe.	Study describes interventions that can be done after EUS-GBD.
Cho DH, Jo SJ, Lee JH et al. (2019) Feasibility and safety of endoscopic ultrasound-guided gallbladder drainage using a newly designed lumen-apposing metal stent. Surgical Endoscopy 33: 2135–41	Case series n=22 Follow up: median 318 days	EUS-GBD with newly designed LAMS is feasible and shows acceptable safety profiles for both the urgent drainage of acute cholecystitis and elective internalisation following PT-GBD in patients with high surgical risk.	Studies with more patients or longer follow up are included.
Choi JH, Kim HW, Lee J- C et al. (2017) Percutaneous transhepatic versus EUS- guided gallbladder drainage for malignant	Non- randomised comparative study n=33	EUS-GBD is a feasible, safe, and effective modality for the treatment of malignant cystic duct obstruction in patients who are not	Small study focusing on acute cholecystitis caused by

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
cystic duct obstruction. Gastrointestinal Endoscopy 85: 357–64		indicated for surgery. It enables improved long-term quality of life in patients with advanced-stage cancer.	malignant cystic duct obstruction. Study is included in the systematic review by Podboy et al. (2022).
Choi J-H, Lee SS, Choi JH et al. (2014) Long-term outcomes after endoscopic ultrasonography-guided gallbladder drainage for acute cholecystitis. Endoscopy 46: 656–61	Case series n=63 Follow up: median 275 days	Technical and clinical success=98% Procedural adverse events included duodenal perforation (n=1) and self-limiting pneumoperitoneum (n=2, 3%), all of which resolved with conservative treatment. Late adverse events developed in 4 patients (7%; 95% CI 6% to 8%), including asymptomatic distal stent migration (n=2), and acute cholecystitis due to stent occlusion (n=2). Two patients with occluded stent were successfully treated endoscopically (reintervention rate of 4%). 96% of patients had no recurrence of acute cholecystitis during follow-up.	Studies with more patients or longer follow up are included. Study is included in the systematic review by Mohan et al. (2020) and Fabbri et al. (2022).
Cucchetti A, Binda C, Dajti E et al. (2022) Trial sequential analysis of EUS-guided gallbladder drainage versus percutaneous cholecystostomy in patients with acute	Meta- analysis and trial sequential analysis n=535 (4 studies)	PT-GBD can provide superior technical success than EUS-GBD if a very large sample size is accrued, thus limiting the single-patient benefit. Clinical success is probably	Only 4 studies were included, all of which are in the overview.

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
cholecystitis. Gastrointestinal Endoscopy 95: 399–406		equivalent. EUS-GBD decreased overall adverse events and unplanned readmissions, but more studies are needed on the need for reinterventions.	
de la Serna-Higuera C, Perez-Miranda M, Gil- Simon P et al. (2013) EUS-guided transenteric gallbladder drainage with a new fistula-forming, lumen-apposing metal stent. Gastrointestinal Endoscopy 77: 303–8	Case series n=13 Follow up: median 100.8 days	This pilot study shows that the lumenapposing stent may be, in the future, a feasible and safe alternative to percutaneous transhepatic gallbladder drainage in patients with acute cholecystitis unsuitable for a surgical approach. However, there are many limitations to this pilot study, so the data may not be generalised. Further prospective, larger, and comparative studies between AXIOS gallbladder drainage and percutaneous transhepatic gallbladder drainage are needed to assess the real efficacy and safety of this novel stent.	Small case series, included in the systematic reviews by Mohan et al. (2020) and Fabbri et al. (2022).
Dollhopf M, Larghi A, Will U et al. (2017) EUS-guided gallbladder drainage in patients with acute cholecystitis and high surgical risk using an electrocautery-enhanced lumen-apposing metal stent device.	Case series n=75 Follow up: mean 201 days	The novel lumen- apposing metal stent with an electrocautery (ECE-LAMS) on the tip for high-risk surgical patients with acute cholecystitis is safe, with a high technical and clinical success rate. Future multicentre studies comparing	Case series, which is included in the systematic reviews by Mohan et al. (2020) and Fabbri et al. (2022).

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Gastrointestinal Endoscopy 86: 636–43		EUS-GBD versus PT-GBD are warranted to determine which procedure is safer and clinically more effective for patients with high surgical risk acute cholecystitis.	
Fugazza A, Colombo M, Repici A et al. (2020) Endoscopic ultrasound- guided gallbladder drainage: Current perspectives. Clinical and Experimental Gastroenterology 13: 193–201	Review	EUS-GBD is now considered a well-established alternative treatment to surgery in case of acute cholecystitis. The data propose EUS-GBD as a valuable safe and efficient procedure in the long-term follow-up, reducing the risk of further biliary events for fragile patients who do not have cholecystectomy, carrying low rates of adverse events.	No meta- analysis.
Garcia-Alonso FJ, Sanchez-Ocana R, Penas-Herrero I et al. (2018) Cumulative risks of stent migration and gastrointestinal bleeding in patients with lumen- apposing metal stents. Endoscopy 50: 386–95	Cohort study n=250 Follow up: median 75 days	LAMSs placed for longer durations (such as enteral anastomoses, biliary and gallbladder drainage) presented an 8% cumulative risk of migration at 2 years. Migration was most common when treating pancreatic fluid collections. There were 13 LAMS-related gastrointestinal haemorrhages (5%), 2 of them fatal, presenting a median of 3 days after deployment. The	Mixed indications.

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		cumulative risk of bleeding at 12 months was 7%.	
Guzman-Calderon E, Chacaltana A, Diaz- Arocutipa C et al. (2022) EUS-Guided gallbladder drainage vs percutaneous transhepatic drainage in patients with acute cholecystitis: a systematic review and meta-analysis. Revista de gastroenterologia del Peru: organo oficial de la Sociedad de Gastroenterologia del Peru 42: 163-170	Systematic review and meta- analysis 6 studies (n=749)	EUS-GBD has a similar clinical success rate and a similar adverse events rate in comparison to PTGBD. The high technical success and the low adverse events rate of the EUS approach to gallbladder make this technique an excellent alternative for patients with acute cholecystitis who cannot have surgery.	All 6 studies are already included in the overview, in tables 2 or 5.
Han D, Inamdar S, Lee CW et al. (2018) Lumen apposing metal stents (LAMSs) for drainage of pancreatic and gallbladder collections: a meta-analysis. Journal of Clinical Gastroenterology 52: 835–44	Systematic review and meta- analysis n=993 (20 trials); 181 gallbladder drainage	Pooled technical success for gallbladder drainage was 95% (95% CI 91% to 99%) and clinical success was 93% (95% CI 90% to 97%).	A more recent systematic review and meta-analysis is included.
Higa JT, Sahar N, Kozarek RA et al. (2019) EUS-guided gallbladder drainage with a lumen- apposing metal stent versus endoscopic transpapillary gallbladder drainage for the treatment of acute cholecystitis (with videos). Gastrointestinal Endoscopy 90: 483–92	Non- randomised comparative study n=78	EUS-GBD has a higher clinical success rate than transpapillary drainage and may be associated with a lower recurrence rate of cholecystitis. However, transpapillary drainage should be considered as the first-line treatment for patients who are surgical candidates but need temporising measures or need an ERCP for other reasons.	Small retrospective non-randomised comparative study that is included in systematic reviews by Podboy et al. (2021) and Mohan et al. (2020).

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Imai M, Takahashi Y, Sato T et al. (2021) Long- term outcomes of elective EUS-guided gallbladder drainage after percutaneous transhepatic gallbladder drainage. Techniques and Innovations in Gastrointestinal Endoscopy 23: 1–7	Case series n=15	Both the technical and clinical success rates were 93% (14/15). Two patients (13%) developed adverse events, with distal stent migration in 1 patient and asymptomatic pneumoperitoneum in the other patient. Cholecystitis recurred only in patients who had stent migration. The median duration of stent patency was 544 days (18 to 1,006 days), without any deaths. The overall stent patency rate was 87% (13/15).	Studies with more patients are included.
Inoue T, Yoshida M, Suzuki Y et al. (2021) Long-term outcomes of endoscopic gallbladder drainage for cholecystitis in poor surgical candidates: An updated comprehensive review. Journal of Clinical Medicine 10: 4842	Review	Long-term stent placement with endoscopic gallbladder stenting and EUS-GBD is a therapeutic method that may be a useful option for the prevention of recurrent cholecystitis. It is expected that the efficacy and safety of these procedures will be better established by future studies.	No meta- analysis.
Irani SS, Sharma NR, Storm AC et al. (2022) EUS-guided transluminal gallbladder drainage in patients with acute cholecystitis: a prospective multicenter trial. Annals of surgery	Prospective single-arm trial n=30 Follow up: 90 days	In this prospective, multicentre study of patients with mild or moderate acute cholecystitis who were not candidates for cholecystectomy, EUS-GBD using LAMS showed high technical	Studies with more patients or longer follow up are included.

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		and clinical success, low recurrence of acute cholecystitis and a low rate of AEs attributable to the stent or procedure despite a patient population with multiple comorbidities.	
Irani S, Ngamruengphong S, Teoh A et al. (2017) Similar efficacies of endoscopic ultrasound gallbladder drainage with a lumen-apposing metal stent versus percutaneous transhepatic gallbladder drainage for acute cholecystitis. Clinical Gastroenterology and Hepatology 15: 738–45	Non- randomised comparative study n=90	EUS-GBD has similar technical and clinical success compared with PT-GBD and should be considered an alternative for patients who are not candidates for surgery. Patients who have EUS-GBD seem to have shorter hospital stays, lower pain scores, and fewer repeated interventions, with a trend toward fewer adverse events. A prospective, comparative study is needed to confirm these results.	Small retrospective non-randomised comparative study that is included in systematic reviews by Fabbri et al. (2022), Podboy et al. (2021) and Mohan et al. (2020).
Irani S, Baron TH, Grimm IS et al. (2015) EUS-guided gallbladder drainage with a lumenapposing metal stent (with video). Gastrointestinal Endoscopy 82: 1110–5	Case series n=15 Follow up: median 160 days	EUS-GBD with a LAMS is technically safe and effective for decompressing the gallbladder for cholecystitis and biliary or cystic duct obstruction in patients who are poor surgical candidates.	Studies with more patients or longer follow up are included.
Itoi T, Coelho-Prabhu N, Baron TH (2010) Endoscopic gallbladder drainage for management of acute cholecystitis.	Systematic review n=321 (endoscopic drainage or stenting)	Although there are now several gallbladder drainage methods to treat acute cholecystitis, the optimal minimally	A more recent systematic review and meta-analysis is included.

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Gastrointestinal Endoscopy 71: 1038–45		invasive, safe, and reliable treatment method needs to be determined.	
Jain D, Bhandari BS, Agrawal N et al. (2018) Endoscopic ultrasound- guided gallbladder drainage using a lumen- apposing metal stent for acute cholecystitis: a systematic review. Clinical Endoscopy 51: 450–62	Review n=189 (10 studies)	The absence of an external drainage tube and widespread applicability in patients with coagulopathy or ascites make EUS-GBD using LAMS an attractive option for patients with acute cholecystitis in whom surgery is contraindicated.	More recent systematic reviews are included.
James T, Baron T (2019) EUS-guided gallbladder drainage: A review of current practices and procedures. Endoscopic Ultrasound 8: 28-s34	Review	EUS-GBD is a promising development in the management of cholecystitis, both acute and chronic, in patients unable to have cholecystectomy. Larger comparative studies between percutaneous drain placement and EUS-GBD are required to determine the optimal strategy based on patient characteristics. Long-term care of patients who have had EUS-GBD as destination therapy is not well known and additional work is needed to determine the optimal stent exchange interval.	No meta- analysis.
James TW, Krafft M, Croglio M et al. (2019) EUS-guided gallbladder	Case series n=15	Technical and clinical success=93%	Small case series, focusing on EUS-GBD in

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
drainage in patients with cirrhosis: Results of a multicenter retrospective study. Endoscopy International Open 7: e1099-e1104	Follow up: mean 373 days	There were 2 adverse events. EUS-GBD is safe and efficacious in managing cholecystitis in patients with Child-Pugh A and B cirrhosis who are non-operative candidates.	patients with cirrhosis.
Jang JW, Lee SS, Song TJ et al. (2012) Endoscopic ultrasound- guided transmural and percutaneous transhepatic gallbladder drainage are comparable for acute cholecystitis. Gastroenterology 142: 805–11	Randomised controlled trial n=59	EUS-GBD is comparable with PT-GBD in terms of the technical feasibility and efficacy; there were no statistically significant differences in the safety. EUS-GBD is a good alternative for high-risk patients with acute cholecystitis who cannot have an emergency cholecystectomy.	Studies with more patients or longer follow up are included. This study is included in the systematic reviews by Podboy et al. (2021) and Mohan et al. (2020).
Jang JW, Lee SS, Park DH et al. (2011) Feasibility and safety of EUS-guided transgastric/ transduodenal gallbladder drainage with single-step placement of a modified covered self-expandable metal stent in patients unsuitable for cholecystectomy. Gastrointestinal endoscopy 74: 176–81	Case series n=15 Follow up: median 145 days	Placement of a modified covered self-expandable metal stent after EUS-guided transgastric or transduodenal gallbladder drainage may be a feasible and safe alternative to treatments such as percutaneous cholecystostomy in patients with acute cholecystitis who are unsuitable for cholecystectomy.	Studies with more patients or longer follow up are included. Study is included in systematic review by Fabbri et al. (2022).
Kalva NR, Vanar V, Forcione D et al. (2018) Efficacy and safety of lumen apposing self-	Systematic review and meta- analysis	Pooled proportion of technical success was 94% (95% CI 91 to 97%) and clinical	A more recent systematic review and

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
expandable metal stents for EUS guided cholecystostomy: a meta-analysis and systematic review. Canadian Journal of Gastroenterology & Hepatology: 7070961	n=233 (13 studies)	success was 93% (95% CI 89 to 95%). Overall complication rate was 18% (95% CI 14% to 24%) and stent related complication rate was 8% (95% CI 4 to 15%) in the pooled percentage of patients. Pooled proportion for perforation was 7% (95% CI 4 to 11%) and recurrent cholangitis or cholecystitis was noted in 4% (95% CI 2 to 8%).	meta-analysis is included.
Kahaleh M, Perez- Miranda M, Artifon EL et al. (2016) International collaborative study on EUS-guided gallbladder drainage: Are we ready for prime time? Digestive and Liver Disease 48: 1054–7	Registry n=35 Follow up: median 91.5 days	EUS-GBD appears to be feasible, safe, and effective. Prospective studies are needed to confirm these findings and identify the best technique to use	Studies with more patients or longer follow up are included. Study is included in systematic review by Fabbri et al. (2022).
Kalva NR, Vanar V, Forcione D et al. (2018) Efficacy and safety of lumen apposing self- expandable metal stents for EUS guided cholecystostomy: a meta- analysis and systematic review. Canadian Journal of Gastroenterology & Hepatology 2018: 7070961	Systematic review and meta- analysis n=233 (13 studies)	EUS-GBD with LAMS is a safe and alternative treatment for patients needing gallbladder drainage, with acceptable intraprocedural and postprocedural complications. However, further controlled trials are necessary to estimate the overall efficacy and safety and the role of EUS-GBD with LAMS in management of nonoperative patients with acute cholecystitis.	A more recent systematic review and meta-analysis is included.

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Kamata K, Takenaka M, Kitano M et al. (2017) Endoscopic ultrasound- guided gallbladder drainage for acute cholecystitis: Long-term outcomes after removal of a self-expandable metal stent. World Journal of Gastroenterology 23: 661–7	Case series n=12 Follow up: median 304 days	Long-term outcomes after removal of the self-expandable metal stent were excellent. Removal of the stents 4 weeks after placement and improvement of symptoms might avoid migration of the stent and recurrence of cholecystitis due to food impaction.	Studies with more patients or longer follow up are included. Study is included in systematic review by Fabbri et al. (2022).
Kanno Y, Kozakai F, Koshita S et al. (2019) Technical issues stemming from endoscopic-ultrasound- guided gallbladder drainage: A single center experience. The Turkish Journal of Gastroenterology 30: 1055–61	Case series n=18	The rates of technical success, clinical effectiveness, severe adverse event occurrence, and recurrence of acute cholecystitis were 94% (17/18), 88% (15/17), 6% (1/18, massive bile leakage), and 27% (4/15), respectively. Distal gastrectomy causing scope instability, the nonswollen gallbladder, and double pigtail stent use caused technical difficulties.	Studies with more patients or longer follow up are included. Study is included in systematic review by Fabbri et al. (2022).
Khan MA, Atiq O, Kubiliun N et al. (2017) Efficacy and safety of endoscopic gallbladder drainage in acute cholecystitis: Is it better than percutaneous gallbladder drainage? Gastrointestinal Endoscopy 85: 76–87	Systematic review and meta- analysis n=809 (23 studies)	Endoscopic gallbladder drainage is an efficacious and safe therapeutic modality for treatment of patients with acute cholecystitis who cannot undergo surgery. It shows a similar technical success as PT-GBD but appears to be safer.	A more recent systematic review and meta-analysis is included.
Kozakai F, Kanno Y, Ito K et al. (2019) Endoscopic	Non- randomised	EUS-GBD after metal stent placement was a	Studies with more patients or

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
ultrasonography-guided gallbladder drainage as a treatment option for acute cholecystitis after metal stent placement in malignant biliary strictures. Clinical Endoscopy 52: 262–8	comparative study n=48	feasible option for treating acute cholecystitis.	longer follow up are included.
Krishnamoorthi R, Jayaraj M, Thoguluva C V (2020) EUS-guided versus endoscopic transpapillary gallbladder drainage in high-risk surgical patients with acute cholecystitis: a systematic review and meta-analysis. Surgical Endoscopy 34: 1904–13	Systematic review and meta- analysis n=857 (5 studies); 259 endoscopic ultrasound- guided	EUS-GBD has higher rate of technical and clinical success compared to endoscopic transpapillary GBD. While the rates of overall adverse events are statistically similar, EUS-GBD has a lower rate of recurrent cholecystitis.	A more recent systematic review and meta-analysis is included.
Kurihara H, Bunino FM, Fugazza A et al. (2022) Endosonography-guided versus percutaneous gallbladder drainage versus cholecystectomy in fragile patients with acute cholecystitis-a high-volume center study. Medicina 58: 1647	Non- randomised comparative study n=163 Follow up: 90 days	Surgery still represents the gold standard for acute cholecystitis treatment. Nevertheless, EUS-GBD is a good alternative to PT-GBD in terms of clinical success, recurrence rate and adverse events in all kinds of patients.	Studies with more patients or longer follow up are included.
Lisotti A, Napoleon B, Fabbri C et al. (2022) Treatment of acute cholecystitis in high-risk surgical patients. Minerva Gastroenterology 68: 154–61	Systematic review 175 papers	The levels of evidence in the literature have evolved from initial descriptive studies to recent randomised controlled trials and meta-analysis of cohort studies. While several articles addressed the comparison among different techniques,	No meta- analysis.

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		some topics and questions are still debated.	
Lisotti A, Linguerri R, Bacchilega I et al. (2022) EUS-guided gallbladder drainage in high-risk surgical patients with acute cholecystitis- procedure outcomes and evaluation of mortality predictors. Surgical Endoscopy 36: 569–78	Case series n=25	Technical, clinical success rate and adverse events rate were 92%, 88%, and 16%, respectively. 30-day and 1-year mortality were 12% and 32%. Severe comorbidities and acute kidney injury were independent predictive factors confirming of long-term mortality after EUS-GBD.	Studies with more patients or longer follow up are included.
Luk S, Irani S, Krishnamoorthi R et al. (2019) Endoscopic ultrasound-guided gallbladder drainage versus percutaneous cholecystostomy for high risk surgical patients with acute cholecystitis: a systematic review and meta-analysis. Endoscopy 51: 722–32	Systematic review and meta- analysis n=495 (5 studies)	Endoscopic ultrasound guided gallbladder drainage was associated with lower rates of post-procedure adverse events, shorter hospital stays, and fewer reinterventions and readmissions compared with percutaneous cholecystostomy in patients with acute cholecystitis who could not have surgery.	A more recent systematic review and meta-analysis is included.
Luo X, Sharaiha R, Teoh AYB (2022) Endoscopic Management of Acute Cholecystitis. Gastrointestinal Endoscopy Clinics of North America 32: 527– 43	Review	Endoscopic management of acute cholecystitis in high surgical risk patients is recommended in tertiary hospitals whereby expertise, resources, and technical support are available.	No meta- analysis.

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		In patients who cannot have surgery, PT-GBD, ETP-GBD), and EUS-GBD are effective and safe alternative procedures to cholecystectomy. EUS-GBD is preferred over PT-GBD because of similar rates of technical success and reduced rates of reintervention and unplanned readmissions. LAMS are associated with reduced risks of adverse events such as bile peritonitis and perforation compared with plastic stents and these stents should be used for EUS-GBD. EUS-GBD is associated with a steeper learning curve and should be done in high volume endoscopy centres where expertise is available.	
Lyu Y, Li T, Wang B et al. (2021) Comparison of three methods of gallbladder drainage for patients with acute cholecystitis who are at high surgical risk: a network meta-analysis and systematic review. Journal of Laparoendoscopic & Advanced Surgical	Systematic review and network meta- analysis 13 studies	Endoscopic ultrasound-guided bladder drainage was associated with the highest probability of clinical success (68%), and the lowest prevalence of adverse events (57%) and recurrent cholecystitis (61%).	Another systematic review and network meta-analysis with a more recent paper is included.

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Techniques. Part A; 31: 1295–1302			
Lyu Y, Li T, Wang B et al. (2021) Endoscopic ultrasound-guided gallbladder drainage versus percutaneous transhepatic gallbladder drainage for acute cholecystitis with high surgical risk: an up-to-date meta-analysis and systematic review. Journal of Laparoendoscopic & Advanced Surgical Techniques. Part A; 31: 1232–240	Systematic review and meta- analysis n=801 (8 studies)	Endoscopic ultrasound-guided bladder drainage was comparable to percutaneous gallbladder drainage regarding clinical success, with less reintervention and readmission, for acute cholecystitis with high surgical risk. The cholecystitis recurrence rate was lower with EUS-GBD with LAMS.	A more recent systematic review and meta-analysis is included.
Magahis PT, Westerveld D, Simons M et al. (2022) A surprising culprit for delayed gastrointestinal bleeding after endoscopic ultrasound-guided cholecystoduodenostomy: the double-pigtail stent. Clinical Journal of Gastroenterology	Case report n=1	6 months after EUS-GBD, the patient presented with upper gastrointestinal bleeding due to a duodenal pressure ulcer from the coaxial 10-Fr double-pigtail stent originally used to prevent such bleeding. The 10-Fr stent was replaced with 2 7-Fr stents with increased flexibility and distribution of pressure across multiple points of contact with the duodenal wall. The patient's clinical course improved with complete resolution of his symptoms of choledocholithiasis and cholecystitis.	Upper gastrointestinal bleeding is already described as an adverse event in the key evidence.

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Manta R, Mutignani M, Galloro G et al. (2018) Endoscopic ultrasound-guided gallbladder drainage for acute cholecystitis with a lumen-apposing metal stent: a systematic review of case series. European Journal of Gastroenterology & Hepatology 30: 695–98	Systematic review n=226 (9 studies) Follow up: median 6 months (range 2 to 12 months)	The stent was positioned successfully in 95% (215/226) of patients (95% CI 92 to 98%). Clinical success=92% (207/226) at intentionto-treat analysis and 96% at per-protocol analysis. A total of 24 (11%) adverse events occurred, including 11 during the procedure, and 13 observed at follow up.	A more recent systematic review and meta-analysis is included.
Matsubara S, Isayama H, Nakai Y et al. (2020) Endoscopic ultrasound- guided gallbladder drainage with a combined internal and external drainage tubes for acute cholecystitis. Journal of Gastroenterology and Hepatology 35: 1821–27	Feasibility study n=23 Follow up: 6 months	EUS-GBD with a combination of double pigtail plastic stent and naso-cystic tube is considered an effective and safe technique both as bridge to surgery and palliation.	Studies with more patients or longer follow up are included.
McCarty T, Hathorn K, Bazarbashi A et al. (2021) Endoscopic gallbladder drainage for symptomatic gallbladder disease: a cumulative systematic review meta-analysis. Surgical Endoscopy 35: 4964–4985	Systematic review and meta- analysis n=1,538 (36 studies)	Endoscopic gallbladder drainage is a safe and effective treatment for high-risk surgical candidates with symptomatic gallbladder disease. EUS-guided transmural drainage is superior to transpapillary drainage and associated with a lower rate of reintervention compared to percutaneous transhepatic drainage.	A more recent systematic review is included.
Minaga K, Yamashita Y, Ogura T et al. (2019)	Case series n=21	Where ongoing gallbladder drainage is	Studies with more patients or

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Clinical efficacy and safety of endoscopic ultrasound-guided gallbladder drainage replacement of percutaneous drainage: A multicenter retrospective study. Digestive Endoscopy 31: 180–87		needed, conversion from PT-GBD to EUS- GBD is a feasible, effective, and safe technique for patients who cannot have cholecystectomy.	longer follow up are included.
Mohan B, Asokkumar R, Shakhatreh M et al. (2019) Adverse events with lumen-apposing metal stents in endoscopic gallbladder drainage: A systematic review and meta-analysis. Endoscopic Ultrasound 8: 241–48	Systematic review and meta- analysis n=393 (8 studies)	The overall rate of adverse events with LAMS was 13%. Early adverse event risk appeared to be 6.5% and delayed risk appeared to be 8%.	Review focuses on adverse events associated with LAMS.
Nishiguchi K, Ogura T, Okuda A et al. (2021) Endoscopic gallbladder drainage for acute cholecystitis with high-risk surgical patients between transduodenal and transpapillary stenting. Endoscopic Ultrasound 10: 448–54	Non- randomised comparative study n=54 Follow up: median 522 days	Technical success rate and procedure time were significantly superior in the EUS-GBD group than in the ETP-GBD group. Recurrent acute cholecystitis tended to be more frequent in the ETP-GBD group, and clinical success tended to be more favourable in the EUS-GBD group, although these 2 variables did not differ significantly between groups.	Studies with more patients or longer follow up are included.
Ogura T, Nishioka N, Yamada M et al. (2021) EUS-guided gallbladder drainage using an improved self-expandable covered metal stent with anti-stent migration	Feasibility study n=12 Follow up: median 189 days	EUS-GBD was successfully done in all patients without any adverse events, and clinical success was achieved in all patients. In 4 patients, stents	Studies with more patients or longer follow up are included. Study is included in the systematic

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
system (with video). Digestive Diseases (Basel, Switzerland) 39: 150–5		were successfully removed after 3 months. No stent migration was seen.	review by Fabbri et al. (2022).
Ogura T, Higuchi K (2019) Endoscopic ultrasound-guided gallbladder drainage: Current status and future prospects. Digestive endoscopy 31: 55–64	Review	Compared with PT-GBD, EUS-GBD involves internal drainage. It is a technically simple procedure compared with ETP-GBD. However, the results of long-term follow up are still unclear, and there is still insufficient evidence on performance of EUS-GBD as the first-line drainage technique.	More recent systematic reviews are included.
Oh D, Song TJ, Cho DH et al. (2019) EUS-guided cholecystostomy versus endoscopic transpapillary cholecystostomy for acute cholecystitis in high-risk surgical patients. Gastrointestinal Endoscopy 89: 289–98	Non-randomised comparative study n=172 Follow up: mean 19 months (for EUS-GBD)	In patients with acute cholecystitis for whom surgery is unsuitable, EUS-GBD may be a more suitable treatment method than endoscopic transpapillary cholecystostomy.	Retrospective non-randomised comparative study that is included in systematic reviews by Fabbri et al. (2022), Podboy et al. (2021) and Mohan et al. (2020).
Park SW, Lee SS (2022) Current status of endoscopic management of cholecystitis. Digestive Endoscopy 34: 439–50	Review	Endoscopic treatments such as EUS-GBD or ETP-GBD are minimally invasive, safe, and reliable. However, they have not yet been established as standard procedures and their roles are limited to treat those who are unfit for cholecystectomy. Furthermore, although	No meta- analysis.

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		no conclusion has been reached regarding which approach is preferred, these procedures should be commonly considered by skilled endoscopists practicing in high-volume institutes.	
Penas-Herrero I, de la Serna-Higuera C, Perez- Miranda M (2015) Endoscopic ultrasound- guided gallbladder drainage for the management of acute cholecystitis (with video). Journal of Hepato-Biliary- Pancreatic Sciences 22: 35–43	Systematic review n=155 (with acute cholecystitis)	Overall, technical success was 97.5% and clinical success was 99.3% in patients with acute cholecystitis. Adverse events developed in less than 8% of patients, all of them managed conservatively.	A more recent systematic review and meta-analysis is included.
Posner H, Widmer J. (2020) EUS guided gallbladder drainage. Translational Gastroenterology and Hepatology 5: 41	Review	EUS-GBD is overall a promising technique, which is being used in increasing numbers at expert centres internationally. With impressive technical and clinical success rates with low rates of adverse events, it should be considered for non-surgical candidates with acute cholecystitis.	A more recent systematic review and meta-analysis is included.
Rajadurai A, Zorron CTPL, Cameron R et al. (2022) Endoscopic ultrasound-guided gallbladder and bile duct drainage with lumen apposing metal stent: A large multicenter cohort (with videos). Journal of	Cohort study n=49 (EUS- GBD) Follow up: median 49 days	Technical success for EUS-GBD was 96% (47/49) and clinical success was 80% (39/49). No patients needed subsequent cholecystectomy. 30-day mortality was 14.3%. The procedure-	Studies with more patients or longer follow up are included.

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Gastroenterology and Hepatology 37: 179–89		related mortality was caused by biliary sepsis (2/49, 4%) or aspiration (3/49, 6%).	
Rerknimitr R, Pham KC (2020) Practical approaches for high-risk surgical patients with acute cholecystitis: The percutaneous approach versus endoscopic alternatives. Clinical Endoscopy 53: 678–85	Review	Although EUS-GBD has the highest technical and clinical success rates over ETP-GBD and PT-GBD for gallbladder drainage especially when it is performed by experienced therapeutic endoscopists, it may not be the first option if laparoscopic cholecystectomy is planned.	No meta- analysis.
Sagami R, Hayasaka K, Nishikiori H et al. (2020) Current status in the treatment of acute cholecystitis patients receiving antithrombotic therapy: Is endoscopic drainage feasible? A systematic review. Clinical Endoscopy 53: 176–88	Systematic review 54 studies (26 on endoscopic ultrasound- guided gallbladder drainage)	The overall technical success, clinical success, and bleeding complication rates of endoscopic transpapillary versus EUS-GBD were 84% versus 96% (p<0.001), 92% versus 97% (p<0.001) and 0.65% versus 2.1% (p=0.005), respectively.	A more recent systematic review and meta-analysis is included.
Sagami R, Hayasaka K, Ujihara T et al. (2020) Feasibility of endoscopic ultrasound-guided gallbladder drainage for acute cholecystitis patients receiving antithrombotic therapy. Annals of Gastroenterology 33: 391–97	Case series n=12 Follow up: mean 261 days	EUS-GBD yielded high technical and clinical success rates and a low recurrence rate. No patients on antithrombotic therapy developed bleeding complications.	Small case series, focusing on patients who are on antithrombotic therapy.

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Saumoy M, Yang J, Bhatt A et al. (2021) Endoscopic therapies for gallbladder drainage. Gastrointestinal Endoscopy 94: 671–84	Review	Nonsurgical gallbladder drainage is recommended for management of acute cholecystitis in patients deemed high risk for surgical cholecystectomy. Selection of the optimal technique (PT-GBD, ETP-GBD, or EUS-GBD) should be individualised	No meta- analysis.
		and determined using a multidisciplinary approach based on clinical determinants and available procedural expertise.	
Saumoy M, Tyberg A, Brown E et al. (2019) Successful cholecystectomy after endoscopic ultrasound gallbladder drainage compared with percutaneous cholecystostomy, can it be done? Journal of Clinical Gastroenterology 53: 231–35	Cohort study n=34	Surgical cholecystectomy after EUS-GBD with lumen apposing metal stent is safe and feasible for the management of cholecystitis. If patient's underlying medical conditions improve, previous EUS-GBD should not preclude patients from undergoing cholecystectomy as part of standard of care.	Small study focusing on the feasibility of cholecystectomy after EUS-GBD.
Small AJ, Irani S (2018) EUS-guided gallbladder drainage vs. percutaneous gallbladder drainage. Endoscopic Ultrasound 7: 89–92	Review	EUS-guided GBD is a viable alternative for patients with cholecystitis needing nonsurgical drainage. Transmural placement of LAMSs can permit permanent drainage with minimal adverse	No meta- analysis.

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		events and has several reported advantages over percutaneous cholecystostomy tubes. EUS internal GBD should be reserved for poor operative candidates and done by highly experienced therapeutic echoendosonographers until additional evidence is accrued.	
Sobani ZA, Ling C, Rustagi T (2021) Endoscopic ultrasound- guided gallbladder drainage. Digestive Diseases and Sciences 66: 2154–61	Review	With multiple available options the method of gallbladder decompression in nonsurgical candidates should be carefully evaluated and tailored to individual patient. When done by skilled endoscopists at high-volume centres, EUS-GBD is an effective and safe alternative therapy for gallbladder drainage with high technical success rate and better long-term clinical outcomes compared to PT-GBD.	No meta- analysis.
Su J, Liu C, Li P et al. (2023) Contralateral gallbladder perforation and hemoperitoneum caused by an electrocautery-enhanced lumen-apposing metal stent during endoscopic ultrasound-guided gallbladder drainage. Endoscopy 55: e42-e43	Case report n=1	Perforation of the contralateral gallbladder wall was caused by the electrocautery tip of the EC-LAMS during EUS-GBD.	Perforation is already described as an adverse event in the key evidence.

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Takagi W, Ogura T, Sano T et al. (2016) EUS-guided cholecystoduodenostomy for acute cholecystitis with an anti-stent migration and anti-food impaction system; A pilot study. Therapeutic Advances in Gastroenterology 9: 19–25	Case series n=16 Follow up: median 181.5 days	Technical and clinical success were 100%. There were no recurrences of acute cholecystitis. Pneumoperitoneum was seen in one patient.	Studies with more patients or longer follow up are included. Study is included in the systematic reviews by Fabbri et al. (2022) and Mohan et al. (2020).
Teoh AYB, Kongkam P, Bapaye A et al. (2021) Use of a novel lumen apposing metallic stent for drainage of the bile duct and gallbladder: Long term outcomes of a prospective international trial. Digestive Endoscopy 33: 1139–45	Cohort study n=27 (EUS- GBD) Follow up: mean 197 days	The self-approximating LAMS with lower lumen apposing force was effective and safe with a low risk of buried stent syndrome and bleeding in the longer term.	Studies with more patients or longer follow up are included.
Teoh A (2019) Outcomes and limitations in EUS-guided gallbladder drainage. Endoscopic Ultrasound 8: 40-s43	Review	EUS-GBD is a safe and effective procedure for the treatment of acute cholecystitis in patients that are at high-risk for cholecystectomy. It also opens up new windows for endoscopic intervention to the gallbladder that was previously impossible. Data from large scale randomised studies are awaited to confirm the efficacy of the procedure.	No meta- analysis.
Teoh AYB, Serna C, Penas I et al. (2017) Endoscopic ultrasound- guided gallbladder drainage reduces adverse	Non- randomised comparative study n=118	EUS-GBD and percutaneous cholecystostomy were both effective means of achieving gallbladder	Studies with more patients or longer follow up are included.

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
events compared with percutaneous cholecystostomy in patients who are unfit for cholecystectomy. Endoscopy 49: 130–8		drainage. EUS-GBD may be a promising alternative to percutaneous cholecystostomy for treating acute cholecystitis in patients for whom surgery is unsuitable, provided that experienced endosonographers are available.	Study is included in systematic reviews by Fabbri et al. (2022), Podboy et al. (2021) and Mohan et al. (2020).
Torres Yuste R, Garcia-Alonso FJ, Sanchez-Ocana R et al. (2020) Safety and efficacy of EUS-guided gallbladder drainage combined with ERCP in the same session. Digestive Endoscopy 32: 608–15	Cohort study n=71	Single-session EUS-GBD combined with ERCP has comparable rates of technical and clinical success to EUS-GBD alone. A combined EUS-GBD and ERCP procedure does not appear to increase adverse events and makes possible comprehensive treatment of gallstone disease by purely endoscopic means.	Study assesses outcomes when the procedure is combined with ERCP.
Toy G, Adler DG (2022) Nonsurgical gallbladder drainage: percutaneous and endoscopic approaches. Techniques and Innovations in Gastrointestinal Endoscopy 24: 90–97	Review	Technical and clinical success rates are similar between the percutaneous and transmural approaches which are higher than those in the transpapillary approach. Taken together, the endoscopic approaches are associated with shorter hospital stays and readmissions. Mortality rates are	Systematic reviews with meta-analyses are included.

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		similar in all the approaches.	
Tyberg A, Jha K, Shah S et al. (2020) EUS-guided gallbladder drainage: A learning curve modified by technical progress. Endoscopy International Open 8: e92-e96	Case series n=48 Follow up: mean 5.4 months	Endoscopists experienced in EUS- GBD are expected to achieve a reduction in procedure time over successive cases, with efficiency reached at 41 minutes and a learning rate of 19 cases. Continued improvement is demonstrated with additional experience.	Studies with more patients or longer follow up are included.
Tyberg A, Saumoy M, Sequeiros EV et al. (2017) EUS-guided versus percutaneous gallbladder drainage. Journal of Clinical Gastroenterology 52: 79– 84	Non- randomised comparative study n=155	EUS-GBD is safe and efficacious, with comparable technical and clinical success rates and no difference in adverse events to PT-GBD. In addition, EUS-GLB offers a potential cost-saving benefit and morbidity benefit by demonstrating fewer repeat interventions.	Retrospective non-randomised comparative study that is included in systematic reviews by Podboy et al. (2021) and Mohan et al. (2020).
Walter D, Teoh AY, Itoi T et al. (2016) EUS-guided gall bladder drainage with a lumen-apposing metal stent: a prospective long-term evaluation. Gut 65: 6–8	Case series n=30 Follow up: mean 298 days	Technical success=90% (27/30) and clinical success=96% (26/27). 7% (2/27) of patients (7%) developed recurrent cholecystitis due to LAMS obstruction. Successful LAMS removal was done in 50% (15/30) of patients after a mean of 91 days. In 15 patients, no LAMS removal was done because of death (n=5), significant tissue	Studies with more patients or longer follow up are included. Study is included in the systematic review by Mohan et al. (2020).

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
		overgrowth (n=2) or other causes (n=8). 15 serious adverse events were reported, including 4 that were possibly stent-related or procedure-related (13%). Overall mortality was 23% (7/30), with 30-day mortality of 17% (5/30).	
Yoo HW, Moon JH, Jo SJ et al. (2021) A novel electrocautery-enhanced delivery system for onestep endoscopic ultrasound-guided drainage of the gallbladder and bile duct using a lumen-apposing metal stent: a feasibility study. Endoscopy 53: 922–26	Case series n=17	Technical success=94% Clinical success=100% Overall adverse event rate=18%	Studies with more patients or longer follow up are included.