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GUIDELINE

TG13: Updated Tokyo Guidelines for acute cholangitis and acute cholecystitis

TG13 indications and techniques for gallbladder drainage in acute cholecystitis (with videos)

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Abstract Percutaneous transhepatic gallbladder drainage (PTGBD) is considered a safe alternative to early cholecystectomy, especially in surgically high-risk patients with acute cholecystitis. Although randomized prospective controlled trials are lacking, data from most retrospective studies demonstrate that PTGBD is the most common gallbladder drainage method. There are several alternatives to PTGBD. Percutaneous transhepatic gallbladder aspiration is a simple alternative drainage method with fewer complications; however, its clinical usefulness has been shown only by case-series studies. Endoscopic naso-gallbladder drainage and gallbladder stenting via a transpapillary endoscopic approach are also alternative methods in acute cholecystitis, but both of them have technical difficulties resulting in lower success rates than that of PTGBD. Recently, endoscopic ultrasonography-guided transmural gallbladder drainage has been reported as a special technique for gallbladder drainage. However, it is not yet an established technique. Therefore, it should be performed in high-volume institutes by skilled endoscopists. Further prospective evaluations of the feasibility, safety, and efficacy of these various approaches are needed. This article

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describes indications and techniques of drainage for acute cholecystitis.

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Keywords Acute cholecystitis · Gallbladder drainage · Endoscopic ultrasound · Percutaneous transhepatic gallbladder drainage (PTGBD) · Endoscopic naso-gallbladder drainage (ENGBD)

Introduction

The Tokyo Guidelines (TG07) defined diagnostic criteria and severity assessment of acute cholecystitis in January 2007[1]. In the TG07, percutaneous transhepatic gallbladder drainage (PTGBD) should be used in patients with grade II (moderate) cholecystitis only when they do not respond to conservative treatment and for patients with grade III (severe) disease [2]. One controlled study (level C) [3] compared PTGBD with medical treatment alone and did not find lower mortality using PTGBD, but this study has several serious limitations as follows; (1) selection bias [the PTGBD group had many intensive care unit (ICU) patients] , (2) drainage methods were changed after a fatal complication, (3) randomization was achieved using a playing card and was not blinded. Thus, PTGBD, which has been endorsed by many studies of case-series but not by proper controlled trials (level C) [4–14], is the most common gallbladder drainage method for elderly and critically ill patients. There are several alternatives to PTGBD. Percutaneous transhepatic gallbladder aspiration (PTGBA) is an alternative in which the gallbladder contents are puncture-aspirated without placing a drainage catheter (level C) [6, 15]. Endoscopic naso-biliary gallbladder drainage (ENGBD) and endoscopic gallbladder stenting (EGBS) are also alternatives via the transpapillary route [16]. With the recent improvement in endoscopic ultrasound (EUS), EUS-guided gallbladder drainage is performed via the antrum of the stomach and the bulbus of the duodenum [16]. However, these alternatives are not fully examined; PTGBD is still recognized as a standard drainage method.

In this article, we describe the indication and details of gallbladder drainage for acute cholecystitis, and show the grades of recommendation for the procedures established by the Guidelines.

Q1. What are the standard gallbladder drainage methods for surgically unfit patients with acute cholecystitis?

PTGBD is an essential technique for non-surgical gallbladder drainage. Thus, we recommend PTGBD for surgically unfit patients with acute cholecystitis (recommendation 1, level B).

We recommend PTGBD as a standard drainage method according to the GRADE system [17]. Factors that affect the strength of a recommendation are summarized in Table 1.

Indications and significance of PTGBD

Although early cholecystectomy, a one-shot definitive treatment for acute cholecystitis, remains the reference standard, perioperative mortality rates in elderly or critically ill patients are reported to be high (up to 19 %) [18]. Therefore, PTGBD is considered a safe alternative, especially in surgically high-risk populations. There is no doubt that PTGBD with administration of antibiotics can convert a septic cholecystitis into a non-specific condition. From a technical point of view, it is a rather uncomplicated procedure with a low complication rate reported to range from 0 to 13 % [4–12]. A systematic review [18] reports that 30-day or in-hospital mortality after PTGBD is high (15.4 %), but that procedure-related mortality is low (0.36 %). Of note, mortality is predominantly related to the severity of the underlying disease rather than the ongoing gallbladder sepsis. By contrast, mortality rates after cholecystectomy in elderly patients with acute cholecystitis have been lower than those of previous years (prior to 1995 vs. after 1995, 12.0 vs. 4.0 %) [18]. Recent advances in anesthesiology and perioperative care may have improved the outcomes of cholecystectomy for critically ill patients. There are no controlled studies evaluating the outcomes of

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Table 1 A critical comparison of drainage methods for acute cholecystitis according to GRADE system [17]

Drainage method[a]	Factors that affect the strength of a recommendation				
	Quality of evidence	The balance between desirable and undesirable effects	Technical difficulty	Patient values and preferences	Cost
PTGBD	B (moderate)	Very good	No	Yes	Low cost
PTGBA	C (low)	Good (insufficient drainage effect)	No	No	Very low cost
ENGBD/EGBS	C (low)	Good (low success rate)	Yes (difficult)	Yes/no	Low cost
Surgical cholecystostomy	C (low)	Good (surgical risk)	No	Yes	High cost

[a] See details in each section

PTGBD versus early cholecystectomy. A few papers report comparative studies in a well-defined patient group. Melloul et al. [19] analyzed a matched case-controlled study of critically ill patients with acute cholecystitis. A series of 42 consecutive patients at a single ICU center during a 7-year period were retrospectively analyzed. Surgery was associated with an increased complication rate of 47 % compared with PTGBD (8.7 %), but mortality rates were not different. One Spanish retrospective study [20] compared mortality rates in 62 consecutive patients critically ill with acute cholecystitis divided between a PTGBD group and a cholecystectomy group, and they found a significantly higher mortality rate in the PTGBD group (17.2 vs. 0 %). This study, however, has several limitations: the study design is not prospective, inclusion criteria in the PTGBD group may have selection bias because the highest-risk patients could have been treated mainly by PTGBD. These biases and shortcomings in the study design make any comparison between the outcomes of PTGBD and early cholecystectomy hazardous. Therefore, it is not possible to make definitive recommendations regarding treatment using PTGBD or cholecystectomy in elderly or critically ill patients with acute cholecystitis. Large multicenter randomized trials of PTGBD versus early cholecystectomy are undoubtedly needed to resolve these controversies.

Optimal timing of gallbladder drainage

For patients with moderate (grade II) disease, gallbladder drainage should be used only when a patient does not respond to conservative treatment. For patients with severe (grade III) disease, gallbladder drainage is recommended with intensive care. One prospective study [21] shows that predictors for failure of conservative treatment are: age above 70 years old, diabetes, tachycardia and a distended gallbladder at admission. Likewise, WBC >15000 cell/μl, an elevated temperature and age above 70 years old were found to be predictors for the failure of conservative treatment at 24-h and 48-h follow-up.

Procedures for gallbladder drainage

Percutaneous transhepatic gallbladder drainage (Video 1)

PTGBD is a standard technique for nonoperative gallbladder drainage. After ultrasound-guided transhepatic gallbladder puncture has been performed with an 18-G needle, a 6- to 10-Fr pigtail catheter is placed in the gallbladder, using a guidewire under fluoroscopy (Seldinger technique; Fig. 1). There was no technical difficulty and the technique could be available around the world (Table 1). However, it has several disadvantages as follows: (1) the drainage tube cannot be extracted until a fistula forms around the tube, (2) there is a risk of dislocation of the tube, (3) patient discomfort may cause self-decannulation of the PTGBD tube.

Percutaneous transhepatic gallbladder aspiration

PTGBA is a method to aspirate bile via the gallbladder with a small-gauge needle under ultrasonographic guidance (Fig. 2). This method is an easy low-cost bedside-applicable procedure, without the patient discomfort seen in PTGBD (Table 1). Theoretically, the drainage effect of single PTGBA is lower than that of PTGBD as described in a randomized controlled trial (RCT) [12]. However, repetitive PTGBA [6, 15] can improve its effectiveness (from 71.1 to 95.6 %) and this methodology has not been compared with PTGBD. Although PTGBA with a small-gauge (21-G) needle has a lower risk of leakage after removal, aspiration of highly viscous bile is difficult with such needles and should be conducted while washing with saline containing antibiotics.

Endoscopic transpapillary gallbladder drainage

Endoscopic naso-biliary gallbladder drainage (Video 2)

ENGBD can be used for patients with severe comorbid conditions, especially those with end-stage liver disease, in

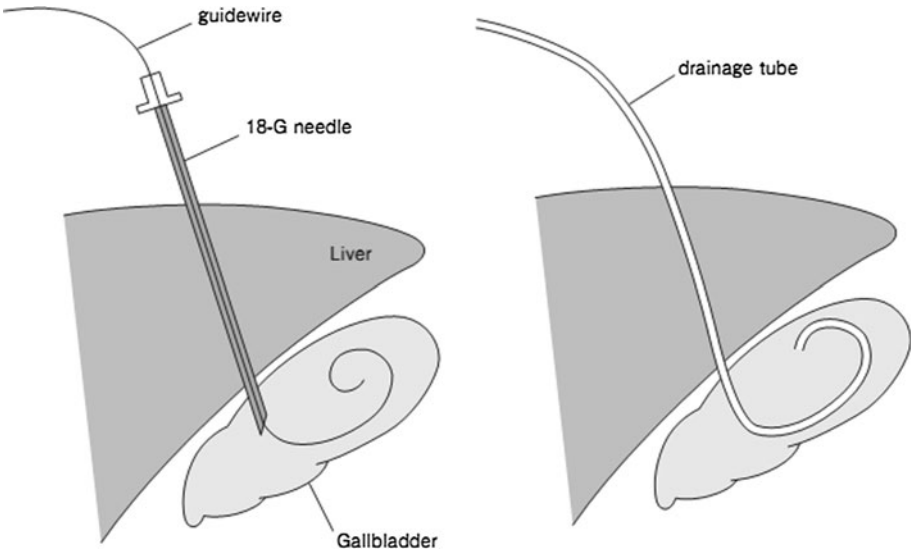

Fig. 1 Percutaneous transhepatic gallbladder drainage (PTGBD) procedure. A guidewire is inserted into the gallbladder after a needle is inserted into the gallbladder (*left*). Then a drainage tube is passed over the guide-wire into the gallbladder (*right*)

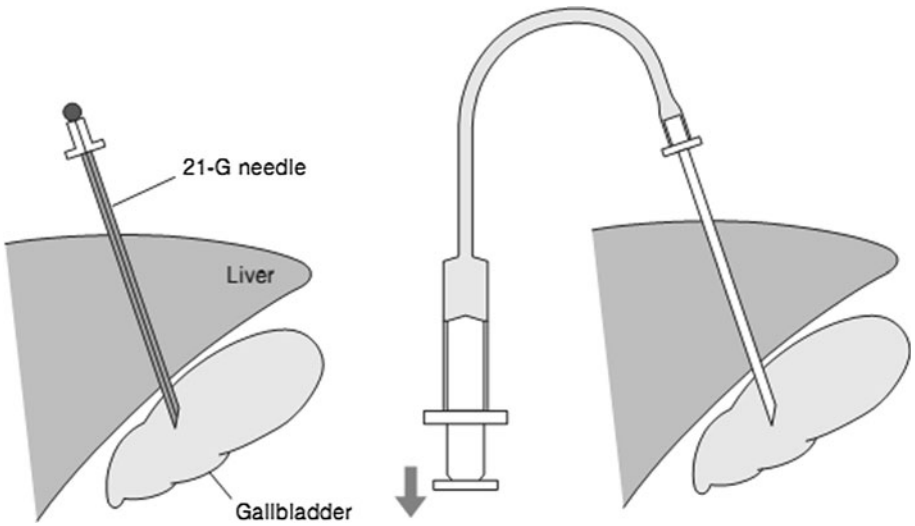

Fig. 2 Percutaneous transhepatic gallbladder aspiration (PTGBA) procedure. Under ultrasound guidance, the gallbladder is punctured transhepatically by a needle (*left*). Then bile is aspirated by using a syringe (*right*)

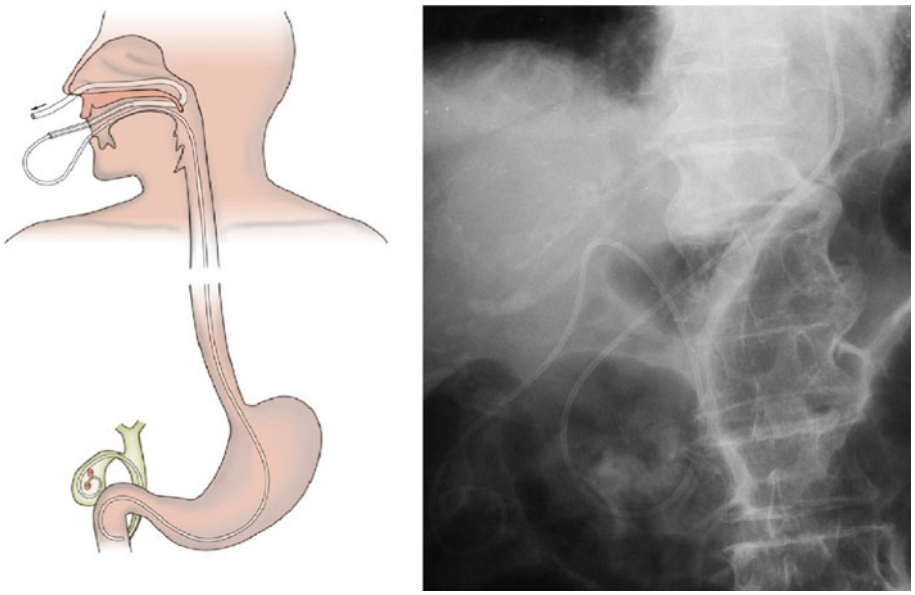

Fig. 3 Endoscopic nasobiliary gallbladder drainage (ENGBD) procedure. *Left* Schema of ENGBD. *Right* X-ray shows nasobiliary catheter placed in the gallbladder

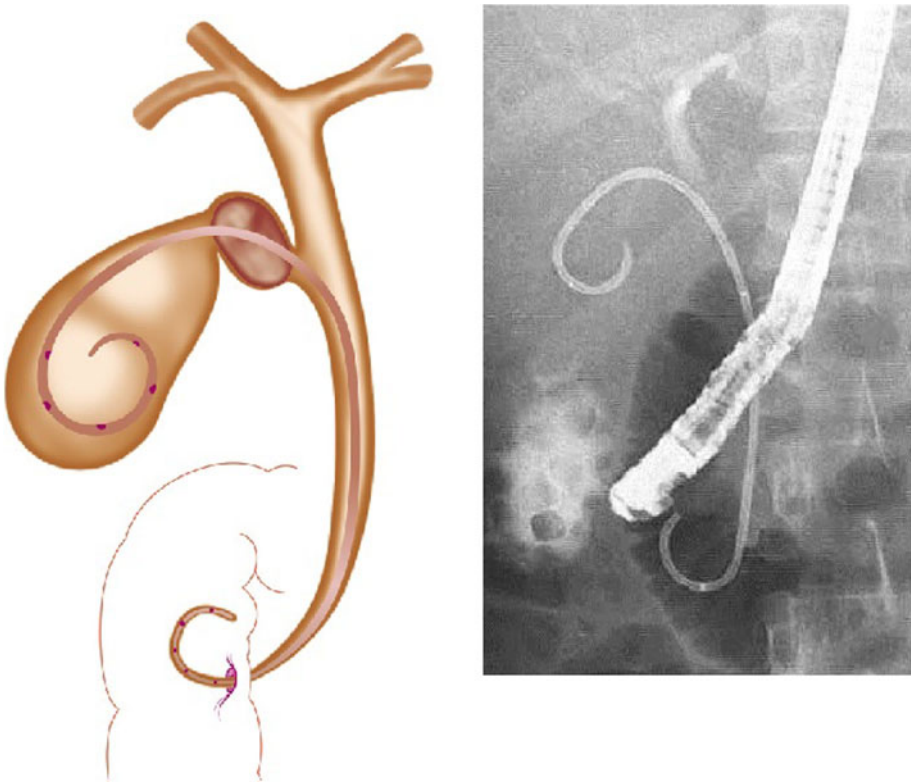

Fig. 4 Endoscopic gallbladder stenting (EGBS) procedure. *Left* Schema of EGBS. *Right* X-ray shows double-pig tail stent placed in the gallbladder

whom the percutaneous approach is difficult to perform. However, because it requires a difficult endoscopic technique (technical success rate varies from 64 to 100 %), and relevant case-series studies have been conducted only at a limited number of institutions [22–28], ENGBD has not yet been established as a standard method. Therefore, it should be performed in high-volume institutes by skilled endoscopists.

ENGBD involves placement of a naso-gallbladder drainage tube and generally does not require biliary sphincterotomy. After successful bile duct cannulation, a 0.035-in. guidewire is advanced into the cystic duct and subsequently into the gallbladder. At times, a hydrophilic guidewire is useful for seeking the cystic duct. Finally, a 5–8.5 Fr pigtail naso-gallbladder drainage tube catheter is placed into the gallbladder (Fig. 3).

Endoscopic transpapillary gallbladder stenting

Since endoscopic transpapillary gallbladder stenting (EGBS) requires a difficult endoscopic technique, and relevant case-series studies have been conducted only at a limited number of institutions [29–36], EGBS also has not been established as a standard method. Therefore, it should be performed in high-volume institutes by skilled endoscopists. The procedure is identical to ENGBD, but a 6–10-Fr diameter double pigtail stent is placed (Fig. 4). When 10-Fr stents or a gallbladder stent and a biliary stent are placed (for example in Mirizzi's syndrome), an endoscopic biliary sphincterotomy is performed to prevent post-ERCP pancreatitis.

Q2. What are the special techniques as gallbladder drainage?

There is endoscopic ultrasonography-guided gallbladder drainage (EUS-guided gallbladder drainage).

EUS-guided gallbladder drainage is performed via the antrum of the stomach and bulbus of the duodenum (Fig. 5) [16, 42]. It includes EUS-guided naso-gallbladder drainage [37, 38] and EUS-guided gallbladder stenting [39, 44] (Table 2). Recently one controlled study [42] showed that EUS-GBD is comparable to PTGBD in terms of the technical feasibility and efficacy. However, EUS-guided gallbladder drainage has not been established as a standard method. Therefore, they should be performed in high-volume institutes by skilled endoscopists [37–46].

Technique of EUS-guided gallbladder drainage [16, 44] (Video 3)

Theoretically, the gallbladder does not have adhesions to the GI tract. Therefore, there is a possibility of bile leakage

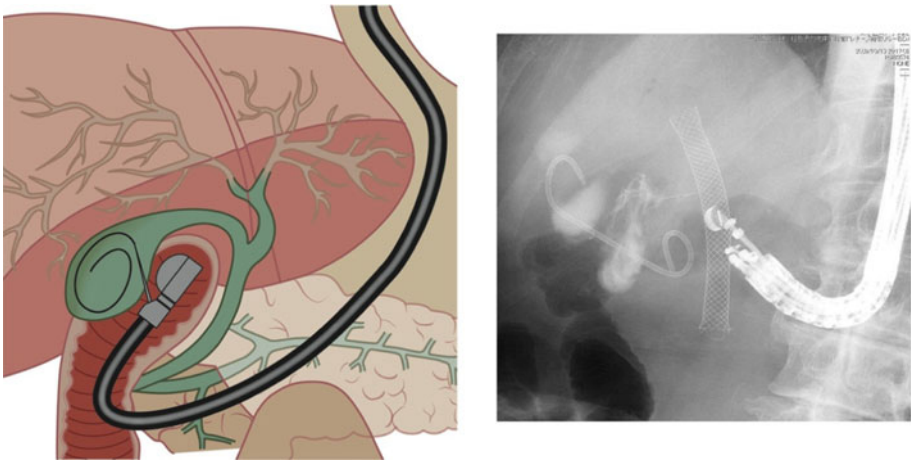

Fig. 5 EUS-guided gallbladder approach via bulbus of the duodenum. *Left* Schema of EUS-guided gallbladder drainage. *Right* X-ray shows double-pig tail stent placed in the gallbladder

Table 2 Outcome of endosonography-guided gallbladder drainage

References	No. of cases	NGD/ Stenting	Approach route	Technical success (%)	Clinical success (%)	Complication (no. of cases)
Baron [39]	1	PS	TD	100	100	None
Kwan [37]	3	NGD	TD	100	100	Bile leakage (1)[a]
Lee [38]	9	NGD	TD	100	100	Pneumoperitoneum (1)
Takasawa [40]	1	PS	TG	100	100	None
Kamata [46]	1	SEMS	TD	100	100	None
Song [41]	8	PS	1TG/7TD	100	100	Bile leakage (1)[a], pneumoperitoneum (1), stent migration (1)
Itoi [42]	2	PS	1TG/1TD	100	100	Bile leakage (1)[a]
Jang [43]	15	SEMS	10TG/5TD	100	100	None
Itoi [44]	5	SEMS	1TG/4TD	100	100	None
Jang [45]	30	NGD	NA	97	100	Pneumoperitoneum (2)

SEMS self-expandable metal stent, *PS* plastic stent, *NGD* naso-gallbladder drain, *TD* transduodenal approach, *TG* transgastric approach, *NA* not available

[a] Minor bile leakage without serious bile peritonitis

during the procedures; in particular, if the procedure fails, serious bile peritonitis can occur. The choice of endoscope position is important to accomplish the procedure safely. The gallbladder is visualized from the duodenal bulb or the antrum of the stomach using a curved linear array echoendoscope in a long scope position (pushing scope position) (Fig. 5). At this time, the direction of the EUS probe is toward the right side of the body. A needle knife (Zimmon papillotomy knife, or Cystotome, Wilson-Cook, Winston-Salem, NC, USA) catheter using electrocautery, or a 19-gauge needle (EchoTip, Wilson-Cook), is advanced into the gallbladder under EUS visualization after confirming the absence of intervening blood vessels to avoid bleeding. After the stylet has been removed, first bile is aspirated and then contrast medium is injected into the gallbladder for cholecystography, then a 0.025- or 0.035-in. guidewire is advanced into the outer sheath. If necessary, a biliary catheter for dilation (Soehendra Biliary Dilator, Wilson-Cook), or papillary balloon dilation catheter (Maxpass, Olympus Medical Systems) are used for dilation of the gastrocholecystic and duodenocholecystic fistula. Finally, a 5-10 Fr naso-gallbladder tube is advanced via the cholecystogastrostomy and cholecystoduodenostomy site into the gallbladder. The basic procedure of EUS-guided gallbladder stenting is the same as EUS-guided naso-gallbladder drainage. A 7-10Fr double pigtail plastic or self-expanding metallic stent is placed in the final step.

There have been 9 retrospective and 1 prospective analyses on 3 EUS-guided naso-gallbladder drainages and 7 EUS-guided gallbladder stentings (4 plastic stent, 3 self-expanding metal stent) (Table 2). The success rates and response rates of both procedures were approximately

100 %, but the incidence of accidents was fairly high (11–33 %), indicating the necessity for further investigations emphasizing safety evaluation. There are several possible procedure-related early adverse events, e.g., bile leakage, stent migration into the gallbladder or intra-abdominal space, deviation of stent from the gallbladder, puncture-induced hemorrhage, and perforation of peritoneum. Late adverse events include relapse of acute cholecystitis due to stent occlusion, and inadvertent tube removal.

Conflict of interest None.

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