J Hepatobiliary Pancreat Sci (2018) 25:87–95
DOI: 10.1002/jhbp.504

GUIDELINE

Tokyo Guidelines 2018: management strategies for gallbladder drainage in patients with acute cholecystitis (with videos)

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Published online: 21 November 2017
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DOI: 10.1002/jhbp.504

Abstract Since the publication of the Tokyo Guidelines in 2007 and their revision in 2013, appropriate management for acute cholecystitis has been more clearly established. Since the last revision, several manuscripts, especially for alternative endoscopic techniques, have been reported; therefore, additional evaluation and refinement of the 2013 Guidelines is required. We describe a standard drainage method for surgically high-risk patients with acute cholecystitis and the latest developed endoscopic gallbladder drainage techniques described in the updated Tokyo Guidelines 2018 (TG18). Our study confirmed that percutaneous transhepatic gallbladder drainage should be considered the first alternative to surgical intervention in surgically high-risk patients with acute cholecystitis. Also, endoscopic transpapillary gallbladder drainage or endoscopic ultrasound-guided gallbladder drainage can be considered in high-volume institutes by skilled endoscopists. In the endoscopic transpapillary approach, either endoscopic naso-gallbladder drainage or gallbladder stenting can be considered for gallbladder drainage. We also introduce special techniques and the latest outcomes of endoscopic ultrasound-guided gallbladder drainage studies. Free full articles and mobile app of TG18 are available at: http://www.jshbps.jp/modules/en/index.php?content_id=47. Related clinical questions and references are also included.

Keywords Acute cholecystitis · Endoscopic transpapillary gallbladder drainage · Endoscopic ultrasound-guided gallbladder drainage · Gallbladder drainage · Percutaneous transhepatic gallbladder drainage

Introduction

Although standard treatment for patients with acute cholecystitis (AC) is well established based on the 2007 Tokyo Guidelines (TG07) [1], revised in Tokyo Guidelines 2013 (TG13) [2], morbidity and mortality rates in patients at high risk for surgery with comorbid medical conditions remain high [3–9]. In TG07, the detailed procedure of percutaneous transhepatic gallbladder drainage (PTGBD) was introduced, while the

recommendation of PTGBD for AC was not established. Since then, TG13 stated that PTGBD should be recommended as the first alternative to cholecystectomy in such patients [2]. However, some studies have evaluated the usefulness of percutaneous transhepatic gallbladder aspiration (PTGBA) without catheter placement as a simple decompression method [10, 11]. Another alternative procedure is endoscopic gallbladder drainage, which can be performed using either a transpapillary or transmural approach. The former method is endoscopic transpapillary gallbladder drainage (ETGBD) including endoscopic nasogallbladder drainage (ENGBD) and gallbladder stenting (EGBS) under endoscopic retrograde cholangiopancreatography (ERCP), through which the gallbladder is drained via the cystic duct with a nasobiliary tube or stent across the papilla. This procedure appears to be especially suitable for patients with severe coagulopathy, thrombocytopenia, or an anatomically inaccessible location. More recently, endoscopic ultrasound-guided gallbladder drainage (EUS-GBD) has been reported to be useful as an alternative gallbladder drainage procedure in patients with AC. TG13 proposed that these endoscopic approaches provide suboptimal drainage because they have not been fully evaluated. Since the introduction of TG13, several studies describing alternative endoscopic techniques have been published; therefore, additional evaluation and refinement of TG13 is required. We describe a standard drainage method for surgically high-risk patients with AC, and the latest developed endoscopic gallbladder drainage techniques. We also discuss the recommendation grades for the procedures [12] established by the updated 2018 Tokyo Guidelines (TG18).

Methods of systematic review and meta-analysis

In the updated TG, we performed systematic reviews and meta-analyses related to each discussion point for gallbladder drainage, where possible, and described the results based on the PRISMA statement. We systematically searched MEDLINE (PubMed), the Cochrane Library, and Japan Medical Abstracts (the largest database of Japanese articles) for studies describing each discussion point for gallbladder drainage. In MEDLINE, we combined the Centre for Reviews and Dissemination/Cochrane Highly Sensitive Search Strategy with the Medical Subject Heading (MeSH) terms. Similar search strategies were adopted in other databases. References from previous review articles and meta-analyses were also hand-searched. Two investigators (YM and TI) thoroughly assessed the quality of each article and selected the final included articles. Disagreement between investigators was discussed and resolved by consensus.

Meta-analysis was conducted using Cochrane Collaboration Review Manager 5.3 software (Cochrane, London, UK). Statistical analysis was performed using the Mantel-Haenszel method, and summary statistics were described as odds ratio (OR). We used a random-effects model with OR <1 favoring the investigation group and the OR point estimate was considered statistically significant at $P < 0.05$ if the 95% confidence interval (CI) did not include the value 1. We also calculated I^2 to assess homogeneity.

Q1. What are the standard gallbladder drainage methods for AC in surgically high-risk patients?

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

Percutaneous transhepatic gallbladder drainage

Percutaneous transhepatic gallbladder drainage should be considered the first alternative to surgical intervention in surgically high-risk patients with AC because several studies have described PTGBD as less invasive and having a lower risk of adverse events compared with cholecystectomy (OS) [13–20] (EO) [21, 22]. The PTGBD procedure is described in the previous guidelines [2], and the technique is relatively easy for general clinicians to perform. Briefly, after ultrasound-guided transhepatic gallbladder puncture has been performed with an 18-G needle, a 6- to 10-Fr catheter is placed in the gallbladder using a guidewire under fluoroscopy. Of note, PTGBD for Grade III (severe) cases based on the TG13 severity grading was reported to be associated with higher mortality, higher readmission rates, and prolonged hospital stay (OS) [23].

Endoscopic drainage

Recently, ETGBD under ERCP including ENGBD and EGBS, and EUS-GBD have been reported as novel effective alternative gallbladder drainage procedures in patients with AC in (RCT) [24–26], (OS) [27–42], (SR) [28, 37, 43, 44], (EO) [29, 32, 45], and a case study (CS) [46]. Although there are no published papers, to our knowledge, comparing PTGBD and ETGBD, SRs have shown no significant difference regarding the technical success rate, clinical success rate, and the frequency of adverse events between PTGBD and EUS-GBD (SR) [31, 37, 43]. The internal drainage

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obtained with endoscopic gallbladder drainage (EGBS/EUS-GBD) results in less post-procedure pain than with the external drainage of PTGBD. However, because these internal procedures require difficult endoscopic techniques, and almost all reports regarding endoscopic drainage have been by skilled pancreatobiliary endoscopists from high-volume centers, these endoscopic techniques have not yet been established as standard procedures. Therefore, ETGBD and EUS-GBD should be considered in high-volume institutes by skilled pancreatobiliary endoscopists; otherwise, PTGBD should be selected as the standard drainage procedure.

Percutaneous transhepatic gallbladder aspiration

Although PTGBA without catheter placement appears to be a simple and easy decompression method, aspiration could be unsuccessful because of replacement of bile with dense biliary sludge or pus (RCT) [19], (OS) [11, 19, 20]. Therefore, PTGBA should not be recommended as a standard procedure for all patients with AC. However, the latest international multicenter study (OS) [47] showed that the clinical success rate within 3 days of PTGBA was significantly higher than that of PTGBD and EGBS, although there was no significant difference within 7 days. Also, the complication rate of PTGBA was lower than that of PTGBD and EGBS. Several possible reasons are suggested when comparing previous reports, including the possibility that the PTGBA groups included patients with mild or moderate grade cholecystitis, and gallbladder lavage using saline during PTGBA was more effective than simple drainage. Prospective RCTs using standardized techniques and devices for PTGBD, PTGBA, and endoscopic gallbladder drainage are warranted.

Gallbladder drainage for patients with coagulopathy or who are receiving antithrombotic agents

There are few reports discussing PTGBD for patients with AC and coagulopathy or who are receiving antithrombotic agents (CPG) [48] (MA) [49] (CS) [50]. The Society of Interventional Radiology guidelines suggest that PTGBD can be performed without discontinuing acetylsalicylic acid if patients have a high risk of thromboembolism; however, the guidelines also recommend discontinuing clopidogrel for 5 days before PTGBD (CPG) [48]. The guidelines also recommend that PTGBD in patients who are receiving anticoagulants should be performed with PT-INR <1.5 and heparin substitution (CPG) [48]. PTGBD for patients receiving both antiplatelet and anticoagulant agents should be avoided because there is no reliable data in these patients. ETGBD should be considered in such conditions when skilled pancreaticobiliary endoscopists are available in the institution.

Q2. What procedure for preoperative drainage should be used for endoscopic transpapillary gallbladder drainage? ENGBD or EGBS?

We suggest that either ENGBD or EGBS may be considered for gallbladder drainage based on the patient's background and endoscopist's decision. (Recommendation 1, level B)

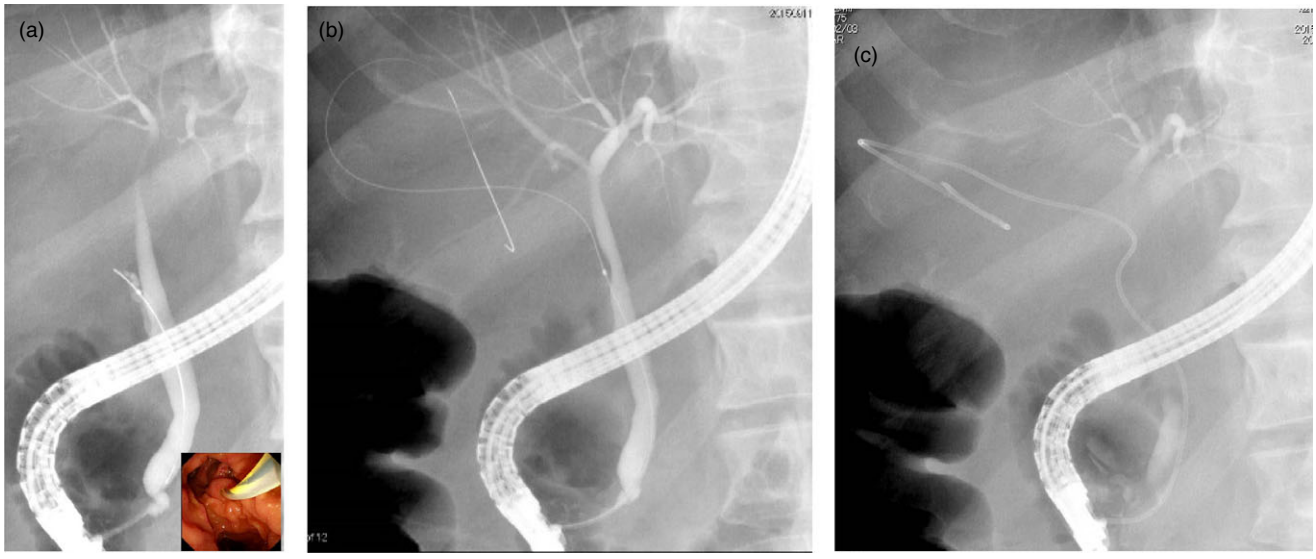

Fig. 1 Detailed procedure for endoscopic naso-gallbladder drainage. After successful bile duct cannulation, a 0.025- or 0.035-inch guidewire is advanced into the cystic duct (**a**) and subsequently into the gallbladder (**b**). Next, the catheter is withdrawn, and the guidewire remains in the gallbladder, then a 5-Fr to 8.5-Fr pigtail naso-gallbladder drainage tube is inserted into the gallbladder (**c**)

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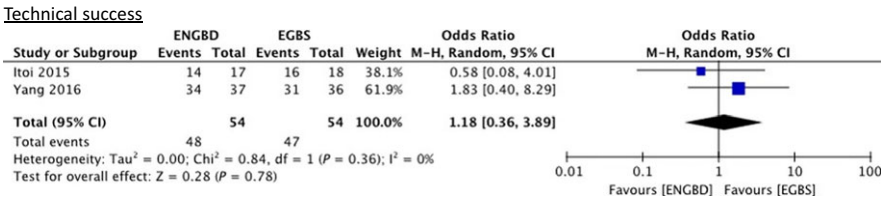

Fig. 2 Forest plot analysis of technical success rate of endoscopic naso-gallbladder drainage versus endoscopic gallbladder stenting

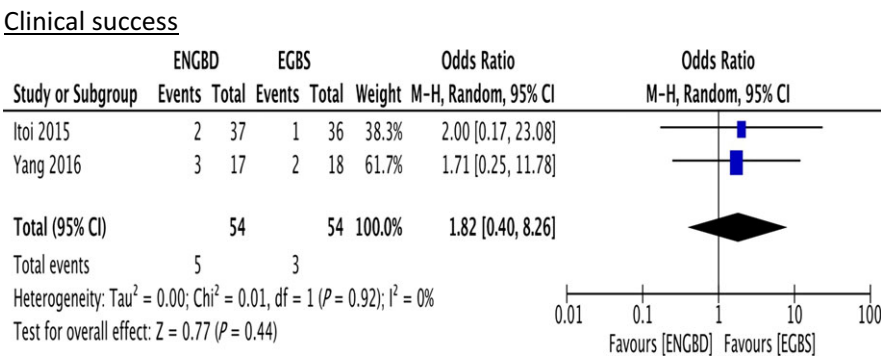

Fig. 3 Forest plot analysis of clinical success rate of endoscopic naso-gallbladder drainage versus endoscopic gallbladder stenting

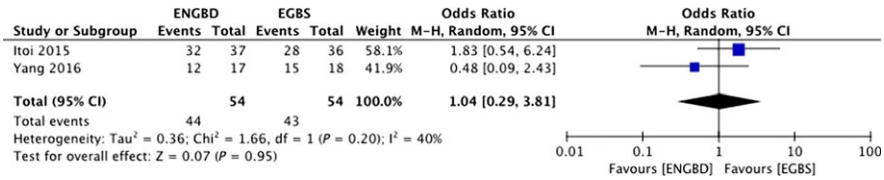

Fig. 4 Forest plot analysis of adverse events of endoscopic naso-gallbladder drainage versus endoscopic gallbladder stenting

Detailed procedures for ENGBD and EGBS

Endoscopic transpapillary gallbladder drainage could be considered in high-volume institutes by skilled endoscopists as described in Q1. ETGBD can be divided into two different methods: ENGBD and EGBS. ENGBD involves placing a naso-gallbladder drainage tube (NGBT) and generally does not require sphincterotomy. The detailed techniques for ENGBD are as follows: After successful bile duct cannulation, a 0.025- or 0.035-inch guidewire is advanced into the cystic duct (Fig. 1a) and subsequently into the gallbladder (Fig. 1b). Next, the catheter is withdrawn and the guidewire remains in the gallbladder, and a 5-Fr to 8.5-Fr pigtail NGBT is inserted into the gallbladder (Fig. 1c, Video S1). In comparison, the EGBS procedure is the same as for ENGBD, but a 6-Fr to 10-Fr internal stent is placed in the gallbladder, instead. Stent placement is not always successful because the cystic duct is frequently not visible on cholangiography, severe cystic duct stenosis and/or impacted stones in the neck of the gallbladder can block advancement of the guidewire and stent, and the tortuous valves of Heister can be difficult to traverse with standard guidewires [26]. These procedures require skillful techniques because prolonged or unsuccessful procedures may lead to serious complications such as post-ERCP pancreatitis and perforation of a cystic duct or gallbladder. Therefore, endoscopists should acquire accurate knowledge and technical skills including selective biliary cannulation and appropriate guidewire technique.

Endoscopic transpapillary gallbladder drainage versus endoscopic gallbladder stenting

Recently, several reports evaluating the feasibility, safety, and efficacy of ETGBD have been published (SR) [30, 43], (OS) [24, 25, 27, 29, 32, 33, 37, 51], (EO) [31]. This procedure appears to be especially suitable for patients with severe coagulopathy, thrombocytopenia, or an anatomically inaccessible location. To date, two RCTs [34, 52] and an SR [27] comparing ENGBD and EGBS have been published. A meta-analysis including these two RCTs was conducted in TG18 and found no statistically significant difference in technical success [odds ratio (OR): 1.18 (95% confidence interval (CI): 0.36–3.89)], clinical success [OR: 1.82 (95% CI: 0.40–8.26)], or adverse events rate [OR: 1.04 (95% CI: 0.29–3.81)] between ENGBD and EGBS (Figs 2, 3 and 4, respectively). Note, however, that ENGBD involves cases in which the tube is removed by patients themselves because of discomfort. While EGBS carries a

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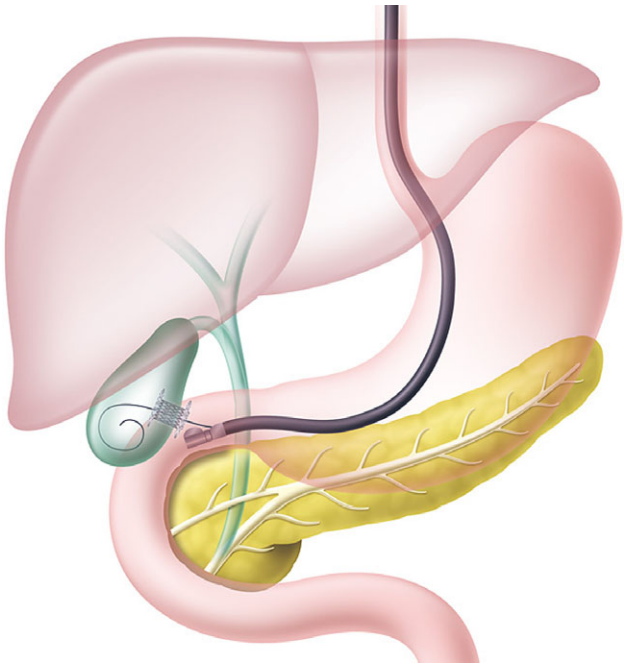

Fig. 5 Schema of endoscopic ultrasound-guided gallbladder drainage

risk of stent obstruction, ENGBD has the advantage of flushing the bile via the transnasal tube [26]. Consequently, the advantages and disadvantages of each drainage method are considered approximately equal, and TG18 suggests that either ENGBD or EGBS may be considered for gallbladder drainage based on the patient's background and endoscopist's decision.

Special technique: endoscopic ultrasound-guided gallbladder drainage

Technique

The gallbladder is punctured from the body or antrum of the stomach or duodenal bulb under direct EUS visualization. A 0.035-inch guidewire is inserted through the outer sheath, and dilation of the tract using a mechanical dilator, electrocautery dilator, or balloon dilator is then performed. Finally, a NGBT, double pigtail plastic stent (PS), or self-expandable metal stent (SEMS) is inserted into the gallbladder (Fig. 5, Video S2). More recently, lumen-apposing metal stents (LAMS) (Fig. 6a,b) [53, 54], the flared end of a covered SEMS (Fig. 6c) [55], and biflanged metal stents (Fig. 6d) [56] provide effective and safe drainage of gallbladder contents.

Outcomes

The latest outcomes regarding overall technical success rate, clinical success rate, and frequency of adverse events were 98.0% (194/198), 94.4% (187/198), and 12.1% (24/

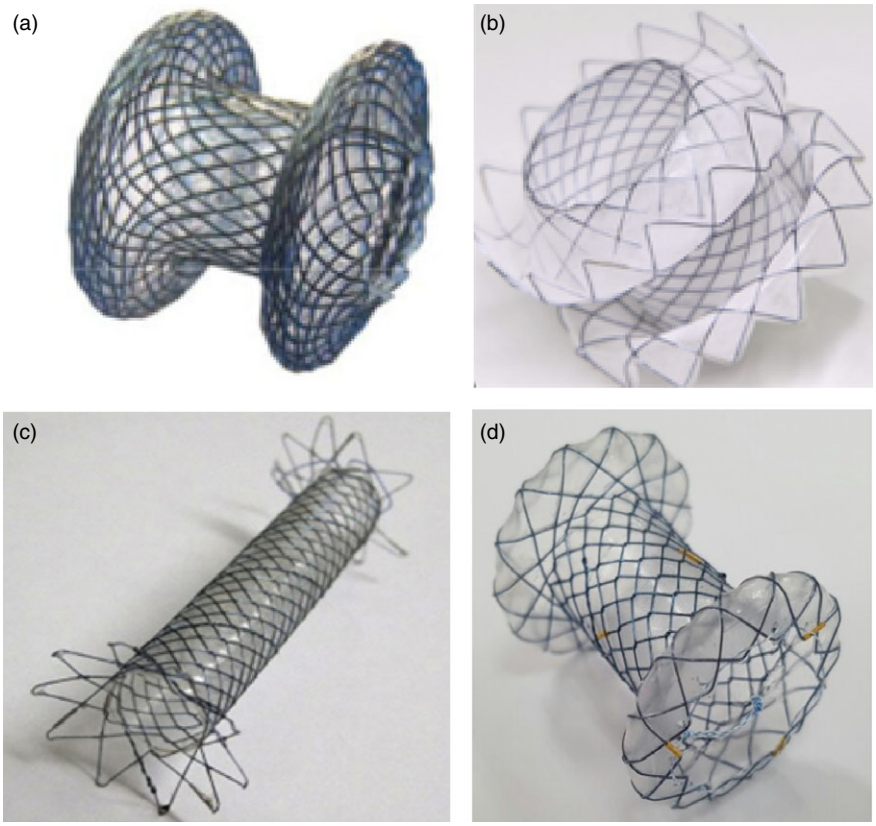

Fig. 6 Metal stents for endoscopic ultrasound-guided gallbladder drainage. (**a**) Fully-covered 10-mm-diameter lumen-apposing stent with dual anchor flanges. (**b**) Fully-covered metal stent with folding-back wide anchoring flanges for lumen apposition. (**c**) The flared end of a covered self-expandable metal stent. (**d**) Biflanged metal stent

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Table 1 Comparison of different gallbladder drainage techniques/materials for technical success, clinical success, and adverse events

	Technical success	Clinical success	Adverse event
NGBT	100% (32/32)	100% (32/32)	12.5% (4/32)
PS	100% (22/22)	100% (22/22)	18.2% (4/32)
SEMS	98.6% (72/73)	94.5% (69/73)	12.3% (9/73)
LAMS	95.8% (68/71)	90.1% (64/71)	9.9% (7/71)
Total	98.0% (194/198)	94.4% (187/198)	12.1% (24/198)

LAMS lumen-apposing metal stent, *NGBT* naso-gallbladder drainage tube, *PS* plastic stent, *SEMS* self-expandable metal stent

198), respectively (Table 1) [44]. The technical success rate was 100% using NGBT, 100% using PS, 98.6% using SEMS, and 95.8% using LAMS, and the clinical success rate was 100%, 100%, 94.5%, and 90.1% using NGBT, PS, SEMS, and LAMS, respectively. There were no significant differences among these stents; however, LAMS may be ideal for EUS-GBD because it was associated with the lowest adverse events rate among the stents [39].

Acknowledgments We express our deep gratitude to the Japanese Society of Hepato-Biliary-Pancreatic Surgery, the Japanese Society of Abdominal Emergency Medicine, the Japanese Society of Surgical Infection, and the Japan Biliary Association, for their substantial support and guidance in the preparation of this article. We also would like to express our deep gratitude to the Japanese Society of Hepato-Biliary-Pancreatic Surgery for the Article Processing Managing Office of the Tokyo Guidelines 2018 for preparing this publication. We appreciate all secretariats of the Japanese Society of Hepato-Biliary-Pancreatic Surgery for their technical support.

Conflict of interest Anthony Yuen Bun Teoh has received consultant fees from Boston Scientific Corporation, USA, Cook Medical, USA, and Taewoong Medical, Korea. Goro Honda has received honoraria from Johnson and Johnson and Medtronic.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Video S1. Detailed procedure for endoscopic naso-gallbladder drainage.

Video S2. Detailed procedure for endoscopic ultrasound-guided gallbladder drainage.

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