EUS-guided cholecystoduodenostomy for acute cholecystitis with an anti-stent migration and anti-food impaction system; a pilot study

Wataru Takagi, Takeshi Ogura, Tatsushi Sano, Saori Onda, Atsushi Okuda, Daisuke Masuda, Akira Imoto, Toshihisa Takeuchi, Shinya Fukunishi and Kazuhide Higuchi

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Abstract

Background: Recently, endoscopic ultrasound-guided gall bladder drainage (EUS-GBD) has been reported using a self-expandable metallic stent. To prevent stent migration and food flowing into the common bile duct through the cystic duct, we perform a novel EUS-guided cholecystoduodenostomy.

The aim of our study was to evaluate the safety and feasibility of EUS-guided cholecystoduodenostomy with an anti-stent migration and anti-food impaction system.

Methods: A total of 16 consecutive patients who underwent EUS-guided cholecystoduodenostomy for acute cholecystitis were included in this study.

Results: Technical and clinical success was obtained in all patients. The median procedure time was 26.9 min (range 19–42 min). Median follow-up time was 181.5 days (range 18–604 days), and in this time, recurrence of acute cholecystitis was not seen in all patients. Adverse events such as stent migration and cholangitis were not seen in any patients, although pneumoperitoneum was seen in one patient.

Conclusion: Our technique may be favorable and effective for the prevention of adverse events on EUS-GBD.

Keywords: EUS, EUS-guided cholecystoduodenostomy, EUS-GBD, EUS-guided gall bladder drainage, interventional EUS

Introduction

It is well recognized that early laparoscopic cholecystectomy is the first-line treatment for acute cholecystitis. However, this treatment is sometimes unsuitable for patients who have advanced cancer or severe cardiopulmonary disease. Alternative treatment strategy for acute cholecystitis is percutaneous gall bladder drainage (PTGBD) [Ito *et al.* 2004; Akhan *et al.* 2002]. However, PTGBD has also several adverse events and disadvantages, such as bleeding and external drainage, and it is unsuitable for patients who have massive ascites or dementia, which may lead to the possibility of self-tube removal [Itoi *et al.* 2010].

Recently, endoscopic ultrasound-guided gall bladder drainage (EUS-GBD) has been reported

[Jang *et al.* 2011, 2012; Song *et al.* 2010; Itoi *et al.* 2012; Serna-Higuera *et al.* 2013; Choi *et al.* 2014; Moon *et al.* 2014; Irani *et al.* 2015; Walter *et al.* 2015]. EUS-GBD can be performed for such patients; however, bile leakage is one of the main adverse events of EUS-guided biliary drainage [Ogura and Higuchi, 2015]. Therefore, several authors have recently performed EUS-GBD using a self-expandable metallic stent (SEMS). However, stent migration may occur in cases undergoing EUS-GBD using a SEMS. In addition, sludge or food may flow into the common bile duct through the cystic duct. Although these adverse events may be not so frequent, stent migration in particular may sometimes be fatal. To prevent these problems, we performed EUS-guided cholecystoduodenostomy using SEMS

Correspondence to:
Takeshi Ogura, MD, PhD
2nd Department of Internal
Medicine, Osaka Medical
College, 2-7 Daigakuchou,
Takatsukishi, Osaka
569-8686, Japan
oguratakeshi0411@yahoo.co.jp

Wataru Takagi, MD
Tatsushi Sano, MD
Saori Onda, MD
Atsushi Okuda, MD
Daisuke Masuda, MD, PhD
Akira Imoto, MD, PhD
Toshihisa Takeuchi, MD, PhD
Shinya Fukunishi, MD, PhD
Kazuhide Higuchi, MD, PhD
2nd Department of
Internal Medicine, Osaka
Medical College, Osaka,
Japan

[Choi *et al.* 2014; Jang *et al.* 2011; Itoi *et al.* 2012; Walter *et al.* 2015] with an anti-stent migration and anti-food impaction system [Widmer *et al.* 2014]. In the present study, the safety and feasibility of EUS-guided cholecystoduodenostomy were evaluated retrospectively.

Materials and methods

Patients

Consecutive patients who underwent EUS-guided cholecystoduodenostomy for acute cholecystitis between August 2013 and February 2015 were retrospectively included.

The indication for EUS-guided cholecystoduodenostomy was basically poor surgical risk. In addition, patients had reasons such as (1) advanced cancer, (2) risk of self-PTGBD tube removal, (3) ascites and (4) recurrence of acute cholecystitis after PTGBD.

Patients' baseline characteristics, adverse events associated with EUS-guided cholecystoduodenostomy and recurrence of acute cholecystitis were reviewed, along with technical and clinical success rates. Patients provided their written, informed consent for all procedures associated with the study.

Technical tips for EUS-guided cholecystoduodenostomy (video available online on the journal website)

All procedures were performed by one therapeutic endoscopist (T.O.). All patients were given antibiotics before undergoing any procedures and underwent computerized tomography (CT) the day after EUS-guided cholecystoduodenostomy.

After the echoendoscope (GF-UGT260; Olympus Optical, Tokyo, Japan) was introduced into the duodenum, the gall bladder neck was visualized. Then, the gall bladder neck was punctured using a 19-G fine needle aspiration (FNA) needle (Sono Tip Pro Control 19G; Medi-Globe GmbH, Rosenheim, Germany). A 0.025-inch guidewire (VisiGlide; Olympus Medical Systems, Tokyo, Japan) was then inserted through the FNA needle (Figure 1a) and, to dilate the fistula, an endoscopic retrograde cholangiopancreatography (ERCP) (MTW Endoskopie, Düsseldorf, Germany) cannula was inserted. Next, if the stent could not be delivered across the duodenum or

gall bladder wall, balloon dilation of the fistula was performed using a 4 mm balloon catheter (Hurricane balloon dilator; Boston Scientific Japan). The stent delivery system was then inserted into the gall bladder, and a fully covered SEMS (FCSEMS) (BONA stent, Standard Sci Tech Inc., Seoul, Korea) was placed from the gall bladder to the duodenum (Figure 1b). Finally, a 7-Fr pig tail plastic stent (Medi-Globe GmbH, Rosenheim, Germany) was placed within the FCSEMS (Figure 1c). If a 6 cm covered SEMS was used, a 10 cm pig tail plastic stent was placed within the SEMS, and if an 8 cm covered SEMS was used, a 12 cm stent was placed.

Definitions

The follow-up period was measured from the day of performing EUS-guided cholecystoduodenostomy to the final observation. Procedure time was measured from echoendoscope insertion to stent placement. Technical success was defined as successful FCSEMS and plastic stent placement. Functional success was also defined as complete resolution of clinical symptoms such as abdominal pain and fever, or decreased inflammation on blood tests. Recurrence of acute cholecystitis after EUS-guided cholecystoduodenostomy was defined based on the typical symptoms with imaging findings. Adverse events were defined according to the American Society for Gastrointestinal Endoscopy lexicon's severity grading system [Cotton *et al.* 2010].

Statistical analysis

Continuous variables are expressed as median or mean values. All data were analyzed using SPSS version 11.0 statistical software (SPSS, Chicago, IL, USA).

Results

Patients' characteristics

Table 1 shows the patients' characteristics. EUS-guided cholecystoduodenostomy was performed for 16 consecutive patients with acute cholecystitis (median age 73.7 years, age range 64–90 years; 12 males, 4 females). Baseline diseases were advanced cancers ($n = 12$), cerebrovascular disorders ($n = 3$) and cardiopulmonary disease ($n = 1$). On EUS imaging, gall bladder stones and cystic duct obstruction due to tumor were both seen in five patients. Ascites was also seen in four patients.

Figure 1. (a) The gall bladder was punctured and the guidewire was inserted. (b) Fully covered self-expandable metallic stent was successfully placed. (c) To prevent stent migration, a pig tail plastic stent was placed within the fully covered self-expandable metallic stent.

Table 1. Patients' characteristics.

Median age (range), years	73.7 (64–90)
Sex (male:female)	12:4
Baseline disease (n)	
Advanced cancer	12
Cerebrovascular disorder	3
Cardiopulmonary disease	1
Ascites (present : absent)	5:10
Gallbladder stones (n)	5
Cystic duct obstruction (n)	5
White blood cell count (mean, range)	13,652.1 (4950–24,520)
C-reactive protein (mean, range)	17.7 (2.35–6.67)
Indications of EUS-guided cholecystoduodenostomy	
Advanced cancer	12
Risk of self-tube removal	4
Recurrence acute cholecystitis after PTGBD	2
Ascites	5

EUS, endoscopic ultrasound; PTGBD, percutaneous gall bladder drainage.

On blood examination, the mean white blood cell (WBC) count was 13,652.1 per μl and the mean C-reactive protein (CRP) was 17.7 mg/dl. Indications for EUS-guided cholecystoduodenostomy were: (1) advanced cancer ($n = 12$); (2) risk

of self-PTGBD tube removal due to dementia ($n = 4$); (3) recurrence of acute cholecystitis after PTGBD ($n = 2$); and (4) ascites ($n = 5$). Also, in our study, all patients underwent antibiotic therapy for a few days but 13 patients did not respond.

Therefore, these 13 patients underwent EUS-GBD. One patient underwent PTGBD, but after self-tube removal occurred, EUS-GBD was performed; two patients started food intake because of a response to antibiotic therapy, but after acute cholecystitis recurred, EUS-GBD was performed.

Results of EUS-guided cholecystoduodenostomy

Table 2 shows the results of EUS-guided cholecystoduodenostomy. EUS-guided cholecystoduodenostomy was performed and was functionally successful in all patients. A period of 7 days after EUS-guided cholecystoduodenostomy, the mean WBC count was 6699.2 per μ l (range 2780–11,350 per μ l) and CRP was 4.03 mg/dl (range 0.22–11.93 mg/dl). The median procedure time was 26.9 min (range 19–42 min). The median follow-up time was 181.5 days (range 18–604 days), and at the time of writing, no recurrence of acute cholecystitis was seen in any of the patients. A total of 12 patients died due to advanced cancer, but 4 patients were still alive. During follow up, adverse events such as stent migration were not seen in any patients, although pneumoperitoneum was seen in one patient.

Discussion

In cases of high surgical risk, gall bladder drainage is considered an alternative treatment, while PTGBD is the first-line drainage method.

However, this drainage method is not indicated for patients who have massive ascites or are on anticoagulant therapy. Furthermore, PTGBD has several disadvantages. Biliary peritonitis, pneumothorax and bleeding can occur in up to 12% of cases [McGahan and Lindfors, 1989]. In addition, patients' quality of life may be reduced due to extra-drainage and post procedural pain, and inadvertent tube dislodgement or migration has been reported in up to 12% of cases [Ito *et al.* 2004]. Furthermore, recurrence of cholecystitis after PTGBD tube removal occurred in 22–47% of cases if surgical treatment was not performed [McKay *et al.* 2012; Kimura *et al.* 2013].

However, EUS-GBD can be performed in cases on anticoagulant therapy because the gastrointestinal tract is less vascular than the liver [Jang *et al.* 2012; Choi *et al.* 2014]. Furthermore, EUS-GBD is an internal drainage method with less post procedural pain and therefore patients' quality of life is improved. If EUS-GBD is performed by SEMS or using another large diameter metal stent, a greater drainage effect may be obtained compared with a PTGBD tube. If PTGBD is performed and the drainage effect is insufficient, however, a larger sized PTGBD tube is needed.

Previous reports about EUS-GBD (including at least five cases and excluding nasobiliary tube only) are summarized in Table 3 [Jang *et al.* 2011, 2012; Song *et al.* 2010; Itoi *et al.*

Table 2. Results of EUS-guided cholecystoduodenostomy.

Technical success (%)	100%
Functional success (%)	100%
Adverse events, <i>n</i> (%)	Pneumoperitoneum, 1 (6%)
Post-WBC, per μ l (mean, range)	6699.2 (2780–11,350)
Post-CRP, mg/dl (mean, range)	4.03 (0.22–11.93)
Procedure time, min (median, range)	26.9 (19–42)
Recurrence of acute cholecystitis	0
Follow-up period, days (median, range)	181.5 (18–604)
Length of FCSEMS (<i>n</i>)	
6 cm	10
8 cm	6
Length of pig tail plastic stent (<i>n</i>)	
10 cm	10
12 cm	6
CRP, C-reactive protein; EUS, endoscopic ultrasound, FCSEMS, fully covered self-expandable metallic stent; WBC, white blood cell.	

Table 3. Summary of reports of EUS-GBD (including at least five cases and excluding nasobiliary tube only).

Reference	<i>n</i>	Approach route (<i>n</i>) gastric / duodenal	Stent	Technical success	Functional success	Adverse events (<i>n</i>)
Song <i>et al.</i> [2010]	8	1 / 7	7-Fr Pig tail plastic stent	100%	100%	Pneumoperitoneum (1) Stent migration (1)
Jang <i>et al.</i> [2011]	15	10 / 5	BONA-AL stent	100%	100%	Pneumoperitoneum (2)
Itoi <i>et al.</i> [2012]	5	1 / 4	AXIOS stent	100%	100%	None
Serna-Higuera <i>et al.</i> [2013]	13	11 / 13	AXIOS stent	84.6%	100%	Hematochezia (1) Abdominal pain (1)
Choi <i>et al.</i> [2014]	63	33 / 30	BONA-AL stent	98.4%	98.4%	Distal stent migration (2) Acute cholecystitis due to stent occlusion (2)
Irani <i>et al.</i> [2015]	15	1 / 14	AXIOS stent Pig tail and SEMS	93%	100%	Fever (1)
Walter <i>et al.</i> [2015]	30	ND [#]	AXIOS stent	90%	96%	ND (15)

EUS-GBD, endoscopic ultrasound gall bladder drainage; ND, not detectable.

2012; Serna-Higuera *et al.* 2013; Choi *et al.* 2014; Moon *et al.* 2014; Irani *et al.* 2015; Walter *et al.* 2015]. The reported technical success rate of EUS-GBD ranged from 84.6% to 100% and the functional success rate ranged from 98.4% to 100%. The puncture sites were transgastric in 47.9% (57/119) and transduodenal in 52.1% (62/119). The stents used with EUS-GBD were pig tail plastic stents, BONA-AL stents or AXIOS stents. The most frequent adverse events were pneumoperitoneum ($n = 3$) and stent migration ($n = 3$). Recurrence of cholecystitis was seen in previous reports [Choi *et al.* 2014; Walter *et al.* 2015]. In the present study, however, technical and functional success was achieved in all patients and adverse events such as stent migration or recurrent acute cholecystitis due to stent occlusion were not seen.

One reason for the differences between our study and previous study may be based on the diameter of the stents. In our study, because EUS-GBD is performed using SEMS combined with a plastic stent, the diameter of EUS-GBD stent is smaller than SEMS only or an AXIOS stent. Therefore, stent occlusion may difficulty occur due to food impaction, sludge, or hypermucosal tissue compared with patients who underwent EUS-GBD using only SEMS.

Technical tips for the present technique are divided into two important points: (1) to puncture

the gall bladder neck; and (2) to use relatively long SEMS and pig tail stents.

EUS-GBD has two puncture sites. One is transgastric and the other is transduodenal. If EUS-GBD is performed from the stomach, the gall bladder body is normally punctured. If EUS-GBD is performed from the duodenum, however, the neck of the gall bladder is punctured. Puncturing of the gall bladder neck is preferred because, compared with the gall bladder body, there is less gall bladder mobility and therefore stent migration is less likely to occur. In addition, the top of the stent is toward the gall bladder tail and therefore sludge or food may have difficulty flowing into the common bile duct through the cystic duct. For these reasons, puncturing the neck of the gall bladder is important to prevent stent migration. If the gall bladder body or tail was punctured from the stomach, bile leakage and distal stent migration occurred more easily than with the duodenal approach. This may be due to the distance between the gall bladder and the stomach [Itoi *et al.* 2011]. However, the neck of the gall bladder approach has several limitations, including that it is a difficult surgical procedure which is technically more challenging than the gall bladder body or tail approach.

Furthermore, in EUS-GBD, if the cystic duct is present, food or sludge may flow into the gall

bladder across the SEMS. In addition, food or sludge may also flow into the common bile duct through the cystic duct. This risk leads to cholangitis or obstructive jaundice. Therefore, we usually obstruct the cystic duct using an SEMS. To perform this, the top of the SEMS must be toward the gall bladder tail. If the gall bladder body or tail is punctured, the top of the SEMS may be toward the cystic duct. However, if the neck of the gall bladder is punctured and a relatively long length of SEMS is used, the top of the SEMS is toward the gall bladder neck to the tail, and the cystic duct may be obstructed by the SEMS itself. However, if EUS-GBD is performed using a short stent such as an AXIOS stent, food may easily flow into the common bile duct through the cystic duct.

Another important point of the present technique is to use a pig tail plastic stent in the SEMS, which has two important roles. On the one hand, it prevents stent migration and, on the other hand, it prevents food flowing into the gall bladder. Indeed, Choi and colleagues have reported recurrence of acute cholecystitis due to food impaction [Choi *et al.* 2014].

Although the present study has several limitations, such as the small sample size, the retrospective study design, the lack of a control group and limited length of follow up, our technique may be effective for preventing various adverse events after EUS-GBD.

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Conflict of interest statement

The authors declare no conflicts of interest in preparing this article.

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