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# Optimal biliary access point and learning curve for endoscopic ultrasound-guided hepaticogastrostomy with transmural stenting

**Dongwook Oh, Do Hyun Park, Tae Jun Song, Sang Soo Lee, Dong-Wan Seo, Sung Koo Lee and Myung-Hwan Kim**

***Abstract***

**Background:** Although endoscopic ultrasound-guided hepaticogastrostomy (EUS-HGS) with transmural stenting has increased for biliary decompression in patients with an inaccessible papilla, the optimal biliary access point and the learning curve of EUS-HGS have not been studied. We evaluated the optimal biliary access point and learning curve for technically successful EUS-HGS.

**Methods:** 129 consecutive patients (male $n = 81$, 62.3%; malignant $n = 113$, 87.6%) who underwent EUS-HGS due to an inaccessible papilla were enrolled. EUS finding and procedure times according to each needle puncture attempt in EUS-HGS were prospectively measured. Learning curves of EUS-HGS were calculated for two main outcome measurements (procedure time and adverse events) by using the moving average method and cumulative sum (CUSUM) analysis, respectively.

**Results:** A total of 174 EUS-HGS attempts were performed in 129 patients. The mean number of needle punctures was 1.35 ± 0.57. Using the logistic regression model, bile duct diameter of the puncture site ⩽ 5 mm [odds ratio (OR) 3.7, 95% confidence interval (CI): 1.71–8.1, $p < 0.01$] and hepatic portion length [linear distance from the mural wall to the punctured bile duct wall on EUS; mean hepatic portion length was 27 mm (range 10–47 mm)] > 3 cm (OR 5.7, 95% CI: 2.7–12, $p < 0.01$) were associated with low technical success. Procedure time and adverse events were shorter after 24 cases, and stabilized at 33 cases of EUS-HGS, respectively.

**Conclusions:** Our data suggest that a bile duct diameter > 5 mm and hepatic portion length 1 cm to ⩽ 3 cm on EUS may be suitable for successful EUS-HGS. In our learning curve analysis, over 33 cases might be required to achieve the plateau phase for successful EUS-HGS.

***Keywords:*** endoscopic ultrasound, biliary obstruction, learning curve, endoscopic ultrasound-guided biliary drainage

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## Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is the standard procedure, with a high success rate, for the treatment of biliary obstruction [Fogel *et al.* 2001; Freeman and Guda, 2005]. However, ERCP may not be possible in patients with selective cannulation failure or an inaccessible papilla due to a surgically altered anatomy or duodenal obstruction [Park *et al.* 2011; Ogura *et al.* 2014]. Percutaneous transhepatic biliary drainage (PTBD) is an alternative form of biliary accesses after failed ERCP. Although PTBD constitutes an effective alternative biliary drainage, it showed a relative high rate of adverse events and physical discomfort related to the external drainage [Van Delden and Lameris, 2008]. Endoscopic ultrasound-guided biliary drainage (EUS-BD) has been proposed as a useful alternative to ERCP [Giovannini *et al.* 2001; Lee *et al.* 2016]. Recently, EUS-guided hepaticogastrostomy with transmural stenting (EUS-HGS) has been used for biliary decompression in patients with an inaccessible papilla. However, EUS-HGS is an inherently



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complicated procedure and can lead to potentially fatal adverse events [Park *et al.* 2013; Song *et al.* 2014]. It still remains a difficult procedure for endosonographers in centers with a low volume of EUS-HGS because it is an operator-dependent process, and reliant upon with an accumulation of experience in EUS-HGS.

Currently, there are a lack of data regarding the optimum biliary access point and the learning curve of EUS-HGS. Therefore, the aim of this study was to evaluate the optimal biliary access point for technically successful EUS-HGS. The secondary aim was to evaluate the EUS-HGS learning curve.

## Method

### *Patients*

A total of 129 patients were enrolled in this study from June 2008 to February 2012. A total of 174 attempts at EUS-HGS were performed by a single experienced endoscopist (D.H.P.). Our inclusion criteria were (1) failure of initial biliary cannulation or bile duct decompression through ERCP because of accompanying duodenal obstruction, periampullary tumor infiltration, surgically altered anatomy, or high-grade hilar biliary stricture, or failed guidewire manipulation in EUS-guided antegrade stenting and (2) patients who refused PTBD. Our exclusion criteria were (1) refusal to participate in the study protocol, (2) patients with accessible papillae and attempt of EUS-guided rendezvous, (3) pregnancy, and (4) patient age less than 20 years. All patients provided written informed consent for participation in this study. The Institutional Review Board approved the study protocol (IRB No. 2016-0380), and specific informed consent was obtained from each patient to perform EUS-BD before the procedure.

### *Procedure*

Antibiotics were administered to all patients before the intervention. EUS-HGS was performed using a GF-UCT 240 linear-array echoendoscope (Olympus Medical Systems, Tokyo, Japan). The echoendoscope was placed in the cardia or lesser curvature of the stomach, and oriented to view the intrahepatic duct. Color Doppler imaging was used to identify the regional vasculature. A bile duct puncture was performed with a 19-gauge needle (EUSN-19-T; Cook Medical, Winston-Salem, USA). To confirm successful biliary access, contrast medium was injected under fluoroscopy to demonstrate biliary opacification. A 0.035-inch guidewire [Tracer (Hybrid Wire Guide guidewire, Cook Medical, Bloomington, USA); Jagwire (Boston Scientific, Natick, USA)] or a 0.025-inch VisiGlide guidewire (Olympus America, San Jose, USA) was advanced thorough the fine-needle aspiration (FNA) needle. Tract dilation was performed after the withdrawal of the FNA needle. A 4F cannula (Glo-tip, Cook Medical, Winston-Salem, USA) was inserted over the guidewire for fistula tract dilation. Thereafter, 6F and 7F biliary dilator catheters (catheter tip, 4F; Cook Medical) were inserted over the guidewire and removed, in that order, to dilate the tract. If there was resistance to advancement of the 6F dilator catheter, a triple-lumen needle-knife (Microtome, Boston Scientific) with a 7F shaft diameter was gently inserted over the guidewire to dilate the tract by using a brief burst of pure cutting current. After fistula tract creation, a straight plastic stent (7–10F in a diameter $\times$ 6–10 cm in length), or a fully covered self-expandable metal stent (FCSEMS) with flared ends or anchoring flaps (6–10 mm diameter $\times$ 6–10 cm in length, fully covered with a silicon membrane, Standard Sci Tech, Seoul, Korea or MI tech, Seoul, Korea) was placed over the guidewire. Measurements were taken for the intrahepatic bile duct diameter at the point of interest, the hepatic portion length (linear distance from the mural wall to the punctured bile duct wall in the measurement of EUS), and bile duct segment (B2 or B3) for each needle puncture attempt, and procedure times (from initial bile duct puncture to successful transmural stenting) in each EUS-HGS session. Withdrawal and repositioning of the EUS fine needle for better access to transmural stenting was permitted following failed opacification of the bile duct during contrast injection, the misplacement of the guidewire, or a difficult fistula dilation process with graded dilation. Based on our algorithm [Park *et al.* 2011, 2013], the EUS-guided rendezvous technique was not considered in this cohort with inaccessible papilla (duodenal invasion or surgically altered anatomy). EUS-HGS was performed by a single, experienced endosonographer trained in both ERCP and EUS. A total of 150 EUS-guided drainage procedures or FNA (25 pseudocyst drainages and 125 EUS-FNA procedures), and more than 2500 career ERCPs were carried out to achieve procedural expertise before commencement of this study [Park *et al.* 2009, 2011].

Consecutive database (from first case) including previous published data [Park *et al.* 2009, 2011, 2013] with conventional fistula dilation technique (graded dilation or needle knife) were prospectively collected and retrospectively reviewed to assess the learning curve. Later cases with use of balloon dilation were not included [Paik *et al.* 2014]. Learning curves of EUS-HGS were calculated for two main outcome measurements (procedure time and adverse events) by using the moving average method, and cumulative sum (CUSUM) analysis, respectively.

### Definition of events

Technical success in EUS-HGS was defined as successful stent placement following EUS needle puncture, guidewire placement and fistula tract dilation at the first attempt of EUS-HGS. Overall technical success was defined as the successful completion of the EUS-HGS procedure with successful stenting, along with the flow of contrast medium and/or bile through the stent regardless of the number of attempts at biliary access in EUS-HGS. Functional success was defined as a decrease in bilirubin or alkaline phosphatase to less than 75% of the pretreatment value within the first month [Park *et al.* 2013]. Stent patency was measured from the day on which the stent for EUS-HGS was placed to the time of stent dysfunction or patient death. Procedural adverse events were defined as any procedure-related adverse events occurring within two weeks of the procedure, including cholangitis, bile peritonitis, biloma, bleeding, pneumoperitoneum, or stent migration [Park *et al.* 2011]. These were classified and graded according to American Society for Gastrointestinal Endoscopy workshop reports [Cotton *et al.* 2010]. Based on these reports, four grades of severity were classified, based primarily on the need for hospitalization: mild, events requiring hospitalization of 1–3 days; moderate, 4–9 days' hospitalization; severe, more than 10 days' hospitalization or requiring surgery or intensive care; and fatal, death attributable to the procedure [Cotton *et al.* 2010]. Late adverse events were any stent-related complication, such as stent migration, and stent occlusion, occurring 14 days after stent placement [Park *et al.* 2011]. Stent occlusion was defined as the recurrence of jaundice and cholestasis and/or evidence of a dilated biliary system on US or CT with a direct view of the upper endoscope, which in all cases would require biliary intervention.

### Statistical analysis

All of the analyses were performed using SPSS version 22.0 (SPSS Inc., Chicago, USA). The results are expressed as mean ± standard deviation. Categorical parameters were compared by using a chi-square test and Fisher's exact test, and continuous variables using a *t*-test. Multivariable analysis was performed using the logistic regression method to examine successful EUS-HGS factors. These EUS-HGS factors were selected according to our experience. Cumulative patency duration was estimated using Kaplan-Meier analysis. A $p$-value $< 0.05$ was considered statistically significant.

Time periods were sorted by procedure time and adverse events to determine the learning curve for EUS-HGS. Procedure time was analyzed using the moving average method [Kayano *et al.* 2011; Jeon *et al.* 2016]. A five-case moving averages was used, as the moving averages for less than five cases exhibited excessive variation. The moving-average method removes individual changes and thus clarifies trends. The optimal cutoff point was determined based on the moving average trend.

CUSUM analysis was used to evaluate adverse events for all cases. This is a method of continuously assessing the performance of an individual or process against a predetermined standard to detect adverse trends and allow for early intervention [Park *et al.* 2015a]. All cases were ordered chronologically to calculate the CUSUM. CUSUM was defined as $S\,(P_i - P_0)$, where $P_i$ is an individual attempt, and $P_0$ the reference or target value for the procedure, with $P_i = 1$ for failure (adverse event) and $P_i = 0$ for success (no adverse event). The $P_0$ for the conversion rate was set at 0.1, reflecting a target conversion rate of 10 %. Therefore, a positive slope would mean failure, and a negative slope, success. In general, the $P_0$ value is set by using the minimum acceptable criteria to assess the competency [Ward *et al.* 2014; Park *et al.* 2015a]. Thus, the expected incidences (30%) of adverse events for EUS-HGS were based on the multicenter report with an experience $<$ 20 EUS-guided cholangiopancreatography [Vila *et al.* 2012].

## Results

A total of 129 patients with a mean age of 62.2 ± 13 years and 81 of whom were male were included in this study. The baseline characteristics of the patients and clinical outcomes are summarized in

**Table 1.** Baseline characteristics of patients.

| Characteristic | Value |
|---|---|
| Mean age (years) ± standard deviation | 62.2 ± 13 |
| Sex (male: female) | 81:48 |
| Reason for EUS-HGS, *n* (%) | |
| Failure of the guidewire pass across the tight stricture | 52 (40.3%) |
| Surgically altered anatomy | 37 (28.7%) |
| Obscured ampulla due to metallic enteral stent | 15 (11.6%) |
| Duodenal obstruction | 13 (10.1%) |
| Obscured ampulla due to invasive cancer | 10 (7.8%) |
| For removal of intrahepatic duct stones in surgically altered anatomy | 2 (1.6%) |

EUS-HGS, endoscopic ultrasound-guided hepaticogastrostomy with transmural stenting.

**Table 2.** The clinical outcomes of the patients who underwent endoscopic ultrasound-guided hepaticogastrostomy with transmural stenting.

| Outcomes | Value |
|---|---|
| Technical success, *n* (%) | |
| Overall patients | 120/129 (93%) |
| Overall attempts | 120/174 (70%) |
| First attempt | 83/129 (64.3%) |
| Functional success, *n* (%) | 105/129 (81.4%) |
| Number of needle punctures, *n* (%)* | |
| First attempt | 90 (69.8%) |
| Second attempt | 33 (25.6%) |
| Third attempt | 6 (4.7%) |
| Access point, *n* (%) | |
| B2 | 49 (38%) |
| B3 | 80 (62%) |
| Mean procedure time (minutes) ± standard deviation | 30.1 ± 13.1 |
| Use of needle knife for fistula tract dilation, *n* (%) | 9 (7%) |
| Mean stent patency duration (days) ± standard deviation | 137.1 ± 243.5 |
| Procedural adverse events, *n* (%) | 32 (24.8%) |

B2, bile duct of segment 2; B3, bile duct of segment 3.
*Per protocol analysis.

Tables 1 and 2. A total of 174 attempts were performed in 129 patients. A total of 113 patients (87.6%) underwent EUS-HGS due to malignant stricture and the rest ($n$ = 16, 12.4%) due to benign disease. The indications for EUS-HGS were failure of guidewire pass across the tight stricture ($n$ = 52, 40.3%), surgically altered anatomy ($n$ = 37, 28.7%), obscured ampulla due to metallic enteral stent ($n$ = 15, 11.6%), duodenal obstruction ($n$ = 13, 10.1%), obscured ampulla due to invasive cancer ($n$ = 10, 7.8%) and intrahepatic duct (IHD) stones with surgically altered anatomy ($n$ = 2, 1.6%).

The overall technical success rate was 93% (120/129) and the functional success rate was 81.4% (105/129). Technical success rate of first attempt was 64.3% (83/129, intention-to-treat analysis), and that for second and third attempts was 82.1% (32/39, intention-to-treat analysis) and 83.3% (5/6, intention-to-treat analysis), respectively (Figure 1). The bile duct of segment 2 (B2) was punctured in 49 patients (38%), and the bile duct of segment 3 (B3) in 80 (62%) patients (Figure 1). Mean hepatic portion length on EUS was 27 mm (range 10–47 mm). Mean diameter of punctured intrahepatic bile duct on

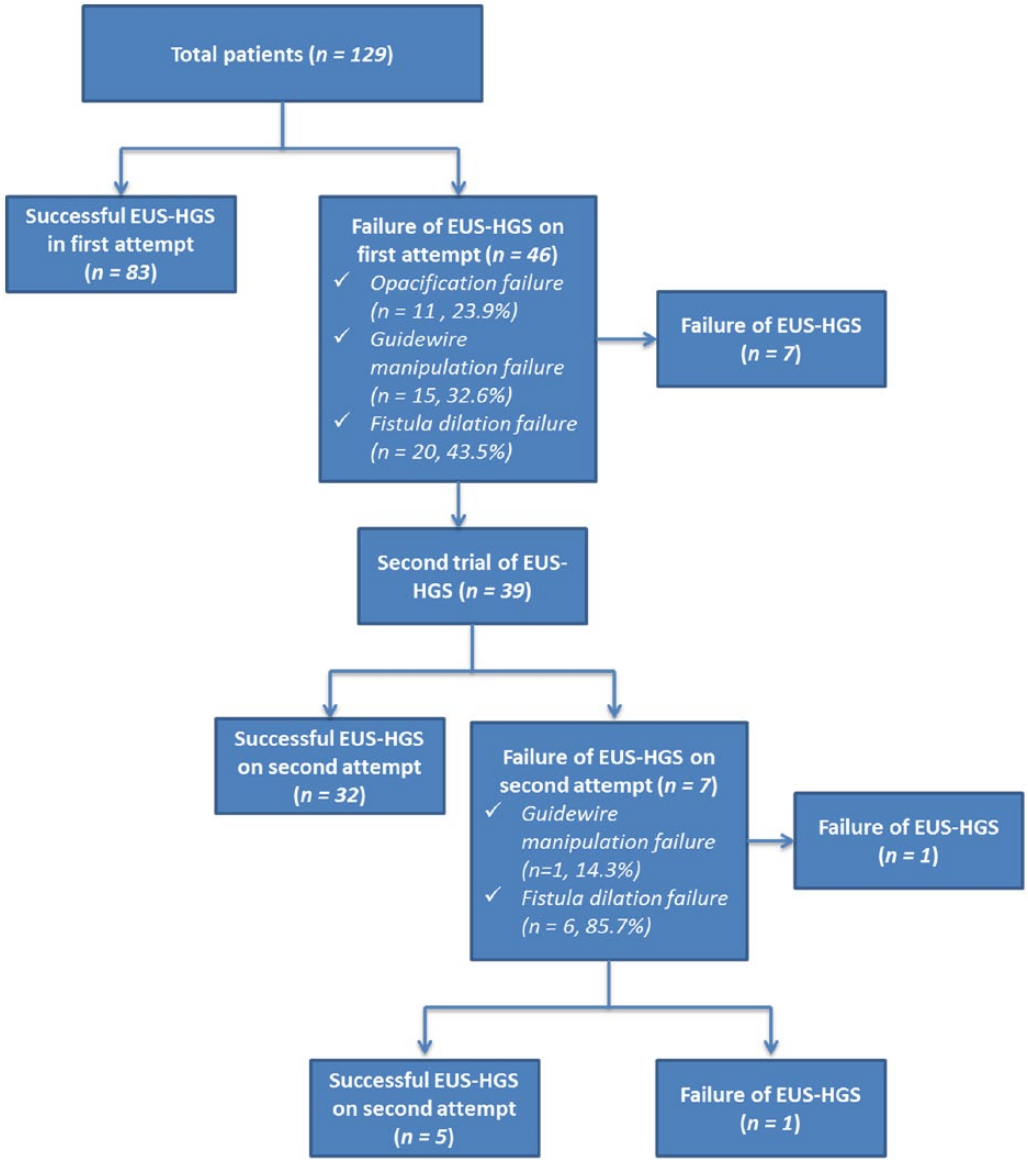


**Figure 1.** Flow diagram for endoscopic ultrasound-guided hepaticogastrostomy with transmural stenting.
EUS-HGS, endoscopic ultrasound-guided hepaticogastrostomy with transmural stenting.

EUS was 7.1 mm (range 3–15.7). The mean procedure time was 30.1 ± 13.1 minutes. FCSEMSs were placed in 118 of 120 patients (98.3%) and plastic stents were used in two of 120 patients (1.7%). Mean stent patency duration was 137.1 ± 243.5 days during mean (288.9 ± 358.1 days) follow-up periods.

Procedural adverse events developed in 32 of the 129 patients (24.8%) and included bacteremia ($n$ = 16, 12.5%), bleeding from the puncture site ($n$ = 5, 3.9%), bile peritonitis ($n$ = 4, 3.1%), self-limited pneumoperitoneum ($n$ = 4, 3.1%) and intraperitoneal stent migration ($n$ = 3, 2.3%). With regard to grades of severity, 16 cases (12.4%) were defined as mild, 14 (10.9%) as moderate, and 2 (1.6%) as severe. Late adverse events occurred in 25 of 120 patients (20.8%), and included distal stent migration ($n$ = 12, 10%) and stent occlusion ($n$ = 13, 10.8%).

To assess the learning curve for EUS-HGS over time, the cases were analyzed by the moving average and CUSUM methods. Based on procedure time according to the moving average method, 129 EUS-HGS procedures were divided into the

**Table 3.** Clinical outcomes for the two periods based on procedure time calculated by the moving average method.

| Outcomes | Group 1 (1–24) | Group 2 (25–129) | *p* value |
|---|---|---|---|
| Overall technical success, *n* (%) | 22/24 (91.7%) | 98/105 (93.3%) | 0.77 |
| Functional success, *n* (%) | 17/24 (70.8%) | 88/105 (83.8%) | 0.14 |
| Number of needle punctures, *n* (%)* | | | 0.55 |
| First attempt | 18/24 (75%) | 72/105 (68.5%) | |
| Second attempt | 5/24 (20.8%) | 28/105 (26.7%) | |
| Third attempt | 1/24 (4.2%) | 5/105 (4.8%) | |
| Mean procedure time (minutes) ± standard deviation | 39.2 ± 12.6 | 28.1 ± 12 | <0.01 |
| Adverse events, *n* (%) | 8/24 (33.3%) | 24/105 (22.9%) | 0.49 |
| Analysis of attempt failure, *n* (%) | | | |
| Opacification failure | 1/24 (4.2%) | 10/105 (9.5%) | 0.35 |
| Guidewire manipulation failure | 3/24 (12.5%) | 12/105 (11.4%) | 0.59 |
| Fistula dilation failure | 3/24 (12.5%) | 17/105 (16.2%) | 0.58 |

*Per protocol analysis.

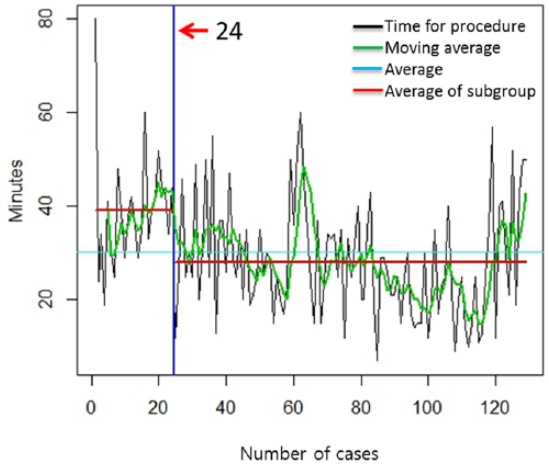


**Figure 2.** Time taken to perform ultrasound-guided hepaticogastrostomy with transmural stenting as a function of the number of cases.
The moving-average method was used to determine changes in procedure time.

first (1–24) and second period (25–129) (Table 3). The mean procedure time during the periods was 39.2 ± 12.6 and 28.1 ± 12 minutes, respectively. Technical proficiency was significantly faster as procedure experience accumulated (Figure 2). Based on adverse events according to the CUSUM method, 129 cases were divided into the first (1–33) and second period (34–129) (Table 4). The rates of adverse events were 36.4 % and 20.8 %, respectively. There were no significant differences between first and second periods ($p = 0.12$). Fluctuation was demonstrated between points 1 and 33 on the slope of the plotted line in the CUSUM chart. However, the rate of adverse events stabilized after 33 cases of HGS (Figure 3). For reaching this number with failed ERCP and inaccessible papilla, 712 consecutive ERCP cases for biliary obstruction was required.

We performed multivariate analysis between 120 successful attempts and 54 failed attempts of 174 overall attempts. In the logistic regression model, intrahepatic bile duct diameter of puncture site $\leqslant$ 5 mm [odds ratio (OR) 3.7; 95% confidence interval (CI) 1.71–8.1; $p < 0.01$] and hepatic portion length $>$ 3 cm (OR 5.7; 95% CI 2.7–12; $p < 0.01$) in all attempts (including first, second, and third attempt) were associated with low technical success. Age, sex, cause of obstruction, the presence of ascites, the lapse of time (group 1 or 2 based on procedure time), and intrahepatic bile duct segment (B2 or B3) were not associated with the technical success in EUS-HGS (Table 5).

## Discussion

To date, little is known about the optimal biliary access point and learning curve of EUS-HGS. Regarding the optimal biliary access point for EUS-HGS, this technique seems to be similar to precutting for transpapillary biliary cannulation because of the free-hand technique employed in both procedures. Therefore, EUS-HGS may be more difficult than EUS-choledochoduodenostomy, requiring a relatively stable scope position and fixed biliary access point (duodenal bulb), even in experienced

**Table 4.** Clinical outcomes for the two periods according to procedural adverse events by the cumulative sum analysis method.

| Outcomes | Group 1 (1–33) | Group 2 (34–129) | *p*-value |
|---|---|---|---|
| Overall technical success, *n* (%) | 31/33 (93.9%) | 89/96 (92.7%) | 0.81 |
| Functional success, *n* (%) | 25/33 (75.8%) | 80/96 (8.33%) | 0.33 |
| Number of needle punctures, *n* (%)* | | | 0.37 |
| First attempt | 25/33 (75.8%) | 65/96 (67.7%) | |
| Second attempt | 7/33 (21.2%) | 26/96 (27.1%) | |
| Third attempt | 1/33 (3%) | 5/96 (5.2%) | |
| Mean procedure time (minutes) ± standard deviation | 36.5 ± 13 | 27.9 ± 12.1 | <0.01 |
| Adverse events, *n* (%) | 12/33 (36.4%) | 20/96 (20.8%) | 0.12 |
| Analysis of attempt failure, *n* (%) | | | |
| Opacification failure | 3/33 (9.1%) | 8/96 (8.3%) | 0.57 |
| Guidewire manipulation failure | 3/33 (9.1%) | 12/96 (12.5%) | 0.44 |
| Fistula dilation failure | 3/33 (9.1%) | 17/96 (17.7%) | 0.21 |

*Per protocol analysis.

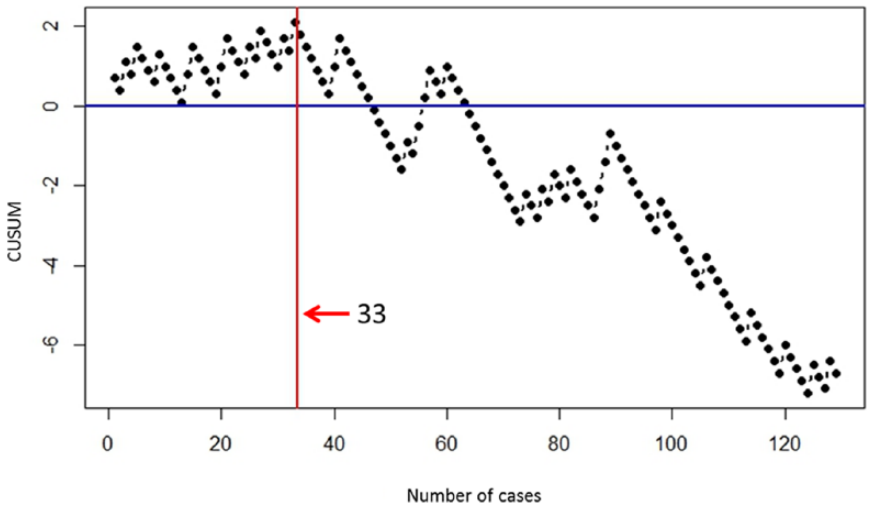


**Figure 3.** The adverse events for ultrasound-guided hepaticogastrostomy with transmural stenting as a function of the number of cases.
CUSUM, cumulative sum.
The CUSUM analysis was used to determine changes in adverse event rates.

endosonographers [Park, 2012]. Furthermore, the absence of studies on the ideal puncture site limit the general popularity of EUS-HGS, which tends to be performed only by experts in a few tertiary centers. Therefore, to the best of our knowledge, this study first evaluated technical proficiency with time trends for the evaluation of the optimal biliary access point and the learning curve of EUS-HGS by single operator.

The overall technical success rate of EUS-HGS achieved in our study was comparable with that of previous studies [Park *et al.* 2010, 2011, 2013; Paik *et al.* 2014]. However, the technical success rate (64.3%, 83/129) of the first attempt was lower than the overall technical success rate. The success rate achieved on the first attempt and subsequent attempts may reflect the effect of a learning curve because outcomes of all the procedures according to time trends were reported. In addition, the difference between these success rates may have resulted from withdrawal and subsequent puncture of the EUS fine needle in 35.7% of the patients to gain better access to the

**Table 5.** Logistic regression model of impact factor for unsuccessful endoscopic ultrasound-guided hepaticogastrostomy with transmural stenting.

| Predictor | OR | 95% CI | *p* value |
|---|---|---|---|
| Intrahepatic bile duct diameter of the puncture site ⩽ 5 mm | 3.7 | 1.7–8.1 | <0.01 |
| Hepatic portion length (linear distance from the mural wall to the punctured bile duct wall > 3 cm in the measurement of EUS) | 5.7 | 2.7–12.0 | <0.01 |

OR, odds ratio; CI, confidence interval; EUS, endoscopic ultrasound.

EUS-HGS with transmural stenting. Interestingly, the proportion of multiple attempts (over two) of needle puncture in each EUS-HGS session showed an increasing tendency without statistical significance in this study (group 1 = 25% *versus* group 2 = 31.5%, $p = 0.55$; two periods based on procedure time). However, the procedure time of group 2 was significantly shorter than that of group 1 (28.1 ± 12 in group 2 *versus* 39.2 ± 12.6 in group 1, $p < 0.001$; two periods based on procedure time). Furthermore, the rate of adverse events showed a decreasing tendency without statistical significance in group 2 (22.9% in group 2 *versus* 33.3% in group 1, $p = 0.49$; two periods based on procedure time). With the accumulation of an operator's experience of EUS-HGS, this repositioning of the EUS fine needle for better access point of EUS-HGS with transmural stenting may have related to technical proficiency achieved without increasing adverse events as in our previous study [Oh *et al.* 2016]. The placement of an FCSEMS may be also helpful for sealing the previously punctured intrahepatic duct as compared with that of plastic stenting [Park *et al.* 2009; Oh *et al.* 2016]. Functional success was achieved in 81.4% (105/129) of the patients. In our study, a substantial number of patients had an advanced stage of malignancy, complex type of hilar stricture, or accompanying duodenal obstruction. These subgroup complexities may have influenced the functional success reported in our study.

Adverse events developed in 24.8% (32/129) patients in the current study, which is comparable with that cited in other studies [Park *et al.* 2009, 2011; Vila *et al.* 2012; Park, 2015]. It was demonstrated in our previous studies that the use of a needle knife for fistula dilation in EUS-BD may be associated with postprocedure adverse events [Park *et al.* 2011]. A needle knife was used more significantly in patients who experienced adverse events (6/32, 18.8%) as compared with its use in patients who had not (3/97, 3.1%, $p < 0.05$). Our results verify that the risk associated with EUS-BD, and the use of a needle knife for fistula dilation in EUS-BD should be avoided if possible.

The ideal puncture site for EUS-HGS is the most important technical issue. It is important to identify the optimal biliary access point in EUS-HGS, especially for those inexperienced in its use because the procedure can be accompanied by significant adverse events such as bile peritonitis, stent migration, pneumoperitoneum, and cholangitis [Martins *et al.* 2010; Paik *et al.* 2014; Hara *et al.* 2016]. However, to date, none of the studies have evaluated the optimal biliary access point for EUS-HGS. Our data suggest that bile duct diameter at the point of interest > 5 mm, and hepatic portion length of 1 cm to ⩽ 3 cm on EUS (Figure 4b) might facilitate successful EUS-HGS. Although shorter hepatic portion length on EUS has an advantage for puncture the intrahepatic bile duct, a certain amount of stent must be located in the hepatic parenchyma to prevent migration or bile leakage as in PTBD [Ogura *et al.* 2015]. As usual, we inserted a metal stent into the left intrahepatic bile duct of 2 or 3 cm length with 3 cm length in the luminal portion during EUS-HGS [Ogura *et al.* 2015]. This intrahepatic bile duct portion is also located in the hepatic parenchyma. This 2 or 3 cm in the left intrahepatic bile duct and hepatic portion length (linear distance from the mural wall to the punctured bile duct wall in the measurement of EUS) in the hepatic parenchyma was considered to prevent stent migration or bile leakage as in PTBD.

A dilated bile duct may be a prerequisite for successful EUS-BD (Figure 4a). However, insufficient intrahepatic bile duct dilatation was frequently observed in failed the first attempt of

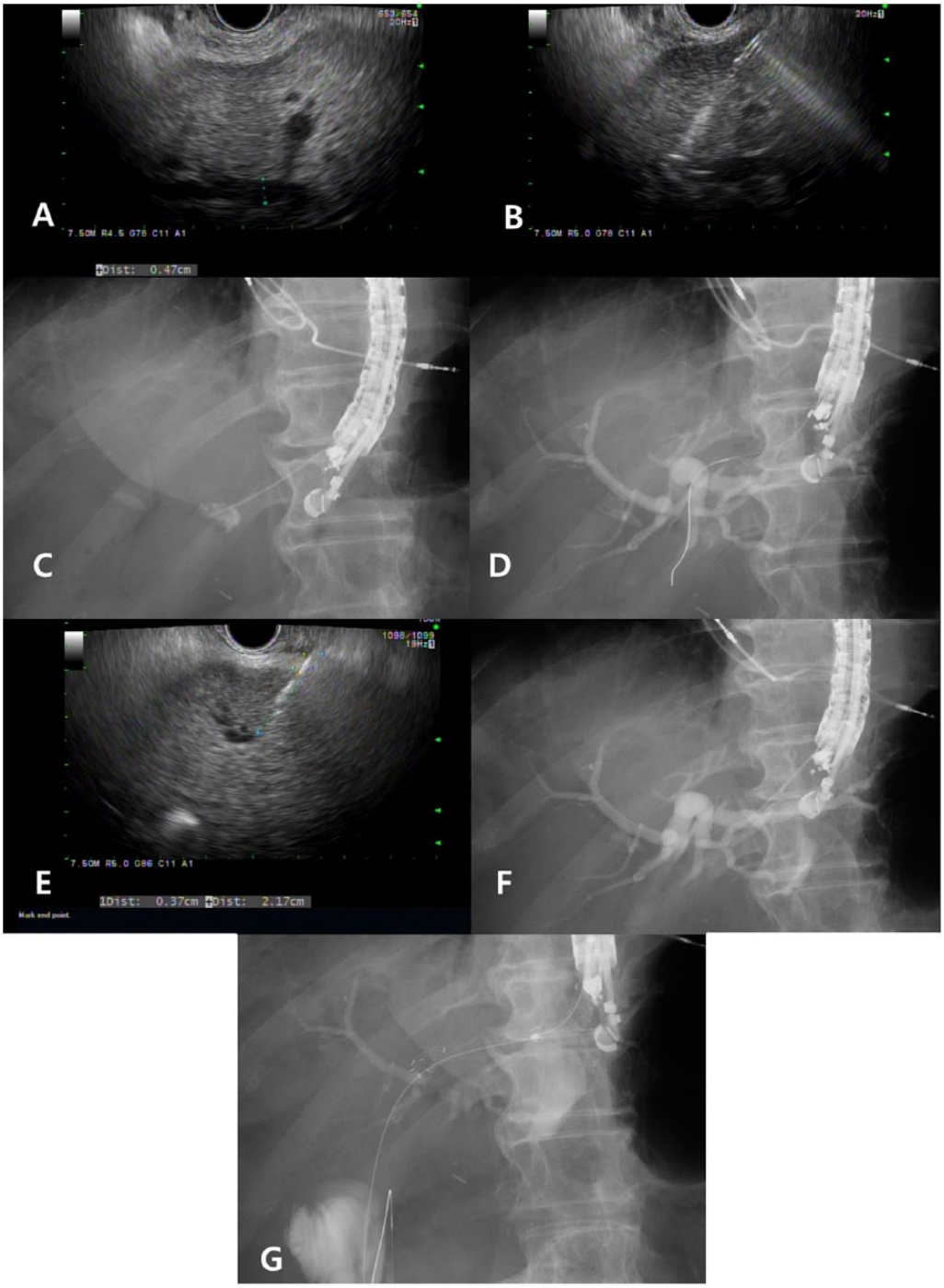


**Figure 4.** A case of endoscopic ultrasound-guided hepaticogastrostomy with transmural stenting. (a) The intrahepatic bile duct diameter was 4.7 mm on endoscopic ultrasound. (b) Endoscopic ultrasound-guided puncture was performed. The linear distance from the mural wall to the punctured bile duct wall was more than 3 cm in the measurement of EUS. (c) Failed biliary opacification was demonstrated on fluoroscopy at the first attempt. (d) Misplacement of the guidewire was also demonstrated on fluoroscopy at the second attempt. (e, f) Reposition of endoscopic ultrasound FNA needle for better access to the transmural stenting was performed. The distance from the mural wall to the punctured bile duct was ⩽ 3 cm. (g) The guidewire was introduced through the endoscopic ultrasound needle and advanced into the bile duct. Then a fully covered metal stent was successfully placed at the third attempt.
EUS, endoscopic ultrasound; FNA, fine-needle aspiration needle.

EUS-HGS. In these circumstances, less than 5 mm of intrahepatic bile duct dilatation should not be chosen as an optimal biliary access point for initial puncture with the EUS FNA needle.

Although the B3 approach may be more suitable for EUS-HGS, a statistically significant difference in the success rates between B2 and B3 was not observed [Park, 2015]. Therefore, we evaluated the parameter for successful fistula dilation and stent placement. In our previous study [Paik *et al.* 2014], the distance from the mural wall to the punctured bile duct may be important for choosing the length of the stent. In this study, additional steps in the fistula dilation process may be required for a distance $>$ 3 cm. This distance may represent the puncture of the central intrahepatic duct, rather than that of the peripheral intrahepatic duct. Theoretically, stent deployment may be difficult in longer distances between the mural wall and the punctured bile duct because a longer stent and angulation on stent deployment may be required. With limited experiences of EUS-HGS, multiple needle-puncture attempts during EUS-HGS may have increased the risk of procedure-related adverse events. Therefore, further multicenter studies are required to confirm our results, which build upon the EUS findings with respect to the first attempt of EUS-HGS.

The results of this study suggest that the technical proficiency required with regard to procedure time needed to perform the procedures improved significantly with experience after 24 cases (Figure 2). Although a statistically significant difference was not noted between the two periods, approximately 33 procedures are needed to acquire the technical skills for EUS-HGS in order to reach a stabilization level in terms of adverse events. (Figure 3). This may be because of the following reasons: (1) increased familiarity with technical maneuvers, such as the correct orientation of the echoendoscope with respect to the position of the dilated intrahepatic duct, (2) identifying an appropriate plane for guidewire manipulation, fistula tract dilation, and stent insertion, (3) the ability to choose stents of the correct length based on the puncture site, and (4) increased experience of the endoscopist.

There were several limitations to this study. First, the technical proficiency reported in this study was evaluated by one endosonographer with expertise in both EUS and ERCP in a large tertiary academic center. Therefore, the number of EUS-HGSs required to achieve mastery for operators in a low-ERCP-volume center may have been underestimated. Thus, a larger, multicenter, prospective study may be needed to confirm our results. EUS-HGS can be performed after failed ERCP. This suggests that evaluation of this procedure is difficult for most low-volume ERCP centers with trainees. Furthermore, EUS-HGS should be performed by endosonographers who are trained in both EUS and ERCP. Therefore, given these limited resources, we conducted this study with a large number of EUS-HGS performed by a single, experienced endosonographer without experience of EUS-HGS before commencement of this study. Although the single-operator experience limits the ability to generalize our results, this study may have clinical impact on successful and robust EUS-HGS procedures because our results may be informative to endoscopists who are starting to perform EUS-HGS with regard to the efficacy and spread of EUS-HGS.

Second, EUS-BD was performed using the conventional fistula dilation process and stent deployment system in this study. A substantial number (33 failed ERCP cases with inaccessible papillae in 712 consecutive ERCP cases for biliary obstruction) of EUS-HGS for technical proficiency was required owing to the complexity of the procedure. Therefore, the development of training models for EUS-HGS are mandatory for beginners in order to shorten time to technical proficiency [Dhir *et al.* 2015]. Furthermore, the EUS-BD learning curve, using a one-step dedicated device, should be evaluated in a future study [Park *et al.* 2015b; Lee *et al.* 2016].

In conclusion, EUS-HGS may be performed successfully when the bile duct is approached at the point of bile duct diameter $>$ 5 mm, with hepatic portion length being 1 cm to $\leqslant$ 3 cm on EUS. Based on our results, performed by a single endosonographer, technical proficiency, with regard to procedure time and adverse events, may be competent after 33 cases of EUS-HGS using the conventional fistula-dilation process and stent deployment system. Given a substantial number of cases requiring a learning curve of EUS-HGS in this study, various and extensive endoscopic teaching tools for EUS-HGS such as an *ex vivo* hands-on model or interventional EUS mechanical simulator may be encouraged prior to self-taught EUS-HGS procedures without supervision.

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## Conflict of interest statement

The authors declare that there is no conflict of interest.

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