

## Use of Curved Linear-Array Endoscopic Ultrasonography Findings to Predict Difficulty in Biliary Access During Endoscopic Retrograde Cholangiopancreatography

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### Abstract

**Objectives:** To assess whether curved linear-array endoscopic ultrasonography (CLAEUS) can predict difficult endoscopic retrograde cholangiopancreatography (ERCP) cases.

**Methods:** Patients with ERCP after CLAEUS between August 14, 2013, and October 15, 2015, were divided into refractory [R] (n = 9) and straightforward [S] (n = 18) groups. The following were compared: pressure-induced biliary collapse at the second duodenal portion (D2), stable probe positioning cranial to the Vater's papilla (ampulla) orifice for visualizing the D2 ampulla, coaxial depiction of the bile and pancreatic ducts at D2, and vertical distance between the bile and pancreatic ducts at D2.

**Results:** The R and S groups had 2 and 0 cases of biliary collapse and 7 and 18 cases without biliary collapse cases, respectively (P = 0.041). The R and S groups had 4 and 2 cases of an inferior ampulla and 5 and 16 non-inferior cases, respectively (P = 0.16). Bile and pancreatic ducts were coaxially visualized in 7 and 5 cases but not in 2 and 13 cases in the R and S groups, respectively (P = 0.037). The mean vertical distance was 4.1 and 4.2 mm in the R and S groups, respectively (P = 0.92).

**Conclusions:** CLAEUS findings of pressure-induced biliary collapse and simultaneous depiction of the bile and pancreatic ducts could predict difficult biliary cannulation during ERCP.

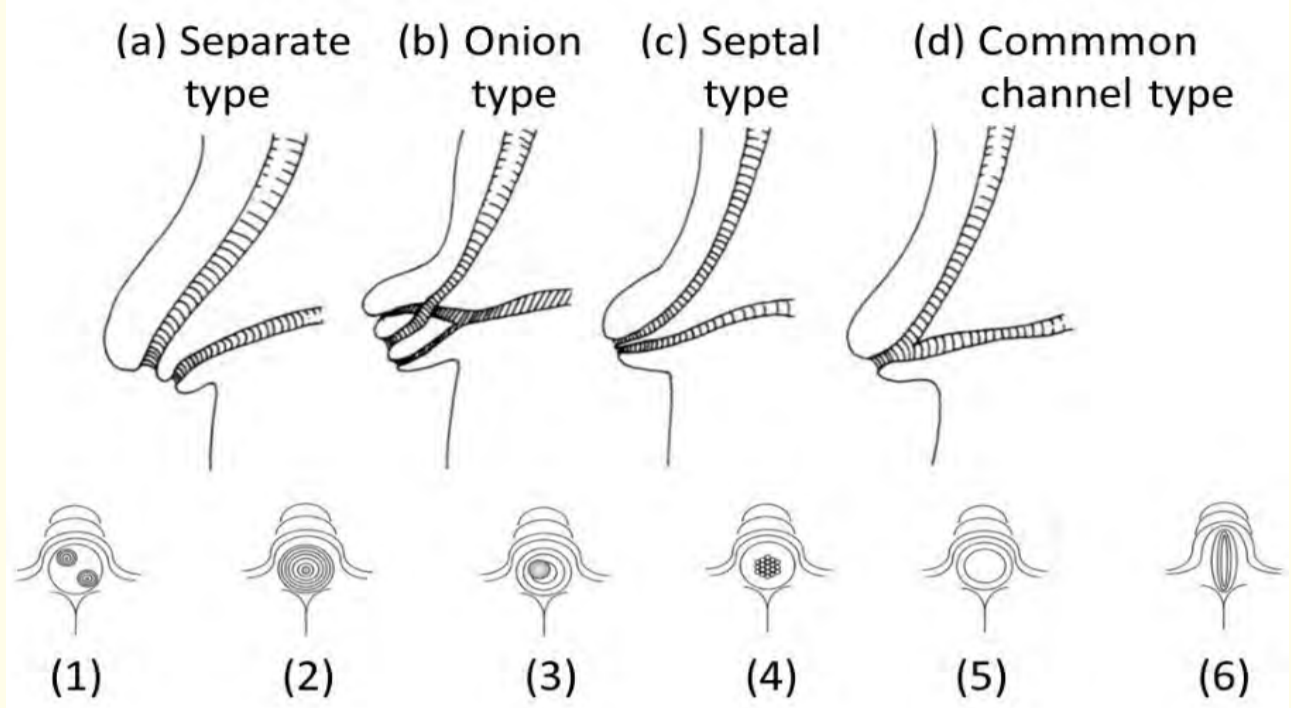
**Keywords:** Biliary Tract; Catheterization; Cholangiopancreatography; Endoscopic Retrograde; Endosonography; Vater's Papilla

### Introduction

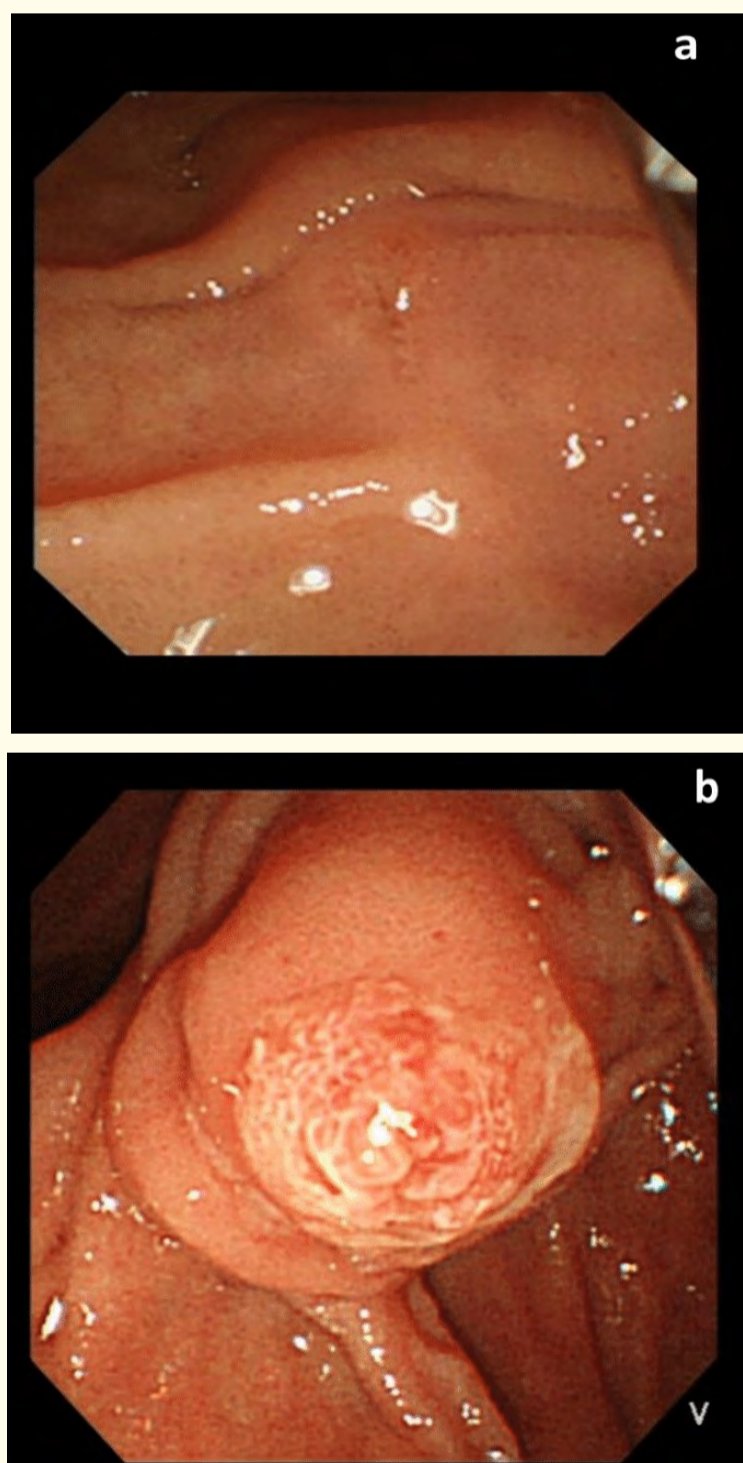
With the recent dramatic progress in less invasive diagnostic modalities such as computed tomography, magnetic resonance imaging and endoscopic ultrasonography (EUS), endoscopic retrograde cholangiopancreatography (ERCP) is mainly used for therapeutic purposes that require secure and selective cannulation of the biliary and pancreatic ducts, particularly deep cannulations of the biliary ducts [1].

Regarding selective biliary duct cannulation, Mammen and Haber [2] previously described that clinicians should strive to achieve a  $\geq 95\%$  cannulation success rate and a  $< 5\%$  incidence of complications. However, selective biliary cannulation can be difficult in certain cases.

Inomata, *et al.* [3,4] speculated that cases in which selective bile duct cannulation would be difficult could be predicted based on the morphology of the Vater's papilla according to Oi's classification [5,6]. With regard to the junction between the common bile duct and the pancreatic duct, Inomata, *et al.* [4] observed that cannulation was most difficult in the "septal-type" junction. As 85% of nodular types and 70% of flat and villous-shaped types in Oi's classification were categorized as septal-type junctions, they speculated that the nodular or flat/villous morphology type of the Vater's papilla contributed to the prediction of cases in which selective bile duct cannulation would be difficult (Figure 1). As for other characteristics regarding the Vater's papilla, Aiura [7] further observed that the degree of difficulty of bile duct cannulation was high if the ampulla was extremely small (Figure 2a) and if it was shaped like an "aquiline nose" or in case of an inferior Vater's papilla (Figure 2b), in which the orifice of the ampulla was directed caudally toward the endoscope screen.



**Figure 1:** Anatomical arrangement of the common bile duct and the main pancreatic duct at the Vater's papilla. (1) Separate opening type, 1.3%; (2) onion type, 27%; (3) nodular type, 35.2%; (4) villous type, 19.6%; (5) flat type, 13.0%; (6) vertically elongated type, 3.9%. "Septal type (c)" is the most difficult junction for selective bile duct cannulation and correlates with 85% of the nodular type (3) and 70% of the villous and flat types (4 and 5).



**Figure 2:** Morphology of the Vater's papilla correlating with difficult cannulation. (a) "Small" Vater's papilla. (b) "Aquiline nose" or inferior Vater's papilla.

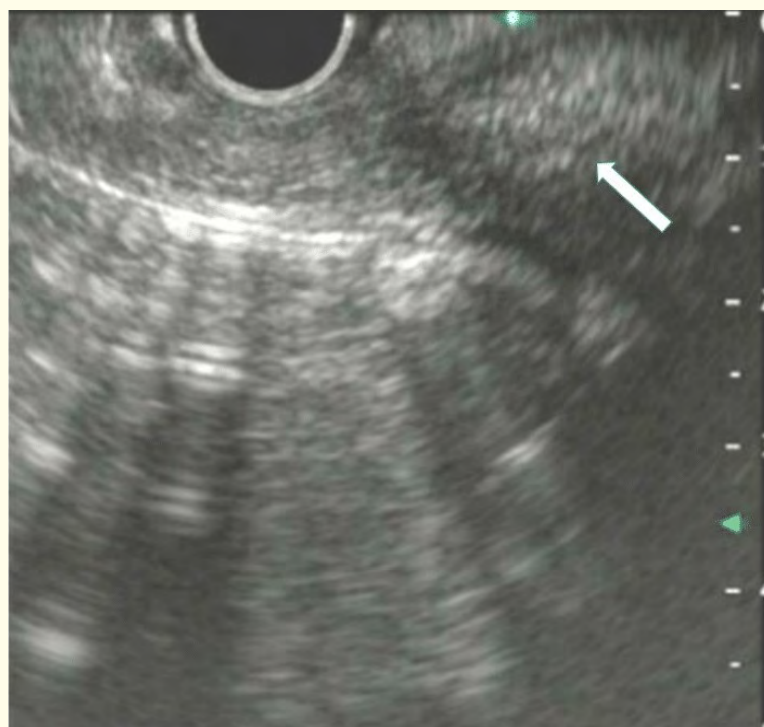
Meanwhile, no previous clinical study has examined in detail the ability of curved linear-array EUS (CLAEUS) findings to predict the difficulty of bile duct cannulation. The purpose of this study was to determine which findings from CLAEUS predict difficult bile duct cannulation during ERCP.

**Methods**

In this single-center study of 712 patients who underwent ERCP between August 14, 2013, and October 15, 2015, those who underwent CLAEUS before ERCP were divided into two groups: the straightforward group (S group), which comprised patients whose entire therapeutic procedure using ERCP was completed within 10 minutes, and the refractory group (R group), which comprised patients for whom access to the bile duct was impossible, patients for whom the precut method was necessary, patients in whom the procedure was performed under CLAEUS guidance (including the rendezvous technique or choledochoduodenostomy), and patients who required a percutaneous transhepatic approach. All endosonographic procedures were performed with a curved linear-array echoendoscope (Olympus GF-UE260, GF-UCT240; Olympus Optical Co., Tokyo, Japan) with a universal ultrasound processor (EU-ME2; Olympus Optical Co.). All ERCP procedures were performed with a therapeutic duodenoscope (JF240, JF260V, TJF 260V; Olympus Optical Co.). A single-lumen cannula (ERCP catheter; MTW Endoskopie, Wesel, Germany) and a guidewire (length, 450 cm; diameter, 0.06 cm; VisiGlide2; Olympus Medical Systems, Tokyo, Japan) were used for cannulation during ERCP. Three endoscopists, all of whom had experience performing more than 500 CLAEUS procedures and more than 700 ERCP procedures, performed the CLAEUS and ERCP.

The following CLAEUS findings were used as study items:

1. Pressure-induced bile duct collapse: Pressure-induced bile duct collapse was considered positive when the bile duct collapsed completely and could only be identified on the basis of the biliary duct wall (Figure 3).



**Figure 3:** CLAEUS image of pressure-induced bile duct collapse. The bile duct could only be identified by the presence of the biliary duct wall (arrow).

- 2. Inferior Vater's papilla: When the stable positioning of an orifice of the ampulla at the second portion of the duodenum (D2) could only be attained if the CLAEUS probe was positioned cranially from the orifice of the Vater's papilla, the patient was considered to have inferior Vater's papilla positivity (Figure 4).



Figure 4: Inferior Vater's papilla.

- 3. Simultaneous depiction of the bile and pancreatic ducts: Simultaneous depiction of the bile and pancreatic ducts was considered positive when the bile and pancreatic ducts were depicted simultaneously in the axis for depiction of the Vater's papilla at D2 (Figure 5).

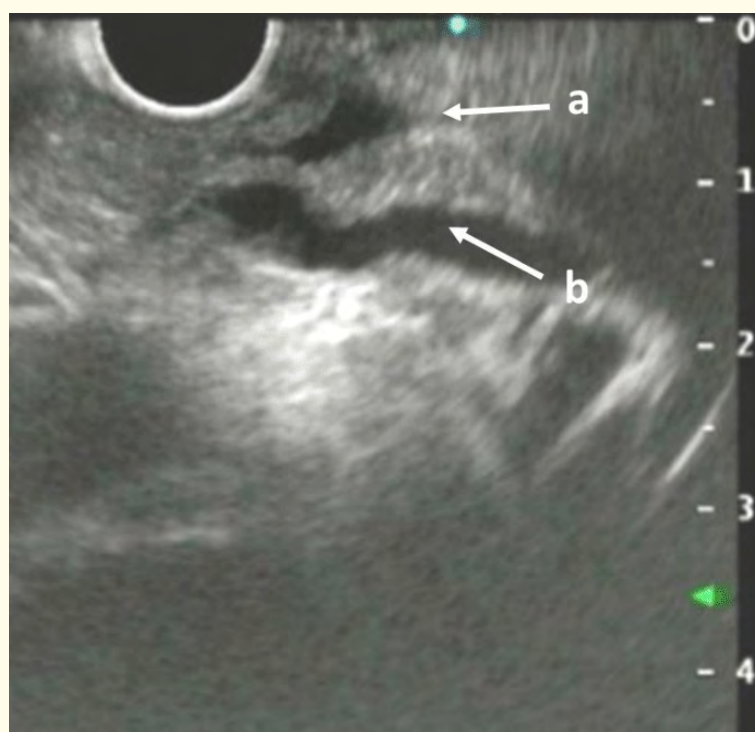
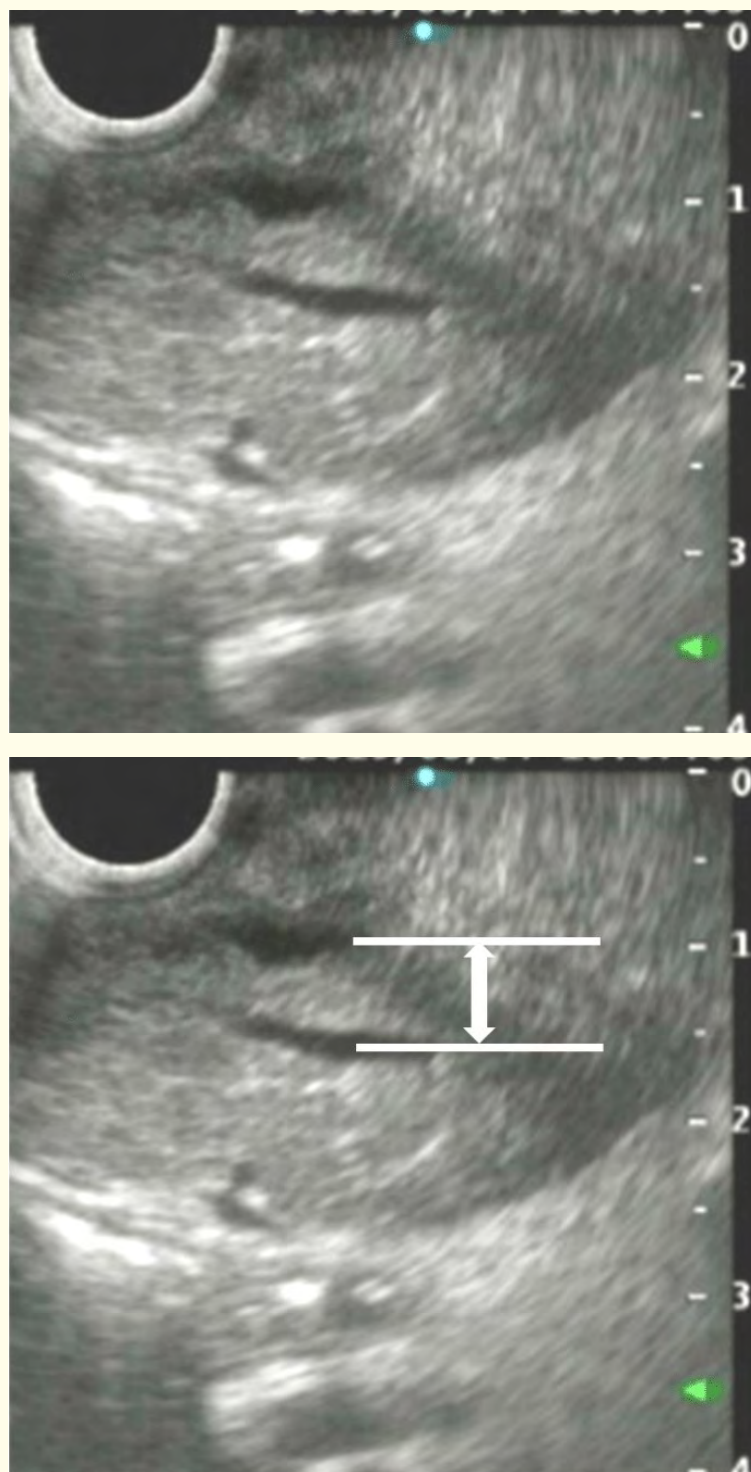


Figure 5: Coaxial visualization of the bile and pancreatic ducts. (a) Common bile duct. (b) Main pancreatic duct.

4. Vertical distance between the common bile duct and the pancreatic duct during simultaneous depiction of the bile and pancreatic ducts: The vertical distance between the common bile duct and the pancreatic duct during simultaneous depiction of both ducts was considered positive and was measured at the location where the bile and pancreatic ducts were simultaneously depicted in parallel, usually visualized when the CLAEUS probe was located approximately 1 - 2 cm cranial to the Vater's papilla (Figure 6a and 6b).



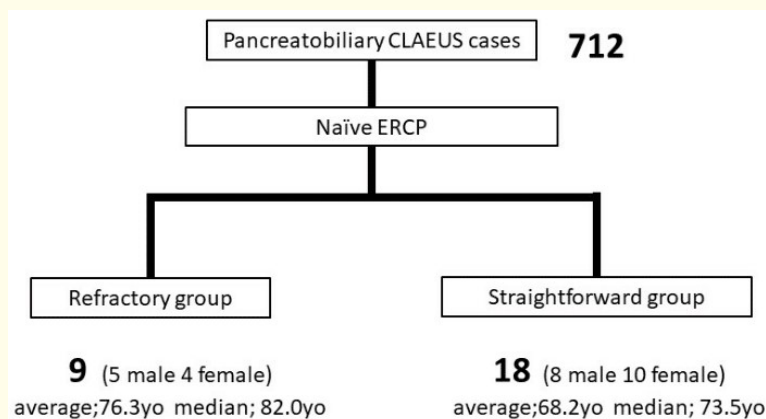
**Figure 6:** Vertical distance between the bile and pancreatic ducts. Panels (a) and (b) show the same CLAEUS image. The vertical distance between the two white lines (white arrow) in (b) corresponds with the vertical distance between the bile and pancreatic ducts.

Meanwhile, we excluded patients who underwent ERCP before CLAEUS and patients who had undergone ERCP in the past. Because of the anonymous nature of the data, the requirement for informed consent was waived. Study approval was obtained from the institutional review board of Okinawa Chubu Hospital. The first author takes complete responsibility for the integrity of the data and accuracy of the data analysis.

Statistical testing of significant differences between the R and S groups based on data from a 2 x 2 contingency table with cells that had an expected frequency of  $\leq 5$  (presence or absence of pressure-induced bile duct collapse, presence or absence of inferior Vater’s papilla, and presence or absence of simultaneous depiction of the bile and pancreatic ducts) was conducted using the Fisher’s exact probability test. The Mann-Whitney U test was performed between the R and S groups for statistical testing of the mean differences in continuous data that did not follow a normal distribution (vertical distance between the common bile duct and the pancreatic duct). The threshold for significance was  $P < 0.05$ . All statistical analyses were performed using the Excel statistical software package (Ekuseru-Toukei 2015; Social Survey Research Information Co., Ltd., Tokyo, Japan).

**Results**

As shown in figure 7, of the 712 patients who underwent EUS in our hospital within a 26-month period, 9 and 18 were categorized into the R and S groups, respectively (Table 1). The CLAEUS findings are presented in table 2. Pressure-induced collapse of the common bile duct ( $p = 0.041$ ) and simultaneous depiction of the bile and pancreatic ducts ( $p = 0.037$ ) were found to be significant factors predicting difficult biliary cannulation during ERCP. The positive and negative predictive values of the pressure-induced collapse of the common bile duct and simultaneous depiction of the bile and pancreatic ducts are shown in table 3, whereas the positive and negative predictive values when significant CLAEUS findings were combined are given in table 4.



**Figure 7:** Diagram of the study protocol.

	<b>S Group</b>	<b>R Group</b>
Sex (male), n	9	18
Mean (years)	5	8
Median (years)	76.3	68.2

**Table 1:** Patients’ characteristics.

*S Group: Straightforward group; R Group: Refractory group*

Findings	R Group		S Group		P-value
	Positive	Negative	Positive	Negative	
Bile duct collapse	2	7	0	18	0.041
Inferior Vater’s papilla	4	5	2	16	0.16
Simultaneous depiction of CBD and MPD	7	2	5	13	0.037
Vertical distance between CBD and MPD (mm)					
Mean	4.1		4.2		0.92
Median	3.5		2.9		0.44

**Table 2:** CLAEUS findings.

CLAEUS: Curved Linear-Array Endoscopic Ultrasonography Group S: Straightforward Group; Group R: Refractory Group; CBD: Common Bile Duct; MPD: Main Pancreatic Duct

CLAEUS findings	PPV (%)	NPV (%)
Bile duct collapse	100	72
Coaxial biliopancreatic duct depiction	58	86

**Table 3:** PPV and NPV of the significant CLAEUS findings.

CLAEUS: Curved Linear-Array Endoscopic Ultrasonography; PPV: Positive Predictive Value; NPV: Negative Predictive Value

PPV if both findings are positive	100%
NPV if both findings are negative	91%

**Table 4:** PPV, and NPV when two significant CLAEUS findings were combined.

CLAEUS: Curved Linear-Array Endoscopic Ultrasonography; PPV: Positive Predictive Value; NPV: Negative Predictive Value

**Discussion**

In this study, we retrospectively assessed EUS findings in patients who underwent CLAEUS before their initial ERCP procedure. In particular, we compared EUS findings from patients in whom bile duct cannulation failed during ERCP using the “usual approach” and who required precutting or an antegrade approach using either a CLAEUS-guided or a percutaneous transhepatic approach and the EUS findings from the patients in whom selective biliary cannulation was performed without difficulty.

Our findings show that “compression-induced common bile duct collapse” and “simultaneous depiction of the bile and pancreatic ducts” were significantly more frequent in the R group than in the S group.

According to the Scandinavian Association of Digestive Endoscopy, to be considered a difficult selective bile duct cannulation, which is related to post-ERCP pancreatitis, one of the following criteria should be met: a bile duct cannulation that must be attempted  $\geq 5$  times and takes  $\geq 5$  minutes or an unintended cannulation of the pancreatic duct occurring twice or more [8]. In addition, in most clinical studies, the “acceptable number of cannulation attempts” ranges from 5 to 10 times [9-11]. Considering the above-mentioned definitions, our

study compared patients with difficult cannulation and patients for whom the entire ERCP procedure, including bile duct cannulation, was completed within 10 minutes.

No previous study has demonstrated the use of CLAEUS findings to predict difficulty in performing selective bile duct cannulation. Hence, we created the aforementioned selection criteria for several reasons. Regarding pressure-induced bile duct collapse, we postulated that the difficulty in cannulating the easily collapsing bile duct with a CLAEUS probe was due to the correlation between pressure-induced bile duct collapse and a small bile duct diameter, low intraductal pressure of the bile duct, or a short distance between the bile duct and the mesotrophic aspect of the D2 wall. Especially in terms of the short distance between the bile duct and the mesotrophic aspect of the D2 wall, the anatomical characteristics resulted in a steep rise of the bile duct from Vater's papilla toward the liver hilum and required steep and delicate manipulation of the side-viewing scope elevator. Regarding the "inferior Vater's papilla," we postulated that the difficulty in performing cannulation in such cases resulted from the correlation between the CLAEUS findings and the morphological characteristics of the caudally directed orifice of the Vater's papilla, which was already known to be a "difficult-to-cannulate" Vater's papilla [7]. Regarding the simultaneous depiction of the bile and pancreatic ducts, we postulated that the finding reflected that the insertion angle between the mesotrophic aspect of the D2 wall and the bile duct was similar to the insertion angle between the mesotrophic aspect of the D2 wall and the pancreatic duct, which enabled the mere cannulation of the pancreatic duct and precluded the selective cannulation of the bile duct. We postulated that the short vertical distance between the common bile duct and the pancreatic duct was in proportion with the similarity of the insertion angle between the mesotrophic aspect of the D2 wall and the bile and pancreatic ducts. This enabled the cannulation of only the pancreatic duct because the insertion angle of the pancreatic duct was less steep than that of the bile duct and played a role in the difficulty of selective cannulation of the bile duct.

Meanwhile, we found that "simultaneous depiction of the bile and pancreatic ducts" and "compression-induced collapse of the common bile duct" were both significant CLAEUS findings that predicted selective deep bile duct cannulation. Furthermore, a positive predictive value of 100% when both findings are positive and a negative predictive value of 91% when both findings are negative can be attained, suggesting more precise results when the two findings are used in combination.

Based on the findings of our study, we conclude that performing CLAEUS before ERCP to evaluate such findings as "simultaneous depiction of the bile and pancreatic ducts" and "compression-induced collapse of the common bile duct" allows for prediction of difficult selective bile duct cannulation during ERCP. Moreover, in cases predicted by CLAEUS to be difficult, serious complications such as post-ERCP pancreatitis can be reduced by using the precut method or EUS-guided rendezvous technique at an early stage, without being fixated on a threshold of  $\geq 5$  cannulation attempts for a duration of  $\geq 5$  minutes.

The limitations of this study were the small number of cases and that it was a case-control study in which two groups were examined according to the outcomes, namely cases in which selective bile duct cannulation was difficult to perform and cases in which the procedure was performed smoothly and completed successfully. Regarding these issues, the results of this study need to be verified prospectively by predicting cases of difficult selective bile duct cannulation according to EUS findings and by dealing with each case in accordance with the algorithm used in our hospital.

Although this was a retrospective, case-control study, the EUS findings of pressure-induced collapse of the common bile duct and of simultaneous depiction of the bile and pancreatic ducts were suggestive of a difficult selective bile duct cannulation during ERCP.



## Conclusions

CLAEUS findings of pressure-induced biliary collapse and simultaneous depiction of the bile and pancreatic ducts could predict difficult biliary cannulation during ERCP.

## Author contributions

S.S. designed and performed experiments, analyzed data, and wrote the paper; K.C. designed and performed experiments, and analyzed the data.

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