Impact of periampullary diverticulum on biliary cannulation and ERCP outcomes: a single-center experience

Fatema Tabak · Guo-Zhong Ji · Lin Miao

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Abstract

Background  Periampullary diverticulum (PAD) is frequently come upon during endoscopic retrograde cholangiopancreatography (ERCP), especially in elderly patients. However, less is known about the role of PAD in biliary cannulation difficulty.

Aim  This study aims to investigate the association of PAD and difficult cannulation and evaluate the impact of different types of PAD on the cannulation success rate and adverse events.

Methods  Prospectively collected data on a total of 636 patients who underwent endoscopic retrograde cholangiopancreatography (ERCP) were divided into two groups based on the presence or absence of PAD. Besides, the patients were classified based on the PAD types into three groups. The primary outcomes were cannulation success rate, cannulation time, and ERCP-related adverse events. Further, the difficult cannulation and presence of PAD were analyzed using logistic regression models.

Results  Significant higher rates of biliary stones, cholangitis, and biliary pancreatitis were observed in the PAD group. Successful selective cannulation was achieved in 97.6% in the PAD group and 95.3% in the control group. The cannulation time was significantly longer in the presence of PAD. There was no significant difference in the rate of overall adverse events and post-ERCP pancreatic PEP. Multivariate analysis showed that type 1 PAD, biliary stones, and cholangitis were factors related to difficult cannulation.

Conclusion  The presence of PAD did not affect the duration or success of the ERCP procedure. However, it was associated with longer cannulation time and an increase in the cannulation difficulty, especially with PAD type 1.

Clinical Trial Study Registration  This study is approved by Nanjing Medical University and registered at ClinicalTrial.gov PRS with ID/NCT03771547/.

Keywords  Endoscopic retrograde cholangiopancreatography · Periampullary diverticulum · Difficult cannulation · Biliary cannulation · Cannulation techniques · Adverse events

Increasing the life expectancy and application of ERCP in the elderly population comes with a higher rate of the periampullary diverticulum (PAD) [1–3]. The incidence of PAD varies according to different diagnostic approaches and the age of the population; it is observed in 5–30% of ERCP cases [4, 5]. Although PAD is an asymptomatic finding in ERCP patients, it could be associated with technical difficulties in the biliary cannulation and higher complication expectations [6–9].

PAD is defined endoscopically as an extraluminal mucosal outpouching of the periampullary region of the duodenum [3, 5]. It usually arises within a radius of 2–3 cm from the ampulla of Vater, and it is classified into three types according to the position of the major papilla from the endoscopic view. The first type refers to the case where the major papilla is located inside of the diverticula; the second type refers to the case where the major papilla is located at the edge of the diverticula, while the third type refers to the case where the major papilla is located outside of the diverticula [1, 3, 8].

There are conflicting data about the influence of PAD presence on the technical success rates and safety outcomes.
of ERCP. The first group of studies published in the 1980s and 1990s suggested a significantly higher rate of cannulation’s failure in patients with PAD, prolonged procedure time, and an increase in adverse events’ rates [10, 11]. The second group of studies showed that there is no significant difference in the cannulation procedure success in case of presence or absence of PAD [12–14]. Moreover, recent prospective studies did not reveal any significant difference in either overall adverse events or a specific event, especially PEP [15–17].

Different techniques are reported in the literature regarding cannulation of the papilla in the presence of PAD [4, 5, 18, 19]. However, more studies should be performed to evaluate the safety and efficacy of techniques used for biliary cannulation with PAD.

This observational study aimed to investigate the association of PAD and pancreaticobiliary diseases, as well as to evaluate the impact of different types of PAD on cannulation success rate, the difficulty of biliary cannulation, and adverse events.

**Materials and methods**

### Data source and participants

This study was performed in the digestive endoscopy center of our institute between July 2016 and January 2018. The study protocol was approved by the institutional review board of our institute. After excluding patients with previous sphincterotomy and patients with altered anatomy, a total of 636 patients who underwent ERCP with native papilla were enrolled in this study. The data were prospectively collected, reporting the clinical features, performed therapeutic procedures, and procedure outcomes of patients. Additionally, the cannulation duration and attempts were carefully taken, and the Charlson Comorbidities Index (CCI) score was calculated for each patient. For analysis, patients who enrolled in the study were divided into two groups based on the presence or absence of PAD. Data describing the patients’ characteristics, including demographics, indications, procedure details, and ERCP-related adverse events, were analyzed.

### Definitions and criteria

The ERCP procedure’s success rate was defined according to the achievement of the pre-procedural goal [13]. Post-ERCP pancreatitis was diagnosed when the patient had new or worsened abdominal pain in addition to elevation in amylase at least three times the upper limit of the normal level, at more than 24 h after ERCP. Post-procedural bleeding was evidenced by hemoglobin dropping by > 2 g/dl. Other adverse events, including perforations, cholangitis, and cardiopulmonary events, were defined according to published criteria [14].

According to the recent guidelines of European Society of Gastrointestinal Endoscopy (ESGE) [4], we considered the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation attempts on the papilla were more than five; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation attempts on the papilla were more than five; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation attempts on the papilla were more than five; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficult if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation difficulty if one of these conditions is satisfied: the cannulation procedure time was more than 5 min; the cannulation attempts on the papilla were more than five; the pancreatic duct was cannulated more than twice.

### Data analysis

Differences among different patient cohorts were determined by using Fisher’s exact test for categorical variables, and non-categorical variables with the Mann–Whitney U test. Both univariate and multivariate regression models were performed with significant variables ($p < 0.05$). Variables of potential significance ($p < 0.10$) were entered the multivariate analysis (logistic regression analysis, enter method). Odds ratios and adjusted odds ratios were reported for each
variable. All statistical analyses were performed using SPSS Statistics version 20.

Results

Study population

A total of 972 patients who underwent ERCP during the study period have entered the study (see Fig. 1). Of these, 336 patients did not meet the requirements of the study and were excluded from the analysis. We excluded the patients with the previous sphincterotomy who underwent ERCP for follow-up, removing stents, or taking a biopsy. Patients with altered anatomy (Billroth II, Roux-en-y reconstruction, and duodenum stricture), were also excluded. Accordingly, only 636 patients who underwent ERCP with native papilla were analyzed and divided based on PAD presence into two groups; the first group A included patients with PAD; 126 patients of overall cases, the second group B included 510 patients without PAD (Table 1). Later, the PAD patients were filtered based on the types of PAD; 93 patients had PAD type 3; 18 patients had type 2, and 15 patients had type 1 (see Table 2).

Patients’ characteristics

Based on the PAD’s presence, 19.8% of patients were considered in the PAD group (group A) with a median age of 75 (Interquartile range (IQR) 62, 80) (see Table 1). The control group included 510 patients with a median age of 65 (IQR 52, 77). A single diverticulum was found in 84.2% of patients with PAD, 15.8% had two diverticulum or more. There was no significant difference in patients’ gender in both groups, with a male percentage (57.9% vs. 51.4%, \( p = 0.175 \)). The presence of PAD was not associated with differences in the overall comorbidities (\( p = 0.078 \)) as well as the proportion of patients with CCI ≥ 2 (23.8% vs. 19.8%, \( p = 0.300 \)).

In the PAD patients’ group, significantly higher rates of biliary stones (88.1% vs. 79.4%, \( p = 0.044 \)), biliary pancreatitis (10.3% vs. 4.5%, \( p = 0.018 \)) and cholangitis (14.3% vs. 7.4% \( p = 0.023 \)) were noted compared with the control group B. Furthermore, patients with PAD had a lower proportion of benign and malignant biliary strictures; cholangiocarcinoma (3.2% vs. 4.7%, \( p = 0.629 \)); pancreatic cancer (3.2% vs. 3.9%, \( p = 0.800 \)), and a significant lower rate of ampullary carcinoma (0% vs. 3.9%, \( p = 0.020 \)).
Outcomes and adverse events

The presence of PAD was associated with significantly longer cannulation time than that in the control group. The median of cannulation time in group A was 4.8 (IQR 1.2, 12.6) minutes, with a significant difference between the two groups (p = 0.013). Considering the cannulation difficulty grading, the proportion of difficult cannulation was significantly higher in group A (30.9% vs. 20%, p = 0.010). However, the two groups had similar procedure time, and no difference was found in the ERCP cannulation success rate (97.6% vs. 95.3%, p = 0.506).

Successful cannulation was achieved using a guidewire with sphincterotomy as the primary biliary and the most common cannulation technique in both groups (71.5% vs. 80%, p = 0.577). On the other hand, the presence of PAD was associated with a higher rate of using needle-knife precut (19.8% vs. 13.9%, p = 0.089) and trans-pancreatic biliary sphincterotomy (TPBS) (8.7% vs. 6.1%, p = 0.328).

However, no significant differences have been noticed in the rates of pancreatic stent placement (11.9% vs. 9.6%, p = 0.237) and the used cannulation techniques between the two groups.

There was no significant difference between the two groups in the adverse event rate, especially post-ERCP pancreatitis (4.8% vs. 5.1% p = 0.535) and perforation (0% vs. 0.6%, p = 0.511). Also, no significant difference was found in Post-ERCP bleeding rate, although there was a higher rate of bleeding with the presence of PAD (3.2% vs. 1.8% p = 0.304).

PAD subtypes' characteristics

In this study, we revealed clinical characteristics according to the PAD subtypes. The most frequently diagnosed subtype of PAD was type 3, with 73.8% of overall PAD cases, followed by type 2 (14.3%) and type 1 (11.9%).

| Parameter | Overall (n=636) | Group A (n=126) | Group B (n=510) | p-value |
|-----------|----------------|----------------|----------------|--------|
| Age [median (IQR)] (year) | 68 (55, 79) | 75 (65, 81) | 65 (52, 77) | 0.963 |
| Charlson score [median (IQR)] | 0 (0,1) | 0 (0,1) | 0 (0,1) | 0.078 |
| Charlson score ≥ 2 | 20.6% (131) | 23.8% (30) | 19.8% (101) | 0.300 |
| ERCP procedure time [median (IQR)] (minute) | 30 (23,45) | 31 (25,45) | 30 (22,45) | 0.197 |
| Cannulation time [median (IQR)] (minute) | 3.6 (0.8, 11.8) | 4.8 (1.2, 12.6) | 3.2 (0.8, 9.5) | 0.013 |
| Male | 52.7% (335) | 57.9% (73) | 51.4% (262) | 0.175 |
| Cannulation success rate | 95.7% (609) | 97.6% (123) | 95.3% (486) | 0.506 |

Table 1 Characteristics’ summary of patients in groups A and B

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correlation between PAD subtypes and clinical characteristics is reported in Table 2.

We noted that patients with type 2 had a significantly higher rate of biliary pancreatitis as an indication of ERCP (6.7% vs. 27.8% vs. 7.5%, \(p < 0.001\)). In addition, cholangitis was more common in patients with type 1 (26.7% vs. 11.1% vs. 12.9%, \(p = 0.030\)). Patients with type 1 had a significantly longer procedure time (\(p = 0.032\)), cannulation time (\(p = 0.001\)), and a higher rate of difficult cannulation (\(p < 0.001\)) (see Fig. 2).

### Impact of PAD on cannulation difficulty

To evaluate the role of PAD in difficult cannulation, we created a multivariate analysis model, including age \(\geq 65\), male gender, CCI \(\geq 2\), indications, and PAD types as independent variables (see Table 3). Logistic regression analysis showed that age \(\geq 65\), male gender, and CCI \(\geq 2\) was not associated with increased cannulation difficulty. Biliary stones (AOR 1.20; 95% CI 1.1, 1.388; \(p < 0.001\)) and cholangitis (AOR 1.50; 95% CI 1.223, 2.132; \(p = 0.041\)) were more likely to be related to difficult cannulation when adjusted for the other variables. Regarding the impact of the three types of PAD, patients with type 1 were the most likely to have cannulation difficulty when adjusted for the other variables (AOR 11.20; CI 3.5, 35.87; \(p < 0.001\)).

### Related factors to PAD’s presence

In the second multivariate model, we studied the factors that were found to be related to the presence of PAD, as it is shown in Table 4. Logistic regression analysis showed that factor of age \(\geq 65\) (AOR 3.281; 95% CI 2.068, 5.206; \(p < 0.001\)), patients with cholangitis (AOR 2.006; 95% CI 1.094, 3.9; \(p = 0.025\)), biliary stones (AOR 2.222; 95% CI 1.193, 4.140; \(p = 0.012\)) and biliary pancreatitis (AOR 2.498; 95% CI 1.168, 5.344; \(p = 0.018\)) were strongly associated with presence of PAD.
Discussion

The current study focused on the association of different types of periampullary diverticulum with ERCP cannulation success. Also, it studied the difficulty and safety of papillary cannulation in the presence of PAD. This structure was found in 19.8% of our participants, which was acceptable comparing with previous reports (3%–25%).

The detailed description of the PAD showed that type 3 was the most common subgroup, followed by type 1 and type 2. Regarding overall comorbidities, using a cutoff of CCI ≥ 2, no significant difference was seen between the two groups.

Several studies have considered PAD as an important risk factor of biliary stones formation [20–24], which is also suggested by our results. We noted that almost all PAD patients with type 2 have biliary stones, being more common than patients with types 1 and 3, although it did not reach a statistical difference. A possible explanation for the association between PAD and cholelithiasis can be related to the spasm of Oddi sphincter caused by diverticula. This dysfunction in the sphincter of Oddi causes increasing in biliary tract pressure and intestinal content reflux leading to biliary stone formation. Besides, the possibility of mechanical compression of the diverticula on the distal bile duct could cause biliary stasis, producing cholangitis. This effect may...
appear more in types of PAD that are larger and closer to the papilla, especially type 1. Thus, our study also supports the fact that cholangitis and biliary pancreatitis are more common in the presence of PAD.

Besides, we found a lower proportion of periampullary malignancy, especially ampullary carcinoma, in group A compared with group B, and a negative correlation between malignancy and PAD. This finding is supported by prior studies that found that neoplastic lesions as colorectal and periangiampullary carcinoma were less common in patients with diverticular disease [25, 26].

Regarding ERCP outcomes, previous studies have shown different results regarding the procedure success rates and visualization rates of main biliary structures in patients with PAD. The experience of the endoscopists, using different cannulation techniques, patients’ characteristics, and study design can be factors that reveal various findings regarding cannulation success and difficulty in patients with PAD [11–14, 17]. In our study, we did not observe significant differences in ERCP success rate and procedure duration between the two groups, although the PAD group was more likely to have cannulation difficulty and longer cannulation time (see Fig. 2). That is related to the challenging location of the papilla, especially when it is lying deep inside the diverticulum, which mostly requires using additional cannulation techniques after the failure of initial cannulation. Therefore, cannulation in PAD patients with type 1 was more challenging and has been associated with significantly longer cannulation time comparing to patients with the other types of PAD.

In the literature, several retrospective studies described different cannulation techniques in the presence of a PAD [27–30]. The most frequently described techniques in those studies were pancreatic duct stent placement, followed by needle-knife precut, and cap-assisted forward-viewing endoscopy.

Our study had compared the efficacy of access common biliary duct by different methods in the presence of PAD. All cannulation techniques were effective in achieving successful biliary access in the two groups without significant differences in overall adverse events. Standard cannulation using guidewire cannulation with sphincterotomy was the most frequent cannulation technique in both groups. Needle-knife precut was a suitable option for difficult cannulation cases and more frequent in the PAD group, especially in type 1, without significant differences. The placement of a pancreatic duct stent was useful to keep the papilla out of the PAD and allow better incision by precut biliary sphincterotomy. Trans-pancreatic biliary sphincterotomy was also available to cannulate the papilla in the presence of PAD, and patients with type 2 had a higher frequency to use this technique. The cannulation success and adverse events rates in the presence of PAD were comparable in all PAD subtypes using different cannulation maneuvers. Therefore, choosing the best method depends on the endoscopist experience and the patient anatomy, including the orientation and morphology of the papilla.

Regarding the evaluation of the role of PAD in cannulation difficulty, using a multivariate analysis model, we confirmed that the presence of periampullary diverticulum type 1 could significantly predict the difficult biliary cannulation. The indication of cholangitis and biliary stones were also independent predictors of difficult cannulation.

In the relation between the presence of PAD and adverse events, different results have been reported according to older and more recent literature [15, 16, 31]. Our study, as well as most recent studies, had not found any significant difference in overall adverse events or a specific event, especially PEP [4, 15]. However, we found that patients of type 1 had a higher frequency of PEP than patients with type 2 or type 3. That is related to the specific location of type 1, which may cause pancreatic duct compression and pancreatitis as a result. In addition, a higher rate of bleeding was related to patients with type 3.

The main strength of this observational study is focusing on difficult biliary cannulation and its relation with PAD using prospectively collected data. There are few limitations in this study; the data were collected at a single center, the low incidence of PAD type 1, and the rarity of specific adverse events though our overall sample size patients were reasonable.

Conclusions

This study has shown that although difficult cannulation ERCP is more common in patients with PAD, procedure time and successful cannulation rates are similar to those without PAD. As well as using different techniques is well tolerated with a similar rate of post-ERCP pancreatitis in patients with and without PAD. Interestingly, our study demonstrated that the presence of PAD type 1, biliary stones, and cholangitis are correlated with difficult cannulation.
Compliance with ethical standards

Disclosures Fatema Tabak, Guo-Zhong Ji, and Lin Miao have no conflicts of interest or financial ties to disclose.

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