Clinical features of gallstone impaction at the ampulla of Vater and the effectiveness of endoscopic biliary drainage without papillotomy

Background and study aims: Gallstone impaction at the ampulla of Vater is a critical condition, and the standard treatment is endoscopic papillotomy. However, the clinical features remain largely unclear, and some patients are reluctant to undergo papillotomy because of a bleeding tendency. The aim of this study was to clarify the clinical features of gallstone impaction at the ampulla of Vater and to examine the effectiveness of endoscopic biliary drainage without papillotomy.

Patients and methods: We retrospectively examined the records of 30 patients who had undergone endoscopic treatment for gallstone impaction at the ampulla of Vater between 2010 and 2015.

Results: According to the severity classification for acute cholangitis in the Tokyo Guidelines (TG13), the condition was mild in 8 patients, moderate in 14, and severe in only 8 (27%), despite the stone impaction at the ampulla of Vater. Hyperamylasemia was observed in 18 patients (60%); computed tomography (CT) revealed clear pancreatitis in 5 cases (17%). Patients were classified into Group A (13 patients who received biliary drainage with papillotomy) and Group B (17 patients receiving biliary drainage without papillotomy). All patients in Group B had 1 or more types of hemorrhage risk. There were no differences between the 2 groups in the success rate of biliary drainage, the rate of elevated serum amylase the following day, or procedure-related complications. Serum amylase levels decreased the following day in all patients, even in Group B (including the 10 patients with hyperamylasemia and the 3 patients with clear pancreatitis on CT).

Conclusions: Even with stone impaction at the ampulla of Vater, typical clinical features of cholangitis and pancreatitis are relatively rare. Biliary drainage without papillotomy is acceptable for gallstone impaction at the ampulla of Vater.

Introduction

Gallstone impaction at the ampulla of Vater can cause cholangitis as well as pancreatitis, and urgent stone removal is critical for improving the patient’s condition [1–6]. Occasionally, the clinical course is fatal. However, the clinical features of the condition remain largely unclear. The standard treatment is endoscopic papillotomy, but in recent years, some patients have been reluctant to undergo this procedure because of having bleeding tendencies as a result of oral antithrombotic agents, disseminated intravascular coagulation (DIC), hemodialysis, or liver cirrhosis. Some of these factors are reported to increase the risk of post-papillotomy bleeding [7–9]. For patients at risk of hemorrhage, we performed biliary drainage without papillotomy, despite the stone impaction, followed by a second procedure for stone extraction.

The purpose of this study was to clarify the clinical features of gallstone impaction at the ampulla of Vater and to examine the effectiveness of endoscopic biliary drainage without papillotomy.

Patients and methods

We retrospectively examined the records of 30 patients who had undergone endoscopic treatment for gallstone impaction at the ampulla of Vater at our hospital between 2010 and 2015. Only patients with gallstones were included, with pancreatic stones excluded; and it was an inclusion criterion that the impacted stone at the ampulla of Vater were endoscopically confirmed (Fig. 1 and Fig. 2). All patients underwent computed tomography (CT) scanning prior to treatment. Duodenoscopes with a backward viewing angle of 15° (JF-260V, Olympus Medical Systems Corp,
Tokyo, Japan) were used in this study. The catheters used were PR-104Q, PR-128Q, and PR-V614M (Olympus). The guidewires used were a 0.035-inch straight jagwire (Boston Scientific Japan, Tokyo, Japan) and a 0.025-inch angle visiglide (Olympus). The sphincterotome used was a CleverCut3V (Olympus). The practitioner and assistant were experts who had treated > 500 patients with endoscopic retrograde cholangiopancreatography (ERCP). The 30 patients were divided according to initial treatment into 2 groups. The 13 patients in Group A had undergone biliary drainage with papillotomy. After biliary cannulation (2 patients required pre-cutting), endoscopic sphincterotomy (EST) was performed with a small-to-medium incision, and a 7-Fr endoscopic nasobiliary drainage (ENBD) tube was installed. The 17 patients in Group B had undergone biliary drainage without papillotomy. All of them had some type of hemorrhage risk. Selective biliary cannulation without pre-cutting was achieved in all patients in Group B. The impacted stone was pushed back into the bile duct using a catheter, and then a 5- or 7-Fr ENBD catheter was put in place (Video 1).

Repeat ERCP for stone removal was performed in 2 of 13 patients in Group A and in all patients in Group B. The second treatment was performed several days after cholangitis had eased in Group A and after treatment to control the risk of bleeding in Group B. The parameters examined for each patient included 1) clinical features; 2) CT findings; and 3) endoscopic treatment. Statistical analyses were performed using the student’s t test and chi-square test to compare the two groups, and probability (P) values of <0.05 were considered to indicate a statistically significant difference.

Results

Clinical features

The clinical features of the patients (21 male and 9 female) are shown in Table 1. The mean ±standard deviation (SD) age was 76.1 ±12.1 years. Hyperbilirubinemia (total bilirubin [T-bil] >2.0 mg/dL) was observed in 23 patients (77%), and hyperamylasemia (serum amylase [AMY] > 125 U/L) in 18 patients (60%). According to the severity classification for acute cholangitis in the Tokyo Guidelines (TG13) [10], the condition was mild in 8 patients, moderate in 14 patients, and severe in 8 patients. Twelve patients met the case definition of acute pancreatitis according to the American College of Gastroenterology (ACG) guidelines [11] (established by the presence of 2 of the 3 following criteria; (i) abdominal pain consistent with the disease; (ii) serum amylase and/or lipase greater than three times the upper limit of normal; and (iii) characteristic findings from abdominal imaging. According to the revised Atlanta classification, 11 patients had mild pancreatitis and 1 had moderate pancreatitis [12]. Complications included DIC (with a score of ≥4 points according to the scoring system of the Japanese Association for Acute Medicine [13]) in 4 patients and hypotension requiring catecholamines in 4 patients. A total of 12 patients (40%) received oral antithrombotic agents. One patient had renal failure requiring hemodialysis, 1 had liver cirrhosis because of hepatitis C (Child–Pugh class C, 10 points), and 1 had idiopathic thrombocytopenia (ITP). Some patients had multiple hemorrhage risks.

CT findings

All patients underwent CT scanning prior to treatment (Table 2). Five patients (17%) had poor common bile duct dilatation (<10 mm). The stone at the ampulla could be identified in the majority of the patients (24/30; 80%), but there were 6 patients in whom it could not be identified (Video 1 and Fig. 4). Five patients had clear pancreatitis (defined as an elevated concentration of fatty tissue surrounding the pancreas), including 4 patients with inflammation up to the anterior pararenal extraperitoneal space, and 1 patient with inflammation beyond the inferior pole of the kidney.

Endoscopic treatment

All patients underwent endoscopic treatment. Biliary cannulation was achieved without pre-cutting in 28 patients (93%), with normal cannulation in 23 of these patients and wire-guided

![Fig. 1](Gallstone impaction at the orifice of the ampulla of Vater.)

![Fig. 2](Although the ampulla of Vater is prominent, the stone cannot be visually confirmed. Gallstone impaction can be diagnosed by papillotomy. The patients in both Fig. 1 and Fig. 2 were diagnosed as gallstone impaction, defined as endoscopically confirmed impacted stone at the ampulla of Vater.)
Gallstone impaction can be seen at the ampulla. Deep biliary cannulation was performed to push the stone using the catheter and remove the impaction. Because the patient had multiple hemorrhage risks (oral administration of antithrombotic and hemodialysis), a 7-Fr endoscopic nasobiliary drainage tube was installed without papillotomy. Online content including video sequences viewable at: http://dx.doi.org/10.1055/s-0042-109265

Table 1  Clinical features of impaction cases.

| Age (mean) | 76.1 (43 – 96) |
| Sex | Male 21: female 9 |
| Hyperbilirubinemia (T-bil > 2.0 mg/dL) | 23 (77%) |
| Hyperamylasemia (AMY > 125 U/L) | 18 (60%) |
| Severity of acute cholangitis | Mild 8 (27%), moderate 14 (46%), severe 8 (27%) |
| Acute pancreatitis | 12 (40%) |
| Disseminated intravascular coagulation (DIC) | 4 (13%) |
| Hypotension requiring catecholamines | 4 (13%) |
| Oral administration of anti-thrombotic agents | 12 (40%) |
| Other bleeding tendencies* | 3 (10%) |

1 According to the severity classification for acute cholangitis in the Tokyo Guidelines (TG13).
2 According to the definition in American Collage of Gastroenterology (ACG) guidelines.
3 Score of ≥4 points according to the scoring system of the Japanese Association for Acute Medicine.
4 Hemodialysis in 1, liver cirrhosis in 1, idiopathic thrombocytopenia in 1.

Discussion

According to the TG13 classification for the severity of acute cholangitis [10], cholangitis was severe in only 8 (27%) of the 30 patients, despite the gallstone impaction at the ampulla of Vater. It was mild in 8 patients and moderate in the other 14 patients. The TG13 guidelines also specify the drainage urgency according to the degree of severity (Fig 5) [14]. Urgent drainage is recommended for severe cholangitis, whereas for mild-to-moderate conditions, conservative treatment can be given priority. However, there is a risk of delaying drainage in impaction cases with mild-to-moderate cholangitis; regardless of the severity of the cholangitis, impaction cases need urgent drainage. The pathology of cholangitis involves inflammation of the bile duct (often associated with bacterial infection), and there is a physical obstruction of bile juice flow with stone impaction at the ampulla of Vater. Therefore, even in patients with impaction, some cases present mild-to-moderate cholangitis. This phenomenon is more commonly observed during early onset of impaction. Hyperamylasemia was observed in 18 patients (60%), and 5 patients (17%) exhibited clear pancreatitis as evidenced by imaging. The definition for acute pancreatitis according to the ACG guidelines was satisfied by 12 patients (40%). There was a lower incidence of pancreatitis than we expected.
Hyperamylasemia was suggestive of the impaired outflow of pancreatic juice; nevertheless, pancreatitis was not obvious in all the patients on imaging studies. This may be attributed to the involvement of factors such as the patency of the accessory pancreatic duct, and the degree of impaction. Kamisawa et al. [15] reported that patency of the accessory pancreatic duct with acute pancreatitis was significantly lower than in control cases. They build up a hypothesis that a patent accessory pancreatic duct may function as a second drainage system for the main pancreatic duct, reducing the pressure in the main pancreatic duct and preventing acute pancreatitis. Furthermore, it may be inferred that the risk of pancreatitis onset differs depending on the degree of impaction. In other words, it is possible that there is a high risk of pancreatitis when severe impaction causing prominent papillary edema and pancreatic duct obstruction is present, whereas the risk of pancreatitis is low when there is mild impaction that only causes biliary obstruction.

Table 3  Comparison of clinical factors between groups.

|                          | Group A: biliary drainage with papillotomy | Group B: biliary drainage without papillotomy | P value |
|--------------------------|------------------------------------------|---------------------------------------------|---------|
| Number of patients       | 13                                       | 17                                          | –       |
| Age (mean)               | 79                                       | 72                                          | n.s.    |
| Sex                      | Male 10, female 3                        | male 11, female 6                          | n.s.    |
| Severity of acute cholangitis | Mild 4, moderate 6, severe 3         | mild 4, moderate 8, severe 5                | n.s.    |
| Hyperamylasemia (AMY > 125 U/L) | 8 (62%)                                 | 10 (59%)                                   | n.s.    |
| Clear pancreatitis by CT | 2 (15%)                                  | 3 (18%)                                    | n.s.    |

1 All patients in Group B had some type of hemorrhage risk: oral administration of antithrombotic agents in 12 patients, disseminated intravascular coagulation in 4 patients, hemodialysis in 1 patient, liver cirrhosis in 1 patient, and ITP in 1 patient.
2 Student’s t test.
3 Chi-square test.
4 Not significant for each grade of cholangitis.

Table 4  Comparison of endoscopic treatment between two groups.

|                          | Group A: biliary drainage with papillotomy | Group B: biliary drainage without papillotomy | P value |
|--------------------------|------------------------------------------|---------------------------------------------|---------|
| Successful biliary drainage | 13 (100%)                              | 17 (100%)                                  | n.s.    |
| Elevated AMY levels the following day | 3 (23%)                                | 0                                           | n.s.    |
| Procedure related complications | 1 (8%)                                 | 0                                           | n.s.    |
| Complete stone extraction in the same procedure | 11 (85%)                          | 0                                           | P<0.00001 |
| Examination time(minutes) | 26 (15–46)                              | 17 (9–28)                                  | n.s.    |
| Hospitalization (Days)   | 7 (4–11)                                 | 16 (7–29)                                  | P<0.05  |

1 Minor bleeding.
2 Chi square test.
3 Student’s t test.
In conclusion, the typical clinical features of cholangitis and pancreatitis were rarely associated with gallstone impaction at the ampulla of Vater. The condition of patients will improve with biliary drainage without papillotomy, even those who have hyperamylasemia and pancreatitis. Initial papillotomy is therefore not essential. A treatment strategy that considers the risk of hemorrhage is recommended.

Competing interests: None

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