AIM: To evaluate the necessity of endoscopic nasobiliary drainage (ENBD) catheter placement after clearance of common bile duct (CBD) stones.

METHODS: Patients enrolled in this study were randomly divided into two groups, according to whether or not they received ENBD after the removal of CBD stones. Group 1 (ENBD group) was then subdivided into three groups: G1a patients received an endoscopic papillary balloon dilatation (EPBD), G1b patients received an endoscopic sphincterotomy (EST), and G1c patients received neither. Group 2 (non-ENBD group) patients were also subdivided into three groups (G2a, G2b, and G2c), similar to Group 1. The maximum CBD diameter, the time for C-reactive protein (CRP) to normalize, levels of serum amylase, total serum bilirubin (TB) and alanine aminotransferase (ALT), and postoperative hospitalization duration (PHD) were measured.

RESULTS: A total of 218 patients (139 males, 79 females), with an average age of 60.1 ± 10.8 years, were enrolled in this study. One hundred and thirteen patients who received ENBD were included in Group 1, and 105 patients who did not receive ENBD were included in Group 2. The baseline clinical characteristics were similar in both groups. There were no significant differences in post-endoscopic retrograde cholangiopancreatography (ERCP)-related complications when Groups 1 and 2 were compared. Seventy-seven patients underwent EPBD, and 41 received an ENBD tube (G1a) and 36 did not (G2a). Seventy-three patients underwent EST, and 34 patients received an ENBD tube (G1b) and 39 did not (G2b). The remaining 68 patients underwent neither EPBD nor EST; of these patients, 38 received an ENBD tube (G1c) and 30 did not (G2c). For each of the three pairs of subgroups (G1a vs G2a, G1b vs G2b, G1c vs G2c), there were no significant differences detected in the PHD or the time to normalization of CRP, TB and ALT. In the EPBD group, the incidence of post-ERCP pancreatitis, hyperamylasemia and overall patient complications was significantly higher for G2a (post-ERCP pancreatitis: 6/36 vs 0/41, \( P = 0.0217 \); hyperamylasemia: 11/36 vs 4/41, \( P = 0.0215 \); overall patient complications: 18/36 vs 7/41, \( P = 0.0029 \)).

CONCLUSION: After successful CBD stone clearance, ENBD is only beneficial when an EPBD procedure has
Endoscopic papillary balloon dilatation; Several studies have compared the efficacy of temporary insertion of an endoscopic nasobiliary drainage (ENBD) tube to a biliary stent until clearance of stones from the common bile duct (CBD) is confirmed. However, few studies have evaluated the benefits in clinical outcomes of ENBD tube placement after clearance of CBD stones. In this study, we found that ENBD is only beneficial when an endoscopic papillary balloon dilatation procedure has been performed.

Core tip: Several studies have compared the efficacy of temporary insertion of an endoscopic nasobiliary drainage (ENBD) tube to a biliary stent until clearance of stones from the common bile duct (CBD) is confirmed. However, few studies have evaluated the benefits in clinical outcomes of ENBD tube placement after clearance of CBD stones. In this study, we found that ENBD is only beneficial when an endoscopic papillary balloon dilatation procedure has been performed.

INTRODUCTION

Cotton et al[1] were the first to use an endoscopic nasobiliary drainage (ENBD) catheter for several days in the common bile duct (CBD) after endoscopic sphincterotomy (EST). ENBD placement provides reliable biliary drainage and perfusion, and allows for cholangiography. ENBD also reduces the need for instrumental stone extraction and repeated endoscopy and cholangiography to assess whether the stones have been fully cleared by transnasal cholangiograms[2]. In further studies[3-7], it was found that EST or endoscopic papillary balloon dilatation (EPBD) followed by ENBD reduced the incidence of post-endoscopic retrograde cholangiopancreatography (ERCP) complications, such as pancreatitis and cholangitis, particularly in patients with persistent stones, infected bile or blood clots in the biliary tree. There are two endoscopic drainage methods currently in use: external drainage (by ENBD) or internal endoscopic biliary drainage (via plastic endoscopic biliary stent). Most endoscopists prefer the routine insertion of an ENDB catheter after the stones have been removed, as the use of a plastic endoscopic biliary stent requires a second endoscopic procedure.

There are caveats to the ENBD technique. The catheter may become dislodged, kinked, blocked or pulled out by a poorly compliant patient due to discomfort related to the catheter’s exit from the nostril. To date, there have been relatively few studies examining the necessity of ENBD tube placement after clearance of CBD stones. The aim of this prospective, randomized trial was to determine whether there were additional clinical outcome benefits in patients with CBD stone extraction if an ENBD catheter was inserted routinely, and which patients would be most likely to benefit from it.

MATERIALS AND METHODS

Patients

The ethics committee of Changshu Hospital, a Suzhou University affiliate, approved this study. All patients provided informed consent prior to study enrollment. The presence of CBD stones was confirmed using 64-channel spiral abdominal computed tomography or magnetic resonance cholangiopancreatography. The following exclusion criteria were applied: (1) patients with acute cholangitis (fever, leukocytosis, jaundice, hyperbilirubinemia, or abdominal pain) or acute pancreatitis pre-ERCP; (2) patients that previously underwent EST or patients who were scheduled to receive percutaneous transhepatic biliary drainage or underwent a subtotal gastrectomy; (3) patients suspected of having an intrahepatic duct stone or a malignant biliary obstruction upon imaging; (4) patients who received an emergency ERCP for any reason; and (5) patients who needed a precut sphincterotomy or needle knife sphincterotomy for CBD cannulation or those who were confirmed to have postoperative residual stones or debris by imaging.

Endoscopic procedures

All ERCP-related procedures, including EST, ENBD or EPBD, were performed by three endoscopists (each with over 10 years ERCP experience) according to a standardized protocol. Patients were sedated by intravenous administration of midazolam (0.08 mg/kg) and meperidine (10 mg). Duodenal atony was induced by intravenous administration of hyoscine butylbromide (10 mg). All ERCPs were performed using a therapeutic duodenoscope (TJF-260; Olympus Optical Co., Ltd., Tokyo, Japan) equipped with a large accessory channel. Using a cholangiography catheter (ERCP cannula; Boston Scientific Co., Marlborough, MA, United States), guide wire-assisted selective cannulation of the CBD was performed. Confirmation of correct catheter localization in the CBD was performed using fluoroscopic imaging. After injection of a contrast agent, patients with a CBD stone > 10 mm were randomly assigned to receive either an EPBD or EST.

For EPBD, a guide wire was first placed into the CBD. Then, a 5.8 F balloon catheter (Boston Scientific Co.) was passed over the guide wire and inserted into the papilla for papilla dilation. The balloon was inflated to a diameter of 10 mm under endoscopic and fluoroscopic control. When the sphincter was
adequately dilated, the fully inflated balloon was maintained in that position for 60 s prior to stone extraction. For EST, a papillary incision was made using a pull-type, 25 mm cutting wire sphincterotome (Fusion; Wilson-Cook Medical Inc., Winston Salem, NC, United States). CBD stones were then extracted using a Dormia basket catheter and a balloon extractor. Stones > 1 cm in diameter were fragmented by mechanical lithotripsy prior to extraction. An ENBD catheter (7.5 F; Boston Scientific Co.) was placed into the CBD after stone extraction. Clearance of CBD stones was confirmed by cholangiography.

Randomization and subgroup assignments
The assignment of EPBD or EST, and whether or not they were followed by an ENBD, was randomized using computer-generated numbers in sealed envelopes. A nurse who did not take part in evaluation of the study outcome opened the envelopes just after guide wire-assisted selective cannulation of the CBD.

Patients were randomly divided into two groups according to whether or not they received an ENBD tube after clearance of CBD stones. Group 1, the ENBD group, was then subdivided into G1a, G1b, and G1c. Patients in G1a underwent EPBD, while patients in G1b underwent EST, and patients who received neither were assigned to G1c. Group 2, the non-ENBD group, was also subdivided into three groups (G2a, G2b, and G2c) just as Group 1.

Evaluation parameters and early complications
Each patient completed a preoperative questionnaire, and the patient’s age, sex, presence of gallstones, and history of cholecystectomy were recorded. Total leukocyte count, C-reactive protein (CRP), levels of serum amylase, total serum bilirubin (TB), alanine aminotransferase (ALT) and aspartate aminotransferase, and the results from a coagulation screening (prothrombin time and platelet count) were measured 24 h before ERCP. These measurements were repeated once every 24 h after ERCP until they returned to normal. We also measured the maximum diameter of the CBD, the time it took for CRP, TB and ALT levels to normalize, and the postoperative hospitalization duration (PHD).

Early complications related to ERCP, such as post-ERCP pancreatitis (PEP), post-ERCP cholangitis (PEC), post-ERCP bleeding (PEB), hyperamylasemia and perforation, were evaluated during hospitalization. PEP was defined as abdominal pain, with at least a 3-fold elevation of serum amylase more than 24 h after the procedure, and requiring treatment for more than two days. The PEP severity was scored as mild, moderate, or severe. Hyperamylasemia was defined as a blood amylase concentration above the normal range of 180 Somogyi U/L. PEC was characterized by a fever, leukocytosis, jaundice, hyperbilirubinemia and abdominal pain that were thought to have a biliary origin. PEB was defined as the need for a blood transfusion, a decrease in hemoglobin level of > 2 g/dL, or hematochezia, melena or hematemesis within 24 h after the procedure.

Statistical analysis
All statistical analyses were performed using SPSS 13.0 software (SPSS Inc., Chicago, IL, United States). Statistical analyses were performed on an intention-to-treat basis. For analysis of categorical data, a χ² test with the Yates correction, or Fisher’s exact test (two-tailed) was used. For continuous data, a normality test was applied to ensure that a t-test was the most appropriate test, otherwise the Mann–Whitney U-test was used for a skewed distribution. All patient characteristics are expressed as the mean ± SD or as percentages when appropriate. All statistical tests were two-tailed and the threshold for statistical significance was set as P < 0.05.

RESULTS
From April 2011 through March 2014, 350 patients with CBD stones were admitted to Changshu Affiliated Hospital of Suzhou University. Of the 350 patients initially admitted, the following patients were excluded: 17 patients with acute suppurative cholangitis who underwent an emergency ERCP, 14 patients with acute pancreatitis prior to ERCP, 23 patients who previously underwent EST, 7 patients who underwent a subtotal gastrectomy, 21 patients with intrahepatic duct stones, 5 patients with malignant biliary obstruction, 26 patients who required a precut sphincterotomy or needle knife sphincterotomy for CBD cannulation, and 19 patients with confirmed postoperative residual stones or debris by imaging. After applying the exclusion criteria, a total of 218 patients (139 males, 79 females), with an average age of 60.1 ± 10.8 years, were enrolled in the study. One hundred and thirteen patients with ENBD were included in Group 1 and the remaining 105 patients did not receive an ENBD tube and were placed in Group 2. When the two groups were compared, there were no statistical differences in the baseline characteristics or laboratory findings (Table 1).

Outcomes comparing the ENBD and non-ENBD groups
No patients pulled out their nasobiliary catheter and there were no incidences of perforations or catheters blocked by bile in either group. When the two groups were compared, the length of PHD was similar (5.7 ± 1.4 d for Group 1 and 5.9 ± 1.5 d for Group 2, P = 0.3098). In addition, there were no significant differences in the time it took for laboratory values to normalize (CRP: 3.3 ± 0.9 d vs 3.5 ± 1.0 d; P = 0.1216; TB: 4.1 ± 1.1 d vs 4.3 ± 1.2 d; P = 0.2006; ALT: 5.1 ± 0.8 d vs 4.9 ± 0.8 d; P = 0.0651). The rates of overall patient complications (OPC) were 26.5% in Group 1
Table 1 Baseline characteristics and results

| Variable              | Group 1 (n = 113) | Group 2 (n = 105) | P value |
|-----------------------|-------------------|-------------------|---------|
| Age (yr)              | 60.1 ± 9.7        | 57.9 ± 10.3       | 0.105   |
| Sex, male/female      | 68/45             | 71/34             | 0.253   |
| Presence of gallstones | 13                | 9                 | 0.473   |
| History of cholecystectomy (n) | 7        | 9                 | 0.501   |
| Total leukocyte count (× 10^3/L) | 5.8 ± 1.8 | 6.1 ± 2.1         | 0.259   |
| Amylase (U/L)         | 88.5 ± 22.3       | 91.2 ± 24.5       | 0.396   |
| TB (mg/DL)            | 4.6 ± 1.1         | 4.5 ± 1.0         | 0.482   |
| ALT (IU/L)            | 124.8 ± 33.6      | 115.6 ± 36.1      | 0.052   |
| Aspartate aminotransferase (IU/L) | 98.6 ± 26.7 | 102.6 ± 33.4      | 0.088   |
| Prothrombin time (s) | 11.2 ± 2.1        | 11.1 ± 2.7        | 0.761   |
| Platelet count (× 10^9/L) | 145.2 ± 33.1 | 151.1 ± 31.2      | 0.176   |
| Maximum diameter of CBD (mm) | 12.5 ± 2.6 | 13.1 ± 2.7        | 0.095   |

Data are expressed as mean ± SD. TB: Total serum bilirubin; ALT: Alanine aminotransferase; CBD: Common bile duct.

and 33.1% in Group 2 (P = 0.2739). There were no significant differences in ERCP-related complications when Group 1 was compared to Group 2 (PEP: 6.2% vs 10.5%, P = 0.4215; hyperamylasemia: 15.0% vs 18.1%, P = 0.6726; PEC: 4.4% vs 7.6%, P = 0.3197; PEB, 3.5% vs 2.9%, P = 0.7751).

Outcomes of subgroup patients

As shown in Table 2, 77 patients underwent EPBD, and of them, 41 patients were then randomly selected to receive ENBD (G1a) and 36 patients were not (G2a). Seventy-three patients underwent EST, with 34 in the ENBD group (G1b) and 39 in the non-ENBD group (G2b). The remaining 68 patients underwent neither EPBD nor EST, with 38 patients in the ENBD group (G1c) and 30 patients in the non-ENBD group (G2c). There were no statistical differences in the baseline characteristics or laboratory findings when the three subgroups were compared (G1a vs G2a, G1b vs G2b, G1c vs G2c). Moreover, no significant differences were detected in the PPHD or the time to normalization for CRP, TB and ALT when the subgroups were compared. In the EPBD group, six patients developed PEP and all six were in the non-ENBD group (G2a). The incidence of PEP was significantly higher in G2a than in G1a. In the EPBD group, more patients developed hyperamylasemia in the non-ENBD group than the ENBD group. The OPC rate was significantly lower in G1a than in G2a. In the other two pairs of subgroups, ERCP-related complications were similar (Table 3).

DISCUSSION

Although recent British and Japanese guidelines have outlined the management of CBD stones and acute cholangitis in detail, they have not specifically addressed whether a routine drainage procedure should be mandatory after endoscopic clearance of the CBD is achieved[11-13]. Lee et al[14] demonstrated that insertion of an ENBD catheter in patients with acute cholangitis undergoing primary endoscopic CBD stone removal did not have an improved clinical course if CBD clearance was achieved. Moreover, the process elongated the procedure time and contributed to increased patient discomfort. However, Yang et al[15] reviewed 191 patients who underwent EST with repeated stone extraction between January 2010 and May 2012 and found that EST followed by ENBD is a simple, safe and effective technique that should be considered in the management of CBD stones.

In this randomized trial, there were no additional benefits in clinical outcomes identified when ENBD patients and non-ENBD patients were compared. However, when patients underwent an EPBD procedure, we found that placement of an ENBD catheter after the procedure decreased the incidence of PEP, hyperamylasemia and OPC. EPBD is a technique designed to facilitate the removal of bile duct stones by dilating the biliary sphincter. Due to the frequency of complications including pancreatitis and cholangitis, EBPD has not become a standard procedure in the United States or Europe[16]. Baron and Harewood[17] analyzed eight published prospective, randomized trials and found no differences in the outcome of successful stone removal (94.3% vs 96.5%) or OPC (10.5% vs 10.3%) when EPBD was compared with EST. Post-ERCP pancreatitis, however, occurred more frequently in the EPBD group (7.4% vs 4.3%, P = 0.05). The main cause of post-EPBD pancreatitis is thought to be due to impaired pancreatic drainage caused by papillary edema or residual stones trapped in the papilla[18,19]. A Japanese study[7] reported similar findings, and the authors speculated that ENBD itself may prevent pancreatic duct obstruction caused by residual stones or papillary edema. We hypothesize that the mechanism of ENBD for prevention of hyperamylasemia and pancreatitis is as follows: an ENBD catheter prevents CBD obstruction caused by papillary edema, which alleviates CBD pressure elevation, decreases the risk of bile entering the pancreatic duct and ultimately prevents the occurrence of acute pancreatitis.

EST is the most frequently used technique, with a success rate of > 90%[20,21]. However, in addition to bleeding, perforation, infection and dysfunction of the papillary sphincter, pancreatitis, which occurs in up to 5% of patients, is the most frequent and most significant complication of EST[22]. Perforation can be a fatal complication, but we did not encounter this in any group within our study, which was similar to the findings in previous studies[23]. Ricci et al[24] analyzed a retrospective study of 850 patients who underwent EST and concluded that routine prophylactic nasobiliary drainage following EST was strongly recommended to prevent post-operative complications. These results, however, are controversial. In our study, regardless of whether an ENBD catheter was placed, the
Table 2 Baseline characteristics of the subgroups

| Variable                  | EPBD (n = 77) | EST (n = 73) | Neither EPBD nor EST (n = 68) |
|---------------------------|---------------|--------------|------------------------------|
| Age (yr)                  |               |              |                              |
| Sex, male/female (n)      | 21/20         | 23/11        | 20/21                        |
| Presence of gallstones (n)| 4             | 5            | 4                            |
| History of cholecystectomy (n) | 3 3       | 2 2          |                              |
| Total leukocyte count (x 10^3/μL) | 5.9 ± 1.9     | 5.4 ± 2.3    | 5.8 ± 1.7                    |
| Amylase (U/L)             | 84.5 ± 23.1   | 87.3 ± 26.2  | 92.0 ± 27.2                  |
| ALT (U/L)                 | 127.4 ± 35.1  | 125.1 ± 37.4 | 119.7 ± 31.4                 |
| AST (U/L)                 | 100.6 ± 29.3  | 100.7 ± 24.9 | 103.7 ± 24.1                 |
| Prothrombin time (s)      | 12.3 ± 1.9    | 10.3 ± 1.7   | 11.3 ± 1.8                   |
| Platelet count (x 10^3/μL)| 139.2 ± 44.1  | 143.5 ± 41.3 | 147.9 ± 43.1                 |
| Maximum diameter of CBD (mm)| 11.5 ± 2.3   | 12.3 ± 2.0   | 11.7 ± 1.8                   |

Data are expressed as absolute n (%) or mean ± SD. EPBD: Endoscopic papillary balloon dilatation; EST: Endoscopic sphincterotomy; TB: Total serum bilirubin; ALT: Alanine aminotransferase; AST: Aspartate aminotransferase; CBD: Common bile duct.

Table 3 Outcomes of the subgroup patients

| Variable                  | EPBD (n = 77) | EST (n = 73) | Neither EPBD nor EST (n = 68) |
|---------------------------|---------------|--------------|------------------------------|
| Time to normalization     |               |              |                              |
| ALT (d)                   | 4.3 ± 0.9     | 3.9 ± 0.9    | 4.0 ± 1.1                    |
| CRP (d)                   | 4.3 ± 0.9     | 3.9 ± 0.9    | 3.3 ± 1.0                    |
| PHD (d)                   | 6.5 ± 1.1     | 5.6 ± 1.1    | 4.1 ± 1.3                    |
| ERCP-related complications|               |              |                              |
| Hyperamylasemia           | 4 (9.8)       | 2 (5.9)      | 5 (13.2)                     |
| PEC                       | 1 (2.4)       | 1 (2.9)      | 3 (7.9)                      |
| PEB                       | 2 (4.8)       | 2 (5.9)      | 3 (10)                       |
| OPC                       | 7 (17.1)      | 9 (26.5)     | 14 (50.0)                    |

Data are expressed as absolute n (%) or mean ± SD. EPBD: Endoscopic papillary balloon dilatation; EST: Endoscopic sphincterotomy; TB: Total serum bilirubin; ALT: Alanine aminotransferase; AST: Aspartate aminotransferase; CBD: Common bile duct.

patients who underwent an EST procedure showed no differences in ERCP-related complications. We hypothesize that this was because most of the patients enrolled in our study were in fairly good health at the time of the procedure. Patients with complications such as acute suppurative cholangitis requiring an emergency ERCP or patients who underwent a subtotal gastrectomy were excluded from the study.

Placement of an ENBD catheter may cause discomfort, trigger a compression ulcer, or the catheter may be pulled out by a poorly compliant patient[5,13,14,21]. Thus, it remains controversial whether an ENBD catheter should be used after endoscopic clearance of CBD stones[14,15]. According to the results of this study, we do not recommend routine placement of an ENBD catheter after endoscopic clearance of CBD stones. This procedure is recommended for patients who have undergone EPBD to prevent the occurrence of PEP.

There are some limitations to this study. First, the current study was a single center study, and independent external validation in other patient populations is required. Second, we only observed early outcomes, and the later complications (e.g., CBD stone recurrence) relating to the presence or absence of an ENBD catheter are unknown; a long-term follow-up study is currently being implemented. Third, more studies are required to evaluate the contribution of the number of stones and maximal stone size on the efficacy of ENBD.

In conclusion, this prospective randomized study demonstrates that not all patients benefit from the placement of an ENBD catheter after clearance of CBD stones. We recommend ENBD placement only when an EPBD procedure has been performed to prevent PEP occurrence. Long-term follow-up for late complications should be performed to investigate clinical outcomes.

COMMENTS

Background

There have been few studies evaluating the necessity of endoscopic nasobiliary drainage (ENBD) catheter placement after clearance of common bile duct (CBD) stones. The benefits of an ENBD catheter are currently controversial among endoscopists.
Research frontiers
British and Japanese guidelines have been published to outline, in detail, the management of CBD stones and acute cholangitis. These guidelines, however, do not address the specific issue of whether a routine drainage procedure should be mandatory after successful endoscopic clearance of the CBD.

Innovations and breakthroughs
Endoscopic papillary balloon dilation (EPBD) is not a standard procedure in the United States or Europe due to the frequency of complications such as pancreatitis and cholangitis. In patients who underwent EPBD procedures in our study, it was found that subsequent placement of an ENBD catheter decreased the incidence of post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis, hyperamylasemia, and overall patient complications.

Applications
In this study, it was found that an ENBD catheter was only beneficial in patients who underwent EPBD with complete removal of CBD stones.

Terminology
During an ENBD procedure, endoscopists insert a nasobiliary drainage catheter for several days into the CBD for biliary drainage, drug perfusion, and to allow for cholangiography. EPBD is a technique used to remove CBD stones by dilating the biliary sphincter.

Peer-review
This paper focuses on an important surgical issue in the treatment of CBD stones. CBD stones are found in 10%-15% of patients suffering from gallbladder stones, and treatment represents a challenge. This study evaluates the clinical outcome benefits of ENBD catheter placement and is well designed with a large patient cohort. Although EPBD is rarely performed in the United States or Europe, it is used in Asian countries such as Japan and China for the treatment of CBD stones. The authors identify that ENBD placement after EPBD is beneficial in reducing post-ERCP pancreatitis, hyperamylasemia, and overall patient complications. This manuscript is clinically relevant and may inform future treatment of CBD stones.

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