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Stepwise Pressure Release Reduces Bleeding Complications after Endoscopic Papillary Balloon Dilation: A Retrospective Cohort Study

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1. Abstract

1.1. Objective

The objective of this study was to investigate whether a stepwise pressure release technique reduces the risk of intraoperative and postoperative bleeding complications after Endoscopic Papillary Balloon Dilation (EPBD).

1.2. Methods

This retrospective cohort study included patients with common bile duct stones who underwent ERCP accompanied by EST and EPBD at Nanhua University Affiliated Nanhua Hospital. The observation group (stepwise pressure release, n=757) consisted of patients treated between April 1, 2022 and October 31, 2025, and the control group (conventional one-time release, n=784) comprised those treated between January 1, 2020 and February 28, 2022. Following EPBD, balloon pressure in the observation group was released in four steps (25 % per step at 60-second intervals), whereas the control group underwent conventional immediate deflation. Outcome measures included intraoperative bleeding severity grade, postoperative reduction in hemoglobin level, incidence of hematemesis and melena, and other complications.

1.3. Results

The baseline characteristics were balanced between the two groups ($P > 0.05$). The distribution of intraoperative bleeding severity differed significantly ($P < 0.001$): the observation group had predominantly Grade 0 (52.18%) and Grade 1 (32.63%) bleeding, while the control group had mainly Grade 1 (43.49%) and Grade 2 (28.06%). The postoperative hemoglobin drop was lower in the observation group (10.57 ± 6.65 g/L) than in the control group (13.62±7.86 g/L, $P < 0.0001$). The incidence of melena was also lower in the observation group (12.95%) compared to the control group (22.45%, $P < 0.01$). No significant differences were found between the groups in the incidence of non-bleeding complications such as post-ERCP pancreatitis and acute cholangitis ($P > 0.05$).

1.4. Conclusion

The stepwise pressure release technique after EPBD significantly reduces intraoperative bleeding severity, minimizes postoperative hemoglobin drop and melena occurrence, without increasing the risk of other complications. It represents a safe and effective technical modification.

2. Introduction

Endoscopic Papillary Balloon Dilation (EPBD) is a standard procedure in ERCP and endoscopic bile duct stone extraction. To minimize trauma to the Oddi sphincter, preserve its function, and achieve the goals of stone clearance or improvement of bile outflow, endoscopists often adopt the technique of minor duodenal papilla incision combined with EPBD-performing a limited sphincterotomy followed by dilation of the narrowed area using a larger balloon. Particularly in the extraction of larger bile duct stones (diameter >10 mm), EPBD is often indispensable.

To preserve the function of the Oddi sphincter, several ERCP-related practice guidelines recommend the use of graded dilation during EPBD procedures [1,2]. However, after balloon dilation is completed, the pressure inside the balloon is typically released all at once. Following the release of pressure, the duodenal papilla often exhibits varying degrees of bleeding at the wound site. However, whether a stepwise release of the balloon pressure can

mitigate this bleeding has not been formally investigated. In recent years, researchers have adopted the method of gradually releasing the balloon pressure after EPBD to observe whether it can reduce the occurrence of hemorrhagic complications.

3. Methods

3.1. Study Participants

This was a retrospective cohort study. This study used a non-concurrent (historical) control design. The observation group consisted of patients with common bile duct stones treated with ERCP, EST, and EPBD between April 1, 2022, and October 31, 2025. The control group was drawn from a separate, earlier time period (January 1, 2020, to February 28, 2022) and underwent the same treatment regimen. All patients were from the same department (Department of Hepatobiliary Surgery, Nanhua University Affiliated Nanhua Hospital).

Inclusion criteria: (1) Patients diagnosed with common bile duct stones based on imaging and laboratory examinations; (2) Age ≥ 18 years; (3) Informed consent and ability to cooperate with postoperative follow-up.

Exclusion criteria: (1) Patients with severe coagulation dysfunction; (2) Patients with other diseases causing biliary obstruction (e.g., ampullary malignancies).

This study has been approved by the Ethics Review Committee of Affiliated Nanhua Hospital, University of South China (Approval No: Y250724).

4. Endoscopic Procedure

4.1. Control Group

The patient was placed in the prone position. A duodenoscope (FUJIFILM ED-580T, Japan) was inserted orally and advanced through the esophagus to the descending duodenum. At the major duodenal papilla, a sphincterotome (Olympus, Japan) with a guidewire (Olympus, Japan) was used for selective cannulation of the bile duct. After injecting contrast medium into the bile duct, X-ray fluoroscopy was employed to observe the biliary structure, diameter, and the location and size of stones. Based on the cholangiogram findings, endoscopic sphincterotomy (EST) was performed first, followed by selection of an appropriately sized dilation balloon (Boston Scientific, USA). A medical balloon pressure pump (Changzhou Jiuhong Medical Equipment Co., Ltd., China) was used to inflate the balloon gradually. After maintaining the target pressure for 30 seconds, the pressure was released in a single, rapid deflation. Immediate bleeding was then observed and scored. Subsequent therapeutic procedures, such as stone extraction or stent placement, were performed. Postoperatively, the patient's vital signs and abdominal symptoms/signs were routinely monitored to prevent and promptly manage potential complications.

4.2. Observation Group

The ERCP and EPBD procedures were identical to those in the control group. Following EPBD, the pressure from the inflation pump was released in a stepwise manner, divided into four stages. At each stage, 25% of the total inflation pressure was released, with a 60-second interval between each stage of pressure release. All other procedural steps and postoperative management were the same as in the control group.

4.3. Observation Parameters

The following were compared between the two groups: baseline patient characteristics, intraoperative bleeding severity score (see Table 1), incidence of postoperative gastrointestinal bleeding (hematemesis and melena), reduction in hemoglobin level, incidence of acute cholangitis, and incidence of post-ERCP pancreatitis.

Table 1: Intraoperative Bleeding Severity Score.

Grade	Endoscopic Findings	Score
Grade 0	The operative field is clean, with no signs of active bleeding or oozing.	0
Grade1	Mild, slow oozing is observed from the wound.	1
Grade 2	Distinct active bleeding, such as flowing blood or pulsatile bleeding from a small arteriole, with a moderate rate of hemorrhage.	2
Grade 3	Active, rapid arterial spurting or extensive, flowing hemorrhage.	3
Grade 4	Life-threatening massive hemorrhage. The endoscopic field is completely obscured by blood, making anatomical structures unrecognizable.	4

4.4. Quality Control

(1) The Department of Hepatobiliary Surgery at Affiliated Nanhua Hospital, University of South China is a provincial-level key clinical specialty in Hunan Province. The medical and nursing team members have undergone rigorous training and possess extensive experience in ERCP procedures and perioperative management.

(2) Case selection strictly adhered to the inclusion and exclusion criteria. The research process was standardized, transparent, and fully safeguarded patients' rights to informed consent and other relevant interests.

(3) All observation indicators were objective. Patient data were collected using standardized methods to ensure completeness, accuracy, and consistency of the data.

5. Statistics

Statistical analysis was performed using SPSS software (version 23.0). Normally distributed continuous data (e.g., age) are presented as mean ± standard deviation (SD) and were compared between groups using the independent samples *t*-test. Non-normally distributed continuous data are presented as median (interquartile range) and were compared between groups using the Mann-Whitney U test. Categorical data are presented as frequency (percentage) and were compared between groups using the chi-square test or Fisher's exact probability test. A two-sided $P < 0.05$ was considered statistically significant.

6. Results

6.1. Baseline Clinical Characteristics

A total of 784 patients in the control group and 757 patients in the observation group were enrolled according to the inclusion and exclusion criteria. No statistically significant differences were observed between the two groups in terms of age, gender, or preoperative bilirubin levels. The baseline clinical characteristics of the patients in both groups are presented in Table 2.

Table 2: Comparison of Baseline Characteristics Between the Two Groups (Mean ± SD).

Characteristic	Observation Group (n=757)	Control Group (n=784)	p-value
Age, years (Mean ± SD)	61.23 ± 8.59	60.78 ± 8.67	0.306
Gender, n (%)			0.849
Male	Male	391 (49.9)	
Female	389 (51.4)	393 (50.1)	
Maximum diameter of bile	9.07 ± 2.44	9.11 ± 2.59	0.761
duct stones (mm)			
Dilation diameter of EPBD (mm)	10.13 ± 0.92	10.09 ± 0.94	0.728
Total Bilirubin Level (μmol/L)	36.18 ± 10.51	35.76 ± 11.72	0.457
APTT, s (Mean ± SD)	29.07 ± 2.88	28.89 ± 3.02	0.233

Table 3: Endoscopic Bleeding Grade Between the Two Groups.

Endoscopic Bleeding Grade	**Observation Group, n (%)**	**Control Group, n (%)**
Grade 0	395(52.18)	187(23.85)
Endoscopic Bleeding Grade	**Observation Group, n (%)**	**Contral Group, n (%)**
Grade 1	247(32.63)	341(43.49)
Grade 2	106(14.00)	220(28.06)
Grade 3	7(0.92)	33(4.21)
Grade 4	2(0.27)	3(0.81)

Table 4: Comparison of Postoperative Complications Between the Two Groups.

Group	**Hematemesis, n (%)**	Melena, n (%)	Post-ERCP Pancreatitis, n (%)	Acute Cholangitis, n (%)	Intestinal or Biliary Perforation, n (%)
Observation Group(n=757)	0(0)	98(12.95)	131(17.31)	54(7.13)	3(0.40)
Control Group(n=784)	4(0.51)	176(22.45)	140(17.86)	65(8.29)	2(0.25)
χ^2-value	N/A	23.85	0.07	0.73	N/A
p-value	0.125	0.001	0.001	0.394	0.681

6.2. Intraoperative Bleeding

Immediate grading after EPBD showed that in the observation group, Grade 0 and Grade 1 bleeding accounted for the highest proportions, at 52.18% and 32.63%, respectively. In the control group, Grade 1 and Grade 2 bleeding were most prevalent, accounting for 43.49% and 28.06%, respectively, with 33 cases (4.21%) classified as Grade 3. Comparison between the two groups revealed a highly statistically significant difference in the distribution of endoscopic bleeding grades ($P < 0.001$). In terms of percentage distribution and effect size, the overall bleeding severity in the observation group was lower than that in the control group (the observation group had a higher proportion of Grade 0 bleeding and a lower proportion of high-grade bleeding).

6.3. Postoperative Hemoglobin Decline

Patients underwent a complete blood count review at 24 hours postoperatively to compare the decline in hemoglobin levels between the two groups. As shown in Figure 1, The results showed a decline in hemoglobin in both groups, with the control group exhibiting a decrease of 13.62 ± 7.86 g/L and the observation group a decrease of 10.57 ± 6.65 g/L. The hemoglobin decline in the observation group was significantly less than that in the control group, with a statistically significant difference ($t = -7.56$, $P < 0.0001$).

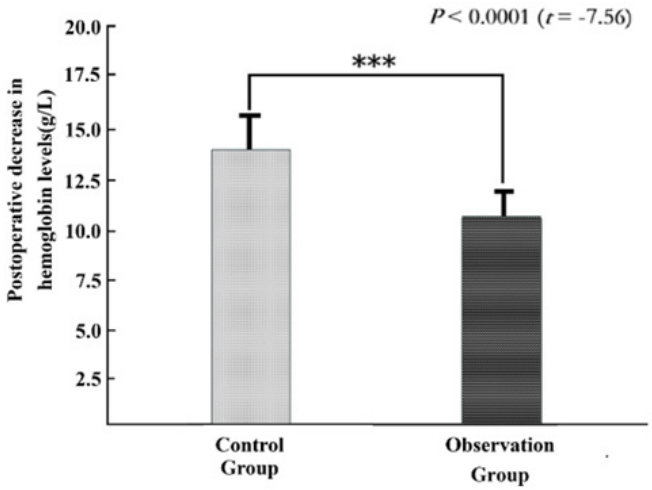

Figure 1: Postoperative hemoglobin decline in two groups of patients.

6.4. Incidence of Postoperative Hematemesis and Melena

The incidence of hematemesis and melena within 72 hours postoperatively was observed. The results showed that no cases of hematemesis occurred in the observation group, while 98 cases (12.95%) experienced melena. In the control group, 4 cases (0.51%) had hematemesis and 176 cases (22.45%) had melena. The incidence of both hematemesis and melena was lower in the observation group compared to the control group, with a statistically significant difference in melena incidence between the two groups ($P < 0.01$).

6.5. Incidence of Postoperative Non-hemorrhagic Complications

The occurrence of complications such as ERCP-related pancreatitis, acute cholangitis, and intestinal or biliary perforation within 72 hours postoperatively was observed in both groups. The results indicated no statistically significant difference in the incidence of these complications between the two groups.

7. Discussion

The duodenal papilla region is highly vascularized, making the prevention and reduction of hemorrhagic complications during and after EPBD and stone extraction a challenging yet essential task for endoscopists. Multiple clinical studies have demonstrated that patients with large bile duct stones (diameter >10 mm) or impacted ampullary stones often require a larger incision and greater dilation during EST and EPBD, which increases mechanical trauma to the surrounding biliary tissues and significantly elevates the risk of postoperative bleeding [3-6]. Compared to performing EST or EPBD alone, the combination of EST and EPBD may represent the optimal approach for treating common bile duct stones in patients with biliary calculi [7]. In conventional EPBD, the balloon pressure is typically released abruptly after dilation, frequently resulting in bleeding from the duodenal papilla wound. Severe cases often necessitate endoscopic hemostasis, such as electrocoagulation, local injection of hemostatic agents, or the application of hemostatic clips.

In recent clinical observations at our center, we noted that varying degrees of wound bleeding occurred in the majority of patients (76.15%) following EST and EPBD. Although hemostasis was successfully achieved in most cases through the application of local hemostatic agents (e.g., norepinephrine, biological hemostatic powders) or hemostatic clips, the incidence of postoperative melena reached 22.45%, accompanied by varying degrees of hemoglobin decline, indicating a persistent risk of delayed bleeding. By modifying the EPBD technique to incorporate stepwise balloon pressure release, we observed a significant reduction in wound bleeding under endoscopy, thereby lowering the risk of delayed postoperative hemorrhage, without a significant increase in complications such as ERCP-related pancreatitis, acute cholangitis, or intestinal/biliary perforation.

As demonstrated by the experimental data, stepwise release of balloon pressure significantly reduced immediate wound bleeding after balloon removal and markedly decreased the incidence of postoperative hemorrhagic complications. We attribute this to several factors: First, Gradual pressure release allows the compressed arterioles, venules, and capillaries within the duodenal papilla to reperfusion progressively, facilitating full activation of the coagulation cascade and promoting the formation of local microthrombi. Second, Stepwise pressure release prevents abrupt reperfusion of the local microcirculation, reducing the sheer force of blood flow on severed vessel ends and minimizing blood extravasation. Furthermore, this method promotes vascular smooth muscle contraction, thereby lowering the risk of bleeding. Finally, gradually reducing Oddi sphincter tension allows for more complete recovery of sphincter fibre contractile function, which may compress the vascular bed and further reduce wound bleeding.

In conclusion, our study demonstrates that stepwise pressure release following EPBD significantly reduces intraoperative bleeding severity, decreases postoperative haemoglobin decline and the incidence of melena, without increasing the risk of other complications. This represents a safe and effective technical refinement. As a single-centre study currently limited to patients with biliary stones and excluding other biliary diseases, our findings may be subject to bias. Future efforts will involve collaboration with other endoscopy centres and extension of this method to other biliary disorders for further validation.

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