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

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Abstract

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).

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.

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 ($P > 0.05$).

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.

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.

METHODS

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 was conducted in accordance with the Declaration of Helsinki. Informed consent was obtained from all patients after a thorough discussion of the surgical procedure and its potential risks; the study protocol was approved by the Ethics Review Committee of Affiliated Nanhua Hospital, University of South China (Approval No.: Y250724).

Endoscopic Procedure

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.

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.

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
Grade 1	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

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.

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.

RESULTS

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	368 (48.6)	391 (49.9)	
Female	389 (51.4)	393 (50.1)	
Maximum diameter of bile duct stones (mm)	9.07 ± 2.44	9.11 ± 2.59	0.761
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

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).

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)
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)

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 Fig. 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 ($t = -7.56$, $P < 0.0001$).

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 ($P < 0.01$).

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.

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	0.791	0.394	0.681

Note: The dash (N/A) indicates that Fisher's exact test was employed because the expected cell count was < 5; thus, the χ^2 value was not calculated.

DISCUSSION

The duodenal papilla is highly vascularized—an anatomical feature that, while essential, makes it particularly prone to bleeding during endoscopic procedures. As a result, minimizing hemorrhagic complications during and after EPBD and stone extraction remains a critical concern for endoscopists. This concern becomes even more pronounced in complex cases. Several studies have shown that patients with large bile duct stones (diameter > 10 mm) or impacted ampullary stones often require a more extensive sphincterotomy and greater balloon dilation during EST and EPBD. These maneuvers inevitably increase mechanical trauma to the surrounding biliary tissues and raise the risk of postoperative bleeding [3–6]. Although combining EST with EPBD may offer advantages over either technique alone for managing common bile duct stones [7], it does not eliminate the inherent bleeding risk associated with tissue disruption.

In conventional EPBD, regardless of whether a graded inflation technique is used, balloon pressure is typically released all at once immediately after dilation. This abrupt decompression can trigger sudden hemodynamic changes in the compressed microvasculature of the papillary wound, frequently leading to immediate bleeding. In our experience, such bleeding is commonly observed upon balloon removal. While minor oozing may stop spontaneously, more severe cases often require endoscopic hemostasis-using electrocoagulation, local injection of vasoactive agents (e.g., diluted epinephrine), or hemoclips. Although effective, these interventions prolong procedure time and can cause additional tissue injury. Moreover, once post-ERCP bleeding develops, management becomes particularly demanding. Patients may require intensive monitoring, repeat endoscopic procedures, surgical salvage, or blood transfusions —all of which place a substantial burden on both the individual and the healthcare system. Given these challenges, exploring simple technical modifications that can reduce bleeding risk has clear clinical value.

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.

Our findings demonstrate that stepwise balloon pressure release significantly reduced immediate bleeding upon balloon removal and lowered the incidence of postoperative hemorrhagic complications. We believe this effect can be attributed to several interrelated mechanisms. First, gradual pressure release allows the compressed arterioles, venules, and capillaries within the duodenal papilla to reperfuse progressively, rather than suddenly. This controlled reperfusion provides sufficient time for the coagulation cascade to become fully activated at sites of vascular injury, enabling timely formation of local microthrombi before hemodynamic forces can dislodge them. Second, by avoiding abrupt

reperfusion, stepwise decompression minimizes the shear stress of blood flow on freshly severed vessel ends, thereby reducing blood extravasation. Third, this technique may promote contraction of vascular smooth muscle, which further helps to curb bleeding. Finally, the gradual reduction in Oddi sphincter tension allows for more complete recovery of sphincter fiber contractile function, potentially compressing the local vascular bed and contributing to hemostasis. Together, these mechanisms suggest that stepwise pressure release creates a more favorable hemodynamic and hemostatic environment during the critical moments following balloon deflation.

In conclusion, this study demonstrates that stepwise pressure release following EPBD significantly reduces intraoperative bleeding severity, attenuates postoperative hemoglobin decline, and lowers the incidence of melena, without increasing the risk of other complications. These findings suggest that this modified technique is both safe and effective in clinical practice. However, as a single-center study focused exclusively on patients with biliary stones, our results may carry inherent selection bias and may not be generalizable to other biliary conditions. Future multicenter collaborations and prospective studies are warranted to validate these findings and to explore the applicability of this technique in a broader spectrum of biliary disorders.

Abbreviations

EPBD: Endoscopic Papillary Balloon Dilation

ERCP: Endoscopic Retrograde Cholangiopancreatography

EST: Endoscopic Sphincterotomy

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the ethical principles of the Declaration of Helsinki. As this is a retrospective study utilizing anonymized clinical data, the requirement for individual informed consent was waived by the Ethics Review Committee of Affiliated Nanhua Hospital, University of South China. The study protocol was reviewed and approved by the same committee (Approval No.: Y250724).

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Disclosures

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Author Contribution

Author ContributionsConceptualization: X.Liu.Methodology & Investigation: X.Liu, J.Long.Data Curation & Formal Analysis: X.Liu, J.Long, Q.Yan, J.Yin, J.Cao, S.Duan.Writing – Original Draft: X.Liu.Writing – Review & Editing: X.Lu, X.Zhou.Supervision: X.Lu, X.Zhou.All authors read and approved the final manuscript.

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Figures

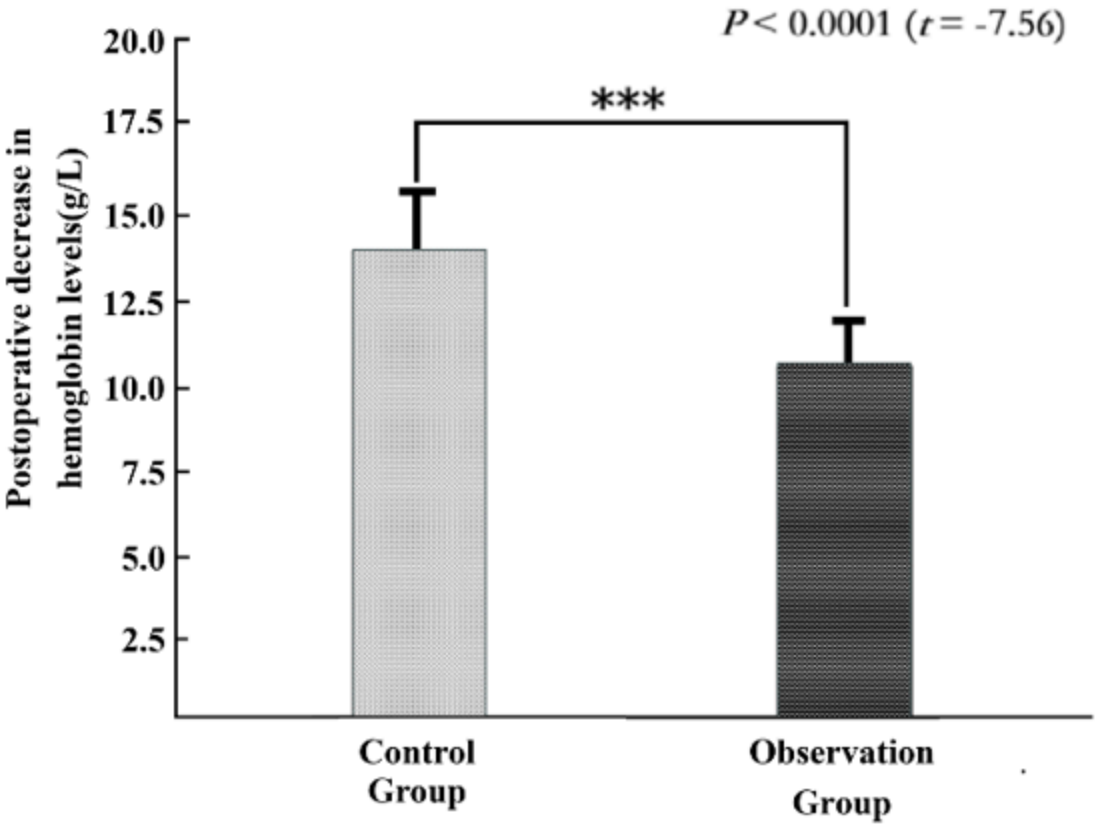


Figure 1

Postoperative hemoglobin decline in two groups of patients