Zagazig University Medical Journal
www.zumj.journals.ekb.eg
https://doi.org/10.21608/zumj.2025.366097.3864 Volume 31, Issue 5, May. 2025
Manuscript ID:ZUMJ-2503-3864
DOI:10.21608/zumj.2025.366097.3864

ORIGINAL ARTICLE

Efficacy and Safety of Balloon Tamponade in Control of Post Sphincterotomy Bleeding During Endoscopic Retrograde Cholangiopancreatography

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Submit Date 2025-03-06
Revise Date 2025-03-24
Accept Date 2025-03-27

ABSTRACT:

Background:EndoscopicRetrograde Cholangiopancreatography (ERCP) has evolved into a therapeutic procedure, with endoscopic sphincterotomy (ES) being the most common intervention. Effective hemostatic techniques involve balloon tamponade, coagulation, and hemoclips for post-sphincterotomy bleeding (PSB). This study aimed to evaluate the efficacy and safety of balloon tamponade in controlling post-sphincterotomy bleeding during ERCP.

Methods: This prospective and retrospective cohort study included 18 eligible patients diagnosed with post-sphincterotomy bleeding during ERCP and categorized into 2 groups: group 1 (G1, n=14) successful hemostasis and G2 (n=4) non-successful hemostasis. Assessments comprised history, physical examination, laboratory tests (complete blood count, international normalized ratio, liver and kidney function, blood glucose, serum electrolytes, hepatitis B and C markers, and HIV), imaging (ultrasonography, chest X-ray, computed tomography, magnetic resonance cholangiopancreatography (MRCP), and ERCP).

Results: Statistically significant differences were revealed between the two groups as regards hemostasis after 3 minutes of tamponading, extended hemostasis to 5 minutes, and adrenaline injection; among group 1 (71.4%) of patients had successful hemostasis at 3 minutes, while none of the patients among group 2 (0%) had successful hemostasis(P=0.02). Also, (28.6%) of patients in Group 1 had successful hemostasis at 5 minutes, while none of the patients in Group 2 (0%) had successful hemostasis(P=0.005). As regards adrenaline injection, (50%) of patients in group 2 had successful adrenaline injections, while all the patients (100%) in group 1 had no adrenaline injection(P=0.005).

Conclusion: A complete understanding of managing bleeding of various severities and potential adverse events is fundamental to delivering efficient patient therapies. Therefore, balloon tamponade could be more effective and safer in the management of post-sphincterotomy bleeding during endoscopic retrograde cholangiopancreatography.

Keywords: Efficacy, Safety, Balloon Tamponade, Post Sphincterotomy Bleeding, Endoscopic Retrograde Cholangiopancreatography

INTRODUCTION

Endoscopicretrograde cholangiopancreatography (ERCP) is nerve-wracking and so widely performed that in the US, over 500,000 procedures are performed annually. There are more than 650,000 ERCP procedures per year in the USA alone. In developing countries, such as China, ERCP has made significant progress. From 2006 to 2012, the number of hospitals in China that can perform ERCP increased from 470 to 1156. The total ERCP volume increased from 63,787 to 195,643, of which >95% were therapeutic [1].

The ERCP comes with certain risks, whether performed alone or in combination with procedures of other organs. The complications that may follow are pancreatitis, hemorrhage, cholecystitis, infections, intestinal perforation, and cardiopulmonary events. The spectrum of these adverse events varies from complete recovery after a short hospital stay to severe, life-threatening conditions that could lead to long-term disabilities or, in rare cases, death. In addition to increased patient morbidity, complications can pose significant challenges for the endoscopist, including concerns about medical malpractice claims [2].

Bleeding is among the most concerning complications of therapeutic biliary endoscopy. Although advancements in equipment and procedural techniques have reduced its incidence, it remains a clinically significant problem. Endoscopists must understand strategies for the prevention and management of ERCP-related bleeding. Endoscopic sphincterotomy of the biliary and/or pancreatic duct is the foremost common cause of ERCP-related bleeding, with incidence rates ranging from as low as 0.1% to as high as 2% [3].

Balloon tamponade of the sphincterotomy site is a technique that utilizes a standard stone removal balloon catheter to achieve temporary hemostasis. This method is beneficial for controlling active intraprocedural bleeding during sphincterotomy. By inflating the balloon maximally, tamponade is created, providing temporary bleeding control and improving visualization of the bleeding site. This technique facilitates the planning and successful application of additional hemostatic interventions. However, balloon tamponade is generally not a definitive treatment for bleeding, and its overall efficacy has not been extensively studied [4].

Most post-ERCP bleeding occurs with sphincterotomy. Most commonly, the bleeding is mild to moderate. Clinically significant bleeding is often managed by medical therapy and/or endoscopic intervention, which should take place as soon as possible in the event of immediate bleeding. Endoscopic methods may include epinephrine injection, hemostatic clip placement, the placement of fully covered self-expandable stents into the common bile duct, and balloon tamponade to control bleeding. So, the present work aimed to evaluate the efficacy and safety of balloon tamponade in controlling post-sphincterotomy bleeding during ERCP.

Methods

This prospective and retrospective cohort study was conducted in the Internal Medicine Department, Faculty of Medicine, Zagaig University Hospitals. Eighteen patients fulfilling the inclusive criteria were enrolled in the study. All the data were collected from the hospital's medical records after ethical approval was obtained from the Hospital Ethical Committee and Zagazig Faculty of Medicine from June 2023 to December 2024.

The study was conducted after obtaining approval from the Institutional Review Board (ZU-IRB#11163-25/10/2023) and written informed consent from all patients. The research was conducted under the World Medical Association’s Code of Ethics (Helsinki Declaration) for human research.

This study included patients aged 18 years or older who were diagnosed with post-sphincterotomy bleeding during an Endoscopic Retrograde Cholangiopancreatography (ERCP) procedure. Uncontrollable hemorrhage occurred either during the ERCP procedure or within 15 days post-procedure.

When bleeding occurred during ERCP, it was considered uncontrollable if the hemorrhage was so massive in amount (oozing or arterial type) that it prevented further biliary interventions; this is because there was no clear visualization of the area and/or if it continued despite conventional endoscopic hemostatic treatment, for at least 5 minutes [5].

Patients were excluded if they were receiving anticoagulant or antiplatelet therapy, were medically unfit for deep sedation with propofol, or had evidence of a bleeding disorder, defined as a platelet count below 50,000/µL, a prothrombin time (PT) greater than 16 seconds, or an international normalized ratio (INR) above 2.

All participants were given a comprehensive medical history focusing on the gastrointestinal tract. Detailed records of previous and existing medications were also maintained.

A full systems examination was conducted on all participants. The examination included a systematic appraisal of each participant's general health status, paying special attention to any indicators of gastrointestinal pathology.

The prospective participants' overall health and the retrospective participants' investigations were collected and checked. From the collected patient records, complete blood count data had been documented, providing insights into the overall cellular composition. Investigations, including prothrombin time, prothrombin activity, and international normalized ratio (INR), have been performed to evaluate the coagulation function. Liver and kidney function tests were also conducted to identify any abnormalities in these vital organs. Fasting blood glucose and two-hour postprandial glucose levels had been assessed to screen for disorders related to glucose metabolism. Serum electrolytes—including sodium, potassium, total calcium, and ionized calcium—had been analyzed to detect electrolyte imbalances. Additionally, records showed that screening for hepatitis B, hepatitis C, and HIV had been conducted.

Various imaging techniques have been employed further to explore the conditions of interest to the participants. Transabdominal ultrasound is a noninvasive means of assessing abdominal organs. Chest X-rays were performed to determine pulmonary and thoracic structures. Computerized tomography (CT) was used to produce cross-sectional imaging of high detail of the abdomen and other areas as required. Where additional imaging on the biliary or pancreatic ducts was warranted, magnetic resonance cholangiopancreatography (MRCP) was performed in selected cases. Finally, ERCP was also performed when indicated for diagnostic or therapeutic purposes.

The severity of bleeding was categorized into three levels. Mild bleeding was characterized by endoscopic evidence of hemorrhage, accompanied by a hemoglobin drop of less than 3 g/dL, without the necessity for blood transfusion. Moderate bleeding was defined as a case requiring up to four units of blood transfusion but not necessitating angiographic or surgical intervention. Severe bleeding, on the other hand, was considered when the patient required more than four units of blood transfusion or required further intervention beyond endoscopic measures [5].

The onset of bleeding was classified into two types: immediate and delayed. Immediate bleeding occurred at the time of sphincterotomy, while delayed bleeding was defined as bleeding after the procedure, such as melena, hematemesis, or hematochezia, with a hemoglobin drop [5].

Endoscopic management was regarded as successful when bleeding ceased altogether or recurred after successful hemostasis with endoscopic therapy. A maximum of two treatment sessions was allowable before endoscopic intervention was deemed unsuccessful [6].

Post-Sphincterotomy Bleeding Management

A total of 18 cases of post-sphincterotomy bleeding were managed through a stepwise approach. Initially, hemostasis was attempted using balloon tamponade for three minutes. Of these cases, 10 were successfully managed with this initial intervention. However, one case developed complications due to a common bile duct (CBD) injury, requiring surgical repair. Balloon tamponade was extended to five minutes for the remaining seven cases where initial hemostasis failed. This resulted in four additional successful outcomes. Among the three cases that still exhibited persistent bleeding, adrenaline was administered as an escalation measure. Adrenaline treatment succeeded in two cases, while one remained unresolved and required plastic stent insertion for definitive management. So, patients were categorized into 2 groups: Group 1 (G1): 14 patients with successful hemostasis; Group 2 (G2): 4 patients with non-successful hemostasis.

ERCP Procedure

ERCP was performed under either conscious sedation or general anesthesia. Conscious sedation was achieved using intravenous midazolam, at doses ranging from 2 to 10 mg, and fentanyl, administered in doses of 0.05 to 0.1 mg. Additionally, intravenous hyoscine butylbromide (40 to 60 mg) or glucagon (1 to 2 mg) was administered to facilitate the procedure. In cases where post-endoscopic sphincterotomy bleeding occurred, endoscopic therapy was implemented using either a side-viewing or an end-viewing endoscope at the discretion of the endoscopist. Hemostasis was achieved through balloon tamponade with a dilating catheter measuring 10 mm × 4 cm. The ballooning was maintained for three to five minutes and, if necessary, repeated to control bleeding effectively [6].

Follow-up

Upon discharge from the ERCP unit, patients were given specific post-procedure instructions. They were advised to avoid nonsteroidal anti-inflammatory drugs (NSAIDs), antiplatelet agents, and coumadin for at least three days. Patients with an INR greater than 1.2 were infused with fresh frozen plasma over four to five days to maintain the INR between 1.2 and 1.5. The mnemonic platelet suspension was given to patients with a platelet count below 50,000/ml to minimize bleeding and ensure a smooth recovery.

Statistical analysis

Data were analyzed utilizing Microsoft Excel software. The data were then imported into the SPSS (version 23.0 for Windows, Armonk, NY: IBM Corp) for further analysis. Qualitative data were presented as numbers and percentages for the analysis, while quantitative data were presented as mean ± standard deviation (SD). We use the Kolmogorov–Smirnov test to assess parametric and nonparametric variables. The following statistical tests assessed differences and associations: the Chi-square test (X^2) for qualitative variables, t-tests or Mann-Whitney tests for quantitative independent groups, and Kappa for agreement. A p-value <0.05 was considered significant. Logistic regression was utilized to predict the presence or absence of an outcome based on a set of independent variables. This method is beneficial when the dependent variable is qualitative (categorical), making it a suitable alternative to linear regression.

RESULTS

Table (1) shows the demographic data of the studied patients, as ages ranged from 22 to 67 years with a mean ± SD of 40.9 ± 10.9. (61.1%) were males and (38.9%) were females. (38.9%) were smokers, and (61.9%) were non-smokers; it shows yellow discoloration in all patients (100%), followed by itching (38.9%), right upper quadrant pain (27.8%), fatigue (22.2%), and back pain (16.7%). Less common symptoms included abdominal pain (11.1%) and paraumbilical pain or limb swelling (5.6%). Preoperative data among 18 patients, mean values were WBC $7.21 \times 10^3/mm^3$, Hb 11.86 g/dL, PLT $325 \times 10^3/mm^3$, INR 1.06, total bilirubin 6.71 mg/dL, ALT 358.5 U/L, AST 331.33 U/L, ALP 343.28 IU/L, GGT 88.11 U/L, creatinine 0.91 mg/dL, and fasting blood sugar 96.3 mg/dL. HCV was positive in 11.1%, while all were negative for HBV and HIV. Regarding radiological imaging, the Liver was normal in 55.6%, enlarged in 27.8%, and fatty in 16.7%. All had dilated IHBR, and CBD measured 10.1 mm (mean). The gall bladder was normal in 55.6%, with calculus in 33.3% and abnormalities in 11.2%. Mild splenomegaly was seen in 5.6% of patients (Table 2).

Table (3) and supplementary Figure 1 shows that 10 patients (55.6%) had successful hemostasis after 3 minutes of ballon tamponading, 7 patients (38.9%) had failed hemostasis, while one patient (5.6%) had complicated hemostasis (CBD injury). Then, among the 7 patients who needed to extend hemostasis to 5 minutes, 4 patients (22.2%) had successful hemostasis, while 3 patients (16.7%) had failed hemostasis. Then, among the 3 patients with failed hemostasis, 2 patients (11.1%) had successful adrenaline injections, while one (5.6%) had failed. Then, the patient (5.6%) with failed adrenaline injection had a successful plastic stent insertion. Also, one patient (5.6%) required surgical repair of CBD.

Postoperative: Tables (4 and 5) show no significant difference between the two groups as regards demographic data, medical or surgical histories or symptoms, preoperative data, general or local examinations, and laboratory or radiologic investigations (P>0.05) (Table 6).

Table (7) shows a statistically significant difference between the two groups as regards hemostasis after 3 minutes of tamponading, extended hemostasis to 5 minutes, and adrenaline injection; among group 1 (71.4%) of patients had successful hemostasis at 3 minutes, while none of the patients among group 2 (0%) had successful hemostasis(P=0.02). Also, (28.6%) of patients in Group 1 had successful hemostasis at 5 minutes, while none of the patients in Group 2 (0%) had successful hemostasis(P=0.005). As regards adrenaline injection, (50%) of patients in group 2 had successful adrenaline injections, while all the patients (100%) in group 1 had no adrenaline injection(P=0.005).

Supplementary Table 1 presents univariate logistic regression analysis for predictors of successful hemostasis, showing that most variables are not statistically significant (p > 0.05). BMI (p = 0.06) and temperature (p = 0.06) are near significance, warranting further investigation.

Table 1: Demographic data, Medical and surgical history,Symptoms among the studied patients

Variables		All patients (n=18)
Age *(years)*	*Mean ± SD*	40.9 ± 10.9
	Range	(22 – 67)
Sex *(n. %)*	Male	11 (61.1%)
	Female	7 (38.9%)
Smoking status *(n. %)*	Non-smokers	11 (61.1%)
	Smokers	7 (38.9%)
Medical history *(n. %)*	None	14 (77.8%)
	Benign prostate hyperplasia	1 (5.6%)
	Diabetes mellitus	1 (5.6%)
	Hypertension	1 (5.6%)
	Hypothyroidism	1 (5.6%)
Surgical history *(n. %)*	None	11 (61.1%)
	Cesarian section	3 (16.7%)
	Appendectomy	1 (5.6%)
	Rt breast lumpectomy	1 (5.6%)
	Tonsillectomy	2 (11.1%)
Pain	No abdominal pain	2 (11.1%)
	Middle & right upper quadrant	2 (11.1%)
	Right upper quadrant & back	3 (16.7%)
	Lower middle quadrant	1 (5.6%)
	Diffuse abdominal pain	2 (11.1%)
	Right upper quadrant	5 (27.8%)
	Middle upper quadrant	2 (11.1%)
	Rt paraumbilical	1 (5.6%)
Lower limb swelling	No	17 (94.4%)
	Yes	1 (5.6%)

Variables		All patients (n=18)
Fatigue	No	14 (77.8%)
	Yes	4 (22.2%)
Itching	No	11 (61.1%)
	Yes	7 (38.9%)
Yellow discoloration	No	0 (0%)
	Yes	18 (100%)

Table 2: Laboratory and radiological data among the studied patients

Variables		All patients (n=18)
WBC *(10^3/mm^3)*	*Mean ± SD*	7.21 ± 1.92
	Range	(4.1 – 10.4)
Hb *(g/dL)*	*Mean ± SD*	11.86 ± 0.81
	Range	(10.7 – 13.2)
PLT *(10^3/mm^3)*	*Mean ± SD*	325 ± 85.96
	Range	(160 – 435)
INR	*Mean ± SD*	1.06 ± 0.09
	Range	(0.9 – 1.2)
Total bilirubin *(mg/dL)*	*Mean ± SD*	6.71 ± 1.77
	Range	(3.2 – 10.2)
Direct bilirubin *(mg/dL)*	*Mean ± SD*	5.04 ± 1.56
	Range	(2.5 – 7.8)
ALT *(U/L)*	*Mean ± SD*	358.5 ± 216.08
	Range	(109 – 755)
AST *(U/L)*	*Mean ± SD*	331.33 ± 197.19
	Range	(140 – 724)
Alkaline phosphatase *(IU/L)*	*Mean ± SD*	343.28 ± 160.04
	Range	(187 – 767)
GGT *(U/L)*	*Mean ± SD*	88.11 ± 19.82
	Range	(58 – 128)
Creatinine *(mg/dL)*	*Mean ± SD*	0.91 ± 0.12
	Range	(0.7 – 1.2)
Urea *(mg/dL)*	*Mean ± SD*	26.44 ± 6.93
	Range	(16 – 43)
Na *(mEq/L)*	*Mean ± SD*	139.33 ± 2.61
	Range	(135 – 143)
K *(mmol/L)*	*Mean ± SD*	4.12 ± 0.31
	Range	(3.7 – 4.7)
HCV*(n. %)*	Negative	16 (88.9%)
	Positive	2 (11.1%)
HBV*(n. %)*	Negative	18 (100%)
	Positive	0 (0%)
HIV*(n. %)*	Negative	18 (100%)
	Positive	0 (0%)
Fasting blood sugar *(gm/dl)*	*Mean ± SD*	96.3 ± 12.24
	Range	(76 – 124)

Variables		All patients (n=18)
Liver*(n. %)*	Enlarged, fatty liver	3 (16.7%)
	Normal size, homogenous	10 (55.6%)
	Enlarged, homogenous	5 (27.8%)
IHBR*(n. %)*	Normal	0 (0%)
	Dilated	18 (100%)
CBD diameter *(mm)*	*Mean ± SD*	10.1 ± 1.63
	Range	(7 – 13)
Gall bladder *(n. %)*	Normal gall bladder	10 (55.6%)
	Calculus gall bladder	6 (33.3%)
	Chronic calculus cholecystitis	1 (5.6%)
	Gall bladder mud	1 (5.6%)
Splenomegaly *(n. %)*	No	17 (94.4%)
	Mild splenomegaly	1 (5.6%)

WBCs: White Blood Cells, Hb: Hemoglobin, PLT: Platelets, INR: International Normalized Ratio, ALT: Alanine Aminotransferase, AST: Aspartate Aminotransferase, ALP: Alkaline Phosphatase, GGT: Gamma-Glutamyl Transferase, Na: Sodium, K: Potassium, HCV: Hepatitis C Virus, HBV: Hepatitis B Virus, HIV: Human Immunodeficiency Virus, IHBR: Intrahepatic Biliary Radicals, CBD: Common Bile Duct, GB: Gall Bladder

Table 3: Outcome of different endoscopic hemostatic therapies among the studied patients

Variables		All patients (n=18)
Hemostasis after 3 minutes tamponading	Success	10 (55.6%)
	Failed	7 (38.9%)
	Complicated (CBD injury)	1 (5.6%)
Need extend to 5 minutes	Not done	11 (61.1%)
	Success	4 (22.2%)
	Failed	3 (16.7%)
Adrenaline injection	Not done	15 (83.3%)
	Success	2 (11.1%)
	Failed	1 (5.6%)
Stent insertion	Not done	17 (94.4%)
	Plastic stent	1 (5.6%)
Need surgical intervention	Not done	17 (94.4%)
	Surgical repair of CBD	1 (5.6%)

Table 4: Comparison between (G1 successful hemostasis and G2 non-successful hemostasis) regarding demographic data, medical, surgical history and symptoms

Variables		Group 1 (n=14)	Group 2 (n=4)	P Value
Age *(years)*	*Mean ± SD*	41.1 ± 12.21	40 ± 4.55	0.86[1]
	Range	(22 – 67)	(34 – 45)	
Sex *(n. %)*	Male	8 (57.1%)	3 (75%)	0.52[2]
	Female	6 (42.9%)	1 (25%)	

Smoking status *(n. %)*	Non-smokers	8 (57.1%)	3 (75%)	0.52^2
	Smokers	6 (42.9%)	1 (25%)	
Medical history *(n. %)*	None	10 (71.4%)	4 (100%)	1.00
	Benign prostate hyperplasia	1 (7.1%)	0 (0%)	
	Diabetes mellitus	1 (7.1%)	0 (0%)	
	Hypertension	1 (7.1%)	0 (0%)	
	Hypothyroidism	1 (7.1%)	0 (0%)	
Surgical history *(n. %)*	None	8 (57.1%)	3 (75%)	1.00
	Cesarian section	2 (14.3%)	1 (25%)	
	Appendectomy	1 (7.1%)	0 (0%)	
	Rt breast lumpectomy	1 (7.1%)	0 (0%)	
	Tonsillectomy	2 (14.3%)	0 (0%)	
Pain	No abdominal pain	1 (7.1%)	1 (25%)	0.81^1
	Middle & right upper quadrant	2 (14.3%)	0 (0%)	
	Right upper quadrant & back	3 (21.4%)	0 (0%)	
	Lower middle quadrant	1 (7.1%)	0 (0%)	
	Diffuse abdominal pain	2 (14.3%)	0 (0%)	
	Right upper quadrant	3 (21.4%)	2 (50%)	
	Middle upper quadrant	1 (7.1%)	0 (0%)	
	Rt paraumbilical	1 (7.1%)	1 (25%)	
Lower limb swelling	No	13 (92.9%)	4 (100%)	1.00^1
	Yes	1 (7.1%)	0 (0%)	
Fatigue	No	11 (78.6%)	3 (75%)	0.88^2
	Yes	3 (21.4%)	1 (25%)	
Itching	No	9 (64.3%)	2 (50%)	0.61^2
	Yes	5 (35.7%)	2 (50%)	
Yellow discoloration	No	0 (0%)	0 (0%)	1.00^1
	Yes	14 (100%)	4 (100%)	

Table 5: Comparison between (G1 successful hemostasis and G2non-successful hemostasis) regarding pre-operative vital signs, general examination, and local examination

Variables		Group 1 (n=14)	Group 2 (n=4)	P Value
SBP *(mmhg)*	*Mean ± SD*	120 ± 8.43	119 ± 8.54	0.85
	Range	(110 – 135)	(110 – 130)	
DBP *(mmhg)*	*Mean ± SD*	77.5 ± 5.8	80.5± 1.29	0.41
	Range	(70 – 90)	(70 – 80)	
Heart rate *(beat/m)*	*Mean ± SD*	86.4 ± 6.26	81.5 ± 4.8	0.17
	Range	(76 – 98)	(76 – 86)	
Respiratory rate *(breath/m)*	*Mean ± SD*	16.1± 2.32	15± 1.41	0.37
	Range	(12 – 20)	(14 – 17)	
Temperature*(C)*	*Mean ± SD*	37 ± 0.26	36.7 ± 0.24	0.03
	Range	(36.5 – 37.4)	(36.5 – 37)	

Variables		Group 1 (n=14)	Group 2 (n=4)	P Value
BMI *(kg/m²)*	*Mean ± SD*	27.2 ± 2.33	31 ± 1.83	0.009[1]
	Range	(24 – 31)	(29 – 33)	
Pallor	No	12 (85.7%)	3 (75%)	1.00[2]
	Yes	2 (14.3%)	1 (25%)	
Skin mark	Free	10 (71.4%)	2 (50%)	0.42[3]
	Scratch marks	4 (28.6%)	2 (50%)	
Lymph node	No	12 (85.7%)	4 (100%)	1.00[2]
	Left axillary	1 (7.1%)	0 (0%)	
	Right inguinal	1 (7.1%)	0 (0%)	
Lower limb	Free	13 (92.9%)	4 (100%)	1.00[2]
	Mild edema	1 (7.1%)	0 (0%)	
Hand	Free	11 (78.6%)	4 (100%)	1.00[2]
	Clubbing	1 (7.1%)	0 (0%)	
	Pallor	1 (7.1%)	0 (0%)	
	Sweaty	1 (7.1%)	0 (0%)	
Purities	No	9 (64.3%)	2 (50%)	0.61[3]
	Yes	5 (35.7%)	2 (50%)	
Face	Free	12 (85.7%)	4 (100%)	1.00[2]
	Eyelid puffiness	1 (7.1%)	0 (0%)	
	Xanthelasma	1 (7.1%)	0 (0%)	
Inspection	Abdominal contour			0.62[1]
	Flat	4 (28.6%)	2 (50%)	
	Rounded	6 (42.9%)	2 (50%)	
	Sunken	4 (28.6%)	0 (0%)	
	Skin marks			0.84[1]
	Free	9 (64.3%)	2 (50%)	
	Right iliac scar of appendectomy	1 (7.1%)	0 (0%)	
	Multiple skin nevus	1 (7.1%)	0 (0%)	
	Strech marks	1 (7.1%)	1 (25%)	
	CS scar	2 (14.3%)	1 (25%)	
Palpation	Tenderness			0.61[2]
	No	9 (64.3%)	2 (50%)	
	Yes	5 (35.7%)	2 (50%)	
	Organomegaly			1.00[1]
	None	8 (57.1%)	3 (75%)	
	Hepatomegaly	5 (35.7%)	1 (25%)	
	Hepatosplenomegaly	1 (7.1%)	0 (0%)	
Percussion	Free	8 (57.1%)	3 (75%)	1.00[1]
	Hepatomegaly	5 (35.7%)	1 (25%)	
	Hepatosplenomegaly	1 (7.1%)	0 (0%)	
Auscultation	No abnormality	11 (78.6%)	4 (100%)	1.00[1]
	Diminished intestinal sounds	3 (21.4%)	0 (0%)	

SBP: Systolic Blood Pressure, DBP: Diastolic Blood Pressure, BMI: Body Mass Index, HR: Heart Rate, RR: Respiratory Rate, C: Celsius, kg/m²: Kilograms per Square Meter.

**Student T test, Non-significant: P >0.05, Significant: P ≤0.05*

Table 6: Comparison between (G1 successful hemostasis and G2 non-successful hemostasis) regarding laboratory data

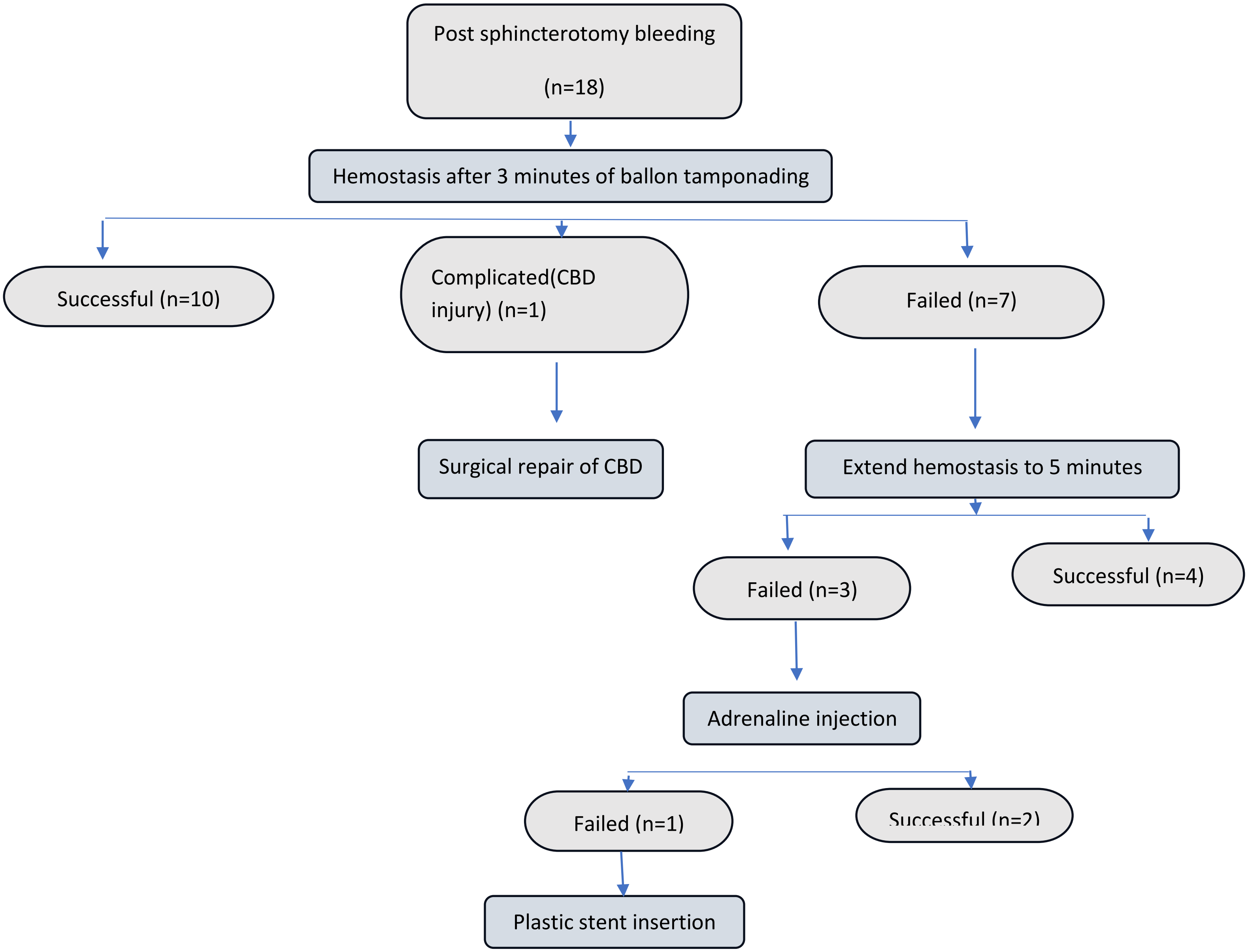
Variables		Group 1 (n=14)	Group 2 (n=4)	P Value
WBC *($10^3/mm^3$)*	*Mean ± SD*	7.26 ± 1.89	7.02 ± 2.31	0.83[1]
	Range	(4.5 – 10.4)	(4.1 – 9.7)	
Hb *(g/dL)*	*Mean ± SD*	11.76 ± 0.79	12.17± 0.89	0.39[1]
	Range	(10.7 – 13)	(11.2 – 13.2)	
PLT *($10^3/mm^3$)*	*Mean ± SD*	308 ± 88.36	384.5 ± 44.46	0.12[1]
	Range	(160 – 435)	(324 – 423)	
INR	*Mean ± SD*	1.06 ± 0.09	1.08± 0.05	0.73[1]
	Range	(0.9 – 1.2)	(1 – 1.12)	
Total bilirubin *(mg/dL)*	*Mean ± SD*	6.95 ± 1.7	5.85 ± 1.98	0.29[1]
	Range	(4.5 – 10.2)	(3.2 – 7.8)	
Direct bilirubin *(mg/dL)*	*Mean ± SD*	5.19 ± 1.58	4.5 ± 1.59	0.45[1]
	Range	(3.2 – 7.8)	(2.5 – 6.2)	
ALT *(U/L)*	*Mean ± SD*	383.2 ± 233.3	272 ± 126.3	0.38[1]
	Range	(109 – 755)	(157 – 421)	
AST *(U/L)*	*Mean ± SD*	362.4 ± 211.8	222.5 ± 74.69	0.22[1]
	Range	(140 – 724)	(145 – 316)	
Alkaline phosphatase *(IU/L)*	*Mean ± SD*	353.07 ± 176.7	309 ± 88.22	0.64[1]
	Range	(187 – 767)	(224 – 424)	
GGT *(U/L)*	*Mean ± SD*	90.79 ± 21.53	78.75 ± 8.18	0.29[1]
	Range	(58 – 128)	(69 – 86)	
Creatinine *(mg/dL)*	*Mean ± SD*	0.91 ± 0.13	0.92 ± 0.1	0.92[1]
	Range	(0.7 – 1.2)	(0.8 – 1)	
Urea *(mg/dL)*	*Mean ± SD*	26.93 ± 7.58	24.75 ± 4.27	0.59[1]
	Range	(16 – 43)	(20 – 30)	
Na *(mEq/L)*	*Mean ± SD*	139.21 ± 2.61	139.75 ± 2.99	0.73[1]
	Range	(135 – 143)	(136 – 143)	
K *(mmol/L)*	*Mean ± SD*	4.15 ± 0.35	4.02 ± 0.09	0.49[1]
	Range	(3.7 – 4.7)	(3.9 – 4.1)	
HCV *(n. %)*	Negative	12 (85.7%)	4 (100%)	1.00[2]
	Positive	2 (14.3%)	0 (0%)	
Fasting blood sugar *(gm/dl)*	*Mean ± SD*	97.93 ± 12.25	90.5 ± 11.9	0.29[1]
	Range	(76 – 124)	(80 – 107)	
Liver *(n. %)*	Enlarged, fatty liver	3 (21.4%)	0 (0%)	0.78[2]
	Normal size, homogenous	7 (50%)	3 (75%)	
	Enlarged, homogenous	4 (28.6%)	1 (25%)	
IHBR *(n. %)*	Normal	0 (0%)	0 (0%)	1.00[2]
	Dilated	14 (100%)	4 (100%)	
CBD diameter*(mm)*	*Mean ± SD*	10.1 ± 1.73	10 ± 1.41	0.94[1]
	Range	(7 – 13)	(9 – 12)	
Gall bladder	Normal gall bladder	9 (64.3%)	1 (25%)	

Variables		Group 1 (n=14)	Group 2 (n=4)	P Value
(n. %)	Calculus gall bladder	4 (28.6%)	2 (50%)	0.23^2
	Chronic calculus cholecystitis	1 (7.1%)	0 (0%)	
	Gall bladder mud	0 (0%)	1 (25%)	
Splenomegaly *(n. %)*	No	13 (92.9%)	4 (100%)	1.00^2
	Mild splenomegaly	0 (7.1%)	0 (0%)	

WBCs: White Blood Cells, Hb: Hemoglobin, PLT: Platelets, INR: International Normalized Ratio, ALT: Alanine Aminotransferase, AST: Aspartate Aminotransferase, ALP: Alkaline Phosphatase, GGT: Gamma-Glutamyl Transferase, Na: Sodium, K: Potassium, HCV: Hepatitis C Virus, IHBR: Intrahepatic Biliary Radicals, CBD: Common Bile Duct, GB: Gall Bladder.
*[1]Student T test, [2]Fisher exact test, Non-significant: P >0.05, Significant: P ≤0.05

Table 7: Comparison between (G1 successful hemostasis and G2 non-successful hemostasis) regarding the outcome of endoscopic therapy

Variables		Group 1 (n=14)	Group 2 (n=4)	P Value
Hemostasis after 3 minutes of tamponading	Failed	4 (28.6%)	4 (100%)	0.02
	Success	10 (71.4%)	0 (%)	
Need extend to 5 minutes	Not done	10 (71.4%)	1 (25%)	0.005
	Success	4 (28.6%)	0 (0%)	
	Failed	0 (0%)	3 (75%)	
Adrenaline injection	Not done	14 (100%)	1 (25%)	0.005
	Success	0 (0%)	2 (50%)	
	Failed	0 (0%)	1 (25%)	
Stent insertion	Not done	14 (100%)	3 (75%)	0.22
	Plastic stent	0 (0%)	1 (25%)	
Need surgical intervention	Not done	14 (100%)	3 (75%)	0.22
	Surgical repair of CBD	0 (0%)	1 (25%)	



Supplementary Figure 1: Post sphincterotomy bleeding outcome

Supplementary Table 1: Logistic regression analysis for predictors of successful hemostasis

Variables	Univariate analysis	
	P value	Odds (CI 95%)
Age	0.85	0.99 (0.88 – 1.10)
Sex	0.53	0.44 (0.04 – 5.41)
Smoking status	0.52	0.45 (0.03 – 4.53)
SBP	0.84	0.99 (0.86 – 1.14)
DBP	0.39	1.11 (0.88 – 1.39)

HR	0.18	0.86 (0.69 – 1.07)
RR	0.35	0.76 (0.43 – 1.35)
BMI	0.06	2.33 (0.98 – 5.54)
Temperature	0.06	0.003 (0.95 – 1.22)
FBG	0.29	0.94 (0.84 – 1.05)
WBCs	0.82	0.93 (0.51 – 1.71)
Hb	0.37	1.99 (0.45 – 8.87)
PLT	0.16	1.02 (0.99 – 1.04)
INR	0.71	1.81 (0.18 – 4.96)
Total bilirubin	0.28	0.67 (0.33 – 1.38)
Direct bilirubin	0.43	0.73 (0.33 – 1.61)
ALT	0.37	0.99 (0.99 – 1.00)
AST	0.26	0.99 (0.98 – 1.00)
Alk. phosphatase	0.62	0.99 (0.98 – 1.01)
GGT	0.29	0.96 (0.91 – 1.03)
S. creatinine	0.92	1.63 (0.76 – 1.51)
Urea	0.57	0.95 (0.79 – 1.14)
Na	0.71	1.09 (0.69 – 1.69)
K	0.48	0.22 (0.003 – 14.1)

WBCs: White Blood Cells, Hb: Hemoglobin, PLT: Platelets, INR: International Normalized Ratio, ALT: Alanine Aminotransferase, AST: Aspartate Aminotransferase, Alk. phosphatase: Alkaline Phosphatase, GGT: Gamma-Glutamyl Transferase, S. creatinine: Serum Creatinine, Na: Sodium, K: Potassium, SBP: Systolic Blood Pressure, DBP: Diastolic Blood Pressure, HR: Heart Rate, RR: Respiratory Rate, BMI: Body Mass Index, FBG: Fasting Blood Glucose.

DISCUSSION

Post-ERCP bleeding is a vital complication leading to both morbidity and mortality. It requires appropriate management and prevention that can be achieved only when various risk factors are well understood, along with expertise in endoscopic hemostasis using a side-viewing duodenoscope [7].

This prospective and retrospective cohort study aimed to evaluate the efficacy and safety of balloon tamponade for controlling post-sphincterotomy bleeding during ERCP. It was conducted in the Internal Medicine Department, Faculty of Medicine, Zagazig University Hospitals. Eighteen patients fulfilling the inclusion criteria were enrolled in the study.

Our study showed that the demographic data of the studied patients ranged from 22 to 67 years, with a mean ± SD of 40.9 ± 10.9. Similarly, Mustafa and Ali [5] evaluated the risk factors of post-ERCP bleeding and the efficacy of endoscopic intervention therapies. They found that the age of patients ranged between 32 and 57 years, with a mean age of 44.5 ± 12.5 years.

A retrospective study by Ishii et al. [8], which used a comparative method, focused on the efficacy and safety of an alternative intervention with minimal endoscopic sphincterotomy (EST) and papillary dilation (ESBD) against the standard EST. The study reviewed 435 patients with an average of 72.7 ± 12.8 years (ranging from 25 to 101 years) at the time of presentation for the intervention. An important observation was that the two groups were different in age compared to one another. Lesmana et al. [9] remarked that their patients were 20 to 98 years old, which agrees with the above authors.

In our study, males were more commonly affected than females; 61.1% were males, and

38.9% were females. Similarly, Ishii et al. [9] found 275 males and 160 females, with no significant difference between the two groups. Lesmana et al. [9] also found that most patients were males.

Mustafa and Ali [5] established that the majority, some 63% (63 cases out of 100), were female, while only 37% (37 cases out of 100) were male, yielding a female-to-male ratio of 1.7:1. This supports the notion that these females were more adversely affected than their male counterparts.

Our study showed that 10 patients (55.6%) achieved hemostasis after 3 minutes of balloon tamponade, while 7 (38.9%) failed, and 1 (5.6%) had a CBD injury. Extending tamponade to 5 minutes succeeded in 4 (22.2%), but 3 (16.7%) still failed. Of these, 2 (11.1%) responded to adrenaline injection, while 1 (5.6%) required a plastic stent. Additionally, 1 patient (5.6%) needed surgical CBD repair.

In our study, delayed bleeding occurred in seven patients from the EST group and five from the ESBD group, similar to the findings by Ishii et al. [9]. In the EST group, hemostasis was achieved with balloon tamponade in 5 patients (71.4%) and HSE injection in 2 (28.6%). In the ESBD group, 3 patients (60%) were treated with balloon tamponade and 2 (40%) with hemostatic clipping. Most cases were moderate and required prolonged hospitalization but no surgery. These outcomes align with Ishii et al. [9], who reported moderate, endoscopically manageable delayed bleeding in both groups.

Our study partially aligns with previous findings, showing no significant differences in vital signs between groups, except for higher temperatures in the successful hemostasis group. Additionally, BMI was lower in this group. Hemostasis at 3 minutes was achieved in 71.4% of group 1 and none of group 2 (P=0.02). After 5 minutes, 28.6% of group 1 achieved hemostasis, while group 2 continued to show no success (P=0.005). Adrenaline injection was needed in 50% of group 2 but not in group 1 (P=0.005).

Our findings agree with earlier data on bile duct clearance rates and the need for multiple ERCPs. An uncontrolled series involving at least 100 patients (435 procedures) reported a 68% success rate in clearing the bile duct during the first ERCP. Nineteen percent required a second ERCP, 9% underwent three or more procedures, 2.3% needed subsequent sphincterotomy, and 3.2% underwent surgery or other interventions. Mechanical lithotripsy was necessary in 35% of cases, highlighting the technical complexity. Morbidity ranged from 7% to 19%, with mild to moderate pancreatitis being most common [10].

However, direct comparison with our study is limited due to differences in study design. Some previous reports were retrospective, potentially underestimating morbidity rates [11]. Moreover, data from referral centers with older populations may not reflect outcomes in younger patients. The absence of standardized morbidity criteria across studies also hinders comparison [12]. Despite these limitations, our results reinforce the impact of patient age and case complexity on post-procedural morbidity.

Our results generally align with those of Ochi et al. [13], though their study showed a slightly higher bile duct clearance rate. In their randomized trial of 110 older patients with larger and more numerous stones, clearance was successful in 73% of the balloon dilation group and 93% of the sphincterotomy group. Morbidity occurred in 6% and 20% of these groups, respectively. However, whether standardized morbidity criteria or gabexate use influenced their outcomes is unclear. The patient selection and technique differences likely account for the slightly better clearance rates than our study.

In contrast to higher morbidity rates reported by Bergman et al. [14] and others, our study demonstrated lower overall morbidity. Bergman et al. [14] observed a 17% morbidity rate with 4% serious complications post-dilation, while another study noted 23% overall and 3% severe complications. These elevated rates may reflect the complexity of cases in tertiary centers, where elderly patients often have more comorbidities. Our lower complication rates may be due to more selective inclusion criteria and individualized procedural approaches.

We agree with the proposed mechanisms of morbidity in balloon dilation reported in previous studies [15]. Edema or spasm from dilation can cause pancreatic duct obstruction, leading to pancreatitis, biliary obstruction, and cholangitis due to incomplete stone removal. In contrast, sphincterotomy facilitates the spontaneous passage of residual stones. Our findings support this, as most complications observed were related to pancreatic or biliary duct obstruction post-procedure.

In this study, balloon tamponade proved to be an effective hemostatic tool for controlling PSB during ERCP, achieving successful hemostasis in 77.8% (14/18) of patients at 3 or 5 minutes. This finding aligns with the definition of endoscopic success described in previous literature, where initial hemostasis without the need for escalation is a key outcome.

Comparatively, our results are consistent with Lin et al. [15], who emphasized the effectiveness of balloon tamponade as part of a multimodal endoscopic approach for immediate PSB, noting its value in improving visibility and stabilizing bleeding sites. However, they reported a higher rate of secondary intervention needs than our cohort. Similarly, Mustafa and Ali [5] highlighted balloon tamponade as an effective method. Still, they noted increased pancreatitis and cholangitis rates with additional therapies such as electrocoagulation—not prominent complications in our series, indicating the safety of balloon tamponade when used alone.

Our results further contrast with Lesmana et al. [9], where novel hemostatic agents (e.g., Purastat®, Beriplast®) were associated with zero rebleeding events, while traditional methods, including balloon tamponade, showed minor failure rates. However, their population excluded coagulopathic patients, unlike ours, which included real-world mixed profiles, making our findings potentially more generalizable.

Notably, in our study, escalation beyond balloon tamponade was required in only 4 patients (22.2%), with adrenaline injection being effective in half of those and only one patient requiring stenting. These figures partially agree with Yildirim et al. [2], who noted balloon tamponade as a temporizing but not always definitive solution. Nevertheless, the high success rate in our study, especially within the first 3–5 minutes, supports balloon tamponade as a frontline hemostatic option.

No significant demographic, clinical, or laboratory predictors of hemostatic success were identified in our study (Tables 4–6), consistent with the findings of Lin et al. [15] and Yildirim et al. [2], who also reported that procedural factors rather than patient comorbidities were more influential. However, BMI and body temperature approached significance in our logistic regression, suggesting potential physiologic modifiers that merit further exploration.

Our findings partially agree with the hypothesis that balloon dilation may reduce long-term sphincterotomy complications. However, long-term data remain limited. Studies with 12–15 months of follow-up suggest only partial functional recovery post-dilation. Histologic analyses have shown mild chronic inflammation and submucosal follicular hyperplasia without fibrosis or muscle disruption—changes with uncertain clinical impact [16, 17].

Long-term safety comparisons between balloon dilation and sphincterotomy show mixed outcomes. In a randomized study with a 62-month follow-up, Tanaka et al. [18] found no significant differences between both techniques in early or late complications. However, stone recurrence occurred earlier in the dilation group. Lin et al. [15] reported similar patterns, with recurrence within 6 months after dilation and between 12–48 weeks after sphincterotomy. These findings highlight the need to weigh short-term benefits against long-term risks when choosing between the two methods.

Our findings support the selective use of papillary balloon dilation in patients with severe coagulopathies or altered anatomy, where sphincterotomy may be technically challenging [19,20]. Although this approach may lower bleeding risk, data on outcomes are limited, and some studies suggest it may increase the incidence of pancreatitis. In such high-risk cases, prophylactic pancreatic duct stenting might be beneficial.

We agree with the conclusions of Disario et al. [19], who found that balloon dilation for stone extraction is associated with higher short-term morbidity—particularly pancreatitis—compared to sphincterotomy. These findings reinforce that balloon dilation should not be considered a first-line technique in routine ERCP cases.

Consistent with Mustafa and Ali's findings [5], we observed that although endoscopic hemostatic methods are generally effective, they may carry increased risks of pancreatitis and cholangitis. These complications underscore the need for careful patient selection and prompt management during post-ERCP bleeding events.

This is the first study to highlight the practical applicability of novel hemostatic management in post-endoscopic sphincterotomy bleeding. Compared to conventional methods, balloon tamponade proved to be a more practical and accessible technique, especially for less experienced endoscopists. Our study demonstrated its advantages in addressing everyday challenges, such as localizing bleeding sites and performing interventions via a side-viewing endoscope.

This study has several limitations. The sample size was relatively small, which may limit the generalizability of our findings. Additionally, this study was conducted at a single center, potentially introducing selection bias. The retrospective data collection for some cases may have led to underreporting of complications. Furthermore, we did not evaluate long-term outcomes beyond the study follow-up period, which limits our ability to assess late complications such as stone recurrence or delayed strictures. Future multicenter, randomized controlled trials with larger sample sizes and extended follow-up are needed further to validate balloon dilation techniques' efficacy and safety.

CONCLUSION

A complete understanding of managing bleeding of various severities and potential adverse events is highly important in delivering efficient patient therapies. Therefore, balloon tamponade could be more effective and safer in managing post-sphincterotomy bleeding during endoscopic retrograde cholangiopancreatography.

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Citation

Askora, A., Ibrahim, A., Elgohary, M., Saad, N., Abu Taleb, M. Efficacy and Safety of Balloon Tamponade in Control of Post Sphincterotomy Bleeding During Endoscopic Retrograde Cholangiopancreatography. *Zagazig University Medical Journal*, 2025; (1911-1927): -. doi: 10.21608/zumj.2025.366097.3864