Open Access

Original Article

Does Endoscopic Sphincterotomy improve Plastic Biliary Stent Patency in Benign Biliary Strictures? A Comparative Analysis

Sohail Zafar, Farrukh Sher, Aliya Farooq, Saad Ali Khan, Zoya Ali Khan

Department of Gastroenterology, Pak Emirates Military Hospital/National University of Medical Sciences (NUMS), Rawalpindi Pakistan

ABSTRACT

Objective: To evaluate whether endoscopic sphincterotomy improves plastic biliary stent patency compared with stent placement without sphincterotomy.

Study Design: Comparative Cross sectional study.

Place and Duration of Study: Department of Gastroenterology, Pak Emirates Military Hospital, Rawalpindi Pakistan, from Oct 2025 to Mar 2026.

Methodology: This study enrolled adult patients with benign biliary strictures undergoing either elective or emergency Endoscopic Retrograde Cholangiopancreatography (ERCP).

Results: A total of 292 patients with benign biliary strictures were enrolled in the study, with 146 patients allocated to the sphincterotomy group (Group-A) and 146 patients to the non-sphincterotomy group (Group-B). Successful stent insertion was achieved in 92.5% of patients in the Group-A and 89.0% in the Group-B. Early complications were uncommon; post-ERCP pancreatitis occurred in 13.7% and 16.4% of patients, respectively, while bleeding was observed only in the Group-A (6.8%). Late complications, including cholangitis due to stent occlusion and stent migration, occurred at comparable rates in both groups. Median stent patency was similar between the Group-A and Group-B (110±12 vs 111±18 days). Successful stent replacement during follow-up was achieved in the majority of patients, with no significant difference between groups.

Conclusion: Routine Endoscopic sphincterotomy (ES) does not significantly improve plastic biliary stent patency and should not be performed solely for this purpose.

Keywords: Endoscopic Retrograde Cholangiopancreatography, Sphincterotomy, Stents, Treatment Outcomes.

How to Cite This Article: *Zafar S, Sher F, Farooq A, Khan SA, Khan ZA. Does Endoscopic Sphincterotomy improve Plastic Biliary Stent Patency in Benign Biliary Strictures? A Comparative Analysis. Pak Armed Forces Med J 2026; 76(Suppl-8): S1383-S1387.*
DOI: https://doi.org/10.51253/pafmj.v76iSUPPL-8.14465

INTRODUCTION

Benign biliary strictures (BBS) are an important cause of biliary obstruction and may result from post-cholecystectomy injury, chronic pancreatitis, inflammatory disorders, and postoperative complications. Endoscopic retrograde cholangiopancreatography (ERCP) with biliary stenting is currently considered the preferred first-line treatment for most patients with BBS because it provides effective biliary drainage while avoiding the morbidity associated with surgical intervention.[1]

Globally, benign biliary strictures develop in approximately 0.2–0.7% of patients undergoing cholecystectomy, while bile duct injury occurs in 0.3–0.7% of cholecystectomy procedures. Chronic pancreatitis-related biliary strictures are reported in 3–30% of patients with chronic pancreatitis, whereas biliary strictures occur in 10–40% of liver transplant recipients.[2,3] In developing countries, including Pakistan, benign biliary strictures continue to represent a significant proportion of ERCP workload because of the high volume of hepatobiliary surgery and chronic pancreatitis cases.[4] In Pakistan, post-cholecystectomy bile duct injury remains one of the leading causes of benign biliary strictures and contributes substantially to the ERCP workload at tertiary care centers.[5,6]

Plastic biliary stents are widely used in the management of benign biliary strictures owing to their low cost, ease of placement, and removability.[7,8] However, stent occlusion remains a major limitation, often necessitating repeated endoscopic procedures and increasing healthcare costs.[9,10] Several factors influence stent patency, including stent diameter, duration of placement, biliary infection, and technical aspects of stent insertion.

The role of endoscopic sphincterotomy (ES) before plastic biliary stent placement remains controversial. While some endoscopists perform routine ES to facilitate stent insertion and biliary

Correspondence: Dr Sohail Zafar, Department of Gastroenterology, Pak Emirates Military Hospital, Rawalpindi Pakistan
Received: 13 Apr 2026; revision received: 16 Jul 2026; accepted: 17 Jul 2026

drainage, others avoid it because of the associated risks of bleeding, perforation, and long-term sphincter dysfunction.[11,12] Most published studies have evaluated the role of sphincterotomy in malignant biliary strictures, whereas data regarding its role in benign biliary strictures remain limited. Therefore, this study was conducted to evaluate whether endoscopic sphincterotomy improves plastic biliary stent patency in patients undergoing ERCP for benign biliary strictures.

METHODOLOGY

This comparative Cross sectional study was carried out in the department of Gastroenterology, at Pak Emirates Military Hospital, Rawalpindi, Pakistan, from Oct 2025 to Mar 2026 after approval by institutional review board (A/28/ERC/158/25). Consecutive non-probability sampling technique was employed.

Inclusion Criteria: Patients of either gender, aged 15–60 years, with confirmed benign biliary strictures based on clinical, biochemical, and imaging findings (ultrasound, MRCP, or CT scan) were included in the study.

Exclusion Criteria: Patients were excluded if they had prior sphincterotomy, previous biliary stenting, altered surgical anatomy, coagulopathy, suspected or confirmed malignant biliary obstruction, or ampullary lesions.

All consecutive patients fulfilling the eligibility criteria and undergoing ERCP with plastic biliary stent placement during the study period were considered for inclusion. Therefore, prior sample calculation was not required. During the study period, 332 patients were screened; after applying the predefined inclusion and exclusion criteria, 292 eligible patients were enrolled and analyzed.

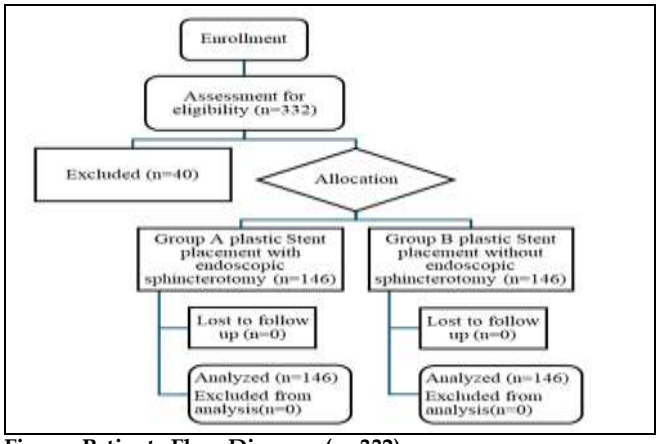

Figure: Patients Flow Diagram (n=332)

All patients undergoing ERCP with plastic biliary stent placement during the study period were screened for eligibility. A total of approximately 332 patients were initially identified. After applying inclusion and exclusion criteria, 292 patients were included in the final analysis. Patients were divided into two groups (each group containing 146 patients) based on whether endoscopic sphincterotomy (ES) was performed prior to stent placement (Figure). In Group-A, patients underwent ES followed by plastic stent placement, whereas in Group-B, stents were placed without prior sphincterotomy. Allocation to Group-A or Group-B was determined by the treating endoscopist according to procedural judgment and clinical requirements. All patients provided written informed consent and were informed of their right to withdraw from the study at any time. A 0.035-inch guidewire was used for selective cannulation of the biliary tree and to traverse the biliary stricture. Patients were sedated with weight based doses of IV midazolam and propofol. Contrast medium iopromide was used in half strength to highlight the biliary tree. Blood pressure, oxygen saturation, pulse were continuously monitored during the procedure. IV atropine was used to reduce the duodenal peristalsis where required. Patients were hydrated with continuous infusion of intravenous 0.9% normal saline during and after the procedure. In Group-A, sphincterotomy was performed using a standard triple lumen sphincterotome (Boston Scientific) prior to stent insertion. In both groups, 10F or 7Fr plastic biliary stents of appropriate lengths were placed across the stricture under fluoroscopic guidance. Successful stent placement was defined as correct positioning of the stent with adequate biliary drainage observed endoscopically and fluoroscopically. Patients were followed for early and late complications. Early complications were defined as those occurring within 30 days of the procedure, including pancreatitis, bleeding, perforation, and cholangitis. Late complications included stent occlusion and recurrent cholangitis occurring after 30 days. Stent patency was defined as the duration from stent placement to documented stent occlusion, need for re-intervention, or patient follow-up endpoint. Stent occlusion was suspected in patients presenting with recurrence of jaundice, cholangitis, or deranged liver function tests. The success of stent exchange during follow-up was also recorded and compared between the two groups.

Data were entered and analyzed using Statistical Package for Social Sciences (SPSS) 22.00. Continuous

variables were assessed for normality and presented as Mean±SD and categorical variables were expressed as frequency and percentage. Chi square test (for qualitative variables), independent sample t-test (for normally distributed continuous variables) were applied and *p*-value of ≤0.05 was considered as statistically significant

RESULTS

A total of 292 patients with benign biliary strictures were included in the study, with 146 patients allocated to each group. The mean age was significantly lower in Group A than in Group B (36.45±5.27 vs. 40.21±4.56 years; *p*-value <0.001). Similarly, the mean serum bilirubin level was significantly lower in Group A compared with Group B (210.35±10.20 vs. 260.21±9.60 µmol/L; *p*-value <0.001). A total of 166(56.8%) patients were male and 126(43.2%) were female. The gender distribution was comparable between the two groups, with males accounting for 59.6% in Group A and 54.1% in Group B (*p*-value =0.343). The distribution of stricture etiology was also similar between groups (*p*-value =0.594) with inflammatory/other causes being the most common etiology (57.2%), followed by post-cholecystectomy strictures (30.5%) and chronic pancreatitis (12.3%). The mean stent length was 6.80±1.70 cm in Group A and 7.10±1.19 cm in Group B, with no statistically significant difference between the groups as *p*-value 0.081 shown in Table-I. However, Successful stent insertion rates were similar in Group A and Group B (92.5% vs. 89.0%; *p*-value =0.312).The incidence of pancreatitis, early stent occlusion, cholangitis and stent migration did not differ significantly between the groups (*p*-values >0.05)

Table-I: Baseline Demographic and Clinical Characteristics of the Study Participants (n=292)

Variables	Group-A (n=146)	Group-B (n=146)	Total (n=292)	*p*-value
Age (years), Mean ± SD	36.45±5.27	40.21±4.56	38.33±4.91	<0.001
Gender, n(%)				
Male	87(59.6%)	79(54.1%)	166(56.8%)	0.343
Female	59(40.4%)	67(45.9%)	126(43.2%)	
Serum bilirubin (µmol/L), Mean ± SD	210.35±10.20	260.21±9.6	235.80±11.32	<0.001
Etiology of stricture, n(%)				
Post-cholecystectomy	46(31.5%)	43(29.5%)	89(30.5%)	0.594
Inflammatory/Others	80(54.8%)	87(59.6%)	167(57.2%)	
Chronic pancreatitis	20(13.7%)	16(11.0%)	36(12.3%)	
Stent length (cm), Mean±SD	6.80±1.70	7.10±1.19	6.95±1.99	0.081

However, bleeding occurred significantly more frequently in Group A than in Group B (6.8% vs. 0.0%; *p*-value =0.002). No procedure-related mortality was observed in either group (Table-II). Patients requiring stent replacement were significantly fewer in Group A than in Group B (68.5% vs. 82.2%; *p*-value =0.007). Although successful stent replacement was higher in Group B (75.3%) than in Group A (65.8%), the difference was not statistically significant (*p*-value =0.074). Similarly, the mean stent patency duration was comparable between the groups (110.00±12.38 vs. 111.92±18.52 days; *p*-value =0.295) shown in Table-III.

Table-II: Comparison of Endoscopic Technique Outcomes Between Patients With and Without Endoscopic Sphincterotomy (n=292)

Outcomes	Group-A With ES (n=146)	Group-B Without ES (n=146)	*p*-value
Successful stent insertion	135(92.5%)	130(89.0%)	0.312
Early complications			
Pancreatitis	20(13.7%)	24(16.4%)	0.513
Bleeding	10(6.8%)	0(0.0%)	0.002
Early stent occlusion	13(8.9%)	17(11.6%)	0.441
Procedure-related mortality	0(0.0%)	0(0.0%)	-
Late complications			
Cholangitis (due to occlusion)	12(8.2%)	15(10.3%)	0.544
Stent migration	6(4.1%)	2(1.4%)	0.152

Table-III: Comparison of Stent Replacement and Patency Outcomes between Patients With and Without Endoscopic Sphincterotomy (n=292)

Variables	Group-A With ES (n=146)	Group-B Without ES (n=146)	*p*-value
Patients requiring stent replacement	100(68.5%)	120(82.2%)	0.007
Successful stent replacement	96(65.8%)	110(75.3%)	0.074
Stent patency (days, Mean±SD)	110.00±12.38	111.92±18.52	0.295

DISCUSSION

The present study evaluated the impact of endoscopic sphincterotomy (ES) on plastic biliary stent patency and procedural outcomes in patients with benign biliary strictures. Our findings demonstrated that routine ES prior to plastic biliary stent placement did not significantly improve stent patency, successful stent insertion, or the rate of stent replacement during follow-up. Furthermore, the incidence of early and late complications was comparable between patients undergoing stent placement with and without ES.

Successful stent insertion was achieved in a high proportion of patients in both groups, with only a small numerical advantage in the Group-A. These findings are consistent with the study by Wilcox *et al.*, which demonstrated that routine sphincterotomy before biliary stenting does not significantly improve technical success rates in most patients undergoing endoscopic biliary drainage.[13] The comparable success rates observed in our study suggest that advances in guidewire-assisted cannulation techniques and endoscopic accessories have reduced the need for routine sphincterotomy solely to facilitate stent placement.

Post-ERCP pancreatitis remains one of the most important complications of biliary interventions. In our study, the frequency of pancreatitis was similar between the Group-A and Group-B. This finding is comparable to the studies by Sofi *et al.,* and Holt *et al.,* showing that sphincterotomy does not consistently reduce the risk of post-ERCP pancreatitis and may not provide additional protection when selective biliary cannulation is achieved.[14,15] The absence of a significant difference in pancreatitis rates in our cohort suggests that factors such as cannulation technique, procedural difficulty, and patient-related risk factors may have a greater influence on pancreatitis development than sphincterotomy itself.

Bleeding occurred exclusively in the Group-A in our study, although all cases were managed successfully without major consequences. This observation is in agreement with published literature demonstrating that sphincterotomy increases the risk of procedure-related hemorrhage. Saeed *et al.,* reported a higher incidence of bleeding among patients undergoing sphincterotomy, particularly in those with cholestasis or coagulopathy.[16] Our findings therefore support a selective rather than routine use of sphincterotomy, especially in benign disease where repeated interventions may be required over several years.

Late complications, including stent occlusion, cholangitis, and stent migration, occurred at comparable frequencies in both groups. Most importantly, median stent patency was nearly identical in patients undergoing ES and those managed without ES. These findings support the observations of Gruszecka *et al.,* who showed that stent patency is primarily determined by factors such as stent diameter, bacterial biofilm formation, sludge accumulation, and duration of stent placement rather than sphincterotomy status.[17] The lack of improvement in stent patency observed in our study suggests that routine ES does not alter the mechanisms responsible for plastic stent occlusion. Similarly, the requirement for stent replacement and the success of subsequent stent exchange procedures were comparable between the two groups. These findings are clinically important because one of the proposed advantages of ES is facilitation of future biliary access.[18] However, our results indicate that successful repeat interventions can be achieved without prior sphincterotomy in the majority of patients. This may be explained by gradual dilation of the papillary orifice caused by the indwelling stent, which facilitates subsequent endoscopic access. Local data regarding the role of sphincterotomy in benign biliary strictures remain limited. To our knowledge, this study represents one of the few analyses from Pakistan comparing outcomes of plastic biliary stenting with and without ES in patients with benign biliary strictures. The findings are consistent with international evidence and suggest that routine sphincterotomy does not provide significant clinical benefit in terms of stent patency or long term outcomes.

Overall, the results of our study indicate that routine ES before plastic biliary stent placement in benign biliary strictures offers no significant advantage in terms of stent patency, technical success, or prevention of late complications, while exposing patients to an increased risk of bleeding. Therefore, ES should be reserved for selected clinical indications rather than being performed routinely before biliary stent placement.

LIMITATION OF STUDY

This study has several limitations. First, it was conducted at a single center, which may limit the generalizability of the findings. In addition, patients were followed for a relatively short duration and long-term outcomes beyond the study period could not be assessed. Furthermore, the study was not randomized, and potential confounding factors related to stricture characteristics and stent selection may have influenced the outcomes. Future multicenter randomized studies with longer follow-up are required to further validate these findings.

CONCLUSION

Routine endoscopic sphincterotomy does not significantly improve plastic biliary stent patency and may be associated with an increased risk of bleeding. Its use should be limited to specific clinical indications rather than performed routinely.

Conflict of Interest: None.

Funding Source: None.

Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

SZ & FS: Data acquisition, data analysis, critical review, approval of the final version to be published.

AF & SAK: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

ZAK: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

REFERENCES

1. Ashat M, Berei J, El-Abiad R, Khashab MA. Benign biliary strictures: A comprehensive review. Turk J Gastroenterol 2024; 35(7): 513–522. http://doi.org/10.5152/tjg.2024.24044
2. Lindström O, Udd M, Grönroos J, Hauge T, Karjula H, Rantanen T, et al. Covered self-expandable metal stents in benign biliary strictures caused by chronic pancreatitis: a randomized controlled trial of 6 versus 12 months of stenting. Surgical Endoscopy 2026: 1-9. https://doi.org/10.1007/s00464-026-12919-x
3. Ma MX, Jayasekeran V, Chong AK. Benign biliary strictures: prevalence, impact, and management strategies. Clin Exp Gastroenterol 2019; 12: 83–92. http://doi.org/10.2147/CEG.S165016
4. Zakaria N, Tahseen MU, Niaz TS, Asim M, Yaseen A, Kadir S, et al. Endoscopic retrograde cholangiopancreatography in pediatric and adult populations: 17-year experience from Pakistan with trends, complications, and global comparison. World J Gastrointest Endosc 2025; 17(11): 109909. http://doi.org/10.4253/wjge.v17.i11.109909
5. Hussain M, Khan AW, Khan MA, Muhammad S, Mehdi H, Butt O. Managing iatrogenic bile duct injuries through a multidisciplinary team approach: A SIUT case series. J Pak Med Assoc 2019; 69(10): 1559–1564. http://doi.org/10.5455/jpma.298245
6. Hadi A, Khan I, Shah FO. Reconstruction of Iatrogenic Bile Duct Injuries following Laparoscopic Cholecystectomy. Pak J Med Sci 2025; 41(9): 2535–2539. http://doi.org/10.12669/pjms.41.9.11870
7. Khan M, Baron T, Kamal F, Ali B, Nollan R, Ismail M, et al. Efficacy of self-expandable metal stents in management of benign biliary strictures and comparison with multiple plastic stents: a meta-analysis. Endoscopy 2017; 49(7): 682–694. http://doi.org/10.1055/s-0043-109865
8. Giri S, Jearth V, Sundaram S. Covered self-expanding metal stents versus multiple plastic stents for benign biliary strictures: an updated meta-analysis of randomized controlled trials. Cureus 2022; 14(4): 24588. http://doi.org/10.7759/cureus.24588
9. Kwon C-I, Lehman GA. Mechanisms of biliary plastic Stent occlusion and efforts at prevention. Clin Endosc 2016; 49(2): 139–146. http://doi.org/10.5946/ce.2016.024
10. Ashat M, Berei J, El-Abiad R, Khashab MA. Benign biliary strictures: a comprehensive review. Turk J Gastroenterol 2024; 35(7): 513. http://doi.org/10.5152/tjg.2024.24044
11. Martins OC, Antunes V, Florêncio de Mesquita C, Correa TL, Fernandes MV, Milioli NJ, et al. The addition of endoscopic sphincterotomy to biliary stent placement and its impact on the risk of adverse events: an updated meta-analysis of randomized controlled trials. Gastrointest Endosc 2024; 100(3): 406-414.e2. http://doi.org/10.1016/j.gie.2024.05.014
12. Singh S. Role of endoscopic sphincterotomy before biliary stent placement: More risks than benefits? Gastrointest Endosc 2024; 100(3): 415-416. https://doi.org/10.1016/j.gie.2024.05.019
13. Wilcox CM, Kim H, Ramesh J, Trevino J, Varadarajulu S. Biliary sphincterotomy is not required for bile duct stent placement: Stent placement without sphincterotomy. Dig Endosc 2014; 26(1): 87–92. http://doi.org/10.1111/den.12058
14. Sofi AA, Nawras A, Alaradi OH, Alastal Y, Khan MA, Lee WM. Does endoscopic sphincterotomy reduce the risk of post-endoscopic retrograde cholangiopancreatography pancreatitis after biliary stenting? A systematic review and meta-analysis: Sphincterotomy and pancreatitis. Dig Endosc 2016; 28(4): 394–404. http://doi.org/10.1111/den.12584
15. Holt N, Saber E, Flores JE, Thomson A. ERCP in patients with prior sphincterotomy has a 50% lower rate of post-ERCP pancreatitis and fewer unplanned hospital admissions. Scand J Gastroenterol. 2022; 57(12): 1517-1521. http://doi.org/10.1080/00365521.2022.2094723
16. Saeed A, Yousuf S, Khan MA, Gangwani MK, Aziz M, Arnab R, et al. Biliary stenting with and without endoscopic sphincterotomy in patients with malignant biliary obstruction: meta-analysis of randomized controlled trials. Eur J Gastroenterol Hepatol 2025; 37(3): 257–262. http://doi.org/10.1097/MEG.0000000000002913
17. Gruszecka J, Filip R. Bacterial biofilms-A threat to biliary stents, understanding their formation, clinical consequences and management. Medicina 2025; 61(3): 512. http://doi.org/10.3390/medicina61030512
18. Fujita N, Yasuda I, Endo I, Isayama H, Iwashita T, Ueki T, et al. Evidence-based clinical practice guidelines for cholelithiasis 2021. J Gastroenterol 2023; 58(9): 801–833. http://doi.org/10.1007/s00535-023-02014-6

.....