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ORIGINAL ARTICLE

Endoscopic management of dominant strictures in primary sclerosing cholangitis: Real-world outcomes from a 12-year single-endoscopist experience

Primer sklerozan kolanjitte dominant darlıkların endoskopik yönetimi: 12 yıllık tek merkez ve tek endoskopist deneyimi

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ABSTRACT • Background and Aims: Dominant biliary strictures are a clinically important complication in primary sclerosing cholangitis that often require endoscopic therapy. Although balloon dilation with or without short-term stenting is recommended, long-term real-world outcome data remain limited. Materials and Methods: We retrospectively evaluated consecutive primary sclerosing cholangitis patients who underwent endoscopic retrograde cholangiopancreatography for dominant strictures between 2011 and 2023 at a tertiary referral center. All procedures were performed by a single experienced endoscopist. Interventions included endoscopic balloon or bougie dilation with subsequent short-term biliary drainage. The primary endpoint was recurrence-free survival at 24 months; secondary endpoints included clinical and biochemical response, disease progression, and safety outcomes. Results: A total of 35 patients (mean age 42.0 ± 13.5 years; 68.6% male) underwent 138 endoscopic procedures, with a median of three interventions per patient. Dilation was performed in 94.3% of cases, and all patients received short-term stenting or nasobiliary drainage (median duration 15 days). At three months, 78.8% of patients were asymptomatic and 80.0% achieved a ≥ 20% reduction in alkaline phosphatase. The 24-month recurrence-free survival rate was 45.4%. The overall complication rate was 8.0% (including cholangitis, pancreatitis, and stent migration), with no procedure-related mortality. Conclusion: Endoscopic management, particularly balloon dilation with short-term drainage, appears to be a safe and effective strategy for dominant strictures in primary sclerosing cholangitis, offering substantial short-term clinical and biochemical improvement with an acceptable safety profile. Nevertheless, the high recurrence rate highlights the chronic relapsing nature of the disease and emphasizes the need for structured long-term surveillance.

Key words: Primary sclerosing cholangitis, bile duct strictures, endoscopic retrograde cholangiopancreatography, balloon dilation, biliary drainage

ÖZET • Giriş ve Amaç: Primer sklerozan kolanjitte görülen dominant biliyer darlıklar, klinik açıdan önemli bir komplikasyon olup sıklıkla endoskopik tedavi gerektirmektedir. Önerilen endoskopik yaklaşım, balon dilatasyonu ile kısa süreli stentleme kombinasyonu veya tek başına balon dilatasyonu şeklindedir. Ancak, bu alandaki uzun dönem gerçek yaşam verileri sınırlıdır. Gereç ve Yöntem: 2011-2023 yılları arasında üçüncü basamak bir merkezde dominant darlık nedeniyle endoskopik retrograd kolanjiyopankreatografi uygulanan ardışık primer sklerozan kolanjit hastaları retrospektif olarak değerlendirildi. Tüm girişimler deneyimli tek bir endoskopist tarafından gerçekleştirildi. Uygulamalar, endoskopik balon veya buji dilatasyonunu takiben kısa süreli biliyer drenajı içermekteydi. Çalışmanın primer sonlanım noktası, 24. ayda nüksüz sağkalım olarak belirlendi. Sekonder sonlanım noktaları ise klinik ve biyokimyasal yanıt, hastalık progresyonu ve güvenlik sonuçlarıydı. Bulgular: Toplam 35 hasta (ortalama yaş: 42.0 ± 13.5 yıl; %68.6 erkek) üzerinde 138 endoskopik girişim gerçekleştirildi; hasta başına medyan üç işlem yapıldı. Olguların %94.3'ünde dilatasyon uygulandı ve tüm hastalara kısa süreli stent veya nazobiliyer drenaj sağlandı (medyan süre: 15 gün). Üçüncü ayda hastaların %78.8'i asemptomatikti ve %80.0'inde alkalen fosfataz düzeyinde ≥ %20 azalma saptandı. Yirmi dördüncü ayda nüksüz sağkalım oranı %45.4 olarak bulundu. Genel komplikasyon oranı %8.0 olup en sık görülenler kolanjit, pankreatit ve stent migrasyonuydu. İşlem ilişkili mortalite izlenmedi. Sonuç: Endoskopik tedavi, özellikle kısa süreli drenaj ile birlikte uygulanan balon dilatasyonu, primer sklerozan kolanjitte dominant darlıkların yönetiminde güvenli ve etkili bir yöntem olarak görünmektedir. Bu yaklaşım kısa dönemde anlamlı klinik ve biyokimyasal düzelme sağlamakta ve kabul edilebilir bir güvenlik profili sunmaktadır. Bununla birlikte, yüksek nüks oranı hastalığın kronik ve tekrarlayıcı doğasına işaret etmekte olup uzun dönemli yapılandırılmış izlemi

Anahtar kelimeler: Primer sklerozan kolanjit, safra yolu darlıkları, endoskopik retrograd kolanjiyopankreatografi, balon dilatasyonu, biliyer drenaj

INTRODUCTION

Primary sclerosing cholangitis (PSC) is a chronic, immune-mediated liver disease characterized by progressive inflammation and fibrosis of the intraand extrahepatic bile ducts, ultimately leading to cholestasis, cirrhosis, portal hypertension, and liver failure (1). The clinical course is heterogeneous, with transplant-free survival ranging between 10 and 22 years (2,3).

Magnetic resonance cholangiopancreatography (MRCP) is the preferred non-invasive imaging modality for diagnosis and follow-up (4,5). Nevertheless, endoscopic retrograde cholangiopancreatography (ERCP) remains a crucial tool in selected cases, particularly for tissue acquisition and therapeutic intervention in dominant biliary strictures (6). These strictures are defined as a narrowing of ≤ 1.5 mm in the common bile duct or ≤ 1.0 mm in the hepatic ducts within 2 cm of the hepatic confluence and are clinically significant when associated with cholestasis, abnormal liver enzymes, or symptoms (7).

Endoscopic therapy—most commonly balloon dilation, with or without short-term stenting—has been shown to improve cholestatic enzymes, relieve symptoms, and delay disease progression. Current international guidelines recommend balloon dilation as first-line treatment, reserving stenting for selected cases (8-13).

Nevertheless, the optimal management strategy remains debated, particularly regarding the role of stents, the frequency of interventions, and long-term outcomes (14,15). Despite these insights, prospective long-term real-world data remain scarce, especially from single-center or single-endoscopist experiences in different geographic regions (16). This study aimed to evaluate the long-term outcomes of endoscopic therapy for dominant strictures in PSC at a tertiary referral center. The primary endpoint was recurrence-free survival, while

secondary endpoints included clinical and biochemical response, disease progression, and safety outcomes.

MATERIALS and METHODS

Study Design and Patient Population

This retrospective study included adult patients (≥ 18 years) with a confirmed diagnosis of PSC who were referred to our center between November 2011 and March 2023 for endoscopic treatment of dominant biliary strictures. Inclusion criteria were: (1) presence of cholestatic symptoms such as pruritus, jaundice, or cholangitis; (2) elevation of cholestatic liver enzymes at least 1.5 times the upper limit of normal; and (3) presence of multifocal strictures in the biliary tract on cross-sectional imaging.

All patients underwent MRCP as part of the diagnostic work-up. In cases requiring urgent biliary drainage, ERCP was performed based on computed tomography (CT) findings, with MRCP scheduled after stabilization to assess the entire biliary tree. Serum IgG4 levels were measured in patients with suspected IgG4-related cholangitis, and carbohydrate antigen 19-9 (CA 19-9) levels were obtained in all patients. Demographic data, clinical features, laboratory parameters, imaging findings, and endoscopic treatment details were retrospectively collected by a clinician blinded to patient outcomes.

Definitions and Endpoints

Dominant biliary strictures were defined as a narrowing of ≤ 1.5 mm in the common bile duct or ≤ 1.0 mm in the hepatic ducts within 2 cm of the hepatic confluence. The primary endpoint was recurrence-free survival at 24 months among patients without initial treatment failure. Secondary endpoints included: (1) clinical success, defined as the absence of ERCP requirement within three

months of the final intervention together with symptomatic improvement and/or $a \ge 20\%$ reduction in cholestatic enzymes and bilirubin levels; (2) development of cirrhosis; and (3) recurrence of a dominant stricture, defined as radiological evidence of a new stricture occurring ≥ 3 months after the last endoscopic treatment. Post-ERCP complications such as pancreatitis and cholangitis were defined based on the Revised Atlanta Classification (17) and Tokyo Guidelines (18), respectively.

Endoscopic Procedures

Endoscopic interventions were performed by a single expert endoscopist with more than 10 years of experience of therapeutic ERCP. All ERCP procedures were performed using a standard side-viewing therapeutic duodenoscope (Olympus TJF260V, Japan). Biliary dilation was carried out using either high-pressure pneumatic balloons (4–8 mm, Boston Scientific, USA) or 7F bougie dilators (Jiuhong-Hanborough, UK). Drainage was achieved using polyethylene plastic stents or 7/10F nasobiliary drains (Micro-Tech, China), depending on individual patient characteristics.

All patients were hospitalized and underwent the procedure under conscious sedation with midazolam or propofol. Prophylactic rectal indomethacin and intravenous antibiotics were administered to minimize procedure-related complications. After selective biliary cannulation, cholangiography was performed using minimal contrast to evaluate extrahepatic and proximal intrahepatic bile ducts and to reduce the risk of post-ERCP cholangitis.

Endoscopic sphincterotomy was performed when necessary to facilitate drainage and stent placement. Depending on the cholangiographic findings and clinical presentation, two treatment strategies were employed: 1) Endoscopic dilation (balloon and/or bougie) followed by stent or nasobiliary drain placement. 2) Direct stent or drainage catheter placement without prior dilation. Balloon inflation was performed until the waist of the balloon disappeared under fluoroscopic guidance, with the insufflation pressure not exceeding 8 mmHg. Brush cytology was routinely obtained from the stricture site when malignancy could not be excluded. Treatment strategies were individualized according to patient presentation and anatomical findings, reflecting real-world clinical practice rather than a standardized protocol. Endoscopic treatment of a dominant stricture in a patient with PSC is demonstrated in Figure 1.

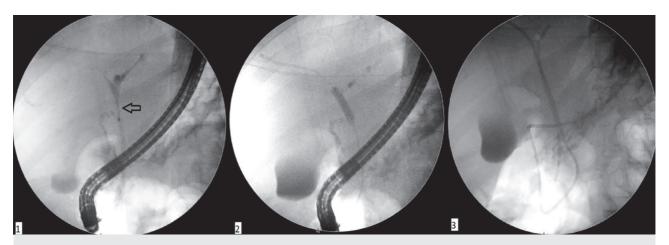


Figure 1 Dominant stricture (arrow) at the level of the common hepatic duct, cholangiogram image (1), endoscopic balloon dilatation of the stricture (2), nasobiliary drain, and plastic stent extending to the intrahepatic biliary tract (3).

Post-Procedural Monitoring and Follow-Up

Liver biochemistry and inflammatory markers (white blood cell count and C-reactive protein) were assessed at 24-, 48-, and 72-hours post-procedure. Repeat endoscopy was performed before discharge if there was insufficient clinical improvement or persistent laboratory abnormalities.

Patients showing symptomatic and biochemical improvement underwent early stent or drain removal. Follow-up visits were scheduled at two weeks and every 3–6 months thereafter, with clinical assessment and laboratory testing during each visit.

In patients with recurrent symptoms or elevated liver enzymes, MRCP was repeated, and if necessary, endoscopic therapy was reinitiated. Patients who did not respond to repeated endoscopic interventions were evaluated for liver transplantation.

Statistical Analysis

All statistical analyses were performed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA). Continuous variables were presented as mean ± standard deviation (SD) or median with interquartile range (IQR), according to data distribution assessed by the Shapiro–Wilk test. Categorical variables were expressed as frequencies and percentages. Recurrence-free survival was estimated using Kaplan–Meier analysis, and differences between subgroups were assessed by the log-rank test. Comparative statistical analyses between subgroups were not performed due to the limited sample size; results are therefore presented as descriptive statistics.

Ethics

This study protocol was approved by Ankara Bilkent City Hospital Medical Research Scientific and Ethics Evaluation Board (Date: 28.05.2025, and number TABED 2-25-1247). The study was complied with The World Medical Association Declaration of Helsinki.

RESULTS

Patient Flow and Baseline Characteristics

A total of 46 patients were initially evaluated for ERCP due to PSC-related biliary strictures. After excluding five patients with incomplete data, four who had undergone recent treatment (< 3 months), and two subsequently diagnosed with IgG4-related cholangitis, 35 patients were included in the final analysis. Of these, 24 were male (68.6%), and the mean age was 42.0 ± 13.5 years.

Sixteen patients (45.7%) had concomitant inflammatory bowel disease (14 with ulcerative colitis, 2 with Crohn's disease), and four (11.4%) had concurrent autoimmune hepatitis. At the time of ERCP, 33 patients were non-cirrhotic, while two had compensated cirrhosis.

Prior to the procedure, 25 patients underwent MRCP, which revealed dominant strictures in 18 cases, biliary irregularities or focal dilatation in 7, and biliary stones in 4. In seven patients, CT imaging demonstrated significant strictures (n = 3) or focal biliary dilatations (n = 4). The sensitivity and specificity of MRCP for identifying dominant strictures were 72% and 100%, respectively. The median CA 19-9 level was 75 U/mL (range: 0.8–2356), and all 20 patients tested for IgG4 had values within the normal range. Patient demographics and pre-procedural clinical characteristics are summarized in Table 1.

Endoscopic Interventions

In total, 138 endoscopic sessions were performed, with a median of 3 sessions per patient (range: 1–11). Dominant strictures were detected in 26 (74.3%) patients during cholangiography. Balloon dilatation was performed in 24 (68.6%) patients, while 9 (25.7%) underwent bougie dilatation. Two patients (5.7%) did not undergo dilatation. All patients received either plastic biliary stents or nasobiliary drains, based on individual clinical and anatomical factors.

In four patients, biliary stones proximal to the stricture were successfully extracted. Brush cytol-

ogy was performed in all patients, yielding a total of 51 samples. Of these, 48 were benign, and three were malignant. Two malignant samples were from the same patient. The median of stent

duration after the initial procedure was 15.0 days (range 7–75). Procedural details and outcomes of endoscopic management are summarized in Table 2.

Table 1 Patient demographics and pre-procedural clinical features	
	Study Population (n = 35)
Age, median (min max.)	39 (18 - 72)
Sex, n (%)	
Female	11 (31.4%)
Male	24 (68.6%)
Concurrent disease, n (%)	
Ulcerative colitis	14 (40.0%)
Crohn disease	2 (5.7%)
Autoimmune hepatitis	4 (11.4%)
Symptoms and findings, n (%)	
Jaundice and/or Itching	27 (77.1%)
Acute cholangitis	8 (22.9%)
Time between diagnosis and ERCP, months, median (minmax.)	19 (0 - 126)
MRCP findings, n (%)	
Dominant stricture	18 (51.4%)
Duct irregularities, segmental stricture and/or saccular dilatation	8 (22.9%)
Biliary stone	4 (11.4%)

ERCP: Endoscopic retrograde cholangiopancreatography; MRCP: Magnetic resonance cholangiopancreatography.

Table 2 Procedural details and outcomes of endoscopic management			
	Study Population ($n = 35$)		
Biliary cannulation, n (%)	35/35 (100.0%)		
Selective	33 (94.3%)		
Precut	1 (2.9%)		
Double guidewire	1 (2.9%)		
Dominant stricture localization, n (%)	26/35 (74.3%)		
Both CBD and IHBD	11 (42.3%)		
CBD	8 (30.8%)		
CHD	5 (19.2%)		
Both CBD and CHD	2 (7.7%)		
Dilatation, n (%)	33/35 (94.3%)		
Balloon dilatation	24 (68.6%)		
Bougie dilatation	9 (25.7%)		
Stent and/or nasobiliary drain placement, n (%)	35/35 (100.0%)		
Stent	19 (54.3%)		
Nasobiliary drain	12 (34.3%)		
Both stent and nasobiliary drain	4 (11.4%)		

CBD: Common bile duct; IHBD: Intrahepatic bile duct; CHD: Common hepatic duct.

Clinical and Biochemical Outcomes

At the time of discharge, 29 (82.9%) patients exhibited clinical improvement. During follow-up, 26 (74.3%) patients remained asymptomatic and free of cholangitis, and no new hepatic decompensation was observed. The two patients with cirrhosis at baseline remained in a compensated state. The median duration of follow-up was 36 months (range: 4–96).

Median alkaline phosphatase (ALP) levels decreased from 346 U/L (range: 159 - 1150) at baseline to 242 U/L (range: 98 - 1069) at 2 weeks post-procedure and 175 U/L (range: 98 - 876) at 3 months. At 3 months, 19 patients (54.3%) had ALP values < 1.5× the upper limit of normal (ULN), and 28 patients (80.0%) achieved a \geq 20% reduction. Liver biochemistry findings prior to treatment and during follow-up evaluations are summarized in Table 3.

The primary endpoint—recurrence-free survival at 24 months—was achieved in 15 patients (45.4%) among the 33 patients with follow-up durations of 24 months or more. Recurrence of dominant stricture occurred in 7 patients (21.2%) within this subgroup, all of whom required additional endoscopic intervention. Figure 2 presents the Kaplan-Meier estimate of recurrence-free survival following endoscopic treatment for dominant biliary strictures, demonstrating a 24-month recurrence-free survival rate consistent with previous reports.

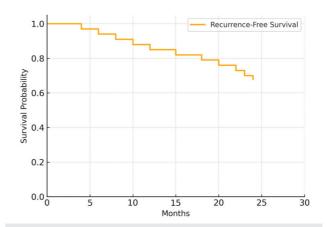


Figure 2 Recurrence-free survival following endoscopic therapy in PSC

(Kaplan–Meier analysis based on 33 patients with sufficient follow-up; censored at last visit or 24 months.)

Disease Progression and Malignancy

Five patients (14.3%) progressed to biliary cirrhosis. Two patients were referred for liver transplantation due to persistent pruritus and jaundice despite repeated endoscopic interventions. Cholangiocarcinoma was diagnosed in two patients (5.7%), who subsequently underwent surgical resection: one via hepaticojejunostomy and the other with a Whipple procedure. The two patients whose brush cytology later revealed malignancy were included in the procedural and short-term clinical analyses, as cholangiocarcinoma was diagnosed only during follow-up and not at the time of endoscopic treatment. However, after confirmation of malignancy,

Table 3 Median changes and percentage reduction in liver biochemical parameters following endoscopic treatment

Parameter	Baseline (median, range)	3 Months (median, range)	% Change From Baseline
AST, U/L	96 (44 - 312)	45 (16 - 104)	↓ 53.1%
ALT, U/L	125 (28 - 749)	54 (9 - 223)	↓ 56.8%
ALP, U/L	346 (159 - 1150)	175 (98 - 876)	↓ 49.4%
GGT, U/L	490 (91 - 1799)	105 (42 - 346)	↓ 78.6%
Total bilirubin, mg/dL	4.4 (1.7 - 15.8)	0.9 (0.5 - 4.6)	↓ 79.5%

AST: Aspartate aminotransferase; ALT: Alanine aminotransferase; ALP: Alkaline phosphatase; GGT: Gamma-glutamyl transferase.

their subsequent outcomes were excluded from recurrence-free survival analyses because therapeutic management diverged from standard PSC treatment.

Procedure-Related Complications and Mortality

A total of 11 complications (8.0%) occurred during 138 ERCP sessions. These included cholangitis in 6 cases (4.4%), pancreatitis in 4 (2.9%), and proximal stent migration in 1 (0.7%). Cholangitis was managed with antibiotics alone (n=1) or in combination with repeat drainage (n=5). All cases of pancreatitis resolved with conservative treatment. The migrated stent was retrieved endoscopically.

No procedure-related mortality occurred. Three patients died during the follow-up period. One patient died from sepsis following colectomy for high-grade dysplasia. Another died of gastrointestinal bleeding due to cholangiocarcinoma, and the third was on the liver transplant waiting list at the time of death.

DISCUSSION

This single-center retrospective study demonstrated that endoscopic therapy for dominant strictures in PSC is both safe and effective. Within three months, nearly 79% of patients achieved symptomatic improvement and 80% showed a biochemical response defined as \geq 20% reduction in ALP. However, the 24-month recurrence-free survival rate was only 45.4%, reflecting the chronic and relapsing nature of PSC. The overall complication rate was low (8.0%), and no procedure-related mortality occurred, confirming that endoscopic management is generally safe in experienced hands.

Our short-term outcomes are comparable to, or slightly better than, those previously reported. Gotthardt et al. (19) demonstrated symptomatic or biochemical improvement in approximately 75% of patients, while Gluck et al. (20) reported rates

around 70%. Similarly, the recurrence-free survival in our cohort (45.4% at 24 months) aligns with prior long-term series, which have shown recurrence in up to half of patients despite technically successful interventions (19,20). These findings confirm that recurrence is expected and should be anticipated during follow-up.

Current international guidelines recommend balloon dilation as the first-line treatment, with selective and short-term use of stents or drains (6,8,13). In our study, all patients received either a stent or nasobiliary drain in addition to dilation, reflecting institutional practice patterns during much of the study period. The median stent duration was relatively short (15 days), which likely contributed to the low complication rate. Although prior studies suggested that stenting may increase complications such as cholangitis and migration (6,21,22), our results demonstrate that short-term drainage can be safe when applied judiciously and under close follow-up. This supports the concept that procedural technique and stent duration are key determinants of safety.

The relatively high recurrence rate in our series may be attributed to the natural course of PSC, ongoing inflammatory activity, and the presence of concomitant inflammatory bowel disease in nearly half of patients. These factors are known to influence disease progression and may limit the durability of endoscopic therapy (19,20,23). Future studies with larger cohorts should aim to identify predictors of recurrence and refine the optimal interval for repeat interventions.

The strengths of this study include a well-defined patient cohort, systematic follow-up, and the unique aspect of all procedures being performed by a single experienced endoscopist, which minimizes operator variability and reflects consistent real-world practice. However, several limitations should be acknowledged. First, the retrospective

design may introduce selection bias and restrict generalizability. Second, the relatively small sample size limited statistical power and precluded reliable regression analyses to identify independent predictors of recurrence. Third, treatment strategies were individualized rather than protocolized, which, while reflecting real-world practice, may have influenced outcomes. Finally, the absence of a non-interventional control group prevents definitive conclusions regarding the superiority of endoscopic therapy over conservative management.

In conclusion, balloon dilation with short-term drainage remains a safe and effective strategy for dominant strictures in PSC. Despite favorable short-term outcomes, recurrence is frequent and long-term surveillance is essential. Our findings support current recommendations while contributing real-world long-term evidence. Future prospective multicenter studies are warranted to refine treatment intervals, identify predictors of recurrence, and clarify the role of adjunctive stenting.

Ethics Committee: This study protocol was approved by Ankara Bilkent City Hospital Medical Research Scientific and Ethics Evaluation Board (Date: 28.05.2025, and number TABED 2-25-1247).

Conflict of Interest: There is no conflict of interest with any institution or person.

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