



Endoscopic treatment outcomes in difficult bile duct stones: A single-center experience with pre-cut sphincterotomy and mechanical lithotripsy

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ABSTRACT

Introduction: Endoscopic treatment success rates and complication profiles in difficult bile duct stones may differ compared to standard cases. This study aimed to evaluate the clinical outcomes and the impact of pre-cut sphincterotomy and mechanical lithotripsy on complications in patients with difficult bile duct stones.

Materials and Methods: A total of 343 adult patients who underwent ERCP for difficult bile duct stones between March 2024 and December 2025 were retrospectively analyzed. Difficult stones were defined as stones ≥ 15 mm in diameter, the presence of multiple stones, distal bile duct stricture, or stones not removable with standard techniques. Demographic data, procedural characteristics, complications, and clinical outcomes were evaluated. Factors associated with the development of complications were analyzed using univariate and multivariate logistic regression analyses.

Results: At least one complication developed in 43 of 343 patients (12.5%). The most common complication was post-ERCP pancreatitis (7.9%). Pre-cut sphincterotomy was performed in 54 patients (15.7%), and mechanical lithotripsy in 41 patients (12.0%). The overall complete stone clearance rate was 83.4%. Although pre-cut appeared to be associated with complications in univariate analysis, it was not identified as an independent risk factor in multivariate analysis. ASA ≥ 3 , stone diameter, difficult cannulation, and procedure duration were found to be independent predictors of complications.

Conclusions: In difficult bile duct stones, pre-cut sphincterotomy and mechanical lithotripsy can be safely performed with appropriate patient selection and in experienced centers. These findings support the effective use of advanced endoscopic techniques in difficult stone cases with an acceptable safety profile.

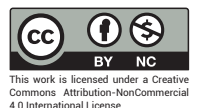
Keywords: ERCP, difficult bile duct stone, mechanical lithotripsy, post-ERCP pancreatitis, pre-cut sphincterotomy



Received: 27.02.2026 Revision: 04.03.2026 Accepted: 06.03.2026

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Introduction

Bile duct stones are a common clinical condition in the adult population and may lead to significant morbidity when symptomatic. Endoscopic retrograde cholangiopancreatography (ERCP) is accepted as the gold standard method for both diagnostic and therapeutic management of common bile duct stones.^[1,2] Complete bile duct clearance can be achieved in approximately 85–90% of cases using endoscopic sphincterotomy and standard extraction techniques.^[1,2] However, in 10–15% of patients, stone clearance becomes challenging due to stone size, number, distal bile duct anatomy, or accompanying technical difficulties, leading to the clinical entity defined as “difficult bile duct stones.”^[3,4]

Difficult bile duct stones are generally associated with stones ≥ 15 mm in diameter, multiple stones, distal common bile duct stricture, sharp angulation, impacted stones, or anatomical variations.^[3,4] In these cases, extraction with a standard balloon or basket is often insufficient, and advanced techniques such as endoscopic papillary large balloon dilation, mechanical lithotripsy, or cholangioscopy-guided laser or electrohydraulic lithotripsy may be required.^[3,5] Mechanical lithotripsy is widely used, particularly for large and hard stones; however, it may prolong the procedure and increase the risk of complications.^[5,6] Recent systematic reviews have shown that although success rates in the management of difficult stones are high, adverse event rates increase significantly as procedural complexity rises.^[4,7]

Difficult cannulation is another frequent issue in patients with difficult stones. Persistent cannulation attempts may increase the risk of post-ERCP pancreatitis (PEP).^[8,9] Therefore, early pre-cut sphincterotomy has been suggested to improve cannulation success and reduce complication rates.^[10] However, the impact of pre-cut on complication risk remains controversial. Recent meta-analyses have reported that early pre-cut, when performed by experienced endoscopists, does not increase the risk of PEP; however, patient selection and timing are critical determinants.^[10,11]

ERCP-related complications include post-ERCP pancreatitis, bleeding, perforation, and cholangitis, with an overall complication rate reported between 5–10%.^[8,12] Difficult stones, prolonged procedure time, repeated cannulation attempts, and the use of advanced techniques are among the factors associated with increased adverse event risk.^[7,9,12] Therefore, evaluating the efficacy and safety profiles

of techniques such as pre-cut sphincterotomy and mechanical lithotripsy in difficult bile duct stones using real-world data is clinically important.

In this study, the outcomes of endoscopic treatments for difficult bile duct stones were retrospectively evaluated in a single-center experience, with particular focus on the success rates and complication profiles of pre-cut sphincterotomy and mechanical lithotripsy.

Materials and Methods

Study Design and Ethical Approval

This was a single-center, retrospective cohort study conducted at the Endoscopy Unit of the Department of Gastroenterological Surgery, Gaziantep City Hospital. The study protocol was reviewed and approved by the Gaziantep City Hospital Non-Interventional Clinical Research Ethics Committee (Decision No: 416/2026, Date: 21.01.2026). The study was conducted in accordance with the Declaration of Helsinki.^[13] As the study was retrospective, written informed consent was not obtained, and all data were anonymized prior to analysis. Adult patients who underwent ERCP between March 2024 and December 2025 and met the criteria for difficult bile duct stones were retrospectively reviewed. A total of 343 eligible patients were included.

Patient Selection

Inclusion Criteria

Patients aged 18 years and older with common bile duct stones detected during ERCP were included. Patients were required to meet at least one of the difficult bile duct stone criteria: Maximum stone diameter ≥ 15 mm, the presence of multiple bile duct stones, distal bile duct stricture, or failure of stone extraction despite standard sphincterotomy with balloon/basket techniques. Additionally, the performance of sphincterotomy, pre-cut sphincterotomy, and/or mechanical lithotripsy during ERCP, as well as complete clinical and endoscopic records, were required for inclusion.

Exclusion Criteria

Patients under 18 years of age were excluded. Cases with primary malignant biliary stricture or biliary obstruction due to malignancy were excluded. Patients with prior choledochostomy, biliary bypass, or similar biliary surgical interventions were also excluded. Patients with-

out bile duct stones detected during ERCP and those with incomplete clinical or endoscopic data were excluded to maintain methodological integrity.

Data Collection and Assessed Parameters

Data were retrospectively obtained from the hospital information management system and the endoscopy unit records.

Demographic and Clinical Data

Within the scope of the study, patients' demographic and clinical data were systematically recorded. Accordingly, age and sex were evaluated as the main demographic variables, and ERCP indications were classified in detail. In addition, concomitant comorbidities were included in the analyses to comprehensively characterize the clinical features of the study population.

Stone-Related Characteristics

Stone-related characteristics were evaluated in detail and recorded. In this context, the number of stones was categorized as single or multiple, and the maximum stone diameter was measured in millimeters and analyzed. The presence of distal bile duct stricture was also recorded as a separate variable and evaluated in terms of its association with difficult stone criteria.

Endoscopic Parameters

Procedure-related endoscopic parameters were recorded in detail and analyzed. In this context, the success of standard cannulation was evaluated, and the performance of pre-cut sphincterotomy, conventional sphincterotomy, and mechanical lithotripsy was recorded as separate variables. The stone extraction method was classified as balloon or basket use. Additionally, biliary stent placement and the type of stent used were documented. Procedure duration was measured in minutes and analyzed in relation to procedural difficulty and the development of complications.

Clinical Outcomes

Clinical outcomes were comprehensively evaluated. Accordingly, the technical success rate was determined, and the achievement of complete stone clearance was analyzed. Completion of the procedure in a single session was recorded, and the need for repeat ERCP was assessed to determine the requirement for additional intervention.

Furthermore, length of hospital stay was calculated in days, and the 30-day mortality rate was analyzed to reflect early outcomes.

Complications

Procedure-related complications were evaluated in detail. Post-ERCP pancreatitis (PEP), procedure-related bleeding, perforation, and cholangitis were recorded separately. In addition, the severity of complications was classified as mild, moderate, or severe according to their clinical course, and this grading was used in the outcome analyses.

Study Definitions and ERCP Technique

The definitions used in the study and the applied endoscopic procedures were standardized in advance. Difficult bile duct stone was defined as the presence of at least one of the following: Maximum stone diameter ≥ 15 mm, multiple stones, distal bile duct stricture, or inability to extract the stone using standard techniques. Complete stone clearance was defined as the absence of residual stones on cholangiography performed at the end of the procedure. Post-ERCP pancreatitis (PEP) was defined as newly developed abdominal pain after the procedure, accompanied by a serum amylase level at least three times the upper limit of normal and requiring hospitalization.^[14] Complication severity was classified as mild, moderate, or severe according to internationally accepted criteria.^[15] The need for repeat ERCP was recorded as a planned second intervention in patients in whom complete clearance was not achieved during the initial session or in whom residual stones were clinically suspected. Difficult cannulation was defined according to ESGE criteria as the presence of at least one of the following: Biliary cannulation lasting longer than 5 minutes, more than five papillary attempts, or multiple unintended cannulations of the pancreatic duct.

All ERCP procedures were performed at a single center by endoscopists with at least five years of experience. Selective biliary cannulation was achieved using a standard cannula or sphincterotome, and pre-cut sphincterotomy was performed in cases of difficult cannulation. Following sphincterotomy, stone extraction was carried out using a balloon or basket catheter; mechanical lithotripsy was preferred in cases of large, impacted, or stones not removable by standard techniques. Temporary biliary stents were placed when deemed necessary. Procedure

duration was recorded in minutes, defined as the time from the duodenoscope reaching the papillary level to completion of the procedure.

Outcome Measures

The primary outcome was the development of any procedure-related complication. ERCP-related adverse events were recorded in accordance with internationally accepted standard definitions.^[15,16]

Secondary Outcomes

Secondary outcomes were defined to provide a more detailed assessment of procedure-related morbidity and clinical efficacy. In this context, the rates of post-ERCP pancreatitis, bleeding, perforation, and cholangitis were analyzed separately. In addition, the distribution of complication severity was evaluated, and the proportions of mild, moderate, and severe cases were determined. To reflect clinical efficacy, the complete stone clearance rate and the need for repeat ERCP were also included among the secondary outcome measures and incorporated into the statistical analyses.

Furthermore, the impact of pre-cut sphincterotomy and mechanical lithotripsy on complication rates was analyzed comparatively.

Statistical Analysis

Data analysis was performed using IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, NY, USA). The normality of continuous variables was assessed using visual and analytical methods. Variables with normal distribution were presented as mean±standard deviation, whereas non-normally distributed variables were expressed as median (minimum–maximum). Categorical variables were presented as number and percentage (%). Variables included in the multivariate model were selected from factors known to be clinically relevant and those found to be significant in univariate analysis. To prevent model overfitting, a limited number of variables were included based on the number of events. Variables included in the model were predetermined according to clinical relevance, and the stepwise method was not used.

For comparisons between groups, the chi-square test or Fisher's exact test was used for categorical variables. Continuous variables were analyzed using the Student's t-test or the Mann–Whitney U test, as appropriate. Univariate analyses were performed to identify factors associated

with the development of complications; variables found to be significant were subsequently included in the multivariate logistic regression model. Results were reported as odds ratios (OR) with 95% confidence intervals (CI). A p-value<0.05 was considered statistically significant.

In addition, a separate multivariate logistic regression analysis was conducted to identify independent factors associated with the development of post-ERCP pancreatitis. In the model constructed for PEP, variable selection was based on clinical relevance and univariate analysis results. To prevent overfitting, the event-per-variable ratio was taken into consideration. As the study was retrospective, all eligible patients meeting the criteria within the specified date range were included in the analysis, and no prior sample size calculation was performed. When constructing the multivariate model, the event-per-variable ratio was considered, and a limited number of variables were included to avoid overfitting. Given 43 complication events, a maximum of four variables were included in the model. Similarly, in the multivariate model constructed for PEP, a limited number of variables were included based on the event-per-variable ratio.

Results

Patient Characteristics

A total of 343 patients meeting the criteria for difficult bile duct stones were included in the study. The mean age was 58.3±18.2 years, and 176 patients (51.3%) were female. The proportion of patients with an ASA score ≥3 was 28.0%. The median maximum stone diameter was 16 mm (IQR: 15–20). Multiple stones were present in 44.6% of patients, impacted stones in 18.1%, and distal bile duct stricture in 21.3%. Difficult cannulation occurred in 19.5% of patients.

Rectal NSAIDs were administered as standard prophylaxis in all patients without contraindications. Rectal NSAID prophylaxis was applied in 82.2% of patients, and a prophylactic pancreatic stent was placed in 6.4%. All baseline characteristics are presented in Table 1.

Clinical Outcomes

Complete stone clearance at index ERCP was achieved in 261 patients (76.1%). After planned repeat ERCP, the final complete clearance rate increased to 83.4%. The need for repeat ERCP was 10.2%. Biliary stent placement was performed in 14.9% of patients. The 30-day mortality rate was 0.6% (n=2). These technical and clinical outcomes are summarized in Table 2.

Table 1. Baseline characteristics of the study population (n=343)

Variable	Value
Age (mean \pm SD)	58.3 \pm 18.2
Female sex (n, %)	176 (51.3)
ASA Score \geq 3 (n, %)	96 (28.0)
Maximum stone diameter (median, IQR)	16 mm (15–20)
Multiple stones (n, %)	153 (44.6)
Impacted stone (n, %)	62 (18.1)
Distal stricture (n, %)	73 (21.3)
Difficult cannulation (n, %)	67 (19.5)
Cannulation time (median, IQR)	6 min (4–10)
Procedure time (median, IQR)	38 min (25–55)
Rectal NSAID (n, %)	282 (82.2)
Prophylactic pancreatic stent (n, %)	22 (6.4)
Pre-cut (n, %)	54 (15.7)
Mechanical lithotripsy (n, %)	41 (12.0)

ASA: American Society of Anesthesiology, IQR: Interquartile range, SD: Standard deviation, NSAID: Nonsteroidal Antiinflammatory Drug.

Table 2. Technical and clinical outcomes

Outcome	n (%)
Index complete clearance	261 (76.1)
Final complete clearance	286 (83.4)
Repeat ERCP	35 (10.2)
Biliary stent	51 (14.9)
30-day mortality	2 (0.6)

ERCP: Endoscopic retrograde cholangiopancreatography.

Stone Characteristics and Procedural Parameters

A considerable proportion of cases had large and/or multiple stones. Patients with a maximum stone diameter \geq 15 mm who met the difficult stone criteria were included in the study. The decision to perform pre-cut was made by an experienced endoscopist based on clinical judgment in cases of failed standard cannulation attempts.

Pre-cut sphincterotomy was performed in 54 patients (15.7%), and mechanical lithotripsy was performed in 41 patients (12.0%). Standard sphincterotomy with balloon or basket extraction was used as the primary approach in all patients, and advanced techniques were applied when

necessary. Complete bile duct clearance was achieved in 286 patients (83.4%) during the initial or planned procedural course. Repeat ERCP was required in 35 patients (10.2%) in whom complete clearance was not achieved during the first session or in whom residual stones were suspected.

Complications

A total of 43 out of 343 patients (12.5%) experienced at least one ERCP-related complication. The most frequent adverse event was post-ERCP pancreatitis (PEP), observed in 27 patients (7.9%). Procedure-related bleeding occurred in 9 patients (2.6%), while perforation was documented in 2 patients (0.6%). Cholangitis developed in 8 patients (2.3%). Overall, the complication profile was consistent with previously reported rates for difficult bile duct stone populations.

Regarding severity distribution, no complications were observed in 300 patients (87.5%). Among patients who developed complications, 31 (9.0%) had mild, 9 (2.6%) had moderate, and 3 (0.9%) had severe adverse events. The most common complication was PEP (7.9%). All patients with severe complications required intensive care, and these cases were analyzed separately.

Although the complication rate was higher in patients who underwent mechanical lithotripsy, the difference was not statistically significant (14.6% vs 11.3%; $p=0.603$) (Table 3).

Logistic Regression Analysis

Complication Development

Univariate analysis demonstrated that the presence of ASA \geq 3, maximum stone diameter, difficult cannulation, and procedure duration were significantly associated with the development of complications. Considering their clinical relevance and statistical significance, these variables were included in the multivariate logistic regression model to control for potential confounding effects and to identify independent predictors.

In the multivariate logistic regression analysis, ASA \geq 3 (OR: 1.85; 95% CI: 1.02–3.34; $p=0.042$), stone diameter (OR: 1.06 per mm increase; 95% CI: 1.01–1.12; $p=0.019$), difficult cannulation (OR: 2.08; 95% CI: 1.10–3.95; $p=0.024$), and procedure duration (OR: 1.02 per minute increase; 95% CI: 1.00–1.04; $p=0.038$) were identified as independent pre-

Table 3. Comparison of patients with and without complications

Variable		Complication (+) (n=43) (%)	Complication (-) (n=300) (%)	p†
ASA	≥3	17 (39.5)	78 (26.0)	0.041
Multiple stones	Yes	24 (55.8)	129 (43.0)	0.118
Distal stricture	Yes	15 (34.9)	58 (19.3)	0.027
Difficult cannulation	Yes	16 (37.2)	51 (17.0)	0.004
Pre-cut	Yes	9 (20.4)	30 (10.1)	0.039
Lithotripsy	Yes	6 (14.6)	34 (11.3)	0.603
		Mean±SD		p‡
Age	Years	55.1±17.9	58.7±18.3	0.214
		Median (IQR)		p*
Stone diameter	Milimeters	18 (16-22)	16 (15-19)	0.032
Procedure duration	Minutes	47 (38-60)	36 (28-48)	0.018

ASA: American Society of Anesthesiology, IQR Interquartile Range, SD: Standard deviation, †: Chi Square Test, ‡: Student's t Test, *: Mann-Whitney U Test.

dictors of complication development. Pre-cut sphincterotomy and mechanical lithotripsy were not independently associated with complications after adjustment for confounding variables. The results of the multivariate logistic regression analysis for complication development are shown in Table 4.

PEP

In univariate logistic regression analysis, difficult cannulation (OR: 2.76; 95% CI: 1.33–5.74; p=0.006), cannulation time (OR: 1.08; 95% CI: 1.01–1.15; p=0.018), procedure duration (OR: 1.03; 95% CI: 1.00–1.06; p=0.031), female sex (OR: 1.82; 95% CI: 1.01–3.27; p=0.048), and absence of rectal NSAID prophylaxis (OR: 2.41; 95% CI: 1.10–5.29; p=0.028) were significantly associated with the development of PEP. Univariate analysis results for post-ERCP pancreatitis (PEP) are presented in Table 5.

Table 4. Multivariate logistic regression analysis for complication development

Variable		OR	95% CI	p
ASA	≥3	1.85	1.02–3.34	0.042
Stone diameter	(mm)	1.06	1.01–1.12	0.019
Difficult cannulation	Yes	2.08	1.10–3.95	0.024
Procedure duration	(min)	1.02	1.00–1.04	0.038

ASA: American Society of Anesthesiology, OR: Odds ratio, CI: Confidence interval.

In the multivariate logistic regression analysis for post-ERCP pancreatitis (PEP), difficult cannulation (OR: 2.36; 95% CI: 1.15–4.84; p=0.019), procedure duration (OR: 1.02 per minute increase; 95% CI: 1.00–1.04; p=0.041), and absence of rectal NSAID prophylaxis (OR: 2.14; 95% CI: 1.03–4.45; p=0.039) were identified as independent predictors of PEP development. The results of the multivariate logistic regression analysis for PEP are shown in Table 6.

Discussion

In this study, the outcomes of 343 patients who underwent ERCP for difficult bile duct stones were evaluated, with particular focus on the impact of pre-cut sphincterotomy and mechanical lithotripsy on technical success and complication rates. The main findings of our study were that the overall complication rate was 12.5%, the complete stone clearance rate was 83.4%, and although pre-cut appeared to be associated with an increased complication rate in univariate analysis, it was not identified as an independent risk factor in multivariate analysis. The contribution of our study to the literature lies in the evaluation of pre-cut and mechanical lithotripsy within the same statistical model in a difficult bile duct stone population using real-world data. A substantial proportion of existing studies focus either on difficult cannulation or on large stone populations, and the number of studies evaluating the combined impact of both advanced techniques on complication profiles is limited. In this respect, our findings directly contribute to clinical decision-making.

Table 5. Univariate Analysis for PEP

Variable		OR	95% CI	p
Age	Years	0.97	0.94-0.99	0.041
Gender	Female	1.82	0.33-3.27	0.048
Difficult cannulation	Yes	2.76	1.33-5.74	0.006
Cannulation time	Minutes	1.08	1.01-1.15	0.018
Procedure duration	Minutes	1.03	1.00-1.06	0.031
Pre-cut	Yes	1.94	0.95-3.95	0.072
NSAID administration	No	2.41	1.10-5.29	0.028
Pancreatic stent	Yes	0.61	0.21-1.78	0.342

NSAID: Non-steroidal Antiinflammatory Drug, OR: Odds ratio, CI: Confidence interval.

Table 6. Multivariate Logistic Regression Analysis for PEP

Variable		OR	95% CI	p
Difficult cannulation	Yes	2.36	1.15-4.84	0.019
Procedure duration (min)	Minutes	1.02	1.00-1.04	0.041
NSAID administration	No	2.14	1.03-4.45	0.039

NSAID: Non-steroidal Antiinflammatory Drug, OR: Odds ratio, CI: Confidence interval.

Difficult bile duct stones are generally defined in the literature as stones ≥ 15 mm in diameter, multiple stones, impacted stones, or stones associated with distal anatomical difficulties, and treatment success with standard techniques is reported to be lower in this population.^[17,18] Recent meta-analyses indicate that first-session success rates in difficult stone cases range between 75–90%, and complication rates are higher compared to the standard ERCP population.^[17-19] The 83.4% complete stone clearance rate observed in our study reflects a level of success consistent with the literature for the difficult stone population.

The overall complication rate in our cohort was 12.5%, which is comparable to the 8–15% range reported in difficult stone groups.^[19,20] The most common complication was post-ERCP pancreatitis (7.9%), while the rates of bleeding (2.6%), cholangitis (2.3%), and perforation (0.6%) were within the ranges reported in the literature.^[20,21] The severe complication rate being below 1% supports that the procedures were performed under experienced center conditions.

The inclusion of only difficult stone cases in our study may explain why the overall complication rate was observed at the upper limit of the range reported in the literature.

In the separate multivariate analysis performed for the development of PEP, difficult cannulation, procedure duration, and the absence of rectal NSAID prophylaxis were identified as independent risk factors. These findings are consistent with the existing literature and particularly demonstrate that difficult cannulation significantly increases the risk of pancreatitis. The absence of an independent association between pre-cut and PEP suggests that early and controlled application of pre-cut may be safe.

The apparent association between pre-cut sphincterotomy and increased complication rates in univariate analysis may be explained by confounding by indication, as this technique is generally applied in more technically challenging cases. When adjusted for major risk factors in multivariate analysis, pre-cut was not found to be an independent risk factor, suggesting that the risk of complications is more closely related to procedural difficulty rather than the technique itself. Studies reporting that early pre-cut performed by experienced endoscopists does not increase the risk of pancreatitis further support this finding.^[22,23]

No statistically significant association was found between mechanical lithotripsy and complication development.

Our findings are consistent with publications indicating that lithotripsy is a necessary technique in the presence of large stones and is safe when performed with appropriate indications.^[17,24,25] Although the complication rate was numerically higher in patients undergoing lithotripsy, this difference did not represent an independent increase in risk.

The strengths of this study include a relatively large patient population, a homogeneous difficult stone cohort, detailed recording of complications, and the performance of both univariate and multivariate analyses. Furthermore, all procedures were performed in a single high-volume center, which provides an advantage in terms of procedural standardization.

This study has certain limitations. First, due to its retrospective design, selection bias and recording errors cannot be completely excluded. Second, being a single-center experience may limit the generalizability of the results. Additionally, although the definition of difficult stones was based on criteria commonly used in clinical practice, variations in definitions across the literature may affect comparability. Moreover, the sample size was determined based on the available patient population, and statistical power may be limited, particularly in subgroup analyses.

Conclusion

Advanced endoscopic techniques can be applied with high success rates in difficult bile duct stones. The risk of complications is primarily associated with patient- and procedure-related factors reflecting procedural difficulty. Pre-cut sphincterotomy and mechanical lithotripsy can be safely used with appropriate indications and in experienced centers.

Particular attention should be paid to difficult cannulation and stone diameter as key determinants of complication development, and preventive strategies such as rectal NSAID prophylaxis should be emphasized in routine clinical practice.

Disclosures

Ethics Committee Approval: This study was approved by the Gaziantep City Hospital Non-Interventional Clinical Research Ethics Committee (No: 416/2026, Date: 21/01/2026).

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

Funding: The author declared that this study has received no financial support.

Authorship Contributions: Concept – S.A., F.K.; Design – S.A., F.K.; Supervision – S.A.; Materials – F.K.; Data collection and/or processing – S.A., F.K.; Analysis and/or interpretation – İ.C.A.; Literature review – F.K.; Writing – S.A., F.K., İ.C.A.; Critical review – S.A., F.K., İ.C.A.

Informed Consent: Written informed consent was obtained.

Use of AI for Writing Assistance: None declared.

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