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Predictive Factors for Recurrence of Choledocholithiasis After ERCP with Sphincterotomy in Benign Biliary Tract Disease

Mercedes Ibáñez-García , Juan Ramón Gómez-López , Jeancarlo Trujillo-Díaz , Pilar Concejo-Cutoli , Carlos Vaquero-Puerta , Juan Carlos Martín-del Olmo *

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Predictive Factors for Recurrence of Choledocholithiasis After ERCP with Sphincterotomy in Benign Biliary Tract Disease

Mercedes Ibáñez-García [1], Juan Ramon Gómez-López [2], Jean Carlo Trujillo-Díaz [2], Pilar Concejo-Cutoli [2], Carlos Vaquero-Puerta [3] and Juan Carlos Martín-del Olmo [2,*]

[1] Department of General Gastroenterology. Hospital Clínico Universitario, 47005 Valladolid, Spain
[2] Department of General Surgery. Hospital de Medina del Campo. Valladolid 47400. Spain
[3] Department of Surgery, Valladolid University. Valladolid 47005. Spain
* Correspondence: jcmolmo@gmail.com; Tel.: +34-62964-6199; Fax: +34-983-83-80-07

Abstract: Background/Objectives: To analyze the factors associated with recurrent choledocholithiasis following endoscopic retrograde cholangiopancreatography (ERCP) with biliary sphincterotomy (BS). **Methods:** A retrospective, observational, and analytical cohort study was conducted. Patients who underwent ERCP with BS for benign biliary pathology and were followed for a minimum of two years were included. Demographic and clinical data were collected, including the indication for the procedure, endoscopic findings, performance and timing of cholecystectomy (before or after ERCP), and the need for repeat procedures. Episodes of choledocholithiasis were defined as those occurring at least six months after the initial ERCP. Follow-up continued until patient death, loss to follow-up, or the conclusion of the study. **Results:** A total of 576 patients were included, with a mean age of 71 years and an average follow-up duration of 131 months. Sixty-nine cases of recurrent choledocholithiasis were documented (11.96%). Multivariate analysis identified the following predictive factors for recurrence: age over 50 years, bile duct dilation on initial evaluation, history of biliary surgery, cytology sampling, placement of biliary stents, repeated ERCP, biliary diversion procedures, and cholecystectomy prior to the index ERCP. **Conclusions:** Biliary duct dilation, advanced age, and any previous manipulation of the biliary tree are associated with an increased risk of recurrent choledocholithiasis. Cholecystectomy performed after the initial ERCP was not associated with a reduced recurrence risk.

Keywords: ERCP; biliary sphincterotomy; choledocholithiasis; recurrence

1. Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is an advanced endoscopic procedure that requires a steep learning curve [1]. Currently, its main indications are therapeutic in nature. When performed by experienced professionals, ERCP proves effective and presents a low complication rate, even in elderly patients or those with significant comorbidities [2,3].

The most commonly recognized complications of ERCP generally occur within the first hours or days post-procedure, with bleeding and acute pancreatitis being the most frequent [4]. However, ERCP combined with endoscopic sphincterotomy (ES) may lead to long-term adverse effects, arising months or even years after the intervention [5]. It has been hypothesized that duodenopancreatobiliary reflux, facilitated after ES, allows the ascent of pathogenic organisms into an otherwise sterile biliary tract. This phenomenon may induce epithelial damage, favor the formation of de novo bile duct stones, recurrent cholangitis, and potentially carcinogenesis [6,7].

Furthermore, several other factors, such as bile duct dilation, placement of biliary stents, biliary diversion surgeries, lithotripsy, and previous cholecystectomy, have also been associated with an increased risk of recurrent choledocholithiasis [8–11].

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The objective of our study was to identify and describe the factors associated with recurrence of choledocholithiasis in patients undergoing ERCP with endoscopic sphincterotomy.

2. Results

A total of 576 patients who met the inclusion criteria were enrolled in the study, of whom 268 (46.5%) were male and 308 (53.5%) female. The mean age was 71 years (SD: 14.41) (Table 1).

Table 1. Patients characteristics, ERCP variables and follow-up.

		n= 576 (%)
Demographic variables and comorbidity	Age	71 (IQR 64-81)
	Age > 50	510 (88,54)
	Male sex	268 (46,50)
	Female sex	308 (53,50)
	HBP	347 (60,24)
	DM	131 (22,74)
	Hepatopathy	35 (6,10)
	Chronic pancreatitis	15 (0,90)
	Peptic ulcer	67 (11,60)
	IBD	5 (0,9)
	Obesity	113 (19,6)
	No bile duct neoplasm	113 (19,60)
	Smoking	139 (24)
	Alcoholism	63 (10,9)
	Dilated BD	332 (57,64)
	Cholecystectomy	135 (23,4)
	Previous biliary surgery	49 (8,70)
ERCP index variables	Repeat ERCP	141 (24,50)
	Cytology	33 (5,70)
	Stent placement	21 (3,60)
Follow-up time (months)		131 (IQR 69-149)
End of follow-up reasons	Death for complication of ERCP	5 (0,87)
	Death for another causes	184 (31,94)
	Loss of follow-up	115 (19,97)
	Study end	272 (47,22)

*DM, diabetes mellitus; ERCP, endoscopic retrograde cholangiopancreatography; HBP, high blood pressure; IBD, inflammatory bowel disease; IQR, intercuartile range. BD, Bile duct.

The mean follow-up period was 131 months (range: 18 months to 24 years); 272 patients (47.2%) completed follow-up through the end of the study period, with 5 patients followed for up to 280 months.

The most frequent indication for the initial ERCP was analytical cholestasis, present in 157 patients (27%), followed by suspected choledocholithiasis on imaging studies in 135 cases (23.4%). Among the 262 patients diagnosed with choledocholithiasis during the index ERCP, 39 (14.88%) experienced recurrence beginning six months after the procedure.

Regardless of the indication, the most frequent diagnosis established was choledocholithiasis (Table 2).

To analyze predictive factors for long-term recurrent choledocholithiasis, the cohort was divided into two groups: patients older than 50 years (n=510) and those aged 50 or younger (n=66). Among the clinical variables recorded prior to the index ERCP, only age over 50 and bile duct dilation on imaging were statistically significant predictors of recurrence ($p < 0.05$) (Table 1).

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Table 2. Indication for ERCP and diagnosis after ERCP.

Indication for ERCP	Normal BD	Choledoco-lithiasis	Biliary sludge	Benign BD stenosis	Biliary fistula	others	Total n (%)
Post-ERCP diagnosis							
Choledocolithiasis	3 (2,22)	85 (62,96)	24 (17,78)	20 (14,81)	1 (0,07)	2 (1,48)	135(23,44)
Cholecystopancreatitis	5 (16,67)	11 (36,67)	7 (23,33)	7 (23,33)	0 (0)	0 (0)	30 (5,21)
Biliary colic	2 (7,14)	12 (42,87)	8 (28,57)	6 (21,43)	0 (0)	0 (0)	28 (4,86)
Acute pancreatitis	11 (9,02)	21 (17,21)	34 (27,87)	51 (41,80)	1 (0,82)	4 (3,28)	122(21,18)
Cholangitis	2 (2,50)	47 (58,75)	15 (18,75)	14 (17,50)	2 (2,50)	0 (0)	80 (13,89)
Cholestasis	5 (3,18)	83 (52,87)	30 (19,11)	34 (21,65)	1 (0,64)	4 (2,55)	157(27,26)
Hydatic cyst	0 (0)	0 (0)	0 (0)	2 (100)	0 (0)	0 (0)	2 (0,35)
Biliary fistula	2 (14,27)	5 (35,71)	0 (0)	3 (21,43)	4(28,57)	0 (0)	14 (2,43)
Others	0 (0)	0 (0)	0 (0)	4 (66,67)	0 (0)	2(33,33)	6 (1,04)
Overall	30 (5,21)	264 (45,84)	119 (20,68)	142 (24,65)	9 (1,41)	12 (2.01)	576 (100)

* ERCP, endoscopic retrograde cholangiopancreatography, BD; bile duct.

The presence of bile duct dilation—either in pre-procedure imaging or during the initial ERCP—was associated with recurrent choledocholithiasis in 16.6% of cases (n=55; 45 with a single episode and 10 with multiple episodes), with statistical significance ($p = 0.010$).

A total of 69 cases (11.96%) of recurrent choledocholithiasis were documented: 54 patients (9.36%) had a single episode, and 15 (2.6%) experienced multiple episodes throughout follow-up.

Repeat ERCP was performed in 141 patients, among whom 68 (48.22%) were diagnosed with choledocholithiasis on the repeated procedure. Of these, 20 patients (14.18%) subsequently developed new episodes, showing a statistically significant association between repeat ERCP and choledocholithiasis recurrence ($p < 0.001$).

History of cholecystectomy and/or biliary diversion surgery was also significantly associated with recurrence ($p < 0.05$). Notably, cholecystectomy performed after ERCP did not behave as a protective factor.

A total of 438 patients underwent cholecystectomy (135 prior to and 303 after ERCP). Among them, 50 (11.42%) experienced a single episode of choledocholithiasis, and 13 (2.97%) experienced multiple episodes. A statistically significant association was found between cholecystectomy (either pre- or post-ERCP) and long-term choledocholithiasis recurrence ($p = 0.047$). Specifically, cholecystectomy performed before the index ERCP showed a stronger association with recurrence ($p = 0.006$).

Regarding previous biliary surgery, 49 patients in the cohort had this history; among them, 12 (24.49%) developed recurrent choledocholithiasis (7 with a single episode, 5 with multiple episodes).

Other forms of biliary tract manipulation—such as stent placement, cytological sampling, and biliary diversion via endoscopic ultrasound (EUS)—were also significantly associated with recurrence ($p < 0.05$) (Table 3).

Table 3. Risk factors for recurrence of choledocholithiasis.

Recurrence choledocholithiasis N=69 (11,96 %)	***1 Episode N=54 (78,26)***	***>1 episode N= 15 (21,74)***	***P valor***
Repeat ERCP N=141 (24,48%)	6 (4,25)	14 (10,64)	0,000
Age > 50 N= 510 (88,54%)	51 (10)	13 (2,55)	0,05
Previous biliary surgery N= 49 (8,51%)	7 (14,29)	5 (10, 20)	0.001
Cholecystectomy	50 (11,41)	13 (2,97)	0.001

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N= 438 (76,04%)			
Cholecystectomy before ERCP N=135 (23,44%)	21 (15,56)	6 (4,44)	0.06
Biliary stent N=88 (15,28%)	15 (17,04)	8 (9,09)	0.000
Cytology N= 20 (3,47%)	7 (35)	3 (15)	0.000
Dilation BD N= 332 (57,65%)	45 (13,55)	10 (3,01)	0.000
BD diversion N= 8 (1,39%)	3 (37,50)	0 (0)	0.03

* ERCP, endoscopic retrograde cholangiopancreatography, BD; bile duct.

Among patients who received stents during ERCP, 15 (17.04%) developed recurrent choledocholithiasis single episode and 8 (9.09%) more than 1 episode.

Additionally, 50% (n=10) of patients who underwent cytological sampling during the index ERCP developed recurrent choledocholithiasis (7 with a single episode, 3 with multiple episodes), with statistical significance ($p < 0.001$).

Finally, biliary access via EUS (performed due to technical necessity) was associated with recurrent choledocholithiasis in 60% of cases (3 patients), also reaching statistical significance ($p < 0.001$).

The study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the Ethics Committee of Medina del Campo Hospital on February 22, 2018 (protocol code PI 18-899)

3. Materials and Methods

A retrospective, observational, and analytical cohort study was conducted without random selection of participants. A total of 576 patients who underwent 171 endoscopic retrograde cholangiopancreatographies (ERCP) with endoscopic sphincterotomy (ES) between 1995 and 2017 at a single tertiary hospital were included.

Inclusion criteria: Patients over 18 years of age, hospitalized, with no evidence of malignant pathology on the initial ERCP, and with clinical follow-up longer than two years.

Exclusion criteria: Patients under 18 years of age, those with suspected biliary neoplasia on ERCP diagnosis, those lost to scheduled follow-up, or who died before completing two years of follow-up.

Clinical and demographic variables were collected, including patient age and sex, as well as the presence of bile duct dilation on prior imaging studies. Additionally, data on the indication for ERCP, final diagnosis, and the need for instrumentation of the common bile duct (CBD) were recorded. This included stent placement, cytological sampling, or biliary diversion to the digestive tract via endoscopic ultrasound (EUS).

Other analyzed variables included recurrence of choledocholithiasis episodes, time elapsed since the initial ERCP, need for repeat procedures, and whether cholecystectomy was performed after ERCP. Only episodes of choledocholithiasis requiring hospital admission and occurring at least six months after the initial ERCP were recorded, in order to exclude residual choledocholithiasis.

Follow-up data for each patient were documented, including the date and reason for study termination. The follow-up cut-off date was December 31, 2021.

For statistical analysis, SPSS version 23.0 software was used. Qualitative variables were described using absolute frequencies and percentages; quantitative variables were expressed as means and standard deviation (SD). Inferential analysis included both univariate and multivariate analyses, with a 95% confidence interval and a significance level set at $p < 0.05$.

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Informed consent for ERCP was obtained from all participants included in the study. The database was anonymized by assigning each patient a unique identification number.

4. Discussion

Recurrent biliary obstruction due to choledocholithiasis is the most common long-term complication following endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy (ES) [12,13]. In most cases, the stones impacting the common bile duct (CBD) are primary de novo formations; they do not originate from the gallbladder and differ in composition from gallbladder stones, with brown pigment stones predominating. This phenomenon has been associated with bacterial colonization and duodenal reflux following sphincterotomy, supporting the hypothesis of secondary stone formation within the CBD [14].

In our cohort, the recurrence rate of choledocholithiasis after ERCP was 12%, a figure consistent with previous studies, especially those involving larger sample sizes and extended follow-up periods [14–17].

Our data suggest that specific factors—such as bile duct dilation at the time of index ERCP, biliary manipulation (e.g., stent placement, cytology sampling), repeat ERCP procedures, prior biliary surgery, and biliary diversion via endoscopic ultrasound (EUS)—were significantly associated with recurrent choledocholithiasis episodes. These findings are in line with the existing literature, which identifies additional risk factors including bile duct diameter, use of lithotripsy, presence of periampullary duodenal diverticulum, stone composition, pneumobilia, and the type of endoscopic intervention performed (sphincterotomy versus balloon dilation), as well as cholecystectomy [18,19].

In particular, biliary stent placement—whether to ensure complete drainage of small stones or as a prophylactic measure to prevent complications such as perforation or bleeding—has been identified as a predisposing factor for recurrence [20,21], a finding confirmed by our study.

Bile duct dilation has also been widely linked to new biliary events [22–24]. This association may be explained by biliary stasis resulting from altered motility, promoting stone formation on an already compromised biliary epithelium [14].

Regarding cholecystectomy, our results show that procedures performed prior to ERCP were associated with a higher risk of long-term benign biliary complications, particularly a higher recurrence rate of choledocholithiasis. A statistically significant difference was observed in patients who had undergone cholecystectomy before ERCP, whereas post-ERCP cholecystectomy did not appear to provide a protective effect or significantly influence complication rates, regardless of age group.

These findings are consistent with those reported by Sugiyama [25], Ando [14], and Costamagna [19], who suggest that systematic cholecystectomy after ERCP should not be universally recommended—even in younger patients—due to the low incidence of subsequent cholecystitis and the potential alteration in biliary motility that may promote recurrence. Moreover, cholecystectomy is discouraged in patients with an acalculous gallbladder, and an individualized approach based on risk factors, such as persistent biliary dilation, is recommended.

Conversely, Kanamori [15] found a higher incidence of long-term pancreatobiliary complications in patients with untreated gallstones after ERCP compared to those who underwent subsequent cholecystectomy. This finding is explained by the potential migration of gallbladder stones into the common bile duct. However, the same author emphasizes that in patients over 80 years of age, the decision to perform cholecystectomy should be individualized based on comorbid conditions.

These observations raise an important clinical question: Should systematic cholecystectomy be recommended after ERCP for choledocholithiasis? If so, in which patients and at what time point? There is also a growing need to identify subgroups of patients at higher risk of recurrence who may benefit from closer follow-up. Some authors have proposed analyzing the composition of stones extracted during ERCP as a tool to guide follow-up, since primary stones (calcium bilirubinate) are associated with higher recurrence rates compared to secondary (cholesterol) stones [26,27].

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5. Conclusions

Our findings reveal a non-negligible frequency of recurrent choledocholithiasis following ERCP, particularly in the presence of risk factors such as advanced age, bile duct dilation, and biliary manipulation. Cholecystectomy performed after ERCP did not demonstrate a protective effect against recurrence, whereas prior cholecystectomy was associated with a higher rate of long-term biliary complications. These findings underscore the need for individualized therapeutic and follow-up strategies in this patient population.

Limitations: The primary limitation of this study is its retrospective design and the absence of a control group, which may introduce bias in the interpretation of the results.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The original contributions presented in this study are included in the article. Further inquiries can be directed to the corresponding author.

Conflicts of Interest: The authors declare no conflicts of interest.

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