

## Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is a 1st-line treatment for post-cholecystectomy bile leaks (PCBL). Despite appropriate initial ERCP interventions that optimize transpapillary bile flow, PCBL can persist. We aim to evaluate baseline clinical factors associated with persistent PCBL after initial ERCP.

## Methods and Materials

We created a retrospective database of patients with PCBL referred for ERCP at Indiana University Health (IUH) University Hospital. Data collected included endoscopic reports, fluoroscopic imaging, patient demographics, type of PCBL, ERCP timing and interventions, technical success, and treatment outcomes.

A high-grade bile leak (HG-BL) was defined as visualization of contrast extravasation from the bile duct before filling of intrahepatic biliary branches with contrast (**Image 1**). The PCBL was deemed to be persistent if > 1 interventional ERCP was required for the leak to resolve on cholangiogram.

## Results

From 2011 to 2021, 369 cases of PCBL were referred for ERCP. After excluding cases with transected bile ducts (n=21) and patients lost to follow up (n=15), 333 cases were included in data analysis (**Image 2**).

21 patients received their initial ERCP at an outside hospital. All patients received biliary sphincterotomy with stenting unless there was coagulopathy or Roux-en-Y gastric bypass (n=12).

Univariate logistic regression analysis identified male gender, steroids use at time of ERCP, presence of duodenal stricture, a HG-BL, Strasberg class D PCBL, presence of biloma, presence of abdominal drain, presence of biliary stricture, and initial ERCP performed at outside hospital to be significant variables for persistent PCBL (**Table 1**).

On multivariate analysis, presence of a HG-BL (OR 7.08, CI 1.96 – 25.58, p = 0.003) and initial ERCP performed at an outside facility (OR 29.14, CI 3.35 – 253.63, p=0.002) remained significantly associated with persistent PCBL. Being a female gender (OR 0.30, CI 0.11 – 0.85, P = 0.022) remained significant for higher odds of PCBL resolution after initial ERCP.

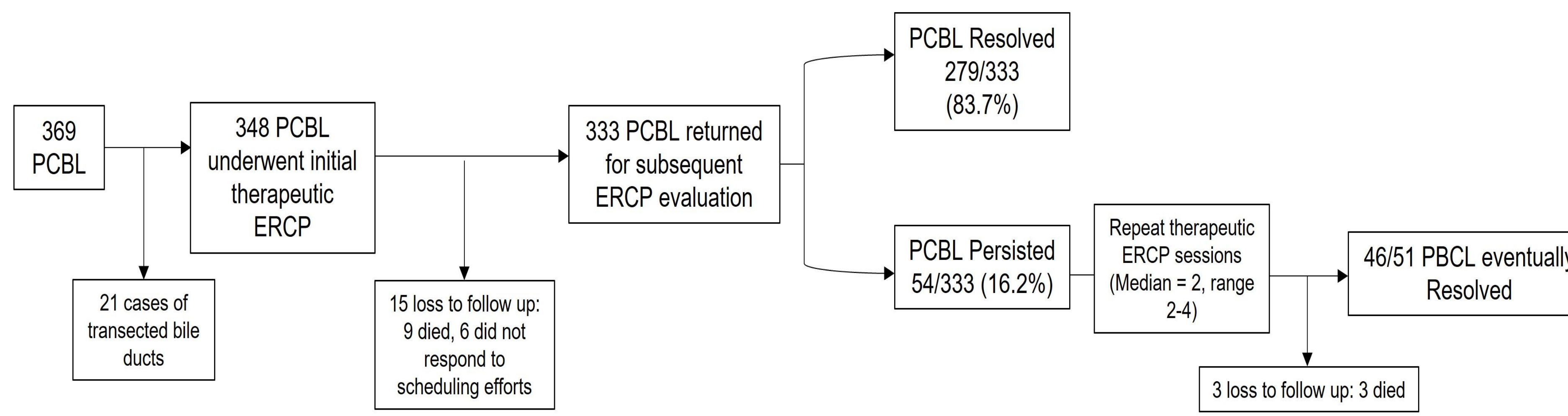
**Table 1.** Univariate analysis of clinical variables for persistent PCBL after initial ERCP treatment.

Variables	Initial ERCP failure	OR (95% CI)	P value
<b>Patient Characteristics</b>			
<b>Female</b>	25/204 (12.25%)	0.49 (0.27 – 0.86)	<b>0.013</b>
Age 55 years old or more	34/175 (19.43%)	1.60 (0.90–2.86)	0.112
Median BMI (IQR)	32.0 (26.0, 36.0)	1.00 (0.98 – 1.03)	0.874
On diabetic treatment	13/58 (22.41%)	1.81 (0.93 – 3.53)	0.083
<b>On steroids</b>	4/6 (66.67%)	10.18 (1.82 – 57.00)	<b>0.008</b>
<b>Major papilla within duodenal diverticulum</b>			
<b>Duodenal stricture/stenosis</b>	5/10 (50.00%)	5.17 (1.45 – 18.48)	<b>0.011</b>
<b>Location and timing of ERCP Procedure</b>			
ERCP performed > 3 days	48/273 (17.58%)	1.00 (0.47 – 2.12)	0.994
<b>Initial ERCP performed at outside facility</b>	17/21 (80.95%)	30.94 (9.96 – 96.06)	<b>&lt;0.001</b>
<b>Bile leak characteristics</b>			
Strasberg Class A bile leaks	44/302 (14.57%)	0.26 (0.12 – 0.54)	<b>&lt;0.001</b>
<b>Strasberg Class D bile leaks</b>	10/31 (32.26%)	2.70 (1.19 – 6.12)	<b>0.018</b>
Bile leak from cystic duct*	34/192 (17.71%)	1.25 (0.70 – 2.24)	0.446
<b>Bile leak from duct of Luschka</b>	4/104 (3.85%)	0.21 (0.09 – 0.50)	<b>&lt;0.001</b>
<b>Bile leak from common bile duct/common hepatic duct</b>	7/25 (28.00%)	2.66 (1.13 – 6.27)	<b>0.025</b>
<b>High-grade bile leak</b>	25/63 (39.68%)	4.80 (2.58 – 8.95)	<b>&lt; 0.001</b>
<b>Concomitant biloma present</b>	27/115 (23.48%)	2.06 (1.13 – 3.76)	<b>0.018</b>
<b>Percutaneous abdominal drain present</b>	42/204 (20.59%)	2.02 (1.07 – 3.82)	<b>0.030</b>
<b>Presence of biliary stones</b>	5/67 (7.46%)	0.34 (0.13 – 0.88)	<b>0.026</b>
<b>Presence of biliary stricture</b>	7/21 (33.33%)	2.63 (1.01 – 6.84)	<b>0.048</b>
<b>ERCP interventions</b>			
Biliary sphincterotomy performed	56/325 (17.23%)	1.04 (0.22 – 4.88)	0.960
Biliary sphincterotomy alone	2/6 (33.33%)	2.46 (0.44 – 13.73)	0.306
Biliary stenting alone	2/12 (16.67%)	0.96 (0.21 – 4.51)	0.960
Bridging biliary stents	20/134 (14.93%)	0.78 (0.43 – 1.43)	0.426
Multiple biliary plastic stents	6/55 (10.91%)	0.55 (0.22 – 1.36)	0.198
Self-expandable metal stent	2/11 (18.18%)	1.09 (0.23 – 5.21)	0.910

**Image 1.** Example of a high-grade bile leak from common bile duct (Strasberg class D) after cholecystectomy.



**Image 2.** Flowchart of the Study.



## Discussion

Our study suggests that a HG-BL in a male patient may justify more aggressive ERCP interventions or more prolonged stent indwell time. As a tertiary referral hospital, we had a significant referral bias in our cohort, which could have acted as a confounder causing statistical significance for lower initial ERCP success rates at outside medical facilities. The relatively high volume of ERCP cases at our center may also have contributed to better ERCP outcomes.