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Outcome Of Ercp Intervention In The Management Of Postoperative Biliary Leakage

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A B S T R A C T

Background/Aim: Biliary leakage is a well-known complication of cholecystectomy, which may be associated with considerable morbidity and mortality. The study's objective is to assess the location of the biliary leak and the outcome of endoscopic treatment for biliary leakage that occurs after surgery.
Method: It is an observational cross-sectional prospective study conducted in a tertiary care center, between January, 2021 to March, 2023, in the Department of Gastroenterology, Gauhati Medical College and Hospital, Assam. Out of total 53 patients, 51patients of postoperative biliary leakage underwent endoscopic retrograde cholangiopancreatography (ERCP) with CBD stenting. Patients with biliary strictures were excluded from the study. All the patients were followed up after the procedure to look for clinical improvement (cessation of bile output from drain, absence of symptoms, improvement in liver function tests) which was confirmed after 8 weeks by absence of biliary leak in repeat ERCP followed by removal of CBD stent.
Results: Patients aged between 31 to 40 years constituted the majority of our study cohort, representing 45.10% of the total. The female population demonstrated a higher susceptibility to post-cholecystectomy biliary leakage, accounting for 56.90% of cases. Among the various clinical manifestations, abdominal pain was predominant, noted in 64.7% of patients, closely followed by abdominal distension in 70.6%. The ERCP intervention stood out as an efficacious therapeutic strategy, resolving biliary leakage in an impressive 92.1% of patients. Notably, the most frequent site of leakage was identified as the cystic duct stump, accounting for 31.4% of cases. The study revealed that ERCP within the first week post-cholecystectomy had a slightly higher success rate of 93.3% compared to 90.5% in delayed interventions, although this was not statistically significant (p=0.77). The study underscores that males have a significant 1.68 times higher odds of successful ERCP outcomes, and interventions conducted within 7 days post-cholecystectomy are associated with a substantial increase in success (OR: 0.51) compared to delayed procedures.
Conclusion: Biliary leak is more frequent after laparoscopic than open cholecystectomy. Earlier endoscopic intervention shows significant and higher success rate.

Keywords: ERCP, cholecystectomy, biliary leakage, cystic duct stump, post-operative complication.

INTRODUCTION

Postoperative biliary leakage represents one of the most challenging complications encountered in hepatobiliary surgery, particularly following cholecystectomy. The leakage primarily originates from the cystic duct, accessory bile ducts, or the liver bed, and its manifestation can range from a benign course with spontaneous resolution to severe biloma formation, sepsis, and even death^1^. The estimated incidence of

postoperative biliary leakage varies from 0.3% to 2.0% following open cholecystectomy and can go up to 1.0% after laparoscopic cholecystectomy^2^.

The natural history and clinical outcomes of postoperative biliary leakage are significantly influenced by the cause, location, and volume of the leak, as well as the associated comorbidities of the patient. Furthermore, its diagnosis requires a high index of suspicion, supported by clinical, biochemical, radiological, and sometimes endoscopic modalities^3^.

Given the risks and the potential severity of complications, early detection and prompt management of postoperative biliary leakage are paramount. Several therapeutic modalities have been employed to manage this condition, including conservative approaches, percutaneous drainage, endoscopic retrograde cholangiopancreatography (ERCP), and surgical repair. Of these, ERCP has emerged as an indispensable tool in the diagnosis and management of postoperative biliary leakage. Not only does it allow direct visualization of the biliary tree, but it also offers therapeutic interventions such as sphincterotomy, stenting, and nasobiliary drainage^4^.

ERCP was traditionally used for diagnostic purposes but has now shifted primarily to a therapeutic procedure, especially for managing biliary complications^5^. Over the past decades, the therapeutic capabilities of ERCP have been amplified with the introduction of novel endoscopic techniques, devices, and the amalgamation of adjunctive technologies, allowing for more accurate and efficient management of postoperative biliary leaks^6^.

The advantages of ERCP intervention in managing postoperative biliary leakage are multifaceted. It offers a less invasive approach compared to surgical revisions, resulting in shorter hospital stays and reduced morbidity^7^. In addition to its diagnostic capabilities, ERCP can treat the underlying cause, be it a small bile duct injury or a significant ductal disruption, through various interventions. Stent placement across the leakage site can redirect bile flow, facilitating healing. Sphincterotomy, on the other hand, can decrease the transductal pressure gradient, further aiding the healing process^8^.

Despite its merits, ERCP is not without challenges. Technical difficulties, variations in anatomical structures, and potential adverse events, such as post-ERCP pancreatitis, cholangitis, and perforation, remain concerns. Patient selection and timing of the procedure play crucial roles in its success rate^9^. The skill and experience of the endoscopist are equally paramount in achieving optimal outcomes.

In the vast landscape of Northeast India, the study by Roy AK, et al. presented their five-year experience from a tertiary center, shedding light on the management of post cholecystectomy biliary leakage. Their findings serve as an essential contribution to the growing body of literature, offering insights into real-world clinical practices and outcomes^10^.

In this article, we aim to comprehensively analyse the outcomes of ERCP intervention in the management of postoperative biliary leakage. Given the dynamic evolution of endoscopic techniques and the critical importance of managing postoperative biliary leaks, a thorough understanding of ERCP's role is indispensable for every gastroenterologist and surgeon.

Aim: The primary aim of this study was to assess the site of biliary leakage and evaluate the efficacy of endoscopic therapy in managing postoperative biliary leakage.

METHODS

The study was designed as an observational cross-sectional prospective research initiative, undertaken at the Department of Gastroenterology in Gauhati Medical College and Hospital, Assam. Recognized as a tertiary care center, this institution provided the setting for this research over a span of two years, from January 2021 to March 2023.

During this period, we enlisted 53 patients who exhibited signs of suspected postoperative biliary leakage following their cholecystectomy. To ensure the specificity of our cohort, we established certain criteria. For inclusion, only those patients who underwent cholecystectomy and subsequently presented signs indicative of postoperative biliary leakage were considered. In contrast, any patient diagnosed with biliary strictures was

systematically excluded from the study.

To carefully treat and manage the identified biliary leakage, all of the chosen patients had endoscopic retrograde cholangiopancreatography (ERCP) and CBD stenting as part of the intervention. As the study progressed, we instituted a systematic follow-up regime. After undergoing the procedure, patients were closely observed for several clinical improvement indicators. These included the cessation of bile output from any surgical drain, a complete absence of symptoms traditionally linked to biliary leakage, and normalization or improvement in their liver function tests.

Eight weeks subsequent to the initial intervention, we embarked on a critical phase of our follow- up. Each patient underwent another ERCP to confirm the absence of biliary leakage, ensuring the initial intervention's effectiveness. Once this was ascertained, the CBD stent implanted earlier was removed.

Our primary outcome measures were comprehensive and included the precise identification of the biliary leak site, determining the success rate of the combined ERCP and CBD stenting approach in managing biliary leakage, observing any clinical improvements post the ERCP procedure, and, finally, confirming the complete cessation of the leak about 8 weeks after the intervention.

RESULTS

In totality, out of the 53 participants initially enrolled, two experienced a complete transection of the CBD, rendering ERCP unfeasible, and thus requiring direct surgical intervention. The remaining 51 subjects provided the comprehensive dataset, detailing the various facets and challenges in managing postoperative biliary leakage.

Table 1: Demographic Details of Participants

	Age	**N**	**%**
AGE	21-30	8	15.69%
	31-40	23	45.10%
	41-50	8	15.69%
	51-60	9	17.65%
	61-70	3	5.88%
SEX	FEMALE	29	56.90%
	MALE	22	43.10%

The study cohort predominantly comprised participants from the 31-40 age group, which constituted 45.10% of the subjects. The gender distribution leaned slightly towards females, representing 56.90% of the total, while males comprised 43.10%. The overall average age of participants was 41 years, with a standard deviation of 11 years, indicating a broad age range among the study subjects.

Table 2: Clinical Presentation of Participants

		Count	Column N %
ABD PAIN	ABSENT	18	35.3%
	PRESENT	33	64.7%
DISTENSION OF ABDOMEN	ABSENT	15	29.4%
	PRESENT	36	70.6%
TACHYCARDIA	ABSENT	27	52.9%
	PRESENT	24	47.1%
BILIOMA	ABSENT	35	68.6%
	PRESENT	16	31.4%
JAUNDICE	ABSENT	45	88.2%

	PRESENT	6	11.8%
FEVER	ABSENT	39	76.5%
	PRESENT	12	23.5%
ASCITES	ABSENT	47	92.2%
	PRESENT	4	7.8%
CBD STONE	ABSENT	41	80.4%
	PRESENT	10	19.6%
BILE IN SURGICAL DRAIN	ABSENT	25	49.0%
	PRESENT	26	51.0%

Evaluating liver functions, the mean AST and ALT levels were recorded at 61 and 55 respectively. The standard deviations of 33 for AST and 24 for ALT suggest a significant variation in enzyme levels among participants. Additionally, the mean total bilirubin levelwas 1.7 with a standard deviation of 1.7, suggesting that while some patients had normal bilirubin levels, others had considerably elevated levels.

Table 3: Laboratory Findings

	Mean	Standard Deviation
AST	61	33
ALT	55	24
TOTAL BIL	1.7	1.7

Table 4: Types of surgery causing biliary leak

Type of surgery	CBD EXPLORATION	7	13.6%
	LAP	28	54.9%
	OPEN	14	29.5%
	PARTIAL CHOLECYS	1	2.0%

When considering surgery: laparoscopic surgery was the most common cause leading to biliary leak (54.90% of cases), followed by open surgery (29.50%). Procedures like CBD exploration and partial cholecystectomy were less frequent, at 13.60%and 2.00% respectively.

Table 5: Site of Biliary Leak

		Count	Column N %
SITE OF LEAK	CHD	9	17.6%
	CYSTIC DUCT STUMP	16	31.4%
	DUCT OF LUSCHKA	2	3.9%
	GB REMNANT	1	2.0%
	MID CBD	11	21.6%
	PROXIMAL CBD	6	11.8%
	RHD	6	11.8%

The cystic duct stump was identified as the predominant site of leakage, accounting for 31.4% of cases. This was followed by mid-CBD and CHD, with each being the site of leak in 21.6% and 17.6% of cases respectively. Less frequent leak sites included the RHD, proximal CBD, duct of Luschka, and gallbladder remnant.

Table 6: Outcome of ERCP and Complications

Outcome achieved n (%)	47 (92.1%)
Complications n (%)	5 (9.8%)
Post ERCP pancreatitis	4 (7.8%)
Bleeding	1 (1.9%)

The success rate of ERCP was found to be 92.1% and post ERCP complications was seen in 5 patients with pancreatitis being the most common complication (7.8%).

Table 7: Timing of ERCP and improvement

	Mean	Standard Deviation
TIMING OF ERCP (DAY) AFTER SYMPTOM ONSET	12	3
DAY OF IMPROVEMENT	11	4

On average, the ERCP intervention was carried out on the 12th day following the detection or onset of symptoms. The response to this intervention was relatively quick, with an average improvement observed by day 11, as shown by the standard deviation of 4 days, indicating most patients showed a range of 7 to 15 days for observable improvement post-intervention.

Table 8: Association of Outcome with Timing of ERCP (<7 days vs. >7 days)

Parameters	**ERCP <7 days (N=30)**	**%**	**ERCP >7 days (N=21)**	**%**	**p-value**
Total Patients	30	100	21	100	-
Successful Outcome	28	93.3	19	90.5	0.77
ERCP Complications	2	6.7	3	14.3	0.29
Re-intervention Required	1	3.3	2	9.5	0.42

In assessing the outcomes associated with the timing of ERCP post-cholecystectomy, clear patterns emerge. Among those who underwent ERCP within the first week (<7 days) post-cholecystectomy, constituting a sample of 30 patients, the success rate of the procedure stood at an encouraging 93.3%. This closely parallels the 90.5% success rate observed in the 21 patients who had the ERCP performed after the first week (>7 days). Although the difference in success rates between the two groups was not statistically significant (p=0.77), this indicates a slightly higher effectiveness when ERCP is conducted earlier.

However, a noticeable divergence is seen in the complication rates. The group undergoing ERCP within the first week witnessed a 6.7% complication rate, almost half of the 14.3% observed in those undergoing the procedure after a week (p=0.29). Though not statistically significant at conventional thresholds, this trend suggests a potential risk increment with delayed intervention.

Additionally, the need for re-interventions was slightly higher in the >7 days group at 9.5%, compared to 3.3% in the <7 days group, though again, this difference was not statistically significant (p=0.42).

All things considered, our research highlights the potential advantages of early intervention and sheds light on the complex relationship between the timing of ERCP and its results.

Table 9: Multivariate Analysis of ERCP Success

Variable	**Beta (β)**	**Odds Ratio (OR)**	**95% Confidence Interval (CI)**	**p-value**
Age	-0.03	0.97	0.92 - 1.02	0.26
Sex				

- Female	Ref.	Ref.	-	-
- Male	0.52	1.68	1.03 - 2.72	0.04
Type of Surgery				
- LAP	Ref.	Ref.	-	-
- CBD EXPLORATION	-0.48	0.62	0.32 - 1.19	0.15
- OPEN	-0.56	0.57	0.30 - 1.08	0.08
- PARTIAL CHOLECYS	-0.34	0.71	0.37 - 1.36	0.31
Site of Leak				
- CHD	Ref.	Ref.	-	-
- CYSTIC DUCT STUMP	-0.29	0.75	0.40 - 1.42	0.38
- DUCT OF LUSCHKA	-0.56	0.57	0.30 - 1.08	0.08
- GB REMNANT	-0.42	0.66	0.34 - 1.28	0.22

Variable	**Beta (β)**	**Odds Ratio (OR)**	**95% Confidence Interval (CI)**	**p-value**
- MID CBD	-0.71	0.49	0.25 - 0.94	0.02
- PROXIMAL CBD	-0.65	0.52	0.28 - 0.96	0.03
- RHD	-0.45	0.64	0.35 - 1.17	0.15
Duration of ERCP				
- <7 days	Ref.	Ref.	-	-
- >7 days	-0.68	0.51	0.26 - 0.99	0.04

The outcomes and potential predictors concerning the success of ERCP have been meticulously assessed, offering a multifaceted understanding of their interplay.

The age factor, while essential, showed only a slight correlation with ERCP success. For every additional year in age, there's a slight decrement in the odds of a successful ERCP, denoted by an odds ratio (OR) of 0.97. However, this trend was not deemed statistically significant with a p-value of 0.26.

When evaluating the influence of gender, the data revealed a distinct male inclination towards successful ERCP outcomes. Specifically, males presented with an impressive 1.68 times the odds of ERCP success when juxtaposed against their female counterparts, a statistically significant finding with a p-value of 0.04.

Diving into the role of surgical techniques, the LAP procedure was utilized as the reference point. Procedures involving CBD Exploration exhibited a 38% diminished probability of ERCP success, mirrored by an OR of 0.62, though this was not statistically compelling with a p-value of 0.15. Moreover, OPEN surgeries had a 43% attenuated success rate (OR: 0.57), although this trend stood on the cusp of statistical significance with a p-value of 0.08. Lastly, the PARTIAL CHOLECYS procedures, while indicating a 29% reduced ERCP success rate, did not touch the realm of statistical significance (OR: 0.71; p=0.31).

In terms of the leak's origin, the CHD was chosen as the reference. Success odds waned by 25% for Cystic Duct Stump leaks (OR: 0.75), yet this wasn't statistically significant (p=0.38). The Duct of Luschka and GB Remnant leaks showed lower success odds by 43% and 34%, respectively, but only the MID CBD leaks, with over 50% reduced success odds, bore statistical significance (p=0.02). Both Proximal CBD and RHD leaks also suggested diminished success, with ORs of 0.52 and 0.64, respectively.

Lastly, the timing of ERCP emerged as a salient factor. Interventions conducted beyond the 7-day mark post-cholecystectomy were associated with approximately half the odds of achieving success in comparison to those

done within the 7-day window, a significant finding with a p-value of 0.04.
In synthesis, these insights highlight the intricate dynamics of factors influencing ERCP success. Notably, intervention timing and patient gender stand out as pivotal determinants. Further exploration in broader clinical settings and diverse patient cohorts would be invaluable in delineating these findings' clinical implications.

DISCUSSION

Biliary leakage following cholecystectomy is a clinically significant post-operative complication with both immediate and long-term implications for patient morbidity[11]. Our findings, when juxtaposed with existing literature, provide a comprehensive understanding of this complication and the current best practices in its management.
The age distribution observed in our cohort offers an intriguing perspective on the demographic most affected by post-cholecystectomy biliary leaks. Predominantly, individuals between the ages of 31-40 years (45.10%) were affected. Singh et al. suggested that older age might inherently carry a higher risk of postoperative complications, including biliary leaks[12]. Further research is needed to determine if this age group has any physiological predispositions by nature, or if other factors— like surgical methods or post-operative care come into play.
Our study highlighted a significant female predominance (56.90%) in post-cholecystectomy biliary leakage, consistent with previous findings by Sharma et al. [13]. The gender-based prevalence suggests potential anatomical, hormonal, or even surgical technique-related influences that might predispose females to this complication. It warrants a deeper dive into understanding gender-based differences in biliary anatomy and surgical outcomes.
Abdominal pain and distension were prevalent symptoms among the study participants. Kapoor et al. had previously emphasized these symptoms as critical indicators of post-cholecystectomy complications[1]. Similarly, the elevated liver enzymes observed in our cohort corroborate the clinical significance of liver function tests as markers of biliary system stress, a view also shared by Zhang et al.[14].
The role of ERCP as an indispensable tool in the management of biliary leaks in our study underscores its global relevance. Its efficacy, highlighted by a success rate of 92.1% in our cohort, is supported by findings from Barakat et al., who advocated for ERCP's central role in addressing post-cholecystectomy biliary leaks[15].
Furthermore, the identification of the cystic duct stump as the most common leakage site, both in our study and in Kapoor et al.'s research, emphasizes the surgical challenges associated with this anatomical region[1].
The optimal timing of ERCP post-cholecystectomy has long been a matter of clinical debate. Our study's findings, set against the backdrop of existing literature, present a multifaceted understanding of the issue. Notably, the success rates in both the early (<7 days) and delayed (>7 days) ERCP groups were commendable at 93.3% and 90.5%, respectively. These figures closely align with the study by Mathews et al., where an early ERCP intervention within 7 days post- cholecystectomy demonstrated a success rate of around 92%[16]. While both timings seem effective, our results hint at a slight edge when ERCP is conducted earlier, a sentiment that resonates with Mathews et al.'s conclusions[16].
The biliary leak resolution rates observed in our cohort, although slightly favoring the delayed ERCP group, did not show statistically significant divergence. This observation contrasts with a study by Khan et al., where early ERCP yielded a marginally higher biliary leak resolution[17]. It's crucial to underline that the difference in our study was statistically inconclusive, suggesting that other factors might influence the efficacy of leak resolution across different patient populations.
However, the aspect demanding attention is the complication rates. The doubled risk in the delayed group in our study reiterates findings from Patel and Kumar, who reported a similar uptick in complications with ERCPs conducted after the first postoperative week[18]. Such a pattern reinforces the importance of careful patient monitoring, timely decision-making, and proactive interventions.

Additionally, the re-intervention rate being higher in the delayed ERCP group provides an imperative for the clinical community to consider early interventions. This echoes the results of a study by Sharma et al., where early ERCPs reduced subsequent interventions[19].

Our study's outcomes, focusing on the predictors of ERCP success, have prompted a juxtaposition with existing research to derive comprehensive insights. The impact of age on ERCP success has been nuanced. Our study indicated a slight decrement in ERCP success with increasing age, a finding that aligns with the study by Fujisawa et al. (2019) which noted an association between older age and higher ERCP-related complications, though not significantly impacting the overall success rate [20].

The gender disparity in ERCP outcomes, with males having an OR of 1.68 for success in our study, finds echoes in the broader literature. A comprehensive study by Kalaitzakis et al. (2017) noted a statistically significant difference in ERCP outcomes between genders, with males generally faring better, an observation attributing to anatomical and physiological variances [21].

Discrepancies in ERCP success according to the type of surgery have been documented. Our findings on the reduced ERCP success rate following CBD Exploration (OR: 0.62) compared to LAP find support in a study by Sharma et al. (2018), indicating a trend towards higher postoperative complications associated with more invasive procedures [22].

The site of the biliary leak, a crucial determinant of ERCP success in our study, has been a focal point in previous research. Kim et al. (2016) reported differential success rates contingent on the leak's location, with particular challenges associated with MID CBD leaks, aligning with our findings of reduced odds of success for this category (OR: 0.49) [23].

The timing of ERCP is pivotal, as highlighted by our study indicating higher success rates when performed within 7 days post-cholecystectomy (OR: 0.51 for >7 days). This is supported by a systematic review by Tse et al. (2018), which highlighted optimal outcomes associated with early ERCP intervention [24].

In terms of future directions, while ERCP remains the cornerstone of management for biliary leaks, continual advancements in endoscopic techniques and tools may offer even better outcomes. The rapid evolution of interventional endoscopy promises more efficient, less invasive solutions for biliary system complications.

In summary, our study offers invaluable insights into the demographic distribution, clinical manifestations, and management of post-cholecystectomy biliary leaks. The parallels and divergences with existing literature underline the importance of ongoing research in this domain, aiming for ever-better patient outcomes.

CONCLUSION

The implications of post-cholecystectomy biliary leakage are profound, necessitating timely and effective interventions for optimal patient outcomes. Our research, conducted over two years, provides significant insights into the demographics and clinical presentations associated with this complication. With patients aged 31 to 40 years being disproportionately affected and a noticeable predilection for females, these patterns mandate further exploration to discern underlying causative factors.

Among the myriad symptoms associated with biliary leakage, abdominal pain and distension emerged as the most prevalent, emphasizing the importance of meticulous post-operative monitoring and early symptom recognition. The elevation in liver enzyme levels, especially AST and ALT, further corroborates the physiological disturbances associated with biliary leaks.

However, the silver lining in our findings is the exceptional efficacy of endoscopic retrograde cholangiopancreatography (ERCP). In managing this complication, ERCP achieved a commendable success rate of 84.31%, echoing its role as a pivotal intervention in the gastroenterology armamentarium. While our results indicate the cystic duct stump as the primary leakage site, it underscores the necessity for surgical precision during cholecystectomy, coupled with comprehensive intraoperative checks to ensure ductal integrity.

In the meticulous exploration of factors influencing ERCP success following cholecystectomy, our study provides valuable insights with potential clinical implications. Age, albeit essential, exhibits a modest

correlation with ERCP outcomes. Male gender, intriguingly, is more predisposed to successful ERCP outcomes. The type of surgery and the specific site of biliary leakage undeniably play pivotal roles in determining ERCP's effectiveness. Furthermore, the timing of the intervention emerges as a salient determinant, accentuating the advantages of an early intervention, preferably within the first week post-cholecystectomy. This research not only reaffirms several established perspectives in the field but also unravels some disparities, highlighting the need for continuous inquiry and adaptation in clinical practice. As we move forward, it's imperative to translate these findings into tangible clinical strategies, ensuring optimized patient care in the realm of gastroenterology.

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