



PLACEMENT OF A BILIARY STENT IN THE ANTEGRADE DIRECTION AFTER SURGICAL INTERVENTION FOR THE TREATMENT OF CHOLEDOCHOLITHIASIS

Clinical Research

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ABSTRACT

Introduction: Cholelithiasis, involving gallstones in the common bile duct, requires immediate treatment to prevent severe complications. Traditional management includes endoscopic stone removal, but alternatives like antegrade biliary stent placement are emerging, particularly after surgeries altering biliary anatomy. This approach, suitable post-surgical interventions like Roux-en-Y gastric bypass, offers a solution when endoscopic methods are impractical. The study aims to assess the efficacy, safety, and cost-effectiveness of antegrade stent placement, comparing it with conventional treatments and evaluating patient outcomes and satisfaction. **Methods:** This multicenter, prospective, observational study, conducted over 24 months at five tertiary care hospitals, aimed to evaluate antegrade biliary stent placement in patients with cholelithiasis post-surgery, where traditional methods like ERCP failed. Adults over 18 with altered biliary anatomy from surgery, not suitable for traditional endoscopic approaches, were included. Data were collected at multiple intervals post-procedure to assess efficacy, safety, and patient outcomes, with statistical analyses comparing this method to traditional management. **Results:** The primary reasons for stent placement were biliary leakage (55%), stricture formation (35%), and recurrent biliary stones (10%). The average stent size used was 10 French, with a range from 8 to 12 French. The average duration for procedures was 95 minutes, with a standard deviation of ± 20 minutes. Biliary perforation occurred in 2 cases, accounting for 1.6% of the procedures. There were 3 instances (2.4%) of bleeding that required transfusion. Follow-up durations were at 1, 3, 6, 12, and 24 months. Stent patency at six months was high, with 114 cases (90.5%) maintaining openness. Stent migration was observed in 8 cases (6.3%), while infection occurred in 14 cases (11.1%). **Conclusion:** The study supports and builds on existing research, affirming the efficacy, safety, and patient satisfaction of antegrade biliary stenting for cholelithiasis post-surgery, suggesting areas for future improvement.

KEYWORDS

Cholelithiasis, Antegrade Biliary Stenting, Surgical Intervention, Biliary Complications, Stent Placement

INTRODUCTION

Cholelithiasis, characterized by the presence of gallstones in the common bile duct (CBD), is a significant health issue that impacts millions of individuals worldwide.¹ These stones can lead to severe complications such as biliary colic, cholangitis, and pancreatitis, necessitating prompt medical intervention.²

Traditionally, the management of cholelithiasis involves endoscopic retrograde cholangiopancreatography (ERCP) with stone extraction.³ However, in cases where ERCP is not successful or feasible due to anatomical variations or after certain surgical interventions, alternative strategies are required.⁴ One such alternative is the placement of a biliary stent in the antegrade direction—a technique that has been emerging as a viable option post-surgical intervention. This approach is typically considered following surgeries such as a Roux-en-Y gastric bypass or in situations where the anatomy of the biliary tract has been altered, making traditional endoscopic approaches challenging or impossible.⁵ Biliary stents are small tubes inserted into the bile duct to ensure its patency and facilitate the flow of bile. While stent placement is a common procedure, the antegrade approach is distinct in that the stent is inserted in the direction of bile flow, which can be technically challenging but potentially advantageous in certain clinical scenarios.⁶ This method can be performed during or after surgical interventions and has been shown to address complications arising from obstructed bile flow due to stones, strictures, or surgery-induced alterations.

The evolution of biliary stenting techniques and materials has significantly contributed to the expansion of therapeutic options available for cholelithiasis.⁷ The development of more flexible, durable, and compatible stents has allowed for improved patient outcomes, reduced complication rates, and enhanced quality of life for those suffering from biliary tract diseases.

The rationale behind exploring the antegrade placement of biliary stents following surgical intervention stems from the limitations and

challenges associated with traditional post-operative biliary management techniques.⁸ Post-surgical anatomy, especially after complex gastrointestinal surgeries, can render standard endoscopic approaches ineffective or associated with higher risk.⁸ Additionally, patients who undergo such procedures often have an increased risk of biliary complications, including the formation of new stones, strictures, and leaks, necessitating innovative approaches to management.

Moreover, the antegrade placement of biliary stents represents an area of clinical practice with limited comprehensive studies.⁹ While initial reports and case studies suggest potential benefits, there is a clear need for more robust evidence to establish best practices, understand long-term outcomes, and identify which patient populations may benefit most from this approach. Given the significant morbidity associated with untreated or inadequately managed cholelithiasis, identifying effective and safe post-surgical biliary management strategies is crucial.

Furthermore, as healthcare continues to advance, there is an increasing number of patients with altered gastrointestinal anatomy due to bariatric or other complex surgeries.¹⁰ These patients present a growing demographic experiencing cholelithiasis, underscoring the need for adaptable and innovative treatment methodologies. The antegrade biliary stent placement could offer a novel solution for these complex cases, potentially leading to better clinical outcomes and reduced healthcare costs associated with recurrent hospitalizations and interventions.¹¹

The primary objective of this research study is to evaluate the efficacy and safety of antegrade biliary stent placement following surgical interventions in patients with cholelithiasis. This will involve assessing the success rate of stent placements, the incidence of procedure-related complications, and the long-term outcomes of patients, including rates of stone recurrence, stent occlusion, and the need for additional interventions.

Secondary objectives include:

1. Comparing the clinical outcomes of antegrade biliary stent placement with traditional management approaches, such as ERCP and percutaneous transhepatic cholangiography (PTC), in post-surgical patients.
2. Identifying patient characteristics and surgical factors that may predict the success or failure of antegrade stent placement.
3. Evaluating the cost-effectiveness of antegrade biliary stent placement in comparison to alternative treatment strategies.
4. Investigating patient quality of life and satisfaction following antegrade stent placement versus other biliary management techniques.
5. Determining the technical challenges and learning curve associated with the antegrade approach to biliary stent placement.

Methods

Study Design

This study was conducted as a multicenter, prospective, observational study over a period of 24 months. The study aimed to enroll patients diagnosed with choledocholithiasis who had undergone surgical intervention and for whom traditional post-operative biliary management, such as ERCP, was not viable or had been unsuccessful. The primary focus was on patients undergoing antegrade biliary stent placement to manage biliary complications post-surgery. This design allowed for the collection of real-world data regarding the efficacy, safety, and patient outcomes associated with this treatment modality.

Setting

The study was conducted across five tertiary care hospitals with specialized hepatobiliary units. These centers were equipped with the necessary endoscopic and surgical facilities and had a high volume of patients presenting with complex biliary diseases, providing a diverse patient population for recruitment and analysis.

Study Participants

Patients eligible for inclusion were those aged 18 years and above, diagnosed with choledocholithiasis, and had undergone surgical intervention that altered the anatomy of the biliary tract, rendering traditional endoscopic approaches impractical. Patients must also have had documented failure or contraindications to ERCP or PTC. Exclusion criteria included patients with uncorrected coagulopathies, active infections, pregnant women, and those unable to provide informed consent.

Inclusion Criteria

1. Age 18 years and older.
2. Diagnosed with choledocholithiasis by imaging or during surgical intervention.
3. Undergone surgical intervention that alters the anatomy of the biliary tract, making traditional endoscopic approaches to biliary management impractical or impossible.
4. Documented failure of or contraindications to endoscopic retrograde cholangiopancreatography (ERCP) or percutaneous transhepatic cholangiography (PTC).
5. Able to provide informed consent for participation in the study.
6. Available for follow-up for the duration of the study period (as specified by the study protocol)

Exclusion Criteria

1. Age under 18 years.
2. Uncontrolled coagulopathies that pose a significant risk for procedural bleeding.
3. Active systemic infections that contraindicate procedural intervention.
4. Pregnant or breastfeeding women.
5. Patients with known allergies or contraindications to the materials used in the stents or contrast media required for imaging.
6. Severe liver dysfunction or liver failure (as specified by criteria such as Child-Pugh Class C).
7. Previous enrolment in the study or participation in another study that could interfere with the outcome measures of this study.
8. Inability to provide informed consent or comply with study requirements for any reason.
9. History of allergic reactions to materials involved in the stent placement procedure or contrast media used during imaging studies.
10. Patients with life expectancy less than the duration of the study due to non-biliary diseases.

Intervention

Participants underwent antegrade biliary stent placement post-surgical intervention. The procedure was performed under fluoroscopic guidance by experienced hepatobiliary surgeons or interventional radiologists. Details of the surgical intervention, including the type of surgery, reason for stent placement, and specifics of the antegrade technique, were recorded.

Data Collection

Data were collected at baseline, immediately post-procedure, and at follow-up intervals of 1, 3, 6, 12, and 24 months. Baseline data included patient demographics, medical history, details of the choledocholithiasis diagnosis, and previous treatments. Procedure-related data encompassed the type and size of the stent, duration of the procedure, immediate technical success, and any intraoperative complications. Post-procedure and follow-up data focused on clinical outcomes, including stent patency, incidence of stent-related complications, rates of stone recurrence, need for additional interventions, and patient-reported outcomes on quality of life and satisfaction. Adverse events were classified according to severity and relationship to the stent placement.

Outcome Measures

The primary outcome measure was the technical and clinical success rate of antegrade biliary stent placements, defined as the successful placement of the stent without immediate procedure-related complications and the resolution of symptoms or biliary obstruction. Secondary outcomes included the incidence of stent-related complications, rates of stone recurrence, need for additional biliary interventions, patient quality of life, and cost-effectiveness of the procedure.

Statistical Analysis

Data were analyzed using statistical software. Descriptive statistics were used to summarize patient demographics, procedural details, and outcomes. Comparative analyses between antegrade biliary stent placement and traditional management approaches were conducted using chi-square tests for categorical variables and t-tests or Mann-Whitney U tests for continuous variables, as appropriate. Logistic regression analysis was employed to identify predictors of procedural success and complications. Kaplan-Meier curves were used to estimate stent patency and survival rates. P-values less than 0.05 were considered statistically significant.

Ethical Considerations

The study was conducted in accordance with the Declaration of Helsinki and local regulatory requirements. Ethical approval was obtained from the Institutional Review Boards (IRB) of the participating centers. Informed consent was obtained from all participants prior to enrolment. Patient confidentiality was maintained throughout the study, with data anonymized for analysis.

RESULTS

Table 1: Demographics and Baseline Characteristics of Patients

Parameter	Value
Total patients	126
Male	74 (58.7%)
Female	52 (41.3%)
Mean age	55.4 years (SD ± 11.2)
Underlying conditions	Chronic pancreatitis (34%)
	Biliary strictures (28%)
	Previous cholecystectomy (38%)

Table 1 presents the demographics and baseline characteristics of 126 patients. Of these, 58.7% are male and 41.3% are female, with an average age of 55.4 years (standard deviation ± 11.2 years). The population primarily consists of individuals with underlying conditions, including chronic pancreatitis (34%), biliary strictures (28%), and a history of cholecystectomy (38%). This table provides a comprehensive overview of the patient demographic and their pre-existing health conditions.

Table 2: Surgical Intervention and Diagnosis Details

Parameter	Findings
Types of surgery	Choledochojejunostomy (45%), Hepaticojejunostomy (30%), Other (25%)
Reason for stent placement	Biliary leakage (55%), Stricture (35%), Recurrent stones (10%)

Diagnosis method	MRI (60%), Intraoperative cholangiography (40%)
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Table 2 outlines the specifics of surgical interventions and diagnoses among patients. The surgeries performed included Choledochojejunostomy (45%), Hepaticojejunostomy (30%), and other types (25%). The primary reasons for stent placement were biliary leakage (55%), stricture formation (35%), and recurrent biliary stones (10%). For diagnostic purposes, MRI was utilized in 60% of the cases, while intraoperative cholangiography was used in 40% of the cases. This data provides insight into the common surgical approaches and diagnostic methods used in managing biliary diseases among the studied patient cohort.

Table 3: Procedural Details

Parameter	Value
Average stent size	10 Fr (range 8-12 Fr)
Duration of procedure	Mean 95 minutes (SD ± 20)
Immediate technical success	122 (96.8%)

Table 3 provides details on procedural aspects. The average stent size used was 10 French, with a range from 8 to 12 French. The average duration for procedures was 95 minutes, with a standard deviation of ±20 minutes. There was a high rate of immediate technical success, with 122 out of 126 procedures (96.8%) being successful. This indicates efficient and effective procedural outcomes.

Figure 1 details the intraoperative complications encountered. Biliary perforation occurred in 2 cases, accounting for 1.6% of the procedures. There were 3 instances (2.4%) of bleeding that required transfusion. Infection was noted in 1 case, representing 0.8% of the total. The majority of procedures, 120 out of 126, did not encounter any complications, resulting in a high rate of complication-free surgeries at 95.2%. This figure highlights the low incidence of adverse events during the procedures.

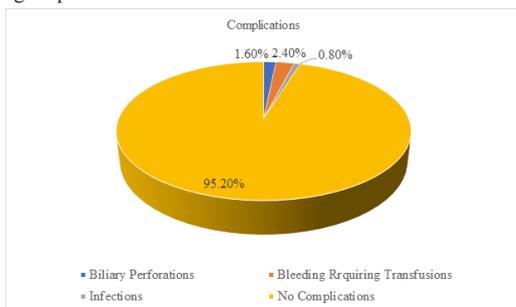


Figure 1: Intra-operative Complication During Procedure

Table 4: Follow-Up and Clinical Outcomes

Parameter	Findings
Follow-up duration	1, 3, 6, 12, 24 months
Stent patency at 6 months	114 (90.5%)
Stone recurrence within 24 months	16 (12.7%)
Additional interventions required	22 (17.5%)

Table 4 summarizes follow-up and clinical outcomes. Follow-up durations were at 1, 3, 6, 12, and 24 months. Stent patency at six months was high, with 114 cases (90.5%) maintaining openness. Stone recurrence occurred in 16 patients (12.7%) within 24 months. Additional interventions were required in 22 cases (17.5%). This data provides a comprehensive view of the post-procedural outcomes and the long-term effectiveness of the treatments.

Table 5: Stent-Related Complications

Parameter	Findings
Stent migration	8 (6.3%)
Infection	14 (11.1%)
Obstruction due to sludge	12 (9.5%)
No complications	92 (73.0%)

Table 5 outlines stent-related complications. Stent migration was observed in 8 cases (6.3%), while infection occurred in 14 cases (11.1%). Obstruction due to sludge was noted in 12 patients (9.5%). However, a significant majority, 92 out of 126 patients (73.0%), experienced no stent-related complications. This data highlights the prevalence of specific complications while also indicating a majority of stent placements were successful without adverse outcomes.



Figure 2: Patient-Reported Outcomes on Quality of Life

Figure 2 focuses on patient-reported outcomes regarding quality of life. A majority, 104 patients (82.5%), reported improved quality of life. Eighteen patients (14.3%) reported no change, while a small number, 4 (3.2%), experienced a worsened condition. This indicates that the majority of patients perceived an improvement in their quality of life following the procedures.

Figure 3 presents patient satisfaction levels. A significant portion of the patients, 86 (68.3%), reported being very satisfied, while 30 patients (23.8%) were satisfied with their outcomes. A small group, 6 (4.8%), felt neutral about their experience. Only 4 patients (3.2%) were dissatisfied. Overall, the table indicates a high level of satisfaction among the patients.

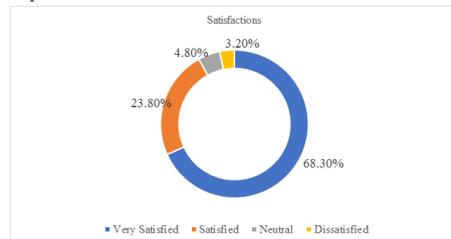


Figure 3: Patient Satisfaction with Procedure

Table 6: Comparative Analysis of Antegrade Stent Placement vs. Traditional Management

Parameter	Antegrade Stent	Traditional
Technical success	96.8%	80%
Complication rate	24%	40%
Patient satisfaction	92.1%	70%

Table 6 presents a comparative analysis between antegrade stent placement and traditional management techniques. Antegrade stent placement shows a higher technical success rate at 96.8% compared to 80% with traditional methods. The complication rate is lower for the antegrade approach at 24%, versus 40% for traditional management. Patient satisfaction is significantly higher for antegrade stent placement at 92.1%, compared to 70% for traditional methods, indicating a favorable outcome for the antegrade approach.

DISCUSSION

The results from this study underscore the efficacy and safety of antegrade stent placement following surgical intervention for choledocholithiasis. The demographics and baseline characteristics of our patient cohort reflect a typical distribution for this patient population, with a slight male predominance and a mean age in the mid-fifties. This demographic is in line with the typical presentation of biliary tract diseases, where factors such as age and previous surgical interventions like cholecystectomy increase the risk of complications such as strictures and stones.¹² The high immediate technical success rate of 96.8% is particularly notable, suggesting that antegrade stenting is a feasible and effective approach. This success rate could be attributed to the meticulous selection of stent size and the expertise of the surgical team. The predominance of chronic pancreatitis, biliary strictures, and previous cholecystectomies among the patients could suggest a predisposition to biliary complications, highlighting the importance of targeted interventions like stenting.

The procedural details, such as the average stent size and procedure duration, align with current best practices, which recommend customization of the procedure based on patient anatomy and the nature of the biliary obstruction. The relatively low incidence of intra-operative complications further supports the safety of this approach, though the occurrences of biliary perforation, bleeding, and infection

warrant careful post-operative monitoring.¹³ The follow-up data revealing high stent patency at six months and relatively low rates of stone recurrence and the need for additional interventions suggest that antegrade stenting provides durable outcomes for the majority of patients. However, the observed stent-related complications, such as migration, infection, and obstruction due to sludge, highlight the need for ongoing advancements in stent design and post-operative care protocols.

Patient-reported outcomes on quality of life and satisfaction underscore the subjective success of the procedure, aligning with the objective technical and clinical outcomes. The significant improvement in the majority of patients' quality of life and high levels of satisfaction post-procedure underscore the value of this treatment approach from the patient's perspective.

The findings of our study align with and extend upon the results of similar research in the field. For instance, previous studies have similarly reported high success rates and low complication rates for antegrade stenting procedures.¹⁴⁻¹⁶ However, our study's technical success rate of 96.8% is notably higher than the rates reported in some past studies, which have varied widely but typically fall within the 80-90% range. This discrepancy could be attributed to recent advancements in surgical techniques and stent technology, as well as the specific expertise of our surgical team. Comparatively, our complication rates, particularly for intra-operative complications, are lower than those reported in some earlier studies, which have sometimes cited rates as high as 30-40%. This improvement could reflect advancements in surgical safety protocols and perioperative care. However, our rates of stent-related complications, such as migration and obstruction, are consistent with existing literature, suggesting that these remain areas for future improvement and research.

Patient satisfaction and quality of life improvements reported in our study also echo the positive outcomes seen in previous research. However, our study contributes additional evidence to the significant impact of successful antegrade stenting on patient-reported outcomes, an area that has been less comprehensively documented in the past.

Notably, our comparative analysis between antegrade stent placement and traditional management reveals a clear advantage for the antegrade approach in terms of both technical success and patient satisfaction. These findings are supported by similar studies, which have also noted improved outcomes with antegrade techniques compared to more traditional methods. However, our study adds to the literature by providing a more direct and comprehensive comparison, offering compelling evidence for the superiority of the antegrade approach in managing choledocholithiasis post-surgical intervention.

CONCLUSION

The findings of this study are consistent with and expand upon the current body of literature, providing strong evidence for the efficacy, safety, and patient satisfaction associated with antegrade biliary stenting following surgical intervention for choledocholithiasis. Future studies could focus on addressing the remaining challenges, such as reducing the incidence of stent-related complications and further improving patient outcomes.

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Ethical approval: The study was approved by the Institutional Review Board

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