



CLINICAL PROFILE, COMPLICATIONS AND MANAGEMENT OUTCOMES IN PATIENTS WITH LONG-TERM RETAINED BILIARY STENTS: A RETROSPECTIVE OBSERVATIONAL STUDY

Medical Gastroenterology

Dr. Malladi Uma Devi

Professor & HOD Department of Medical Gastroenterology, Gandhi Medical College, Secunderabad

Dr. Chinta Ram Manindra Chowdary

Final Year Post Graduate, Medical Gastroenterology, Gandhi Medical College, Secunderabad

ABSTRACT

Background:Endoscopic biliary stenting is the standard procedure performed for various biliary diseases. It is imperative to remove or replace these stents periodically to prevent complications that adversely affect patient outcomes. This study aims at determining the complications of long-term indwelling biliary stents, its management and clinical outcomes of the affected patients. **Methods:**The current study is a retrospective observational study that included 118 patients who were older than 18 years of age and had biliary stents retained for more than 3 months from January 2023 to December 2025 in the department of Gastroenterology by consecutive sampling. Retained biliary stents are biliary stents that have been left in place longer than is advised (usually 3 to 6 months). The stent related complications and the management outcomes were assessed in all patients utilising descriptive statistics. **Results:**Among the 118 patients, 68(57.6%) had retained stent duration between 3-6 months while 50 patients had duration of more than 6 months. The common indication for stent placement is choledocholithiasis in 54 patients (45.7%) followed by CBD stricture in 34 patients (28.8%) 66(56%) patients had cholangitis at their clinical presentation. Endoscopic retrieval was successful in 85(72%) patients, skilled manoeuvres adopted for 30(25.4%) while few others 2.54% required advanced interventions like cholangioscopy and surgery. **Conclusion:**This study highlights that poor awareness among patients on retained stents and ineffective communication by healthcare providers resulted in various complications posing challenges even to the treating physicians. Adequate counselling, phone calls and message service reminder for stent removal can be practised to improve adherence to treatment.

KEYWORDS

Forgotten biliary stents, endoscopic retrieval, cholangitis, fractured stents, cholangioscopy

INTRODUCTION

Endoscopic Retrograde Cholangiopancreatography (ERCP) is one of the most commonly performed procedures by gastroenterologists across the world. ERCP combined with Endoscopic sphincterotomy and stone extraction is the standard procedure to treat patients with evidence of choledocholithiasis. The success rate of this procedure ranges from 80%-95% depending on various parameters [1].

Endoscopic biliary stenting is indicated for various conditions like irretrievable biliary stones, benign biliary strictures and most commonly post-surgical bile leaks.[3,4]. Recommendations for placing a temporary plastic biliary stent in cases of complex and irretrievable biliary stones have been suggested in previous studies. In benign biliary strictures, a plastic biliary stent is to be kept and replaced every 3-4 months for a maximum of 12 month duration. Prolonged duration of a stent in-situ progresses to complications like stent occlusion, migration, formation of stent-stone complex(stentolith) and biliary obstruction leading to cholangitis[6].

In Indian settings, given the lack of awareness by patients on retained stents and ineffective communication by healthcare providers, the operated patients fail to show up for further management. This predisposes to the development of various complications endangering patient lives and pose challenges to the treating physician. There are only limited studies on long term biliary stents in the southern part of India. Hence this study aims to investigate the complications of retained biliary stents, its management and clinical outcomes of the affected patients in Gandhi Medical College, a tertiary health centre in Secunderabad.

MATERIALS & METHODS:

Study design and setting

This study was designed to address the issue of retained biliary stents in patients who underwent biliary stent placement at Gandhi Medical College, a tertiary care centre in Secunderabad, from January 2023 to December 2025, in the Department of Gastroenterology.

Study population

Subjects retained biliary stents of more than 3 months duration were found using the hospital medical records system. By consecutive sampling, a total of 118 patients were identified and approached for counselling.

Inclusion criteria

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- Age > 18 years
- 2. Retained biliary stent for more than 3 months diagnosed by History, previous records and imaging studies.

Exclusion criteria

- Age < 18 years.
- All pregnant patients.
- Patients in whom the diagnosis of retained biliary stent could not be confirmed on imaging.

Data collection

The data were collected retrospectively by the principal investigator from medical records, laboratory reports, and a detailed review of imaging studies of the study population. Data regarding patient demographics, indication for stent placement, duration between stent insertion and presentation, clinical symptoms and associated complications were recorded. More detailed information regarding the position of the stent and the technique used for its removal was obtained. Respective variables were omitted from analyses for cases with missing data. No data imputation was done. All data collected were anonymized to ensure patient confidentiality.

Intervention and procedures

ERCP was the primary procedure performed to retrieve the indwelling biliary stents. Skilled manoeuvres such as balloon sweep/biliary basket were adopted for stent retrieval through ERCP for cases with distal stent migration. Additional stents were placed beside old stents to assist biliary drainage for patients with proximal migration. Patients were promptly educated post-ERCP for timely follow up. A small proportion of patients had to undergo cholangioscopic retrieval of the retained stents whereas cholecystectomy with CBD exploration and choledochoduodenostomy was performed when cholelithiasis was developed as a complication to retained stents.

A biliary stent retained beyond its recommended duration (typically 3 to 6 months) is known as a retained biliary stent or a forgotten biliary stent (especially if left in place for over a year) Proximally migrated biliary stents are considered if their distal end is not endoscopically detected at the duodenal papilla and the stent is visible in the biliary tree during fluoroscopic examination. Distal migration is confirmed when the stent is located below its original position or it is not detected on the endoscopic and fluoroscopic examination.

Outcome measures

- Spectrum of complications observed at initial presentation and during the procedure.
- Factors contributing to neglected stents.
- Success rate of endoscopic retrieval of retained biliary stents.
- Alternative approaches handled in case of failed retrieval.

Statistical analysis

Descriptive and inferential statistics were applied for the data collected. Age, stenting duration, serum total bilirubin, and alkaline phosphatase values were reported as mean $\pm$ SD since they are continuous variables. For categorical variables like gender, indications for stenting, clinical presentation, reasons for stent neglect, techniques used for stent removal, and complications frequencies and percentages were utilized. The association between the duration of stent retention and the occurrence of cholangitis was evaluated using the Chi-square test. Statistical significance was p -value <0.05 .

The results obtained from the above-mentioned research were then compared to two other researches that have been published previously using descriptive statistical analysis like mean, standard deviation, frequency, and percentages.

RESULTS:

Table 1: Gender distribution

Gender	n	%
Male	83	70.3
Female	35	29.7
Total	118	100

Table 1 showed gender distribution where 83 males (70.3%) and 35 females (29.7%) were covered in the study. All these patients had undergone stenting with double pigtail plastic biliary stents. The minimum size of biliary stent was 7fr and 7 cm and maximum size was 10fr and 10cm. Mean Age of patients was 48.7 ± 16.2 years. Mean duration of stenting was 4.4 months. 68 patients had duration of stent in between 3-6 months and 50 patients had duration of more than 6 months. The maximum duration of neglected stent was 14 years in one patient.

Table 2: Indications for index Biliary stenting

Indication	n	Percentage
Choledocholithiasis	54	45.8
CBD stricture(benign)	34	28.8
Stone + Stricture	14	11.9
Cholangiocarcinoma	12	10.1
Primary Sclerosing Cholangitis	2	1.7
Combined CBD+CHD stricture	2	1.7
Total	118	100

Abbreviation: CBD, common bile duct; CHD, common hepatic duct

Table 2 demonstrated the indications for index biliary stenting. The most common indication index biliary stenting was choledocholithiasis in 54 patients (45.8%) followed by CBD stricture in 34 patients (28.8%) and combined stone and stricture in 14 patients (11.9%). Cholangiocarcinoma was the indication in 12 patients (10.1%). Two patients (1.7%) had primary sclerosing cholangitis and 2 patients had combined CBD and CHD stricture (1.7%).

Table 3: Laboratory parameters in study subjects

Parameter	Mini mum	Maxi mum	Mean	Std. Deviation
White blood cell count (WBC)	4113	23300	11903.40	5614.806
Alanine aminotransferase (ALT)	13	417	97.62	83.494
Aspartate aminotransferase (AST)	11	523	87.92	98.855
Total serum bilirubin (TSB)	0.8	20	6.20	4.735
Alkaline phosphatase (ALP)	76	987	351.94	204.422

Table 3 revealed the major laboratory parameters of the study subjects at presentation. Mean Total bilirubin was 6.2 ± 4.735 mg/dl and mean Alkaline phosphatase was 351.94 ± 204.422

Table 4: Association between stent retention duration and occurrence of cholangitis

stent retention duration	Cholangitis, n (%)	No Cholangitis, n (%)	Total, n
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3-6 months	9 (42.9%)	12 (57.1%)	21
>6 months	57 (58.8%)	40(41.2%)	97
Total	66 (55.9%)	52(44.1%)	118

Acute cholangitis was diagnosed according to the Tokyo Guidelines 2018 criteria, requiring evidence of systemic inflammation, cholestasis, and imaging findings suggestive of biliary obstruction. Cholangitis was present in 66 (55.9%) of 118 patients. Of these, 57 (86.4%) had stent retention of >6 months and 9 (13.6%) had 3-6 months stent retention. Cholangitis was more common in patients with stent retention >6 months than in patients with retention of 3–6 months (58.8% vs. 42.9%). However, this difference was not statistically significant ($\chi^2 = 1.75$, $p = 0.186$).

Table 5: Reasons for loss to follow up

Reason for loss to follow up	n=118	%
Non compliance	24	20.3
Presumed Stent removal during cholecystectomy	16	13.6
Unawareness of retained stent	38	32.2
Communication failure	40	33.9

Table 5 highlighted the most common reason for neglected biliary stent was not having understood the need for stent exchange or removal which was the case in 40 patients (34%). 38 (32.2%) patients of believed that their stent had been removed during cholecystectomy and all these had undergone ERCP for choledocholithiasis.

Table 6: Methods of management of retained stent

Management	n =118
Endoscopic retrieval	85
Additional stent placement	23
Balloon sweep/biliary basket by ERCP	7
Cholangioscopy	2
Surgery	1

Table 6 illustrated that all these patients were posted for Endoscopic retrieval and subsequent ERCP based upon indications. Endoscopic retrieval was successful in 85 patients (72%). Among these 85 patients, 47(40%) patients had broken distal tip which was visible in the duodenum and remaining patients had distal pig tail intact. In 30(25.4%) patients, the distal pigtail was not visible in the duodenal lumen (proximally migrated). Among these 30 patients, in 7 patients, stent retrieval was done by balloon sweep/biliary basket usage during ERCP procedure. In remaining 23(19.4%) patients with proximal migration, stent could not be retrieved and an additional stent was placed for biliary drainage. Two patients had to undergo cholangioscopic retrieval of the neglected stent and one patient had to undergo surgery (Table 4). Stone formation as a complication of retained biliary stent was noted in 35 patients (29.6%).

DISCUSSION:

Endoscopic Biliary stenting with plastic stents is a standard and widely accepted procedure to decompress the biliary system. Ideally, these stents have to be either removed or replaced every 3 months to prevent untoward complications like migration, blockade, stone formation or cholangitis.[14]

The problem of retained biliary stents is an under looked entity in daily clinical practice. High volume centres face serious difficulties in managing such long-term retained biliary stents, which puts both the treating doctors as well as patients under stress.

In the present study, most of the patients with neglected biliary stents were in the age group of 40 to 50 years(mean age 48 years).This finding was in contrast to study published by Sohn et al in which mean age of patients with retained biliary stent was 73.7 years. [7] and consistent with the study by Saket Kumar et al in which mean age of study subjects was 47 years.[8]

Majority of the study subjects were males (70.3%) and is similar to the study published by Odabasi et al in which male to female ratio was 3:2 but contrast to the study by Saket Kumar et al where 80.9% study subjects were females [6][8]

Most commonly observed complication of retained biliary stent over a period 6-month duration was acute cholangitis (56%). This is in line with the study published by Sunkara et al (83.3%).[9] However, the association did not reach statistical significance. This can be explained by stent clogging, stent itself acting as a foreign body and a nidus for

stone formation and patient related characteristics. Sphincterotomy during index procedure may lead to duodenobiliary reflux triggering bacterial colonisation, formation of biofilm on the stent surface and calcium bilirubinate deposition.[11,12,13]

The most common consequence of long term retained biliary stent was broken stent (40%) followed by stone formation (29.6%) and proximal migration (25.4%). These findings are in contrast to the study by Ali Erkan Duman et al in which stone formation (79%) was the predominant clinical outcome. [13]

Endoscopic retrieval of retained biliary stents was successful in 85 patients (72%). This is in accordance with the study published by Sunkara et al in which success rate of stent retrieval by ERCP was 66.6%.[9]

Stents were successfully removed from 72% of the patients, but there were two cases where stent removal had to be done by means of cholangioscopic intervention. There was one case where stent had to be surgically removed because there was fracture of the proximal pigtail with the migration of the stent into the intrahepatic system. Patients who have stents which are obstructed do not always develop symptoms because even when the stent is obstructed, bile flow occurs on the surface of the stent, as reported by Sohn et al. [7]

Lack of awareness on the part of the patients as to the importance of undergoing follow-up care and timely stent replacement or removal has been the most crucial factor associated with long term retained biliary stents. This has resulted in most of the loss to follow-up cases in the present study (40 patients). The key findings of the present study were compared with similar studies and summarised in table 7

Table 7: Comparative analysis of demographic characteristics, clinical profile, complications and management outcomes and causes of missed follow up across different studies

Parameters	Present study	Sunkara et al	Duman et al	Abhijit Chandra et al
Demographic characteristics				
Study Duration (months)	36	8	48	72
Total cases (n)	118	12	48	21
Mean age (SD) in years	48.7 16.2	48(medi an)	71.23 ±12.16	47(median)
Female: Male ratio	83:35	7:5	25:23	17:21
Indication for stenting %				
CBD strictures	45.8	25%	10.4%	19.05%
CBD stones	28.8	83.3%	83.3%	76.2%
Bile leak	0%	0%	6.2%	4.76
Clinical presentation %				
Cholangitis	56%	83.3%	64.7%	66.7%
Jaundice	27.1%	NR	17.6%	NR
Biliary pancreatitis	0%	NR	5.8%	NR
asymptomatic	NR	NR	11.7%	NR
Complications %				
Fractured stents	16.7%	33.3%	8.8%	4.76%
Broken distal pig tail	40%	16.7%	NR	NR
Impacted stent	NR	8.3%	NR	NR
Migrated stent	25.4%	8.3%	26.4%	4.76%
Giant stone	NR	0%	NR	NR
Stentolith	29.6%	0%	79%	4.76%
Management outcomes%				
ERCP stent removal	72%	66.6%	100%	23.8%
ERCP with adjunctive techniques	25.46%	NR	NR	NR
Advanced interventions				
(a)Cholangioscopy assisted removal	1.7%	16.7%	NR	NR
(b)Surgery	0.85%	16.7%	NR	76.2%
Reasons for loss to follow up %				
Non compliance	20.3%	NR	12.5%	57.1%
Communication failure	33.9%	NR	56.25%	33.3%
Unawareness of retained stent	32.2%	NR	NR	9.52%
Assumed stent was removed during cholecystectomy	13.6%	NR	14.6%	NR
Dependency on phone call follow up	NR	NR	12.5%	NR

Covid 19 related disruption	NR	**** (not quantified)	4.17%	NR
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Abbreviations: CBD, common bile duct; ERCP, endoscopic retrograde cholangiopancreatography; NR, not reported; SD, standard deviation

The present study is one of the largest series of long-term retained biliary stents published so far and involved 118 patients. The average age of the patients was similar to that reported by Sunkara et al. and Abhijit Chandra et al. but was older than that reported by Duman et al. Similar to previous studies, the major indications for stenting were choledocholithiasis and benign biliary strictures. The most common clinical sign in all studies was cholangitis, seen in 56% of patients in this series. Most of the patients were managed successfully endoscopically with less than 1% requiring surgical intervention. The rate of surgical intervention was significantly less than that reported by Abhijit Chandra et al. (76.2%). Loss to follow-up was mainly due to communication failure, unawareness of retained stents and non-compliance of patients highlighting that structured stent tracking systems and patient education are of utmost importance.

Limitations of the present study include its retrospective design and potential bias as its consequence, single- centre study, not including metal stents, limited availability of cholangioscopy as a therapeutic entity and lack of long term follow up

CONCLUSION:

This study contributes to the literature by providing valuable insights into the clinical profile, complications, and management of long term retained biliary stents, particularly in resource-constrained settings where patient follow-up is often challenging. Prolonged stent duration, particularly beyond six months, increases the risk of complications, with cholangitis being the most common. It underscores the importance of addressing patient education and improving communication strategies to mitigate the risks associated with long-term stent neglect, an area with limited data from the southern region of the country.

Authorship contribution

Funding: No financial support was granted internally or externally for this study

Conflict of interest: None

Ethical considerations

The study received approval by Institutional Ethics Committee of Gandhi Medical College, Secunderabad (IEC Approval No. IEC/GMC/2024/04/230) and was conducted in compliance with declaration of Helsinki and guidelines of good clinical practice. Informed consent was obtained from all patients prior to endoscopic and/or surgical intervention as part of routine clinical management. Individual consent for data collection was exempted as it was a retrospective analysis.

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