



Retained Biliary Plastic Stents: Clinical Presentation, Complications, and Management

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Abstract

Background Biliary plastic stent (PS) mandates timely removal or replacement. The coronavirus disease 2019 (COVID-19) pandemic had affected the accessibility to medical therapy resulting in delay. We evaluated the burden of retained biliary PS, clinical profile, and impact of COVID-19 pandemic on stent retention.

Material and Method Endoscopy database records between November 2019 and April 2022 were reviewed retrospectively to identify patients who had undergone stent exchange or removal > 3 months, that is, retained stents. Demography, comorbidity, indication and outcomes of index endoscopic retrograde cholangiopancreatography, size and duration of indwelling biliary PS, clinical presentation, imaging findings, cholangiography findings, stent-related complications, and stone formation and endotherapy details were noted.

Results A total of 252 patients (100 [39.68%] males; median age 47 years [interquartile range [IQR] 32–56 years]) had common bile duct (CBD) stent retention. Median duration of retained CBD stent was 5 months (IQR = 4–6 months). Seventy (27.8%) were symptomatic with cholangitis (22, 8.7%), only jaundice (16, 6.3%), and only biliary abdominal pain (32, 12.7%). Sixty-one of 70 (87.1%) had abnormal imaging; 59/70 (84.3%) had new onset biliary stone or sludge ($p \leq 0.005$). Stent retention > 6 months was significantly associated with stent fragmentation (0 vs. 20, $p < 0.005$) and choledocholithiasis (9 vs. 58, $p < 0.005$). Small caliber stent retention was more symptomatic (7 vs. 10 French [12/28 [42.85%] vs. 58/224 [25%], $p = 0.049$). Univariate logistic regression analysis showed serum aspartate aminotransferase (AST), alkaline phosphatase levels, and CBD stent retention > 6 months were significantly associated with complications. On multivariate logistic regression analysis, serum AST > 2× upper limit normal (odds ratio [OR] = 5.487, 95% confidence interval [CI] = 3.1–9.9, $p \leq 0.005$) and CBD stent retention > 6 months (OR = 8.6, CI = 3.1–23.92, $p \leq 0.005$) were associated with complications. Out of 101 COVID-19 pandemic-attributed delay, 56/101 (55.44%) had symptomatic stent dysfunction. Endoscopic technical success rate was 97%, unsuccessful ones were due to large stones and impacted stents; with no mortality.

Keywords

- ▶ biliary plastic stents
- ▶ retained stent
- ▶ choledocholithiasis
- ▶ jaundice
- ▶ cholangitis
- ▶ endoscopic retrograde cholangiopancreatography

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Conclusion CBD PS stent retention, although mostly asymptomatic, can result in significant morbidity like jaundice, cholangitis, stent migration, fragmentation, or impaction in one-fourth of patients. Use of 7 Fr stent, retention duration > 6 months, abnormal imaging findings, and AST > twice the upper limit were significantly associated with complications. Endoscopic management was successful in 97% of patients.

Introduction

Biliary plastic stents (PSs) are tubular devices which are placed in the bile duct to maintain patency for flow of bile. Among various indications, they are often used for shorter duration followed by removal whereas longer duration placement needs periodic replacement.¹ The complications associated with long-term use includes stent block, cholangitis, stent migration, stentolith formation, and rarely perforation.^{2,3} Hence, it is recommended to replace or remove biliary PSs every 3 months to prevent these complications.¹ However, there is limited data regarding natural history of biliary stents beyond 3 months. Jaleel et al assessed 45 patients with retained biliary stents longer than 3 months and noticed that majority were asymptomatic with acute cholangitis in 9, choledocholithiasis in 2, and cholangitic abscess in 1 case.⁴ Sohn et al evaluated 38 patients with biliary stent left for more than 12 months and found acute cholangitis in 36 (94.7%) cases and stones and sludge in 35 (92.1%) cases.⁵ In a case series of 48 patients with plastic biliary stents retained for > 12 months, by Duman et al, the most frequent complications were stone formation (79%) and proximal stent migration (26.4%).⁶ The coronavirus disease 2019 (COVID-19) pandemic exposed us to this scenario where due to delay in elective surgeries and stent exchanges a lot of patients presented with retained stents. Hence, we conducted an audit to study the clinical presentation, complications, and outcome of patients with retained common bile duct (CBD) stents.

Material and Methods

Data collection was started after ethics committee approval (Project no. EC/OA-125/2022).

Patients: We analyzed prospectively maintained endoscopy database from November 2019 to April 2022 to identify patients who had undergone endoscopic retrograde cholangiopancreatography (ERCP) procedures for biliary indications. All patients with retained CBD PS were included in the study. Retained CBD stent was defined as indwelling PS for more than 3 months from the date of placement. All patients with self-expandable metal stents (SEMS), indwelling PSs in SEMS, and externally migrated stents were excluded from study. Demography, comorbidity, indication, and outcomes of index ERCP, size and duration of indwelling biliary PS, clinical presentation, imaging findings, ERCP findings and retrieval or exchange of stent, stent-related complications, and stone formation were noted. Stent-related complications were defined as those related to stent dysfunction like jaundice, abdominal pain,

cholangitis, cholangitic abscess, or related to structural integrity like fragmentation or internal migration. The reason for delay in stent exchange or removal due to COVID-19 pandemic or other causes were noted separately.

Endoscopy procedure: All ERCP procedures were performed by experienced operators with more than 500 successful ERCPs and capable of performing grade 3 ERCP. In patients with cholelithiasis and choledocholithiasis with previous complete CBD clearance stent was removed, and balloon sweeps and occlusion cholangiogram were taken to confirm CBD clearance but stent was not placed. Patients with incomplete CBD clearance with or without cholecystectomy, CBD clearance was performed. If successful, stent was placed only in those patients awaiting cholecystectomy. In all patients with incomplete CBD clearance, PS was placed. In patients with benign and malignant biliary strictures, stent exchange was performed. Straight biliary PSs of various sizes were used (Cook Medical, Bloomington, Indiana, United States). In patients with internal migration double pigtail PS was used after extraction of migrated stent.

Procedure was performed under total intravenous anaesthesia or general anaesthesia with TJF Q180V duodenoscope (Olympus, Tokyo, Japan). Previously placed stents if visualized at the papilla, were retrieved using snare (Cook Medical) or grasping forceps (rat tooth alligator jaw grasping forceps, Olympus). All internally migrated stents were retrieved using standard techniques. Details about stent fragmentation, stentolith, and presence of CBD calculi were documented. Further stone extraction, stricture dilation, and stent replacement was done according to standard treatment protocol.

Outcome measures: Prevalence of retained CBD stent, clinical presentation, and complications associated with it. Impact of COVID-19 pandemic on prevalence of retained CBD stents and its complications.

Data collection and statistical analysis: Data was collected and analyzed using SPSS version 24 (IBM Corporation, Armonk, New York, United States). Quantitative variables were represented using mean, median, and standard deviation. Qualitative variables in proportions were compared using chi-square test or Fisher's exact test. Univariate and multivariate logistic regression was performed to determine predictors of complications (obstructive jaundice, cholangitis and cholangitic abscess, stent migration, and fragmentation).

Results

In the study period (November 2019–April 2022), 2,937 ERCP were performed for biliary indications. After reviewing medical

Table 1 Demographic characteristics and laboratory investigations

Age	47 y (32–56)
Sex (male; female)	100 (40%); 152 (60%)
Bilirubin (total; direct), mean \pm SD (mg/dL)	1.96 (1.267) \pm 1.59 (1.08)
AST, mean (\pm SD) IU/dL	33.69 \pm 32.86
ALT, mean (\pm SD) IU/dL	37.28 \pm 35.03
ALP, mean (\pm SD) IU/dL	222.9 \pm 100

Abbreviations: ALT, alanine aminotransferase; ALP, alkaline phosphatase; AST, aspartate aminotransferase; SD, standard deviation.

records 252 (8.47%) patients with retained CBD stents were identified and included in the study. Out of 252, 71 (28.2%) index procedures were performed elsewhere and patients presented to us for retained CBD stent management.

Demography and clinical presentation: The median age of our cohort was 47 years (interquartile range [IQR] 32–56 years) with 152 (60%) females and 100 (40%) males. **Table 1** shows mean biochemical parameters at presentation. **Table 2** shows comparative values of all variables in different time

frames. Of the 252 patients, 180 (71.4%) presented within 3 to 6 months of stent placement, 47 (18.6%) in 7 to 9 months, 19 (7.5%) in 10 to 12 months, and 6 (2.4%) after 12 months. At presentation, 182 (72.2%) patients had no symptoms and 70 (27.8%) were symptomatic. Among the symptomatic patients 32 (12.7%) had abdominal pain while cholangitis and jaundice were noted in 22 (8.7%) and 16 (6.3%) patients. Choledocholithiasis was the most common indication for baseline ERCP with 106 (42.08%) patients. Other indications for index ERCP were benign biliary stricture ($n = 52$), malignant biliary obstruction ($n = 47$), bile leak ($n = 9$), and portal cavernous cholangiopathy ($n = 38$). Indication for index ERCP did not significantly affect the presence or absence of symptoms Symptoms (choledocholithiasis group 22/106 [22.75%], benign biliary stricture group 18/52 [34.6%], malignant biliary obstruction group 16/47 [34.04%], bile leak group 2/9 [22.22%], portal cavernous cholangiopathy group 12/38 [31.57%], $p = 0.55$). The abnormal findings on imaging with ultrasound (USG) or contrast-enhanced computed tomography (CECT) included dilated biliary tract, CBD stone, and sludge in 101 (56.1%), 6 (3.3%), and 17 (9.4%) in the 3- to 6-month group; 29 (61.7%), 26 (55.3%), and 10 (21.3%) in the 7- to 9-month group; 11 (57.9%), 13 (68.4%), and 2 (10.5%)

Table 2 Clinical presentation and other parameters in various time groups

		CBD stent retention groups			
		3–6 mo	7–9 mo	10–12 mo	> 12 mo
Indication for index CBD stenting	Choledocholithiasis	65	25	11	5
	Benign biliary stricture	42	6	3	1
	Malignant biliary stricture	36	10	1	0
	Bile leak	7	0	2	0
	Portal cavernoma	30	6	2	0
Clinical presentation	Only biliary abdominal pain	21 (11.66%)	6 (1.27%)	3 (1.57%)	2 (33.33%)
	Cholangitis	15 (8.33%)	5 (1.06%)	1 (5.26%)	1 (16.66%)
	Only jaundice	12 (6.66%)	3 (6.38%)	1 (5.26%)	0
	Asymptomatic	132 (73.33%)	33 (70.21%)	14 (73.84%)	3 (50%)
Total		180	47	19	6
Laboratory investigations	AST (IU/L)	37.238 \pm 37.58	22.84 \pm 6.45	27.89 \pm 22.55	29.5 \pm 7.94
	ALT (IU/L)	41.06 \pm 40.404	26.13 \pm 5.03	30.44 \pm 19.32	31.83 \pm 6.73
	ALP (IU/L)	245.6 \pm 110.29	166.45 \pm 15.48	175.27 \pm 31.17	139 \pm 31.81
	Total bilirubin (mg/dL) Direct bilirubin (mg/dL)	2.06 \pm 1.53 1.32 \pm 1.07	1.78 \pm 1.46 1.01 \pm 1.16	1.7 \pm 2.47 1.51 \pm 1.13	0.73 \pm 0.16 0.35 \pm 0.083
Imaging - USG abdomen/CECT abdomen	Normal biliary tract	56 (31.1%)	8 (17%)	6 (31.6%)	2 (33.3%)
	Dilated biliary tract	101 (56.1%)	29 (61.7%)	11 (57.9%)	3 (50%)
	CBD stone	6 (3.3%)	26 (55.3%)	13 (68.4%)	2 (33.3%)
	CBD sludge	17 (9.4%)	10 (21.3%)	2 (10.5%)	1 (16.7%)
Internal stent migration		3 (1.7%)	1 (2.1%)	0	0
Stent fragmentation		0	4 (8.5%)	12 (63.2%)	4 (66.7%)

Abbreviations: ALT, alanine aminotransferase; ALP, alkaline phosphatase; AST, aspartate aminotransferase; CBD, common bile duct; CECT, contrast-enhanced computed tomography; USG, ultrasound.

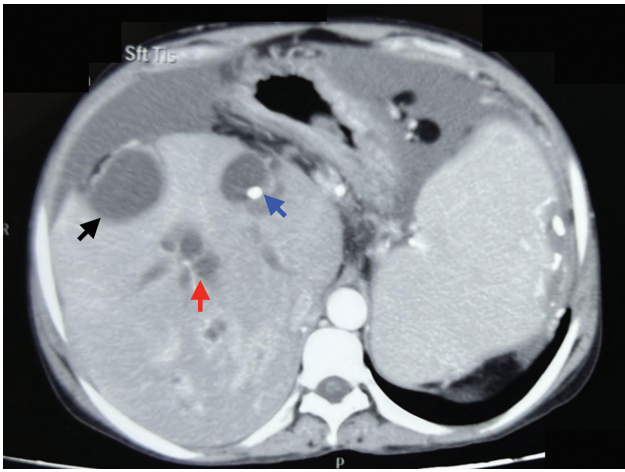


Fig. 1 Computed tomography image showing dilated biliary radical (red arrow) with plastic stent in situ (blue arrow) and cholangitic abscess (black arrow).

in the 10- to 12-month group; and 3 (50%), 2 (33.3%), and 1 (16.7%) in the >12-month group. Of the symptomatic patients, 61/70 (87%) had abnormal findings on USG or CT scan ($p < 0.005$). **►Fig. 1** shows abnormal CECT imaging finding in form of retained PS along with dilated biliary radicals and cholangitic abscess. All patients with internal stent migration ($n=4$) were symptomatic. Out of 70 patients with symptoms, 59 (84%) had stone or sludge formation in the biliary tree ($p \leq 0.005$). Most stents used were 10 Fr \times 10 cm straight ($n=29$). Stents of other sizes were 7 Fr \times 7 cm straight ($n=15$), 7 Fr \times 12 cm straight ($n=13$), and 10 Fr \times 5 cm double pigtail ($n=13$) and were used either singly or in combination. No significant difference was found between symptomatic presentation and the type of stent used ($p = 0.28$). Among the 70 symptomatic patients use of 7 Fr diameter stents was associated with significantly higher rate of symptomatic presentation compared with 10 Fr, 12/28 (42.85%) versus 58/224 (25%), $p = 0.049$.

ERCP findings and management of patients with retained CBD stents: Index or last performed ERCP data showed incomplete CBD clearance in 10/106 (9.4%) patients in the choledocholithiasis group and 3/38 (7.89%) in portal cavernous cholangiopathy. Of these patients with previous incomplete CBD clearance, current CBD stone or sludge was seen in 13/13 (100%) versus 95/239 (39.74%) patients.

All patients with retained stent underwent ERCP with either removal or replacement of previously placed stent. After removal of previously placed stent, CBD stones were noted in 67/252 (26.6%) (54 patients with new onset CBD stones, 13 patients with index incomplete CBD clearance) cases while sludge was noted in 41/252 (16.26%) cases. Indwelling stent for > 6 months was associated with significantly increased risk of stone formation, 58/72 (80.5%) versus 9/180 (5%), $p = 0.0049$. Complete bile duct clearance was achieved in 105/108 (97.22%) patients with standard accessories. Three patient with large stone further required cholangioscopy-guided electrohydraulic lithotripsy. Four (1.6%) patients had proximal stent migration in the biliary



Fig. 2 Fluoroscopic image of internally migrated plastic stent in left hepatic duct (black arrow).

tree for which additional manipulation with balloon sweeps, rat tooth forceps, and Soehendra stent retriever was required to retrieve the stent. **►Fig. 2** shows fluoroscopic image of internally migrated stent into left hepatic duct. Stent fragmentation was noted in 20/252 (8%) cases. Fragmented stent were pulled out of the bile duct using stone extraction balloon and removed using snares or rat tooth forceps. **►Fig. 3** shows image of a fragmented biliary PS being removed with rat tooth forces. In three cases fragment of the stent got impacted in the biliary tree requiring successive cholangioscopy-guided removal. So, overall technical success

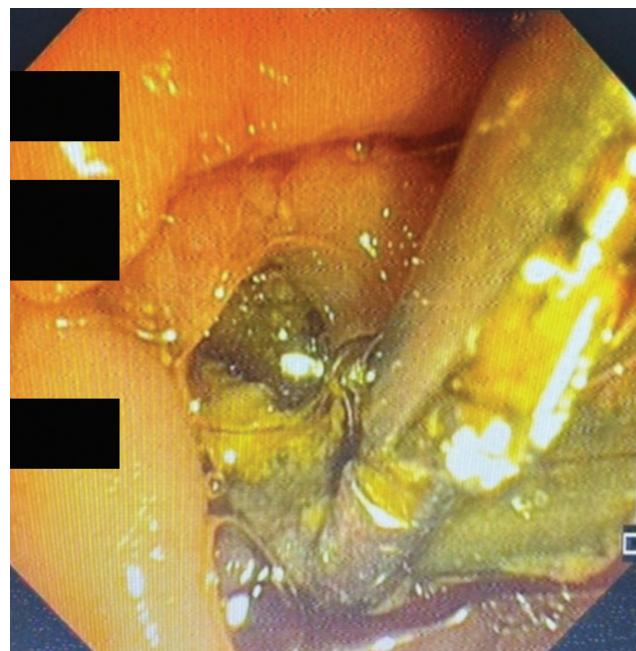


Fig. 3 Fragmented biliary plastic stent being removed with rat tooth forces.

for retained CBD stent retrieval and complete clearance of calculi and sludge was achieved in 97.6% (246/252) with one session of ERCP, while 2.38% (6/252) required second session with cholangioscopy-guided clearance. Indwelling PS for more than 6-month duration was associated with stent fragmentation (< 6 vs. > 6 months = 0 vs. 20, $p \leq 0.005$). In patients with benign strictures ($n = 52$) stent exchange was performed with higher caliber stent or multiple stents were placed with 100% technical success. In patients with malignant biliary obstruction ($n = 47$), PS exchange was done in 40 (85.1%) cases whereas replacement with SEMS was done in 8 cases due to disease progression and metastasis. In all patients with bile leak ($n = 9$) stent was removed as leak was healed and there was no stricture on cholangiogram. All patients ($n = 38$) with portal cavernoma cholangiopathy without shunt vessel underwent clearance of bile duct of stone or sludge with replacement of stent. During initial analysis of records, a total of 9 patients were found to have external migration of the stent (3- to 6-month group [$n = 3$], 7- to 9-month group [$n = 2$], 10- to 12-month group [$n = 2$], > 12-month group [$n = 2$]). As the stents were expelled, and not retained in the CBD, these patients were not included in the analysis.

On univariate logistic regression analysis, serum aspartate aminotransferase (AST) levels, serum alkaline phosphatase levels, and presentation beyond 6 months of index ERCP were significantly associated with complications. On multivariate logistic regression analysis serum AST levels > 2 upper normal limit (odds ratio [OR] 5.487, 95% confidence interval [CI] = 3.1–9.9, $p \leq 0.005$) and interval between primary ERCP and stent exchange or removal of > 6 months (OR = 8.6, CI = 3.1–23.92, $p \leq 0.005$) were significantly associated with complications.

Impact of COVID-19 pandemic on scheduled stent exchange or removal: COVID-19 pandemic resulted in significant disruption of scheduled appointments for stent exchange or stent removals. In our series, 101 (40.07%) patients had delay in presentation to hospital due to delayed appointments (34 patients), inability to reach hospital (43 patients) due to nationwide lockdown, and 24 patients did not report due to anxiety of acquiring COVID-19 infection if they leave home. Out of 101 patient with delayed stent exchange or removal during the COVID-19 pandemic, 56 had symptoms related to stent dysfunction (abdominal pain 26, cholangitis 24, cholangitic abscesses 4, stent migration 2) and presented to the hospital. During COVID-19 pandemic 30/101 (29.70%) patients had delay of more than 6 months for stent exchange or removal while 38/151 (25.1%) had delay of more than 6 months during non-COVID days ($p = 0.092$). Although difference was near statistical significance we feel this delay could be the reason for the same.

Discussion

Biliary PS provide a measure of biliary drainage but these endoprostheses need removal or exchange after 3 months of insertion.¹ A longer duration is usually associated with common complications like stent block and migration while

bleeding, duodenal perforation, and cholecystitis are rare. Stent block occurs due to accumulation of sludge and/or bacterial biofilm.⁷ In addition to microbial colonization, duodenal reflux of food constituents (e.g., fibers) and several other factors have been suggested to be involved in the occlusion of these endoprostheses. These factors include stent design, physicochemical properties of the constitutive materials, surface irregularities of the devices promoting microbial biofilm formation, and biliary sludge accumulation.⁸

The durations of CBD PS retention in various studies by Chandra and colleagues, Sohn et al, and Jaleel et al was 3.53 years (range 1–14 years), 22.6 ± 12.8 months, and 144 days (94–3,929 days), respectively.^{4,5,9} In other studies, it was shown that CBD PS patency ranges from 2.7 to 7 months for benign diseases and from 1.8 to 5.7 months for malignant biliary diseases.^{10–14} In our study, the median duration of stent retention was 5 months (IQR = 4–6 months). Kumar et al and Sohn et al reported cholangitis as the most common presentation when stent retention was more than 12 months, while Jaleel et al found majority (68.9%) were asymptomatic when stents were retained > 3 months.^{4,5,9} The reported incidence of cholangitis associated with plastic biliary stents ranges from 8 to 40% of patients.^{15–17} Reported mortality in patients with stent-related cholangitis is as high as 6.7% in long-term biliary stenting for choledocholithiasis.¹⁵ In our study, the majority 182 (72.2%) were asymptomatic but 22 (8.7%) had cholangitis and 16 (6.3%) had only jaundice, while 32 (12.7%) had biliary abdominal pain. There were no mortality associated with cholangitis and other complications. In the study by Sohn et al internal migration of stent was seen in 3 (10.7%) in the 1- to 2-year stent retention group and in 2 (20%) in the > 2 year stent retention group.⁵ In our study, stent structural integrity-related complications, that is, stent migration and stent fragmentation, were seen in 4 (1.6%) and 20 (8%) patients, respectively, and retention duration > 6 months was significantly associated with stent fragmentation and choledocholithiasis.

The biliary stent itself may serve as a nidus for stone formation, hence increases the risk of formation of biliary stones.¹⁸ Sohn et al reported that 35/38 patients with CBD stent retention > 12 months developed CBD stone or sludge even when the primary indication of stenting was for biliary stricture without CBD stone.⁵ All stones observed in the above study were brown pigment stones, thus implying the role of ascending infection. In the study by Kaneko et al, regarding stone-stent complex (SSC), it was found that duration of more 301 days and increase in CBD diameter during the period of PS placement is a predictive factor for SSC formation in this situation.¹⁹ In our study, stone formation were seen in 67 (26.6%) cases which was significantly associated with stent retention duration of > 6 months.

Multivariate logistic regression analysis showed that serum AST levels > 2 upper normal limit and interval between primary ERCP and stent exchange or removal of > 6 months were significantly associated with complications. Hence, abnormalities in liver function test (AST) and stent retention duration > 6 months were associated with symptomatic cases and complications related to stent retention.

The effect of COVID-19 pandemic for CBD stent retention was seen, as 101 (40.07%) patients had a delay in their scheduled stent exchange due to various reasons during COVID-19 pandemic. Out of these patients, 56 were symptomatic (55.44%). However, there was no statistically significant effect of COVID-19 pandemic on symptomatology or complications. In the study by Freitas et al regarding CBD PS exchange of 120 patients in COVID-19 pandemic, there were no differences in clinical presentation and complication between the delayed (> 6 months) versus early removal (< 3.5) group.²⁰

All the patients in our study were managed medically and endoscopically with technical success rate of 96.66%, failures being due to large stone ($n = 3$) and impacted stents ($n = 3$) in whom technical success could be achieved in another session with cholangioscopy. Similarly, in the study by Jaleel et al, all patients were managed medically and endoscopically (18/45 patients required further sessions) while Kumar et al reported definitive endoscopic treatment only in 5 patients (23.8%) and necessity of surgical exploration in remaining 16 (76.2%) cases.^{4,9} Sohn et al reported successful endoscopic management of retained CBD stent in 35 of 38 patients (92.1%).⁵ While most studies have reported > 90% success with endoscopic measure, Chandra and colleagues had lower success which can be attributed to selection and referral bias from a surgical center, lack of technical expertise, and access to various newer accessories and cholangioscopy.

Various limitations of the study are retrospective cohort, single-center study, and the COVID-19 infection as a confounding factor with its unknown effect on liver and bile lithogenicity. The communication to patient regarding nature of the disease and stressing on complications of delayed follow-up is very important. This can further be strengthened by setting up reminder system in the endoscopy unit for calling patients for follow-up. A separate team and electronic reminder system can be set up in the endoscopy unit for the same. Further studies would need to be done to derive more exact cutoff times.

Conclusion

Retained biliary PS although mostly asymptomatic can result in significant morbidity like jaundice, cholangitis, stent migration, fragmentation, or impaction in one-fourth of patients. Use of 7 Fr stent, retention duration > 6 months, abnormal imaging findings, and AST > twice the upper limit were significantly associated with complications. COVID-19 pandemic caused a delay in stent exchange in one-third patients without any significant effect on symptomatology or complications. All patients were managed endoscopically with a technical success rate of 97%, without any mortality.

Conflict of Interest

None declared.

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