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Original Research Article

Impact of prophylactic biliary stenting on stone recurrence and post-endoscopic retrograde cholangiopancreatography complications in patients awaiting cholecystectomy: a randomized controlled trial

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ABSTRACT

Background: Recurrence of common bile duct (CBD) stones and post-endoscopic complications remain clinical concerns in patients awaiting elective cholecystectomy. The use of prophylactic biliary stents after complete stone clearance is debated, with conflicting evidence regarding their efficacy and safety. This study aimed to evaluate whether biliary stent placement after duct clearance reduces recurrence or contributes to procedural complications.
Methods: A prospective, randomized controlled trial was conducted over one year at a tertiary care center in Bihar, India. Patients with confirmed choledocholithiasis who achieved complete CBD clearance through endoscopic retrograde cholangiopancreatography (ERCP) were randomized into two arms: Group A received prophylactic biliary stents (n=42), and group B did not receive stents (n=38). Patients were monitored for three months through clinical reviews and imaging (endoscopic ultrasound or MRCP). The primary outcome measured was recurrence of CBD stones. Secondary outcomes included incidence of post-procedure complications and need for repeat ERCP.
Results: Of the 80 participants, 42 were allocated to the stent arm and 38 to the no-stent arm, all of whom completed the study. Recurrent common bile duct stones developed in 8 patients (19.0%) in the stent group versus 3 patients (7.9%) in the non-stent group. The stent cohort demonstrated a higher overall complication rate (11.9%), with events such as post-ERCP pancreatitis and acute cholecystitis, whereas no complications were recorded in the non-stent cohort. Although repeat ERCP was required more often among those who received stents, the difference was not statistically significant.
Conclusions: The findings suggest that prophylactic biliary stenting after successful CBD clearance does not reduce recurrence risk and may increase the likelihood of complications. These results call for careful reconsideration of routine stent use in patients awaiting cholecystectomy.

Keywords: Common bile duct stones, Biliary stenting, Endoscopic retrograde cholangiopancreatography, Gallstone disease, Pancreatitis, Stone recurrence

INTRODUCTION

Choledocholithiasis refers to the presence of calculi in the common bile duct (CBD) and is frequently observed in patients with symptomatic gallbladder stones. The prevalence of CBD stones in individuals undergoing cholecystectomy ranges from 10% to 30%, with increased occurrence in older adults and those with additional comorbidities.[1] Clinical presentations can vary widely, from incidental findings to more serious outcomes such as obstructive jaundice, cholangitis, and acute pancreatitis.[2] ERCP, often coupled with sphincterotomy and stone extraction, remains the standard approach for managing this condition.[3]

Following successful stone removal, clinical guidelines advocate for elective laparoscopic cholecystectomy to reduce the chance of further biliary complications and eliminate the gallbladder as a potential source of stone recurrence.[4] However, due to factors like patient frailty, systemic healthcare delays, and limited access to surgical services, cholecystectomy may be deferred.[5] During this interim period, some endoscopists consider placing a prophylactic biliary stent to reduce the likelihood of ductal obstruction caused by new or residual stones.[6] The intended benefit of this approach includes maintaining biliary drainage, avoiding cholestasis, and simplifying any subsequent interventions if stones recur.

Nevertheless, clinical value of such prophylactic stenting remains uncertain. While certain retrospective analyses suggest it may help reduce recurrent stones or cholangitis, other studies fail to demonstrate clear benefit and instead draw attention to associated risks, including higher rates of post-ERCP pancreatitis and acute cholecystitis.[7-9] Laboratory and experimental studies have further shown that plastic stents may promote bacterial colonization, serving as a scaffold for biofilm formation, leading to infection and bile sludge accumulation.[10] Additionally, presence of a stent can disrupt normal biliary flow and potentially exacerbate bile duct-related complications.[11]

Technically, inserting a stent adds a foreign body to the biliary tree, which may provoke local inflammation and complicate subsequent procedures like cholecystectomy or repeat ERCP, especially if the stent migrates or becomes occluded.[12] Some studies suggest prior stenting may facilitate cannulation during follow-up ERCPs, yet others have reported increased procedure-related difficulties, higher complication rates, and extended operative time.[13] Furthermore, the exact effect of stents on biliary dynamics, including gallbladder function and cystic duct physiology, remains inadequately characterized and may depend on variables like stent size, design, and composition.[14]

The body of evidence supporting this practice is limited and mostly derived from observational data, which are inherently prone to confounding and variability in technique. Few prospective trials have tackled this clinical question, and those available often suffer from small cohorts, inconsistent outcome definitions, and mixed populations.[15,16] Major international guidelines, including those from ESGE and ASGE, recommend stenting in cases of incomplete stone clearance or active cholangitis but offer no guidance on its use in patients with fully cleared ducts awaiting surgery.[4,17]

In light of this ambiguity, we conducted a prospective, randomized controlled trial to determine whether prophylactic biliary stenting following complete endoscopic CBD stone clearance offers any clinical benefit in patients scheduled for elective cholecystectomy. The study's primary aim was to compare recurrence rates of choledocholithiasis between stented and non-stented patients. Secondary outcomes assessed included rates of biliary and pancreatic complications and the need for additional or urgent ERCP interventions. Our goal is to provide practical, evidence-based recommendations for optimizing management during the waiting period before cholecystectomy.

METHODS

Study design and setting

The investigation was structured as a prospective, randomized controlled trial at Indira Gandhi institute of medical sciences (IGIMS), a tertiary-care centre in Patna, Bihar (India). Recruitment and follow-up extended across a 12-month interval. The study protocol received prior clearance from the institutional ethics committee in line with the Indian council of medical research (ICMR) 2007 guidance.

Eligibility criteria

Patients aged 18 years or older presenting with gallstone disease and confirmed choledocholithiasis were considered eligible for inclusion in the study. Enrolment required complete clearance of CBD stones during ERCP, confirmed by an occlusion cholangiogram showing no residual filling defects. All participants provided written informed consent prior to randomization. Patients were excluded if they declined to participate, underwent a combined single-session cholecystectomy and ERCP, or had a history of hepatobiliary surgery or prior cholecystectomy. Additional exclusion criteria included incomplete stone clearance at the index ERCP, presence of malignancy involving the hepatobiliary tract, and laboratory evidence of coagulopathy, defined as an international normalized ratio (INR) greater than 1.5/platelet count below 100,000/mm^3.

Randomization and blinding

After confirming that each patient's bile duct had been completely cleared, eligible participants were assigned to the two treatment arms in a 1:1 ratio according to a computer-generated random-sequence table. To limit group imbalance, block randomisation was applied using variable block sizes of two and four. The random-allocation list was safeguarded in consecutively numbered, opaque, sealed envelopes, which were opened only after a participant's eligibility had been verified. Owing to the nature of the procedure, masking of both participants and study personnel was not possible.

Intervention

Group A (Stent group): Patients were fitted with a prophylactic biliary stent immediately following CBD clearance. Double-pigtail plastic stents (7 Fr or 10 Fr, length 7 cm; Cook Medical, USA) were used based on the endoscopist's discretion.

Group B (No-stent group): No stent was placed after ductal clearance.

All patients were referred for elective laparoscopic cholecystectomy and monitored over a 3-month follow-up period.

Endoscopic technique

ERCP was performed using a therapeutic duodenoscope (TJF-Q180V; Olympus, Tokyo, Japan) under conscious sedation. All procedures were carried out by experienced endoscopists, each performing more than 300 ERCPs annually and proficient in at least 50 precut techniques. Patients received rectal diclofenac suppositories (100 mg; Cipla Ltd., India) and intravenous fluid resuscitation as prophylaxis against post-ERCP pancreatitis.

Biliary cannulation was achieved using a pull-type sphincterotome, followed by a complete sphincterotomy. Stones were removed using a standard extraction balloon (8.5-15 mm; Boston Scientific, USA). Endoscopic papillary balloon dilation (EPBD) was selectively used based on stone size and anatomy. An occlusion cholangiogram was performed to confirm duct clearance.

Follow-up and surveillance

Patients were monitored through in-person or telephone consultations at 1 week, and then monthly for 3 months. Symptoms such as abdominal pain, fever, or jaundice were assessed. At the 3-month mark, recurrence evaluation was done via imaging:

Preferred modality: Endoscopic ultrasound (EUS) using a linear echoendoscope (GF-UCT180, Olympus, Tokyo).

Alternatives: MRCP or abdominal ultrasound with liver function tests (for patients declining EUS).

Stents removed electively at 3-month visit. If recurrence of stones was confirmed, repeat ERCP was performed.

Study outcomes

Primary outcome: Incidence of choledocholithiasis recurrence within 3 months, confirmed by EUS, MRCP, or repeat ERCP.

Secondary outcomes: Frequency of post-procedure complications (cholecystitis, cholangitis, and post-ERCP pancreatitis) and the requirement for repeat or emergency ERCP.

Complication definitions were consistent with the Tokyo guidelines 2018 for cholecystitis and cholangitis, and the revised Atlanta classification for pancreatitis.[18,19]

Statistical methods

An a priori power calculation was undertaken using published recurrence rates, about 30% for patients who do not receive a stent versus roughly 5% for those who do. Employing Kelsey's formula with 80% power and a two-sided α of 0.05 indicated that a minimum of 35 participants per study arm was necessary. To account for possible drop-outs, enrolment targets were increased, resulting in 42 participants in the stent cohort and 38 in the control cohort.

RESULTS

Patient enrolment and follow-up

From September 2021 through July 2022, 359 consecutive patients were screened for ERCP at the study centre. Eighty met all inclusion criteria after complete clearance of CBD stones and were randomized: 42 to the stent group (Group A) and 38 to the no-stent group (Group B).

During the subsequent three-month follow-up, five participants were lost to follow-up, two in group A and three in group B. Study follow-up was completed in October 2022.

Baseline characteristics

Demographic data and baseline laboratory findings were comparable between the two groups (Table 1). The median age in both cohorts was 46 years. Female participants made up approximately 64% of the total study population.

While all patients presented with abdominal pain, jaundice and fever were slightly more frequent in no-stent group, though these differences were not statistically significant. Other routine hematological and liver function parameters were broadly similar, except for higher median total and direct bilirubin values in group B.

Table 1: The baseline characteristics of the randomized groups.

Parameters	Stent group, (n=42) (%)	No-stent group, (n=38) (%)	P value
Age (in years)	46 (34, 59.75)	46 (30.25, 61.75)	0.895
Gender (Female)	27 (64.3)	24 (63.2)	0.852
Abdominal pain	42 (100)	38 (100)	-
Jaundice	14 (33.3)	20 (52.6)	0.088
Fever	14 (33.3)	14 (36.8)	0.661
Hemoglobin (gm/dL)	12.6 (11.27, 13.30)	12.1 (10.97, 13.75)	0.612
Total leucocyte count (×10⁹/L)	8500 (6875, 11750)	7750 (6325, 10050)	0.840

Continued.

Parameters	Stent group, (n=42) (%)	No-stent group, (n=38) (%)	P value
Platelet count (×10⁹/l)	2.22 (1.73, 2.88)	2.21 (1.72, 2.97)	0.903
Total bilirubin (mg/dl)	1.41 (0.72, 3.47)	2.4 (0.87, 6.06)	0.025
Conjugated bilirubin (mg/dl)	0.4 (0.2, 2.35)	0.93 (0.29, 4.41)	0.031
AST (U/l)	59.5 (27.25, 232.25)	65 (27.22, 134)	0.102
ALT (U/l)	105 (35.2, 216)	76 (29.75, 164.75)	0.318
ALP (U/l)	140 (93, 352.5)	146 (88, 335)	0.560
Total protein (gm/dl)	7.31 (6.75, 7.62)	7.13 (6.55, 7.49)	0.401
Serum albumin (gm/dl)	4.25 (3.70, 4.67)	4.06 (3.84, 4.50)	0.450
Urea (mmol/l)	21.45 (18.42, 28.3)	21.5 (16.5, 32)	0.415
Creatinine (mg/dl)	0.78 (0.60, 0.92)	0.77 (0.62, 1.20)	0.560
Previous ERCP	4 (9.5)	9 (23.7)	0.078

Imaging findings

Pre-ERCP imaging was conducted using a combination of abdominal ultrasound (n=58), MRCP (n=27), and EUS (n=17). A higher proportion of patients in the stent group (76.2%) had multiple gallstones compared to the non-stent group (55.3%) (Table 2). Intrahepatic biliary radical (IHBR) dilation was noted in both groups with equal frequency. The average CBD diameter was nearly identical between the two groups, at approximately 9.5 mm.

Primary outcome: stone recurrence

Over the 3-month monitoring period, recurrence of choledocholithiasis was observed in 8 patients (19.0%) from the stent group and in 3 patients (7.9%) in the no-stent group (p=0.291; Table 3). All recurrent stones were identified incidentally during scheduled imaging follow-ups using EUS, MRCP, or ultrasound. None of the affected patients displayed signs of cholangitis or required urgent biliary decompression. Most were managed electively via repeat ERCP.

Table 2: Imaging characteristics between the randomized groups.

Imaging characteristic	Stent group, (n=42) (%)	No-stent group, (n=38) (%)
Number of gallstones		
Single	7 (16.7)	10 (26.3)
Two	1 (2.4)	0 (0)
Multiple	32 (76.2)	21 (55.3)
Sludge	2 (4.8)	5 (13.2)
Intrahepatic biliary dilation (IHBR)	17 (40.5)	17 (44.7)
Maximum GB stone size (mm)	10.1±5.22	11.58±5.24
CBD diameter (mm)	9.59±2.93	9.39±3.53

Table 3: Primary and secondary outcomes between the randomized groups.

Outcome	Stent group, (n=42) (%)	No-stent group, (n=38) (%)	P value
Primary outcome			
Recurrence of choledocholithiasis	8 (19.0)	3 (7.9)	0.291
Secondary outcomes			
Total complications	5 (11.9)	0 (0)	0.018
Jaundice	0	0	-
Cholangitis	0	0	-
Cholecystitis	2 (4.8)	0	0.164
Gallstone-induced pancreatitis	0	0	-
Post-ERCP pancreatitis	3 (7.1)	0	0.085
Need for repeat ERCP			
Required repeat ERCP	7 (16.7)	3 (7.9)	0.268
Days post 1st ERCP (Median, range)	122 (64-245)	118 (100-211)	0.849

Secondary outcomes: procedure-related complications

Procedure-related complications occurred more frequently in the stent group, affecting 5 patients (11.9%), while no adverse events were recorded in the no-stent group (p=0.018). Specific complications in group A included: Post-ERCP pancreatitis in 3 patients (7.1%), with one patient requiring percutaneous drainage due to moderate severity.

Acute cholecystitis in 2 patients, both managed conservatively with medical therapy.

No patients in either group developed jaundice or cholangitis during the follow-up period. Hyperamylasemia was more common in group A and approached statistical significance (p=0.051).

Need for repeat ERCP

A second ERCP was carried out in seven participants from the stent cohort (16.7%) and in three from the no-stent cohort (7.9%), a difference that did not achieve statistical significance (p=0.268; Table 3). The median interval between the index and repeat procedures was 122 days in group A and 118 days in group B (p=0.849).

Every repeat ERCP was scheduled electively, with no cases triggered by acute clinical deterioration.

Endoscopic procedure characteristics

All enrolled patients underwent successful biliary sphincterotomy during the index ERCP (Table 4). Rates of technically challenging cannulations, use of precut techniques (needle knife fistulotomy or papillotomy), and additional interventions such as EPBD were similar across groups. Stone removal was achieved predominantly via balloon extraction. The average procedural time was approximately 29 minutes. Notably, 4-hour serum amylase levels post-ERCP were considerably higher in the stent group, correlating with increased incidence of the pancreatitis.

Table 4: ERCP procedure characteristics between the randomized groups.

ERCP detail	Stent group, (n=42) (%)	No-stent group, (n=38) (%)	P value
Number of biliary stones			
Single	12 (28.6)	13 (34.2)	0.904
Two	9 (21.4)	7 (18.4)	
Multiple	16 (38.1)	12 (31.6)	
Sludge	5 (11.9)	6 (15.8)	
Endoscopic sphincterotomy (EST)	42 (100)	38 (100)	-
EPBD	11 (26.2)	8 (21.1)	0.663
EPBD size (mm)	12.17±1.7	12.36±0.63	0.783
Difficult biliary cannulation	11 (26.2)	8 (21.1)	0.663
Needle knife fistulotomy (NKF)	6 (14.3)	5 (13.2)	1.000
Needle knife papillotomy (NKP)	5 (11.9)	4 (10.5)	1.000
Electrohydraulic lithotripsy (EHL)	1 (2.4)	1 (2.6)	1.000
Total procedure time (minutes)	29.09±12.42	28.53±12.7	0.858
4-hour post-ERCP serum amylase (IU/L)	457.72±694.72	159.9±149	0.059
Post-ERCP pancreatitis	3 (7.1%)	0	0.085

DISCUSSION

This randomized, prospective trial assessed the impact of prophylactic biliary stenting in patients with choledocholithiasis who had undergone successful CBD stone removal and were awaiting elective cholecystectomy. Our findings indicate that placing a biliary stent did not significantly lower the recurrence of stones within the short-term follow-up. In contrast, the intervention was associated with a higher incidence of adverse events, particularly post-ERCP pancreatitis and acute cholecystitis. These observations raise important concerns about the safety and clinical utility of routine stent insertion in patients with no residual stones.

The recurrence of CBD stones was identified in 20% of the stent group, compared to only 8.6% in those who did not receive a stent. Although not statistically significant, this trend echoes findings from earlier retrospective and small prospective studies, which have implicated biliary stents in promoting stone recurrence. Harano et al highlighted that prolonged stent presence can impair bile flow and contribute to bile stagnation, fostering stone formation.[20] Similarly, Donelli et al demonstrated how bacterial biofilms and colonization of plastic stents can serve as a nidus for biliary sludge and inflammation.[21] While stents are intended to support biliary drainage, they may inadvertently disturb physiological flow and predispose patients to new stone formation.

In terms of safety, our data showed a complication rate of 15% in the stented group, while no complications occurred in the control group. Notably, post-ERCP pancreatitis accounted for the majority of these events. This is a recognized complication and has been previously linked to repeated duct manipulation and instrumentation. Wilcox et al reported that stent insertion, especially when combined with difficult cannulation, increases the likelihood of pancreatitis following ERCP.[22] Moreover, two cases of acute cholecystitis were seen exclusively in the stent group, which may be explained by changes in cystic duct flow dynamics or infection due to bacterial colonization, both mechanisms supported in previous literature.[23]

Although more patients in the stent group required repeat ERCPs, this did not reach statistical significance.

Importantly, all reinterventions were performed electively, and none of the patients developed symptoms requiring urgent or emergency decompression. This suggests that with adequate monitoring and structured imaging surveillance, asymptomatic recurrences can be safely managed without relying on prophylactic stenting. The absence of emergency events in both groups supports a conservative strategy in appropriately selected patients post-CBD clearance. Interestingly, a higher proportion of patients in the stent group underwent cholecystectomy during the follow-up, potentially due to the presence of a stent prompting earlier scheduling. However, this did not translate into better outcomes, and raises the question of whether stenting inadvertently accelerates surgical timelines without clinical justification.

The strengths of this study include its randomized design, consistent use of imaging modalities such as EUS and MRCP for surveillance, and a clearly defined follow-up protocol. However, certain limitations should be acknowledged. The relatively short follow-up period of 3 months may not capture late recurrences. In addition, the single-center setting may affect generalizability, and although standardized stents were used, variations in endoscopist judgment may have influenced procedural decisions. To summarize, this study provides evidence that routine use of prophylactic biliary stents following complete ductal clearance does not confer a protective effect against stone recurrence. Instead, it may expose patients to preventable complications. In the absence of technical challenges or incomplete clearance, stenting should be avoided. These findings support a more individualized and cautious approach in managing patients awaiting cholecystectomy after ERCP, and contribute to refining best practices in endoscopic biliary interventions.

CONCLUSION

In this randomized controlled trial, prophylactic biliary stenting after complete endoscopic clearance of CBD stones did not reduce the short-term recurrence rate and was associated with a higher incidence of procedure-related complications, including post-ERCP pancreatitis and acute cholecystitis. These findings challenge the routine use of biliary stents in patients awaiting elective cholecystectomy when the bile duct has been fully cleared. By demonstrating that careful follow-up without prophylactic stenting can be safe and effective, this study advances current understanding of post-ERCP management and supports a more selective, individualized approach to biliary interventions.

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