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Indian Survey on Management of Choledocholithiasis—Opportunities for Improvement and Future Studies

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Abstract

Background In clinical practice, decision about management of choledocholithiasis is driven by availability of resources and expertise, patients and healthcare professional preferences. This survey is aimed to describe the approach of physicians and surgeons for the management of choledocholithiasis.

Method A 36-question online survey was conducted using Google Forms on various aspects of management of choledocholithiasis.

Results The responses from 323 participants were included, of which 202 (62.54%) were physicians and 121 (37.46%) were surgeons. The proportion of responders who do not follow American or European Society of Gastrointestinal Endoscopy guidelines is associated with increasing age and experience of responders ($p = 0.0001$), while place of work (private vs. teaching) and broad specialty (physician vs surgeon) are not associated ($p > 0.05$). For patients with high likelihood of choledocholithiasis, 123 (38.1%) participants prefer to do endoscopic ultrasound/magnetic resonance cholangiopancreatography (EUS/MRCP) rather than directly performing endoscopic retrograde cholangiopancreatography/intraoperative cholangiography (ERCP/IOC). For intermediate likelihood, MRCP is more commonly preferred compared with EUS, due to local availability (44%), expertise (39.6%), healthcare professionals preference (30.7%), and patients preference (17.3%). For difficult common bile duct (CBD) stones, short biliary sphincterotomy with large balloon sphincteroplasty (59.4%), followed by laparoscopic CBD exploration are commonly used approaches. Prophylactic CBD stent placement after ERCP and CBD clearance is common practice. Preoperative ERCP

Keywords
- choledocholithiasis
- guidelines
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- risk stratification
- survey

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followed by cholecystectomy is more preferred approach than cholecystectomy and CBD exploration.

Conclusion There is considerable variability in the management of choledocholithiasis. The practices such as use of EUS/MRCP for high likelihood group, use of prophylactic CBD stent placement after ERCP and CBD clearance, and use of single stage approach especially in patient with intermediate likelihood group should be addressed in future studies.

Introduction

Patients (10–25%) with cholelithiasis develop complications such as biliary pain, cholecystitis, choledocholithiasis, and pancreatitis.[1,2] Common bile duct (CBD) stones are present in 10 to 18% of patients undergoing cholecystectomy for symptomatic cholelithiasis.[3] American and European Society of Gastrointestinal Endoscopy (ASGE and ESGE) recently updated guidelines for evaluation and management of CBD stones.[4,5] Both guidelines recommend CBD stone extraction to all patients irrespective of symptoms, who are fit to tolerate the intervention. Liver function tests and abdominal ultrasound are initial diagnostic steps and combinations of these tests are used to risk stratification for defining likelihood of choledocholithiasis.[4,5] There are few differences in diagnostic algorithm of two guidelines; it has been shown than ESGE risk stratification is more specific than ASGE.[2]

Early removal of CBD stones can reduce risk of severe complications such as acute cholangitis or pancreatitis.[6] CBD stones are managed either by endoscopic retrograde cholangiopancreatography (ERCP) followed by cholecystectomy or surgically during cholecystectomy. There are similar success rates between single-stage procedure (cholecystectomy and CBD exploration) and two-stage procedure (ERCP and cholecystectomy). Single-stage procedure may be more cost-effective.[7,8] In clinical practice, decision about CBD stone management is driven by various factors such as presence of cholangitis, patients preference, and available expertise.[9]

We conducted a survey on the management of CBD stones in India. Our aim of this survey was to describe the adherence and the approach of physicians and surgeons in the management of choledocholithiasis according to the current guidelines in the clinical practice in India.

Methods

Study Design

A 36-question online survey was created using Google Forms software. The survey was then shared on an online social media for participants, which includes trainees and consultants in general surgery, general medicine, medical and surgical gastroenterology who are actively involved in evaluation and management of CBD stones. Responses from other broad or super specialties were excluded.

The survey was conducted between June 2020 and August 2021. The participants were invited by personal email, mobile numbers, and through social media. The name of participants and the centers were not collected. Email address were mentioned in questionnaire to avoid multiple responses; however, during data analysis emails were removed.

Demographic information sought from the participants included age, training level, post-residency experience, specialty (general medicine or surgery, medical or surgical gastroenterology), and place of work (academic, teaching, private). Additional information was collected from participants regarding use of ASGE or ESGE guidelines, patterns of ERCP, cholecystectomy, and CBD exploration.

Statistical Analysis

SPSS version 26 (IBM Corp., Armonk, New York, United States) and MedCalc version 19.1.3 (MedCalc Software bv, Ostend, Belgium) were used for statistical analysis. All variables were categorical and expressed as percentages. Categorical variables were compared with chi-squared test. *p*-Value of less than 0.05 was considered as statistically significant.

Results

Responses were received from 380 participants, of whom 323 met inclusion criteria. Of them, 57 (17.6%) were trainee or fellow, while 90 (27.9%) and 176 (54.5%) were assistance professors/junior consultant and associate professor/senior consultant, respectively. Majority of respondents (212/323; 65.6%) were aged between 30 and 50 years. One-hundred seventy-six (54.5%) respondents were affiliated to academic hospitals, and 111 (34.4%) were working in private hospitals. There were 202 (62.54%) physicians and 121 (37.46%) surgeons in participants. The baseline characteristics are summarized in ►**Table 1**.

ASGE risk stratification for the evaluation of suspected choledocholithiasis was used by 190 (58.8%) respondents, while ESGE criteria were used by 57 (17.7%). Remaining 76 (23.5%) respondents do not follow either of the guidelines and proceed as per there clinical experience or judgement. The proportion of participants who do not follow either of the guidelines is significantly higher in senior consultants or associate professors as compared with others (30.11 vs. 15.65%; $p = 0.0035$). Similarly, proportion of responders

Table 1 Baseline characteristics of study participants

Parameter	*n* (%)
Age group	
Less than 30 years	39 (12.1)
30–39 years	113 (35)
40–49 years	99 (30.6)
50–59 years	53 (16.4)
More than 60 years	19 (5.9)
Broad specialty	
Physicians	202 (62.5)
Surgeons	121 (37.5)
Level of training	
Fellow	57 (17.6)
Assistant Prof/junior consultant	90 (27.9)
Associate Prof/senior Consultant	176 (54.5)
Place of practice	
Academic	176 (54.5)
Nonacademic teaching	36 (11.1)
Private	111 (34.4)

Table 2 Diagnostic workup for suspected choledocholithiasis

Question	*n* (%)
Which risk stratification guidelines do you follow in your clinical practice?	
ASGE	190 (58.8)
ESGE	57 (17.7)
None	76 (23.5)
For high likelihood of choledocholithiasis, do you directly refer patient for ERCP?	
Yes	178 (55.1)
No (prefer EUS or MRCP) before ERCP	123 (38.1)
Maybe	22 (6.8)
For intermediate likelihood of choledocholithiasis, what investigation do you perform before ERCP or IOC?	
EUS	45 (13.9)
MRCP	150 (46.4)
Either EUS or MRCP	113 (35.1)
Refer directly for ERCP or IOC	15 (4.6)

Abbreviations: ASGE, American Society of Gastrointestinal Endoscopy; ESGE, European Society of Gastrointestinal Endoscopy; ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasound; IOC, intraoperative cholangiography; MRCP, magnetic resonance cholangiopancreatography.

who do not follow ASGE or ESGE guidelines is associated with increasing age and experience of responders ($p = 0.0001$), while place of work (private vs. teaching and broad specialty (physician vs. surgeon) is not associated ($p > 0.05$).

For patients with high likelihood of choledocholithiasis, 123 (38.1%) participants prefer to do endoscopic ultrasound (EUS) or magnetic resonance cholangiopancreatography (MRCP) rather than directly performing ERCP or intraoperative cholangiography (IOC) (►**Table 2**). For patients with intermediate likelihood of choledocholithiasis, 308 (95.4%) participants prefer to perform EUS or MRCP to confirm choledocholithiasis. MRCP was preferred investigation for 150 (46.4%) and EUS was preferred by 45 (13.9%), either of two was preferred by 113 (35%) of participants. Fifteen (4.6%) participants proceed to ERCP or IOC in the patients with intermediate probability of CBD stones without considering EUS or MRCP. This decision is driven by local availability (44%), expertise (39.6%), healthcare professionals preference (30.7%), and patients preference (17.3%).

ERCP prior to cholecystectomy is preferred treatment strategy for 314 (97.2%) participants, only 5 (1.5%) participants consider laparoscopic cholecystectomy and CBD exploration as a preferred therapeutic approach. This strategy depends on availability of ERCP for 128 (39.6%), while 134 (41.5%) participants considered this should be preferred therapeutic approach irrespective of availability of ERCP.

For the management of difficult CBD stones, short biliary sphincterotomy with large balloon sphincteroplasty (59.4%) was most common treatment option, followed by laparoscopic CBD exploration (42.1%), endoscopic mechanical lithotripsy (32.5%) followed by endoscopic intraductal therapies including laser lithotripsy and electrohydraulic lithotripsy (26.3%). Patients are advised to undergo cholecystectomy during same presentation after CBD stone retrieval by 196 (60.7%) participants and by 55 (17%) participants within 2 weeks. One hundred two (31.6%) participants advised patients to undergo cholecystectomy after 2 weeks. Prophylactic CBD stent placement after ERCP and CBD stone clearance was performed by 176 (54.5%) participants in all cases, while 115 (35.6%) participants do it only if cholecystectomy is not planned within 2 weeks. This CBD stent is removed after 2 weeks of cholecystectomy by 249 (77.1%) participants with routine balloon sweep in all cases by 113 (35%) participants.

All surgeons perform laparoscopic cholecystectomy. Of 121 surgeons, only 6 (4.96%) choose to perform IOC in all patients after preoperative ERCP. IOC during cholecystectomy after preoperative ERCP was performed by 102 (84.30%) surgeons if there was incomplete or doubtful CBD clearance during ERCP. Only 14 (11.57%) surgeons perform more than 10 laparoscopic CBD explorations per year. For CBD exploration during laparoscopic CBD exploration, 74/101 (73.27%) prefer to use choledochotomy approach and 17/101 (16.83%) prefer to use transcystic approach while 10/101 (9.9%) do not have any preference. Postoperative drain after laparoscopic CBD exploration was placed in all cases by 88/103 (85.44%) and in selective cases by 15/103 (14.56%) surgeons. Postoperative drain was kept for more than 48 hours by 53/101 (52.47%) and removed within 48 hours by 48/101 (47.53%) surgeons. After laparoscopic CBD exploration, 87/121 (71.90%) surgeons perform liver function test in all cases, 34/121 (28.10%) surgeons perform it selectively.

Discussion

This survey involved physicians and surgeons practicing in both academic and private hospitals with different levels of experience. In the current survey, there is nonadherence to either ASGE or ESGE risk stratification criteria in 23.5% of participants; these participants follow their clinical judgement and experience. This difference is associated with increasing age and seniority of post (associate professor/senior consultant) and not with place of work and broad specialty. ASGE risk stratification criteria are followed by more participants than ESGE; though clinical utility of ESGE appears better than ASGE criteria.[2]

During the evaluation of suspected choledocholithiasis, though guidelines recommend direct ERCP, 38.1% of participants prefer to do EUS or MRCP prior to ERCP in high likelihood group. A recent randomized controlled trial evaluating the role of EUS in a high likelihood of patients without cholangitis showed the EUS-first strategy significantly decreased the rate of diagnostic ERCP and hospital stay but did not achieve a significant reduction in negative endoscopic procedure outcomes.[10] Majority participants choose confirmatory test such as MRCP or EUS for the evaluation of intermediate likelihood group prior to ERCP. The choice between MRCP or EUS is driven by local availability of resources or expertise and preference of healthcare professional or patient as EUS and MRCP have comparable sensitivity and specificity.[11] However, usage of IOC during cholecystectomy might be more cost-effective for intermediate likelihood group compared with EUS/MRCP followed by ERCP and subsequent cholecystectomy or it can be substratified to reduce need for EUS or MRCP.[12,13]

For patients with gallstones with CBD stones, two-step procedure (ERCP followed by cholecystectomy) is most commonly preferred approach compared with one-step procedure (cholecystectomy and CBD exploration). Though single-step procedure appears more cost-effective, it reduces hospital visits and stay with similar efficacy and safety.[7] Similar results have been reported in America where 86% of surgeons opted for preoperative ERCP and European surgeon preferred single-stage procedure in only 12% of cases.[3,14] For difficult CBD stones, short biliary sphincterotomy with large balloon sphincteroplasty and laparoscopic CBD exploration are most commonly preferred modalities. Majority participants advise cholecystectomy at same admission or within 2 weeks after ERCP. If cholecystectomy is expected to be delayed beyond 2 weeks, prophylactic CBD stent is placed after CBD clearance by approximate one-third of participants. However, more than half of participants place prophylactic CBD stent irrespective of expected time interval of cholecystectomy after ERCP and CBD clearance. This approach can reduce possibility of obstructive jaundice due to slippage of stones into CBD from gallbladder either spontaneously or during cholecystectomy. However, it adds another procedure for removal of stent after cholecystectomy, and can lead to increased morbidity in case of loss of follow-up.

All participant surgeons perform laparoscopic cholecystectomy; however, only 11.57% surgeon perform more than 10 laparoscopic CBD exploration and choledochotomy is most commonly used approach. The possible reasons for low numbers of laparoscopic CBD exploration may be an excellent ERCP service, lack of equipment availability, caseload pressures, and increased operating time.[9] There is clear downward trend for the management of CBD stones with laparoscopic CBD exploration in United States and upward trend for utilization of ERCP for the management of CBD stone.[15]

We acknowledge that there are several limitations to this survey. The survey was distributed via social media and emails to physician and surgeons; therefore, response rate is difficult to estimate. There is also possibility of selection bias in the survey, though we could collect participants with various degree of experience and workplace (both academic and nonacademics). Also, surgeons constituted more than one-third of total participants.

This comprehensive survey has evaluated approach to management of choledocholithiasis by Indian physicians and surgeons. There is considerable variability in terms of diagnostic evaluation of suspected choledocholithiasis especially for high likelihood group. The two-stage procedure is more preferred approach than single stage. There is a need for national consensus for standardization of management of choledocholithiasis. The practices such as use of EUS/MRCP for high likelihood group, use of prophylactic CBD stent placement after ERCP and CBD clearance, and use of single stage approach especially in patient with intermediate likelihood group should be addressed in future studies.

Authors' Contributions
Nitin Jagtap, Sudatta Waghmare, and Rohan Khairatkar conceptualized and designed the study. Nitin Jagtap, Sridhar Sundaram, and Shreeyash Modak provided materials. Nitin Jagtap, Sridhar Sundaram, and Shreeyash Modak helped in data collection and/or processing. Jagtap Nitin and Sridhar Sundaram contributed to analysis and/or interpretation. Rohan Khairatkar and Nitin Jagtap were involved in literature search. Nitin Jagtap, Manu Tandan, and Sudatta Waghmare wrote manuscript. Sundeep Lakhtakia, G Venkat Rao, and D Nageshwar Reddy critically reviewed the manuscript. All authors provided final approval.

Conflict of Interest
None declared.

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