BMJ Open

Protocol for the CREST Choles (Chinese REgistry Study on Treatment of Cholecysto-Choledocholithiasis) study: an ambispective, multicenter, observational, open-cohort study

Jie-Gao Zhu,[1,2,3,4] Shanshan Wu,[3,5] Qiushi Feng,[6] Fei Li,[7] Wei Han,[8] Dianrong Xiu,[9] Haidong Tan,[10] Jianzhu Fu,[11] Xun Li,[12] Dong Shang,[13] Houbao Liu,[14] Binglu Li,[15] Li Yang,[16] Yuanyuan Kong,[3,5] Siyan Zhan ,[17] Wei Guo,[1,2,3,4] Zhong-Tao Zhang[1,2,3,4]

To cite: Zhu J-G, Wu S, Feng Q, *et al*. Protocol for the CREST Choles (Chinese REgistry Study on Treatment of Cholecysto-Choledocholithiasis) study: an ambispective, multicenter, observational, open-cohort study. *BMJ Open* 2019;**9**:e030293. doi:10.1136/bmjopen-2019-030293

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2019-030293).

Received 07 March 2019
Revised 25 September 2019
Accepted 08 November 2019

For numbered affiliations see end of article.

Correspondence to
Professor Zhong-Tao Zhang; zhangzht01@126.com

Professor Wei Guo; guoweibfh@163.com

ABSTRACT

Introduction The best approach for choledocholithiasis remains a matter of debate. Choledocholithiasis is usually treated with endoscopic sphincterotomy (EST), laparoscopic common bile duct exploration (LCBDE) or laparoscopic transcystic common bile duct exploration (LTCBDE). Data pertaining to the clinical outcomes of these approaches in the management of patients with cholecysto-choledocholithiasis in China are limited. An analysis of the economic burden associated with these treatments is lacking. The Chinese REgistry Study on the Treatment of Cholecysto-Choledocholithiasis (CREST Choles) was designed to address these issues in a real-world setting.

Methods and analysis CREST Choles was an ambispective, multicenter, observational, open-cohort study. A total of 2700 patients undergoing one of the three treatments (EST+laparoscopic cholecystectomy (LC), LCBDE+LC and LTCBDE+LC) during the period from 1 January 2013 to 1 December 2018 at participating centres were enrolled in the study. Patients with gallstones and confirmed common bile duct stones were included. Data pertaining to demographics, disease history, procedural details, imaging features and follow-up were collected. Follow-up was conducted at least 6 months after enrolment in the study and annual follow-up will be conducted until December 2020. The primary outcome is the rate of adverse outcomes within 3 years postoperatively. Economic analysis (eg, incremental cost-effectiveness ratio) would be performed to compare expense across treatments.

Ethics and dissemination Ethical approval was obtained at all participating centres. The registry presented is the first attempt to comprehensively evaluate the cost of treatment for cholecysto-choledocholithiasis in China. Findings are expected to be available in 2020 and will facilitate clinical decision making in such cases.

Trial registration number NCT02554097.

Strengths and limitations of this study

- In a real-world setting, we compare the three treatments used most commonly for cholecysto-choledocholithiasis in China (endoscopic retrograde cholangiopancreatography/endoscopic sphincterotomy+laparoscopic cholecystectomy (LC), laparoscopic common bile duct exploration+LC and laparoscopic transcystic common bile duct exploration+LC) in terms of outcomes and cost.
- The primary outcome measure is the rate of adverse outcomes. This is a composite endpoint that included recurrent or residual common bile duct stones, intrahepatic stones and complications related to treatment.
- The main limitation is that this study is an investigation of real-world patients with cholecysto-choledocholithiasis, and some confounders may induce a certain degree of bias.
- Another limitation is that this study will recruit from a population of Chinese and so applications to other populations will require further study.

INTRODUCTION

The prevalence of gallstones is 6%–12% in the Chinese population.[1 2] Choledocholithiasis is estimated to affect 3%–16% of individuals with gallstones.[3] Blockage of the common bile duct (CBD) by calculi results in obstructive jaundice. Complications such as cholangitis, hepatic abscess or pancreatitis can also develop, sometimes resulting in death. Timely treatment is critical to prevent disease progression.[4 5] Cholelithiasis with or without choledocholithiasis represents a major healthcare burden throughout the world.

Laparoscopic cholecystectomy (LC) is the gold standard for the treatment of gallstones.[4] However, the best approach for choledocholithiasis remains a matter of debate.[5 6] Choledocholithiasis is usually managed by endoscopic sphincterotomy (EST) and/or endoscopic retrograde cholangiopancreatography (ERCP),[7] especially in cases requiring the relief of biliary obstruction. LC may be performed at the same time or at a later date.[4] Alternatively, LC may be performed in combination with intraoperative CBD exploration.[7–9]

Meta-analyses[8 10] of randomised clinical trials have reported similar rates of stone clearance, postoperative morbidity and mortality for LC with intraoperative CBD exploration as well as ERCP followed by LC. A recent review[11] compared laparoscopic transductal CBD exploration (LCBDE) with laparoscopic transcystic CBD exploration (LTCBDE). The authors found no strong evidence to support use of one approach over the other. In China, few studies have investigated the baseline characteristics, management and clinical outcomes of patients with cholecysto-choledocholithiasis. A comparison of treatments in terms of cost-effectiveness is also lacking. The Chinese REgistry Study on Treatment of Cholecysto-Choledocholithiasis (CREST Choles) was designed to compare the three treatments used most commonly for cholecysto-choledocholithiasis in China (ERCP/EST+LC, LCBDE+LC and LTCBDE+LC) in terms of outcomes and cost.

METHODS

Patient registration

The CREST Choles study is an ambispective, multicenter, observational, open-cohort study. We screened all patients who underwent one of the aforementioned treatments during the period from 1 January 2013 to 1 December 2018. Clinical research coordinators (CRCs) invited patients to join our study telephonically at the time of the first follow-up. Recruitment was non-competitive and did not influence the clinical management of patients in the prospective cohort after the study started. Patients were recruited retrospectively from January 2013 to December 2016 and prospectively during the period from January 2017 to December 2018. Follow-up will be conducted until December 2020.

Inclusion criteria

1. Patients between 18 and 80 years of age with gallstone(s) confirmed by one of the imaging studies (ultrasonography, MRI and CT).
2. Patients with CBD stone(s) confirmed by MRI, CT, intraoperative cholangiography or transcystic CBD exploration.
3. Patients were treated with one of the three approaches (ERCP/EST+LC, LCBDE+LC or LTCBDE+LC). Patients undergoing LCBDE with primary CBD closure or T-tube drainage were included. In the ERCP/EST+LC group, we only included the management of ERCP/EST followed by LC and the time interval between procedures was ≤3 months.

Exclusion criteria

1. Patients with Mirizzi syndrome or intrahepatic bile duct stones.
2. History of EST/ERCP, percutaneous transhepatic biliary drainage, gallstone removal with gallbladder preservation or partial cholecystectomy prior to admission.
3. Patients with open cholecystectomy, single-incision cholecystectomy or robotic cholecystectomy.
4. Patients with severe cardiorespiratory, cerebral or metabolic disease.
5. Pregnant women.
6. Patients not willing or unable to provide consent for the study.

Outcome measures

In this study, the primary outcome measure was the rate of adverse outcomes. This was a composite endpoint that included biliary-related complications (cholangitis, bile duct stricture, bile duct injuries, bile leak and biliary carcinoma), stone-related outcomes (retained stone, recurrence of choledocholithiasis and stone reformation in the intrahepatic bile duct), pancreatitis, incision or abdominal or pulmonary infection, incisional hernia, and postoperative haemorrhage, bowel perforation, pancreatitis, abscess, death and other complications evaluated by researchers related to treatment.

Secondary outcome measures were as follows:

- Biliary stone recurrence-free survival rate: the time interval from the date of operation until the final follow-up examination or detection of biliary stone(s).
- Total cost: the total cost during hospitalisation.
- Failure rate: the incidence of failure of the primary procedure.
- Hospital stay: the total duration of hospitalisation (including hospital stay during ERCP/EST).
- Operation time: the total time required for the surgeries (including the ERCP/EST).
- Blood loss: total estimated blood loss during surgery.
- Mortality: all-cause mortality and mortality caused by complications.

Data collection

A standard case report form (CRF) was designed at the start of our study and transferred to an electronic data capture (EDC) system (http://a.est-b.medbanks.cn/). The EDC system provides a graphical user interface for data entry. It has a validation component for cross-checking user data and a reporting tool for analysis. Trained CRC from MedPISOn (Medical Technology Co, Shanghai, China) obtained all required information from the medical records and entered it into the electronic database. Data were recorded primarily in the electronic database. Clinical research associates (CRA) from Beijing Funhau Medicine Technology Co monitored the electronic database.

Table 1 Checklist for the first and follow-up visits in CREST Choles

	First entry of the clinical data	First day after surgery	Visits at 3-month intervals	Visits at 6-month intervals	Visits at 1-year intervals	Visits at 2-year intervals	Visits at 3-year intervals
Patient identification number	■						
Date of registration	■						
Admission time	■						
Age	■						
Gender	■						
Jaundice	■						
Smoking and drinking habits	■						
Disease history (hypertension, diabetes mellitus, coronary heart disease, chronic obstructive pulmonary diseases)	■						
History of previous upper abdominal surgery	■						
Routine blood tests	■	■	○	○	○	○	○
Biochemical investigations	■	■	○	○	○	○	○
CT and/or MRI (number and diameter of CBD stones and diameter of CBD)	■	○	○	○	○	○	○
Emergency or not	■	○	○	○	○	○	○
ASA	■	○	○	○	○	○	○
Surgical information	■	○	○	○	○	○	○
Discharge time	■	○	○	○	○	○	○
Complications	■		○	○	○	○	○
Cost	■	○	○	○	○	○	○
Adverse outcomes	■	■	■	■	■	■	■
Adverse event	○	○	○	○	○	○	○

○, optional; ■, mandatory.
ASA, American Society of Anesthesiologists physical status class; CBD, common bile duct.

The CRF was designed to collect the necessary information (table 1), as follows:

1. Demographics and disease history: age, gender, habits related to smoking and drinking, jaundice, admission, hypertension, diabetes mellitus, coronary heart disease, chronic obstructive pulmonary diseases, history of upper abdominal surgery.
2. Preoperative examinations: the results of routine blood tests and biochemical investigations, especially alanine transaminase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), gamma-glutamyl transpeptidase (GGT), total bilirubin (T-Bile) and direct bilirubin (D-Bile), the number and diameter of CBD stone(s), and the diameter of CBD from MRI, MRCP and/or CT data, the severity of acute pancreatitis assessed based on findings from CT.
3. Surgical information: emergency or elective, date of operation, American Society of Anesthesiologists physical status class, duration of operation, blood loss, number and diameter of CBD stone(s), diameter of CBD. Details about the methods used for CBD clearance and closure: primary suturing, T-tube drainage, endoscopic nasobiliary drainage, balloon expansion, microincision of the cystic duct, intraoperative lithotripsy, conversion to open surgery, conversion to an LCBDE or completing the LC and performing a post LC ERCP/EST in LTCBDE group, failure to clear CBD stones and abdominal drainage.
4. Outcomes: duration of hospitalisation, the results of routine blood tests and biochemical investigations (especially ALT, AST, ALP, GGT, T-Bile, D-Bile and amylase) on the first day after surgery, in-hospital complications, cost and death.

Follow-up

The first follow-up was conducted by CRC at participating hospitals through telephonic interviews that took place 3–6 months from the date of enrolment. Annual follow-up will be conducted until December 2020. Follow-up interviews were designed to acquire information about adverse events, complications related to treatment and the recurrence of stones following initial presentation. These events will be confirmed by the researchers together with the principal investigator through a comprehensive review of related medical records and details pertaining to follow-up. Abdominal ultrasound and liver function

tests were carried out if any abdominal symptom(s) developed during the follow-up period. MRCP was performed in the case of abnormal results on ultrasonography or liver function tests.

Quality control

Data were checked for completeness and precision at the point of entry by an independent authority (Beijing Funhau Medicine Technology Co). All the data have the standard and/or definition as mentioned in the CRF Reference Data. The CRA checked all data sourced from medical records and follow-up visits for accuracy. When analysing data with multiple timepoints after the point of entry, the quality check results and data modification traces were recorded in the EDC system.

Statistical analysis

All continuous data are described as medians with interquartile ranges or as means with SD. Categorical data are presented as proportions, frequencies or percentages. Continuous group data will be compared using Student's t-test for normally distributed variables or the Mann-Whitney test for skewed variables. The χ^2 test or Fisher's exact test will be used for categorical variables. Kaplan-Meier curve analysis will be used to compare the rate of stone recurrence among groups. The Cox proportional hazards model will be used to evaluate the HR for adverse outcomes and stone recurrence. P values <0.05 will be considered statistically significant.

Analyses were conducted in accordance with the intention-to-treat principle. If a patient after failed ERCP/EST underwent LCBDE or any other operation and subsequently developed bile leak, the patient was included in the ERCP+LC group and counted in the failure rate. The complications such as bile leak occurring due to secondary procedures such as LCBDE were neither counted in EST group nor in LCBDE group. In LTCBDE group, we would also record the conversion to an LCBDE or completing the LC and performing a post LC ERCP/EST. All these patients' data would be analysed in the perioperative data and would not be included in the long-term efficacy analysis.

Determination of sample size

The sample size calculation is based on estimates of the rate of adverse outcome obtained from previous systematic review and meta-analysis[12–14] and the data of our centres.[15] In order to achieve a power of 80% and an α value of 0.05, with a 18% adverse outcome rate in EST group, 12% in LCBDE group and 8% in LTCBDE group, the estimated total sample size required for the trial is at least 1755 patients (585 in each group). The withdrawal rate is assumed to be 20% during follow-up, thus the sample size for this study will need to be at least 2194 patients to show a crude difference of managements. Nevertheless, the present study is observational, and some patients will be recruited to allow us to have sufficient information on subgroups of patients to do further analysis. Hence, an estimated sample size of 2700 enrolled patients is required.

Patient and public involvement

Patients and public were not involved in the design, the recruitment or conduct of the study.

DISCUSSION

The optimal treatment for choledocholithiasis must have a high rate of success and a low rate of complications. The equipment needed for all components of treatment must be readily available and cost-effective for most patients. Unfortunately, there is no universal consensus on the management of CBD stones. The CREST Choles registry will update the clinical epidemiology of cholecystocholedocholithiasis in China and record the outcomes of the three minimally invasive treatments used most commonly for treatment. The primary outcome measure is the rate of adverse outcomes, a composite endpoint that includes in-hospital mortality, retained stones and complications over a long-term period such as recurrence of CBD stones, stenosis of the bile duct and cholangitis. The purpose of this study is to compare outcomes and costs of various treatment approaches to cholecystocholedocholithiasis in China and to facilitate evidence-based clinical decision making.

LC is the gold standard treatment for the treatment of gall bladder stones.[4] However, the best approach for choledocholithiasis remains a matter of debate.[5 6] In the past, the most commonly applied procedure was open CBD exploration combined with cholecystectomy for treating patients with cholecysto-choledocholithiasis. Along with the improvement of endoscopic techniques, ERCP/EST plays an increasingly important role in the diagnosis and management of CBD stone[7] and is recommended by the 2016 European Association for the Study of the Liver (EASL) clinical practice guidelines.[3] The most commonly applied procedure is preoperative ERCP/EST followed by LC,[3] especially in cases requiring the relief of biliary obstruction.[4] Nevertheless, accumulated evidence suggests that sphincter of Oddi damage after EST could lead to potential biliary infection and stone recurrence secondary to reflux of duodenal contents into the bile duct.[16] A recent meta-analyses[17] of 13 studies reported that LCBDE+LC is superior to pre-EST+LC in terms of short-term as well as long-term postoperative efficacy. However, half of the studies lacked the follow-up information. The LCBDE group in this study included transcystic and transductal exploration, which are two different surgical procedures. One recent review[11] compared transcystic and transductal exploration as a single-stage treatment for choledocholithiasis and concluded that transductal exploration was associated with a higher rate of complications. Another study found that LTCBDE for surgically fit patients with choledocholithiasis does not alter the length of the postoperative stay or increase morbidity compared with LC alone.[18] We have also reported that LTCBDE is

associated with far fewer complications; selected patients may be discharged safely in <24 hours.[19] Therefore, transcystic exploration should be considered an independent treatment for choledocholithiasis.

Although the transcystic approach avoids the difficult and tedious task of laparoscopic suturing required for laparoscopic choledochotomy, transcystic exploration may not be feasible in all cases of CBD stones due to the inability to cannulate the cystic duct, the large size of CBD stones and other technical difficulties. On the contrary, transductal exploration can be performed in most cases, except those with CBD diameter less than 7 mm. However, if CBD stones are diagnosed early, then they are likely to be small with a normal CBD. In such cases, the success rate of the transcystic exploration is greatly increased. Multiple reports[18 20–22] on LTCBDE have been published and different modalities have been applied with success. For CBD stones larger than the cystic duct, microincision of the cystic duct and its confluence was performed. This technique has its advantages, including easy access to the CBD and the straightforward removal of larger stones, and eliminates the need for routine drainage of the CBD.[23] Lithotripsy is particularly helpful for impacted biliary tract stones.[24] In one recent study, the use of lithotripsy to fragment stones made the transcystic approach feasible, resulting in success, without any increase in the incidence of complications.[15]

To the best of our knowledge, this is the largest observational study to systematically investigate the three invasive treatments performed most commonly. By exploring the long-term outcomes of these therapies for cholecysto-choledocholithiasis (including the recurrence of stones in the biliary tract), we can identify the risk factors that contributed strongly to stone recurrence. This study will also provide information on which laparoscopic procedure is most beneficial for patients with cholecysto-choledocholithiasis. Furthermore, by investigating the preoperative factors associated with short-term and long-term complications, we will be able to identify modifiable factors in order to prevent complications in the future. In summary, the current study will improve our understanding of the development of cholecysto-choledocholithiasis and factors influencing its outcomes, which will eventually facilitate the optimisation of individualised treatment.

As the current study is observational and partly retrospective, it has limitations related to selection bias and the inadequacy of data recording. Some key statistics such as diameter and number of CBD stones cannot be measured accurately in some cases, and biases may affect the assessment of factors that increase risk for adverse outcomes. To overcome these limitations and ensure a high quality of treatment and data recording, we selected tertiary hospitals with extensive clinical and research experience with choledocholithiasis. We also conducted third-party monitoring throughout the study and meetings. Researchers were trained at least twice per year, in order to ensure the accuracy of the data and promote adherence to the protocol. As most of the patients with cholecysto-choledocholithiasis will be treated at these tertiary hospitals in China, this study appears to have contributed to alterations in the nature of care provided for Chinese patients with cholecysto-choledocholithiasis.

ETHICS AND DISSEMINATION

This study was designed as an ambispective, observational registry, and the information was collected after discharge. Therefore, clinical practice will not be influenced by the study.

We have transferred the CRFs to an electronic database (http://a.est-b.medbanks.cn/), which will be stored in a hard disk and cloud environment. Result dissemination in professional peer-reviewed journals is expected to commence in 2020.

Author affiliations
[1]Department of General Surgery, Beijing Friendship Hospital, Capital Medical University, Beijing, China
[2]Beijing Key Laboratory of Cancer Invasion and Metastasis Research, Beijing, China
[3]National Clinical Research Center for Digestive Diseases, Beijing, China
[4]Beijing Institute of Clinical Medicine, Beijing, China
[5]Clinical Epidemiology and Evidence-Based Medicine Unit, Beijing Friendship Hospital, Capital Medical University, Beijing, China
[6]Endoscopy Center, Peking University First Hospital, Beijing, China
[7]Department of General Surgery, Xuanwu Hospital, Capital Medical University, Beijing, China
[8]Department of General Surgery, Beijing Luhe Hospital, Capital Medical University, Beijing, China
[9]Department of General Surgery, Peking University Third Hospital, Beijing, China
[10]Department of General Surgery, China-Japan Friendship Hospital, Beijing, China
[11]Department of General Surgery, Beijing Tongren Hospital, Capital Medical University, Beijing, China
[12]Department of General Surgery, The First Hospital of LanZhou University, Lanzhou, China
[13]Department of General Surgery, First Affiliated Hospital of Dalian Medical University, Dalian, China
[14]Department of General Surgery, Zhongshan Hospital Affiliated to Fudan University, Shanghai, China
[15]Department of General Surgery, Peking Union Medical College Hospital, Beijing, China
[16]Department of Health Policy and Management, School of Public Health, Peking University, Beijing, China
[17]Department of Epidemiology and Biostatistics, School of Public Health, Peking University, Beijing, China

Acknowledgements School of Public Health, Peking University and 11 tertiary hospitals in China participated in the study: Beijing Friendship Hospital, Capital Medical University; Peking University First Hospital; Xuanwu Hospital, Capital Medical University; Beijing Luhe Hospital, Capital Medical University; Peking University Third Hospital; China-Japan Friendship Hospital; Beijing Tongren Hospital, Capital Medical University; The First Hospital of LanZhou University; The First Affiliated Hospital of Dalian Medical University; Zhongshan Hospital Affiliated with Fudan University; Peking Union Medical College Hospital. We would like to thank the chief investigators at participating hospitals: Xiaona Zhou and Jun Liu (Beijing Friendship Hospital, Capital Medical University); Dapeng Bian and Huan Zhang (Peking University First Hospital); Yamin Zheng (Xuanwu Hospital, Capital Medical University); Peng Liu (Beijing Luhe Hospital, Capital Medical University); Gang Wang and Long Cui (Peking University Third Hospital); Li Xu (China-Japan Friendship Hospital); Jiajun Ji (Beijing Tongren Hospital, Capital Medical University); Ping Yue and Wenbo Meng (The First Hospital of LanZhou University); Guixin Zhang (The First Affiliated Hospital of Dalian Medical University); Tao Suo (Zhongshan Hospital Affiliated with Fudan University); Zhibo Zheng (Peking Union Medical College Hospital).

Contributors Z-TZ is the principal investigator and together with WG and SZ has coordinated and actively participated in all the phases of trial design. These authors, as well as J-GZ, SW and LY assisted in drafting the protocol. WG, QF, FL, WH, DX, HT, JF, XL, DS, HL and BL developed the ethics board application and assisted in patient enrolment. J-GZ, SW, LY and YK designed the statistical analysis plan. J-GZ and WG wrote the main manuscript. Z-TZ and SZ critically revised the methodology and design of the trial protocol, as well as the writing of the manuscript. All authors contributed to the writing of the manuscript and agreed with submission of the final version for publication.

Funding The author(s) disclose receipt of the following financial support for the research, authorship and/or publication of this article: This program is sponsored by Capital Health Research and Special Development (No 2016-1-1111), National Key Technologies R&D Program (No 2015BAI13B09), Beijing Municipal Administration of Hospitals Incubator Program (No PX2016001 and No PX2019004).

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval This registry protocol was reviewed and approved by the Ethics Committees of Beijing Friendship Hospital, Capital Medical University; Peking University First Hospital; Xuanwu Hospital, Capital Medical University; Beijing Luhe Hospital, Capital Medical University; Peking University Third Hospital; China-Japan Friendship Hospital; Beijing Tongren Hospital, Capital Medical University; The First Hospital of Lanzhou University; The First Affiliated Hospital of Dalian Medical University; Zhongshan Hospital Affiliated to Fudan University; Peking Union Medical College Hospital. Patients admitted to the hospital for cholecysto-choledocholithiasis before the prospective study protocol received ethical approval were telephonically contacted for verbal agreement. After ethical approval of the prospective study protocol, signed informed consent was obtained from patients admitted to participating hospitals. The present study was conducted in accordance with the provisions of the Declaration of Helsinki.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iD

Siyan Zhan http://orcid.org/0000-0001-7252-5349

REFERENCES

1 Wang S, Kou C, Liu Y, *et al*. Rural-urban differences in the prevalence of chronic disease in northeast China. *Asia Pac J Public Health* 2015;27:394–406.
2 Chen L-Y, Qiao Q-H, Zhang S-C, *et al*. Metabolic syndrome and gallstone disease. *World J Gastroenterol* 2012;18:4215–20.
3 European Association for the Study of the Liver (EASL). Electronic address: easloffice@easloffice.eu. EASL clinical practice guidelines on the prevention, diagnosis and treatment of gallstones. *J Hepatol* 2016;65:146–81.
4 Tazuma S, Unno M, Igarashi Y, *et al*. Evidence-based clinical practice guidelines for cholelithiasis 2016. *J Gastroenterol* 2017;52:276–300.
5 Williams E, Beckingham I, El Sayed G, *et al*. Updated guideline on the management of common bile duct stones (CBDS). *Gut* 2017;66:765–82.
6 Internal Clinical Guidelines T. *National Institute for health and care excellence: clinical guidelines. gallstone disease: diagnosis and management of cholelithiasis, cholecystitis and choledocholithiasis*. 2014. London: National Institute for Health and Care Excellence (UK) Copyright (c) National Clinical Guideline Centre, 2014.
7 Baucom RB, Feurer ID, Shelton JS, *et al*. Surgeons, ERCP, and laparoscopic common bile duct exploration: do we need a standard approach for common bile duct stones? *Surg Endosc* 2016;30:414–23.
8 Dasari BV, Tan CJ, Gurusamy KS, *et al*. Surgical versus endoscopic treatment of bile duct stones. *Cochrane Database Syst Rev* 2013;12.
9 Williams EJ, Green J, Beckingham I, *et al*. Guidelines on the management of common bile duct stones (CBDS). *Gut* 2008;57:1004–21.
10 Alexakis N, Connor S. Meta-analysis of one- vs. two-stage laparoscopic/endoscopic management of common bile duct stones. *HPB* 2012;14:254–9.
11 Reinders JSK, Gouma DJ, Ubbink DT, *et al*. Transcystic or transductal stone extraction during single-stage treatment of choledochocystolithiasis: a systematic review. *World J Surg* 2014;38:2403–11.
12 Prasson P, Bai X, Zhang Q, *et al*. One-stage laproendoscopic procedure versus two-stage procedure in the management for gallstone disease and biliary duct calculi: a systemic review and meta-analysis. *Surg Endosc* 2016;30:3582–90.
13 Yin Z, Xu K, Sun J, *et al*. Is the end of the T-tube drainage era in laparoscopic choledochotomy for common bile duct stones is coming? A systematic review and meta-analysis. *Ann Surg* 2013;257:54–66.
14 Lu J, Cheng Y, Xiong X-Z, *et al*. Two-stage vs single-stage management for concomitant gallstones and common bile duct stones. *World J Gastroenterol* 2012;18:3156–66.
15 Zhu JG, Han W, Guo W, *et al*. Learning curve and outcome of laparoscopic transcystic common bile duct exploration for choledocholithiasis. *Br J Surg* 2015;102:1691–7.
16 Toouli J. Sphincter of Oddi: function, dysfunction, and its management. *J Gastroenterol Hepatol* 2009;24:S57–62.
17 Pan L, Chen M, Ji L, *et al*. The safety and efficacy of laparoscopic common bile duct exploration combined with cholecystectomy for the management of Cholecysto-choledocholithiasis: an up-to-date meta-analysis. *Ann Surg* 2018;268:247–53.
18 Hanif F, Ahmed Z, Samie MA, *et al*. Laparoscopic transcystic bile duct exploration: the treatment of first choice for common bile duct stones. *Surg Endosc* 2010;24:1552–6.
19 Zhu J-gao, Han W, Zhang Z-tao, *et al*. Short-term outcomes of laparoscopic transcystic common bile duct exploration with discharge less than 24 hours. *J Laparoendosc Adv Surg Tech A* 2014;24:302–5.
20 Lyass S, Phillips EH. Laparoscopic transcystic duct common bile duct exploration. *Surg Endosc* 2006;20:S441–5.
21 Rojas-Ortega S, Arizpe-Bravo D, Marín López ER, *et al*. Transcystic common bile duct exploration in the management of patients with choledocholithiasis. *J Gastrointest Surg* 2003;7:492–6.
22 Paganini AM, Guerrieri M, Sarnari J, *et al*. Thirteen years' experience with laparoscopic transcystic common bile duct exploration for stones. Effectiveness and long-term results. *Surg Endosc* 2007;21:34–40.
23 Chen X-M, Zhang Y, Cai H-H, *et al*. Transcystic approach with micro-incision of the cystic duct and its confluence part in laparoscopic common bile duct exploration. *J Laparoendosc Adv Surg Tech A* 2013;23:977–81.
24 Raestrup H, Kanehira E, Weiss U, *et al*. Laparoscopic treatment of common bile duct stones. Phantom experiments using electrohydraulic and pulsed dye laser lithotripsy. *Endosc Surg Allied Technol* 1993;1:137–43.