Endoscopic Retrograde Cholangiopancreatography followed by Laparoscopic Cholecystectomy versus Laparacosopic Cholecystectomy and Common Bile Duct Exploration in Concomitant Gallstone and Common Bile Duct Stone

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ABSTRACT

Aim: *Cholecystolithiasis is frequently accompanied with choledocholithiasis, with the incidence ranged from 8-20%. The current management of concomitant cholecystolithiasis and choledocholithiasis is varied**,** either Endoscopic Retrograde Cholangiopancreatography (ERCP) followed by Laparoscopic Cholecystectomy (LC) or LC followed by ERCP, or single-step procedure, i.e. LC with common bile duct exploration (LCBDE). This evidence-based case report (EBCR) will compare the efficacy, effectiveness, and safety between the ERCP+LC and LCBDE.*

Method: *The article search was done through PubMed, EBSCO, dan Cochrane at 1st December 2015 using keywords ERCP, LC, gallstone, common bile duct. Two meta-analyses and two randomized clinical trial were found and critical appraisal was done to all four articles.*

Results: *All four studies showed similar stone clearance for both procedures. One meta-analysis showed better clearance in single procedure (OR = 1,56; 95% CI: 1,05-2,33; p: 0,03; heterogeneity: I^2 = 42%). Mortality and morbidity rate, complication, and the need of another procedure were no difference between single-step and two-step procedure. Length of stay and cost effectiveness were better in single-step procedure in all studies.*

Conclusion: *Single-step procedure may show better result in stone clearance, cost-effectiveness, and length of stay. However, this procedure may be limited, thus can only be done in health center with sufficient resources. ERCP followed by LC is still the preferred procedure, especially in patient with worse performance status and limited health center.*

Keywords: *concomitant, gallstone, common bile duct stone, endoscopic retrograde cholangiopancreatography (ERCP), laparoscopic cholecystectomy (LC), laparascopic with common bile duct exploration (LCBDE), stone clearance, mortality*

ABSTRAK

Tujuan: *Kolesistolitiasis (batu pada kandung empedu) seringkali disertai dengan koledokolitiasis (batu pada saluran empedu), dengan angka kejadian bervariasi, yaitu 8-20%. Tatalaksana pada pasien dengan masalah di atas bervariasi, baik dilakukan dua tahap, yaitu Endoscopic Retrograde Cholangiopancreatography (ERCP) diikuti dengan Laparoscopic Cholecystectomy (LC), atau pun satu tahap, yaitu LC disertai eksplorasi saluran empedu (LCBDE). Laporan kasus berbasis fakta ini akan membahas efikasi, efektivitas, maupun keamanan di antara kedua tindakan (ERCP + LC versus LCBDE).*

Metode: *Pencarian artikel dilakukan melalui PubMed, EBSCO, dan Cochrane pada 1 Desember 2015 menggunakan kata kunci ERCP, LC, gallstone, common bile duct, didapatkan 2 meta-analisis dan 2 uji klinis. Dilakukan telaah kritis pada keempat artikel tersebut.*

Hasil: *Keempat studi menunjukkan bersihan batu yang serupa pada kedua prosedur. Pada satu meta analisis dijumpai hasil yang lebih baik pada prosedur tunggal, yaitu LC+LCBDE, dibandingkan dengan ERCP diikuti LC (OR = 1,56; 95% CI: 1,05-2,33; p: 0,03; heterogeneity: I^2 = 42%). Angka mortalitas, komplikasi, morbiditas pasca operasi, perlunya tindakan tambahan tidak berbeda bermakna pada seluruh studi. Lama rawat dan biaya yang diperlukan lebih baik pada prosedur tunggal dari seluruh studi.*

Simpulan: *Prosedur tunggal (LC+LCBDE) menunjukkan hasil lebih baik dalam bersihan batu, biaya, dan lama rawat. Akan tetapi, prosedur ini terbatas, sehingga hanya dapat dilakukan pada pusat kesehatan yang memiliki infrastruktur dan sumber daya yang cukup, ERCP diikuti LC tetap menjadi pilihan utama pada pasien dengan kondisi yang lebih buruk dan dengan fasilitas kesehatan yang belum memadai.*

Kata kunci: *batu empedu, batu saluran empedu, endoscopic retrograde cholangiopancreatography (ERCP), laparoscopic cholecystectomy (LC), laparascopic with common bile duct exploration (LCBDE), bersihan batu, mortalitas*

INTRODUCTION

Choledocholithiasis is a medical term of stones found in common bile duct, while cholecystolithiasis is defined as stones in gallbladder. In general term, it may be said as cholelithiasis. The occurrence of choledocholithiasis along with cholelithiasis is approximately 3-10%, while other literatures stated the frequency is varied between 8-20%.[1-4] There has been a number of different approaches in managing the concomitant gallstone and common bile duct, i.e single-step and two-stage therapy. Single-step strategy comprises of laparosopic cholecystectomy (LC) and laparoscopic common bile duct exploration (LCBDE).[2] The two-stage therapy consists of LC and pre- or postoperative endoscopic retrograde cholangiopancreatography (ERCP).[1,2]

The use of ERCP has been accepted as the treatment of choice before cholecystectomy in patient with concomitant gallstone and common bile duct stone.[5] The technique was carried out as a day-care procedure, under intravenous sedation. The steps are as followed: scope is inserted until duodenum, and then sphyncteroctomy. The next step is cannulation and, if the stone is visible, stone extraction is done. Cannulation was assisted by guide wire, before contrast dye injected to confirm the presence of CBD stone. Biliary sphincterotomy was performed using a combination current of cutting and coagulation, with extraction of the stone was followed using Dormia basket.[5] The laparoscopic cholecystectomy that followed after was done by ligating the cystic duct and artery, partially dissecting the gallbladder, and removing the stones and debris from CBD by either flushing with a copious amount of normal saline or by using forceps.[5]

The two-stage therapy is the more common therapy, as well as selected therapy accepted in many part of the world for the treatment of choledocholithiasis and cholecystolithiasis.[1,2] This is done to avoid the complexities of laparoscopy cholecystectomyand potential problems from T-tube drainage.[1] Preoperative ERCP is done to avoid the possibility of having to 'open' patients at LC, hence lower the possibilities of having further surgery if the LC is failed.[2,6] However, there has been debate regarding the two-stage therapy, since the length of stay would probably be longer than the single-stage, and the side effect of ERCP thatmay be experienced in patients, complicating the operation. The single-step therapy is also not without some drawbacks, since the common bile duct (CBD) is closed with T-tube drainage after LCBDE and patients are needed to carry the drain for several

Table 1. Search strategy in each search tool

EBSCO	ERCP AND cholecystectomy AND gallstone AND common bile duct stone	14
PubMed	(("cholangiopancreatography, endoscopic retrograde"[MeSH Terms] OR ("cholangiopancreatography"[All Fields] AND "endoscopic"[All Fields] AND "retrograde"[All Fields]) OR "endoscopic retrograde cholangiopancreatography"[All Fields] OR "ercp"[All Fields]) AND ("cholecystectomy"[MeSH Terms] OR "cholecystectomy"[All Fields]) AND ("gallstones"[MeSH Terms] OR "gallstones"[All Fields] OR ("common"[All Fields] AND "bile"[All Fields] AND "duct"[All Fields] AND "stone"[All Fields]) OR "common bile duct stone"[All Fields]) AND ("gallstones"[MeSH Terms] OR "gallstones"[All Fields] OR ("gallbladder"[All Fields] AND "stone"[All Fields]) OR "gallbladder stone"[All Fields] OR "cholelithiasis"[MeSH Terms] OR "cholelithiasis"[All Fields] OR ("gallbladder"[All Fields] AND "stone"[All Fields]) OR "gallbladder stone"[All Fields] OR "cholecystolithiasis"[MeSH Terms] OR "cholecystolithiasis"[All Fields] OR ("gallbladder"[All Fields] AND "stone"[All Fields]))) AND (Clinical Trial[ptyp] AND "loattrfull text"[sb])	57
Cochrane	ERCP,cholecystectomy, gallstone, common bile duct stone	1

weeks before removal.[2] There are risks related to T-tube drainage, such as bile leakage, bile infection and wound infection. In this evidence-based case report, we would like to evaluate the clinical safety as well as effectiveness of the two-stage (ERCP + LC) versus single-stage (LC+LCBDE) management for patients with concomitant gallstone and CBD stone. The outcome that we expect to find in this EBCR was the comparison of efficacy of removing CBD stones and gallbladder between two stage (ERCP+LC) and single stage approach (LCBDE).

CLINICAL QUESTION

A-57 year old patient was admitted to Cipto Mangunkusumo Hospital, referred from Gatot Subroto Hospital with jaundice since 2 months prior to admission. Pale stool, dark-colored urine, nausea and vomiting was also experienced in the past 2 months, while weight loss and fever were denied. The patient felt intermittent right-upper quadrant and epigastric pain. Patient denied experienced jaundice previously nor the use of needle, surgery, blood transfusion, and promiscuity. From the physical examination, we found icteric sclera and right upper pressure pain, with visual analog scale was 3. From the laboratory examination we found hyperbilirubinemia, with high direct bilirubin component. Other laboratory examination results were found within normal limit.

The patient brought with him the result of magnetic resonance cholangiopancreatography (MRCP) done previously in Gatot Subroto Hospital, with cholelithiasis and choledocholithiasis in common bile duct proximal as the result, causing the dilatation of intrahepatic biliary duct right and left, both 1 cm in diameter. Acute hepatitis and cholelithiasis were found in abdomen ultrasonography done in Gatot Subroto Hospital.

In Cipto Mangunkusumo Hospital, ERCP was done to find and remove the CBD stone. Several yellowish stone were found and extracted from balloon extractor. There were some stones left in bile duct, so the patient was then consulted to Digestive Surgery Department. He was scheduled to undergo laparoscopic cholecystectomy. The patient was stable before, during ERCP, and after the procedure, and the elective laparoscopic cholecystectomy was decided. In patient with concomitant gallbladder and common bile duct stone, is preoperative ERCP and laparoscopic cholecystectomy superior than laparoscopic cholecystectomy and bile duct exploration?

METHOD

The article searching was conducted in PubMed, EBSCO, and Cochrane in 1st December 2015, using search tools containing ERCP, LC, gallstone, and common bile duct stone as the keywords (Table 1). Search strategy, inclusion and exclusion criteria can be seen in Figure 1.

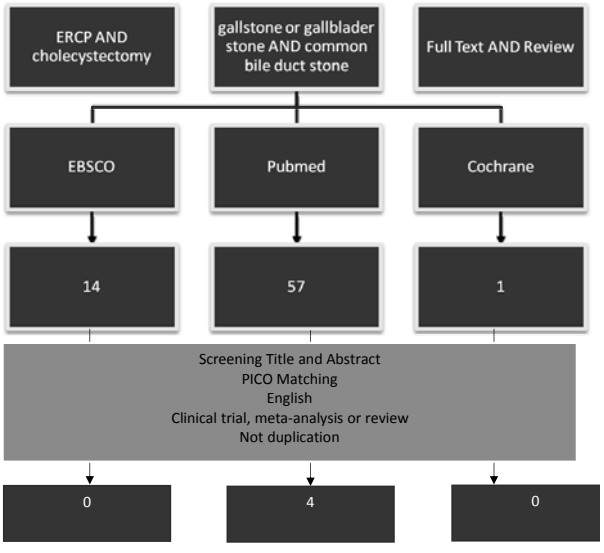

Figure 1. Flow chart of search strategy

There were 4 articles found during the research, after omitting the articles unmatched to the PICO question, duplication of the articles, and not review type of article. Three articles are meta-analysis and the other two are clinical trial. All of the articles were available and taken to be appraised.

Table 2. Critical Appraisal of randomized controlled trial

RCTs	Relevance				Validity						Importance			
	Patient	Intervention	Comparison	Outcome	Random	Long follow up	All patient analyzed	Blind	Treated equally	Similar at start	RR	ARR	RRR	NNT
Bansal et al, 2014	+	+	+	+	+	+	+	No	+	+	0.58	0.083	0.42	12
Ding et al, 2014	+	+	+	+	+	+	+	No	+	+	1.17	-0.009	-0.17	-111

RCT: randomized controlled trial; RR: relative risk; ARR: absolute risk reduction; RRR: relative risk reduction; NNT: number needed to threat

Table 3. Critical Appraisal of meta analysis

Meta Analysis	Relevance				Validity					Importance		
	Patient	Intervention	Comparison	Outcome	From RCT	Including all trial	Assessing individual validity	Consistency	Individual or aggregate data	OR (favorable to)	PEER	NNT
Alexakis, 2012	+	+	+	+	+	+	+	-	individual	0.89 (2-stage) (95% CI: 0,65-1,21)	0.25	47.15
Zhu et al, 2015	+	+	+	+	+	+	+	+	individual	1.56 (1-stage) (95% CI: 1,05-2,33)	0.17	13.86

RCT: randomized controlled trial; NNT: number needed to threat, PEER: patient expected event rate

The two meta-analysis were appraised using meta-analysis review form. All two clinical trials had been included in the meta-analysis. The appraisal forms for each study were obtained from http://www.cebm.net/critical-appraisal/ and presented in Table 2

RESULTS

Alexakis et al did a meta-analysis and found 9 studies from 1998 to 2011. From the meta-analysis they found that the two-stage procedure had slightly better result in terms of stone clearance. They compare the one stage as the first group and two stage as the second group and found OR= 0,89 (95% CI: 0,65-1,21), favoring two stage management. The difference, however, is not significant (p = 0.46), while the heterogeneity is good, with low heterogeneity (I^2 = 69%).[7] Mortality and morbidity also showed similar result, with both strategies show no differences. However, from the discussion, it may seems that majority of the trials are underpowered, meaning lack of number of samples. The meta-analysis also shows differences in ERCP success rate, which may indicate differences in the skills of different centers. From this meta-analysis, it is also known that LC+LCBDE was not widespread favor amongst the surgical community, due to only experienced laparoscopic surgeons may be able to do it.

Zhu et al also did similar meta-analysis and found different result. They included 8 studies, up to August 2014 and a slightly-but significant-higher percentage of stone clearance in one-stage procedure, with OR = 1,56 (95% CI: 1,05-2,33), with p = 0,03 and heterogeneity is low (I^2 = 42%).[2] The mortality, conversion to other procedure, and post-operative morbidity were found not significant. The length of stay and total operating times were analyzed in this meta-analysis and found that the single-stage strategy showed better result. Both forrest plot in terms of stone clearance can be seen in Figure 1 and 2.

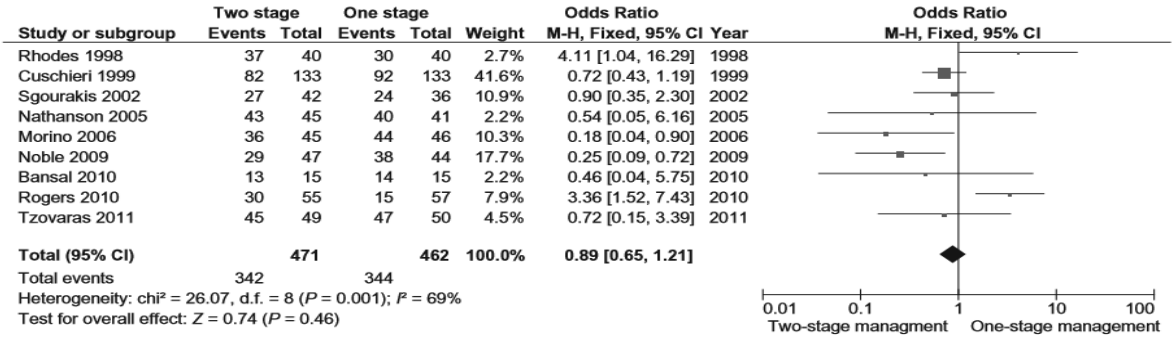

Figure 1. Forrest plot of Alexis et al[7]

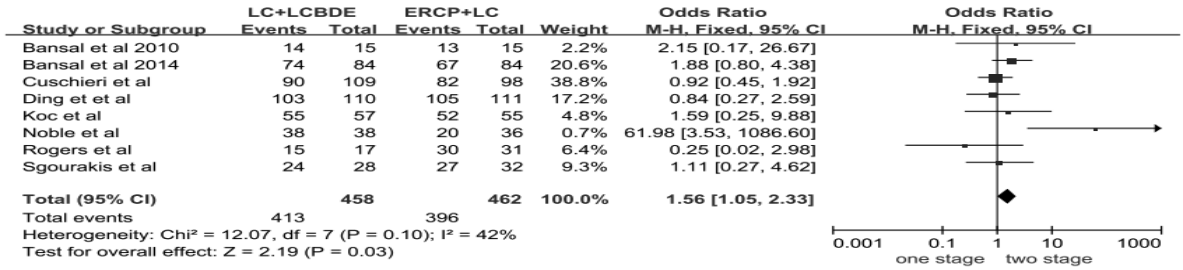

Figure 2. Forrest plot of Zhu et al[2]

Bansal et al compared 168 patients in two groups, with 84 patients in group 1 undergone LC+LCBDE and the other group ERCP + LC. The success rates of both groups were similar, 88.1% in group 1 and 79.8% in group 2.[5] The overall operative time was significantly longer in group 1, while major complications, postoperative wound infection, pain, and mortality was found similar in both groups. The length of stay and cost in group 1 is significantly lower than group 2.[5]

Ding et al compared 211 patients in two groups, with group 1 undergone single-stage approach and group 2 (111 patients) undergone two-stage approach.[1] The success rate of both groups were also similar, 93.64% vs. 94.59% (p = 0.76), with also similar complication rate and no fatal complications occurred in either group.

DISCUSSION

The occurrence of choledocholithiasis along with cholelithiasis is approximately 3-10%, while other literatures stated the frequency is varied between 8-20%.[1-4] There has been a number of different approaches in managing the concomitant gallstone and common bile duct, i.e. single-step and two-stage therapy. Single-step strategy comprises of laparoscopic cholecystectomy (LC) and laparoscopic common bile duct exploration (LCBDE) (LC+LCBDE).[2] The two-stage therapy consists of LC and pre- or postoperative endoscopic retrograde cholangiopancreatography (ERCP).[1,2]

The two-stage therapy is the more common therapy, as well as selected therapy accepted in many part of the world for the treatment of choledocholithiasis and cholelithiasis.[1,2] This is done to avoid the complexities of laparoscopy choledochotomy and potential problems from T-tube drainage.[1] Preoperative ERCP is done to avoid the possibility of having to 'open' patients at LC, hence lower the possibilities of having further surgery if the LC is failed.[2,6]

The use of ERCP has been accepted as the treatment of choice before cholecystectomy in patient with concomitant gallstone and common bile duct stone.[5] The technique was carried out as a day-care procedure, under intravenous sedation. Cannulation was assisted by guide wire, before contrast dye injected to confirm the presence of CBD stone. Biliary sphincterotomy was performed using a combination current of cutting and coagulation, with extraction of the stone was followed using Dormia basket.[5] The laparoscopic cholecystectomy that followed after was done by ligating the cystic duct and artery, partially dissecting the gallbladder, and removing the stones and debris from CBD by either flushing with a copious amount of normal saline or by using forceps.[5]

ERCP was first reported in 1968 and was quickly accepted as a safe, direct technique for evaluating pancreatobiliary disease, particularly biliary obstruction due to choledocholithiasis and other benign diseases of the biliary tract, such as biliary strictures and postoperative biliary leaks.[8] ERCP has evolved from diagnostic procedure to one that is almost exclusively therapeutic.[8] successful ERCP with relief of biliary obstruction achievable in more than 90% of patients.[8] In this era, ERCP may be done before or even after laparoscopic cholesystectomy, if the stone cannot be cleared with common duct exploration.[8] LC was done 2-3 weeks after ERCP.[5]

The complication of ERCP is pancreatitis with the risk factors are age less than 60-70 years, female, and low probability of structural disease. Other co-morbid conditions may increase risk include cirrhosis, previous post-ERCP pancreatitis and coagulopathy, if the sphincterotomy is undertaken.[9] The procedure is relatively safe, although may cause some serious adverse effects, such as bleeding, perforation, pancreatitis, disruption of the intact sphincter of Oddi.[2,3]

Pancreatitis is the most common serious complication, with the incidence is around 3.5%.[10]

The procedure may cause transient increase in serum pancreatic enzymes in as many as 75% of patients, but such increase does not necessarily develop into pancreatitis.[10] Most ERCP-associated bleeding is intraluminal, although intraductal bleeding and hematomas can occurred, with the prevalence was 1.3% and the bleeding was mild.[10] Other serious complication, such as perforation (0.1-0.6%) and infection (cholangitis (1%) and cholecystitis (0.2-0.5%) may also occurred, but the incidence is low.[10]

The introduction of laparoscopic technique in the management of stone of biliary system has given the physician an alternative in treating patient with concomitant bile duct and gallbladder stone. In laparoscopic cholecystectomy and common bile duct exploration (LC+LCBDE), the surgical procedure is as follow: laparoscopic cholecystectomy was performed, with gallbladder was partially dissected from its bed and used for retraction.[4,5] The cystic duct was dissected close to the gallbladder and clipped after identification to prevent migration during surgery.[4] nA longitudinal supraduodenal choledochotomy was made using Endoknife.[5] Further dissection of the cystic duct was done towards the common bile duct to do intraoperative cholangiography and facilitate the introduction of flexible choledochoscopy to give the operator the information of stone location, size, number and the structure of cystic and common bile duct.[4] The stones debris from the CBD were removed using either a flexible choledochoscopy or rigid nephroscope.[5] Using choledochoscopy, the upper portion of CBD, lower part of CBD up to papilla, right and left hepatic ducts, and secondary and tertiary ducts can be visualized. Any residual stone then removed using a Dormia basket, Fogatry catheter, or triflange forceps. A mechanical lithotripter was used to break impacted stones and the fragments were removed. A check choledocoscopy was performed to ensure CBD clearance. The choledochotomy was closed using absorbable suture either primarily or over a T-Tube.[5]

Several studies have tried to evaluate the effectiveness of the two-step approach in concomitant gallstone and common bile duct stone. The primary outcome of all studies that we found was the stone clearance. Meta-analysis of eight studies from Zhu et al found that significant difference between two groups in terms of stone clearance, with the success rate of single-stage was 90.2% vs. 85.7% in the two-stage group and the heterogeneity was low (OR = 1.56; 95% CI = 1,05-2,33, Chi^2 = 12,07, p = 0,1, I^2 = 42%), which means all the studies showed similar result.[2] Other meta-analysis of 9 studies conducted by Alexakis et al showed different result, with the clearance between two groups do not differ (72.6% in two-step vs. 74.4% in single-step (OR = 0.89; 95% CI = 0,65-1,21; p = 0.46), also with low heterogeneity (Chi^2 = 26,07, p = 0,001, I^2 = 69%)[7] Other studies by Ding et al and Bansal et al included in Zhu et al also highlight the same result as Alexakis et al (94,59%, vs. 93,64%, p = 0,75 and 79.8% vs. 88.1% , p = 0,20 respectively).[1,2,5,7]

Other study conducted by Rogers et al tried to compare ERCP + LC and LC + LCBDE in only common bile duct stone found that the finding of common bile duct was more common (56% vs. 30%, p = 0.007), due to the ERCP technique allowing the physician to find small stone and sludge through fluoroscopic and endoscopic identification.[11] In LCBDE, the small stones seemed to be cleared during the injection of contrast during antegrade cholangiography phase of LCBDE.[11] The success rate of stone removal was not significant between groups in the study (98% in two-step vs. 88% in single-step, p = 0.28).[11]

Other secondary outcomes, such as mortality, morbidity, length of stay, total operative times, and conversion to other procedures have been analyzed in the meta-analysis and randomized-controlled trial. As for mortality, morbidity, and conversion to other procedures, all of the literatures stated that no significant difference between the two strategy.[2,7] As for the length of stay and total operative times, the single-step show advantages over the two-step, with the single step had statistically significant lesser length of stay (MD = 1,02; 95% CI: -1,99 to -0,04, p = 0,04 in Zhu et al) and total operative time (MD =16,87; 95% CI: -27,55 to -6,01, p = 0,002 in Zhu et al)[2]

In terms of cost-effectiveness, most studies shown that the single step procedure is the most cost effective. Bansal et al reviewed the total cost needed for each group, with two-step strategy cost $506.50, while the single-step strategy was significantly cheaper, cost only $394.10 (p = 0.001).[5] Meta-analysis conducted by Alexakis et al only found two studies reported cost analysis, and found that the two-stage approach had significantly higher cost ($1319 higher in USA study and €1005 in Italian study).[7] However, Rogers et al reported no statistically significant difference in total hospitalization charges between two groups.[3, 11]

Both meta-analysis, however, stated that one-step therapy for concomitant common bile duct and gallbladder stone may be only done in a center with available infrastructure and expertise for laparoscopic CBD exploration.[2,7] ERCP, however, still play important role due to its availability to release biliary obstruction in acute suppurative obstructive cholangitis patients in a timely fashion, which causes the patient to tolerate the surgery more easily.[2] Two-stage strategy is still favored over single-stage, since it is indicated for relatively higher risk patients, including those with cholangitis, deep jaundice, coagulopathy, severe pancreatitis, and retained stones or post cholecystectomy CBD stones.[5,6] For fit patient with uncomplicated concomitant gallbladder and CBD stones, along with availability of expert and facilities in laparoscopic CBD exploration, LC+LCBDE has better outcome.[5,12]

CONCLUSION

There has been a number of different approaches in managing the concomitant gallstone and common bile duct, i.e. single-step and two-stage therapy. Single-step strategy comprises of laparoscopic cholecystectomy (LC) and laparoscopic common bile duct exploration (LCBDE) (LC+LCBDE).[2] The two-stage therapy consists of LC and pre- or postoperative endoscopic retrograde cholangiopancreatography (ERCP).[1,2]

There is no clear consensus regarding the optimal management strategy of concomitant gallbladder stone and common bile duct stone, with both strategy has the strength and weakness point from a number of randomized controlled trial and meta-analysis. There were no difference statistically in terms of stone clearance, morbidity, mortality, nor conversion to other procedures.

The two-step strategy is more applicable in patients with worse condition, while the single-step strategy has lesser length of stay and total operative times, and also more cost-effective. However, the single-step strategy is not applicable in many healthcare, since it requires specific skill of surgery, which may not be found in every healthcare, and the patient need to be in good condition pre-operatively. Single step may be an alternative for two-step strategy, if all requirements needed to conduct the single step strategy, such as surgery skills and facilities are available at the health center.

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