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SSAT PLENARY PRESENTATION

Comparing One-Stage vs Two-Stage Approaches for the Management of Choledocholithiasis

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Abstract

Background The management of symptomatic choledocholithiasis remains a controversial issue. At present, the three most common management options for choledocholithiasis include a preoperative endoscopic retrograde cholangiopancreatography with sphincterotomy and stone extraction followed by laparoscopic cholecystectomy, then by either an intraoperative endoscopic retrograde cholangiopancreatography with sphincterotomy or a laparoscopic common bile duct exploration. The purpose of this study was to assess the consequences of the decision to pursue each of these three methods.

Methods We conducted a review of the existing data comparing these three management options. The literature from 2009 to 2021 pertaining to these three methods was reviewed for data on duct clearance, morbidity, mortality, recurrence rate, length of stay, and operative time. Next, we constructed decision trees for each method using a utility score analysis, and these utility scores were used to create a sensitivity analysis based on stone clearance rate.

Results Laparoscopic cholecystectomy with intraoperative endoscopic retrograde cholangiopancreatography had a utility score of 0.9910, a stone clearance rate of 95.5%, a morbidity of 6.3%, and a mortality of 0.2%. Preoperative endoscopic retrograde cholangiopancreatography with laparoscopic cholecystectomy had a utility score of 0.9629, a stone clearance rate of 85.5%, a morbidity of 13.3%, and a mortality of 0.8%. Laparoscopic cholecystectomy with common bile duct exploration had a utility score of 0.9882, a stone clearance rate of 88.3%, a morbidity of 12.9%, and a mortality of 0.3%.

Conclusion We have shown that a laparoscopic cholecystectomy with an intraoperative endoscopic retrograde cholangiopancreatography is associated with the best overall outcomes.

Keywords Choledocholithiasis · Endoscopic retrograde cholangiopancreatography · Stone clearance

Introduction

Gallstones are thought to affect 10–15% of the population, and of those, a further 10–15% develop concomitant common bile duct (CBD) stones.[1] Patients often present with obstructive jaundice and right upper quadrant pain and more severely with pancreatitis or ascending cholangitis.[2]

However, optimal management of CBD stones remains controversial. There are currently four options for management: a preoperative endoscopic retrograde cholangiopancreatography followed by a laparoscopic cholecystectomy (Preop ERCP + LC), a laparoscopic cholecystectomy with an intraoperative ERCP (LC + Intraop ERCP), a laparoscopic cholecystectomy with an intraoperative common bile duct exploration (LC + CBDE), or a laparoscopic cholecystectomy followed by a postoperative ERCP (postop ERCP).[3] If the patient is presenting with pancreatitis or cholangitis, the ASGE guidelines suggest that a Preop ERCP + LC is the best treatment choice.[4] Otherwise, there is no clear consensus to guide optimal management.[1–3]

In recent years, the use of magnetic resonance cholangiopancreatography (MRCP) as well as endoscopic ultrasound (EUS) has allowed for a greater degree of preoperative prediction of choledocholithiasis.[5] The authors have previously shown in 2008 that a one-stage approach using

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LC + CBDE was superior to a two-stage approach with a Preop ERCP + LC, but this was done prior to the widespread use of preoperative MRCP.[6] Since then, many studies have been published comparing success rates, morbidity, and mortality for these various methods.[2,7,8] Given these advancements in diagnostic and surgical techniques, as well as an abundance of new data, a re-evaluation of the optimal treatment strategy was deemed necessary. The aim of this study was to compare the differences in outcomes between the various management methods to guide treatment choice.

Materials and Methods

Initially, a review of the existing data was conducted to compare the outcomes of the various management options for symptomatic choledocholithiasis. We made the assumption that the preoperative diagnosis was confirmed by some non-invasive method, such as MRCP, CT scan, or ultrasound. We acknowledge that some health care facilities may not have these capabilities, but this was done to eliminate the issue of "suspected, but not proven" choledocholithiasis, which, we feel, is a different decision problem and we want to focus on the success of stone clearance of these techniques.

The three choices modeled were preop ERCP + LC or LC with either Intraop ERCP or CBDE. We chose not to assess the option of LC + postop ERCP as stone clearance is a priority in most cases. The literature from 2009 to 2021 pertaining to these three methods was reviewed for data on stone clearance, morbidity, mortality, recurrence rate, length of stay (LOS), and operative time. The primary outcomes were stone clearance, morbidity, and mortality. The secondary outcomes were recurrence rate, LOS, and operative time. Morbidity was defined as being Clavien–Dindo grade II or higher. Initially, we included cost as well as physician expertise in the data, but few studies reported these measures, so we chose to exclude them. All studies published in 2009 or after that compared Preop ERCP + LC, LC + postop ERCP, or LC + CBD for management of CBD stones were eligible for inclusion. Study designs included RCTs, meta-analysis, systematic reviews, and prospective reviews. All studies had to report the primary outcomes. Exclusion criteria included studies published prior to 2009 or studies that did not report the primary outcomes. The data from the review was used to construct a decision analysis to quantify the various management methods based on the presentation of a patient with suspected choledocholithiasis and an acceptable operative risk. This baseline decision tree is shown in Fig. 1.

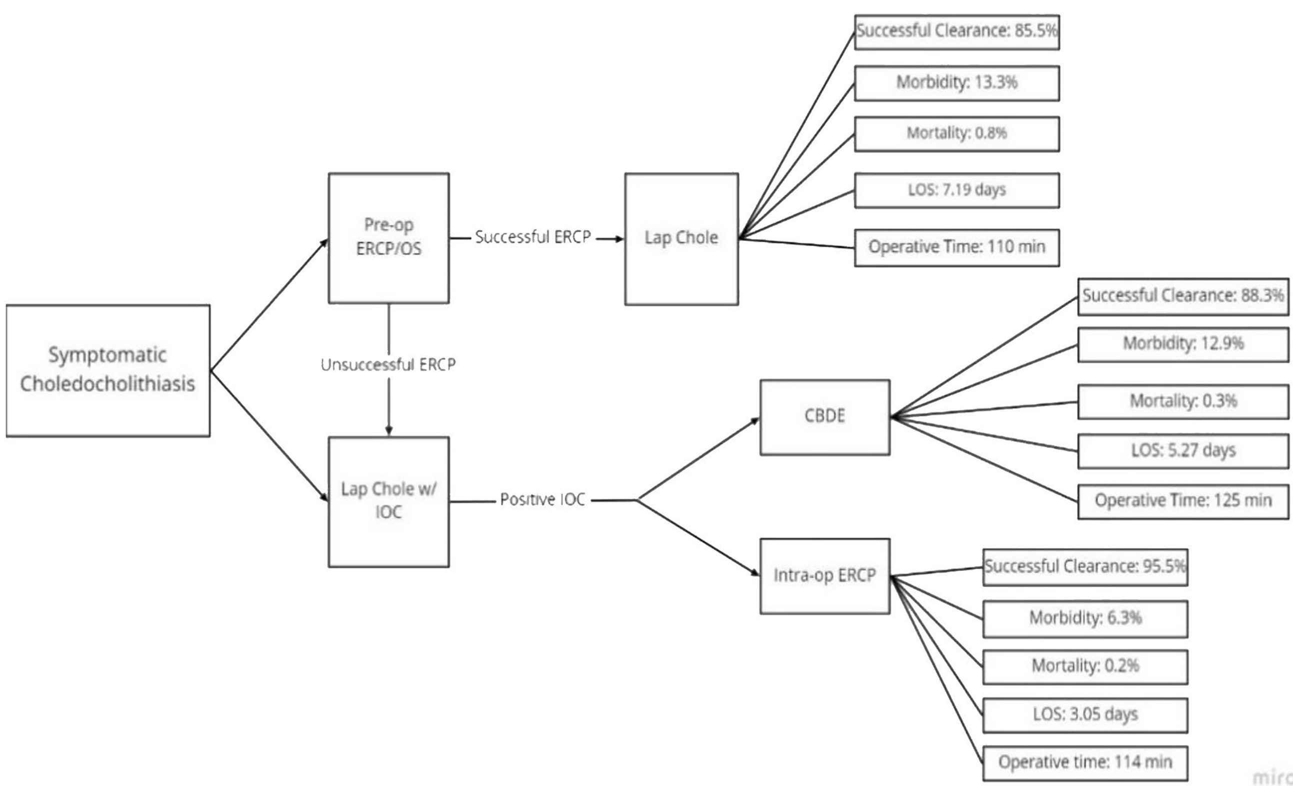

Fig. 1 This figure demonstrates the basic decision tree for the management of symptomatic choledocholithiasis obtained from the data found in the systematic review

Next, a utility score analysis was used to analyze the data and construct independent decision trees for each of the three methods. A utility score is a method of quantifying outcomes based on favorability. Utility scores are based on "quality multipliers" in decision analysis models.[23,24] The theoretical foundation is that every medical outcome will affect the quality of life of a patient. An outcome leading to perfect health would be 1 and an outcome of death 0. In determining a quality-adjusted life expectancy [23], the quality multiplier is multiple by the life expectancy of the patient. Outcomes which lead to some patient detriment, e.g., complications, persistent symptoms, and a reduction of quality of life, would have some fraction between 0 and 1, depending on the severity of the detriment. As we are not determining the quality-adjusted life expectancy after treatment of choledocholithiasis, we use these quality multipliers as utility scores to rank the outcomes from most favorable to least favorable.[24] We have previously used this method in determining the effects of pancreaticoduodenectomy for pancreatic cancer [25] and for use of mesh in paraesophageal hernia repair.[26] We assigned a utility score of 1 to stone duct clearance by any means with a laparoscopic cholecystectomy without complications. Post-procedure death was assigned a utility score of 0. Any persistent retained stone was assigned a utility score of 0.7. Any morbidity or failed stone duct clearance reduced the utility score of the outcomes by 0.1. Although we acknowledge that these utility score assignments were somewhat arbitrary, the main goal was to differentiate outcome favorability among the treatment options based on the probability of the various outcomes. These utility scores were then multiplied by the probabilities acquired from the data review for each method, to give a final number that approximates the relative utility of each approach. Using this method, a decision tree was constructed for Preop ERCP + LC shown in Fig. 2, LC + CBDE shown in Fig. 3, and LC + intraop ERCP shown in Fig. 4, and a utility score was derived for each of the three methods. Data on the successful clearance and morbidity of postoperative ERCP was derived from other studies.[27–31]

Finally, a sensitivity analysis was used to vary the chances of different outcomes occurring to determine the effects of different probabilities on the decisions. This analysis was based on percent stone duct clearance, as this was the main outcome of interest. The analysis was constructed using data from the studies review as well as the utility scores derived for each of the methods.

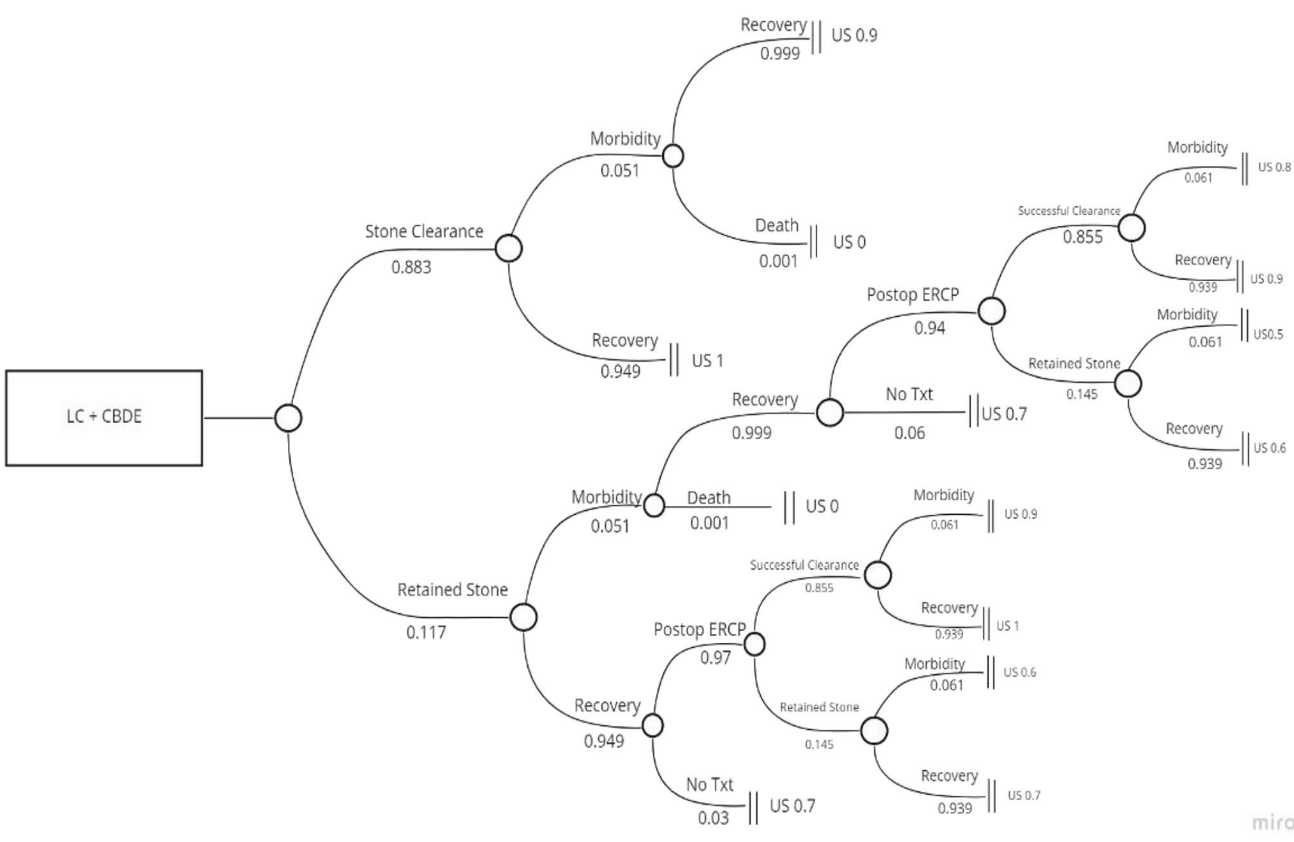

Fig. 2 The figure demonstrates the decision tree constructed for the LC + CBDE method with the utility score analysis. The final utility score for this method was 0.9882

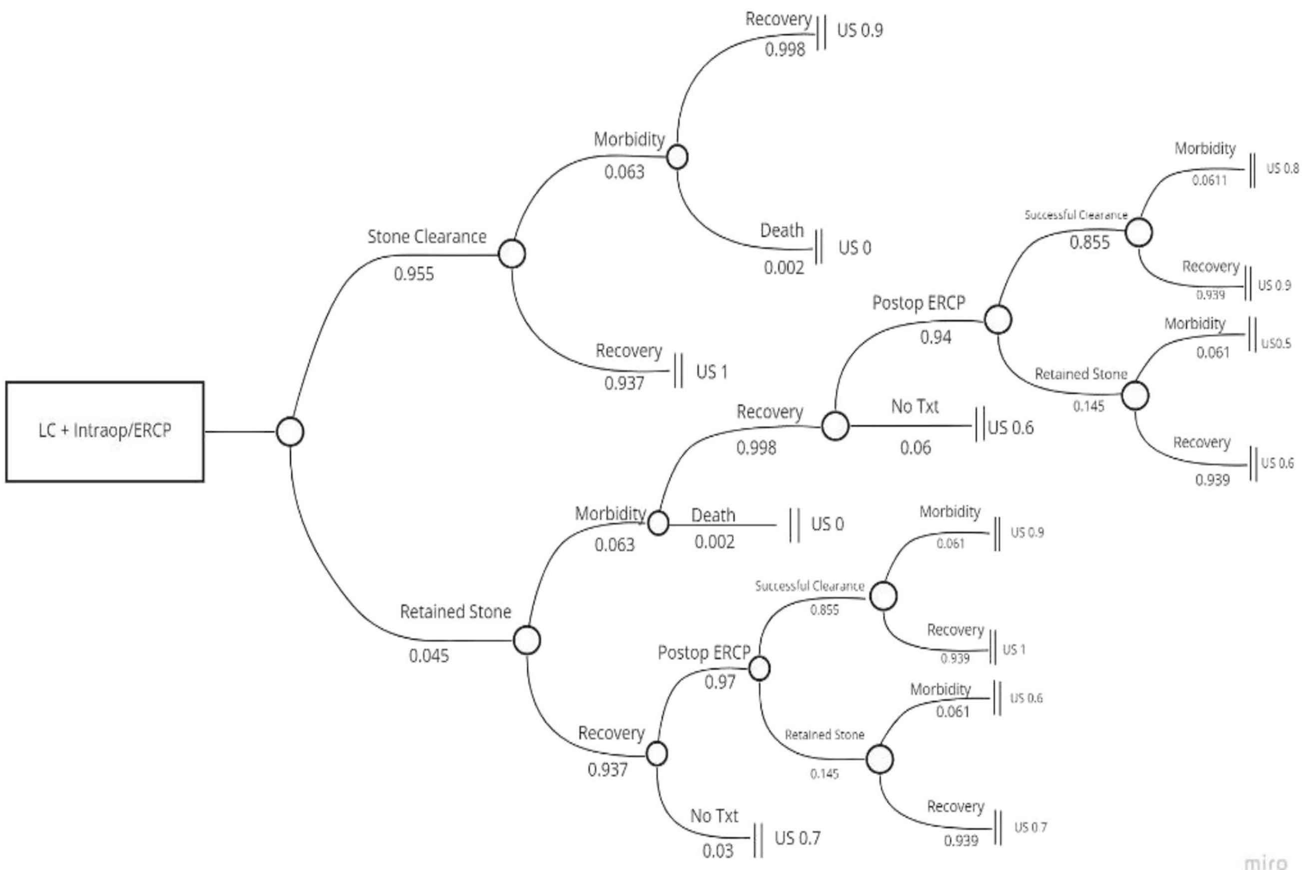

Fig. 3 The figure is the decision tree constructed for the LC + Intraop/ERCP method with the utility score analysis. The final utility score for this method was 0.9910

Results

Data Review

A total of 18 studies were found that compared some or all the primary and secondary outcomes. This data is shown in Table 1. These studies consisted of randomized control trials, meta-analyses, systematic reviews, and prospective cohort studies. The data for both Preop ERCP + LC and LC + CBDE was obtained from 14 studies, and the data for LC + Intraop ERCP was obtained from 6 studies. Preop ERCP had the largest sample size at $N = 5284$, followed by LC + CBDE ($N = 4744$), then LC + Intraop ERCP ($N = 1073$).

Primary Outcomes

Stone Clearance

LC + Intraop ERCP was associated with the greatest stone clearance (95.5%), followed by LC + CBDE (88.3%), then Preop ERCP + LC (85.5%).

Morbidity

LC + Intraop ERCP was associated with the least morbidity (6.3%), followed by LC + CBDE (12.9%), then Preop ERCP + LC (13.3%).

Mortality

LC + Intraop ERCP was associated with the least mortality (0.2%), followed by LC + CBDE (0.3%), then Preop ERCP + LC (0.8%).

Secondary Outcomes

Recurrence Rate

Only six studies included recurrence rate in their analysis, none of which included the LC + Intraop ERCP method. This was therefore removed as a secondary outcome.

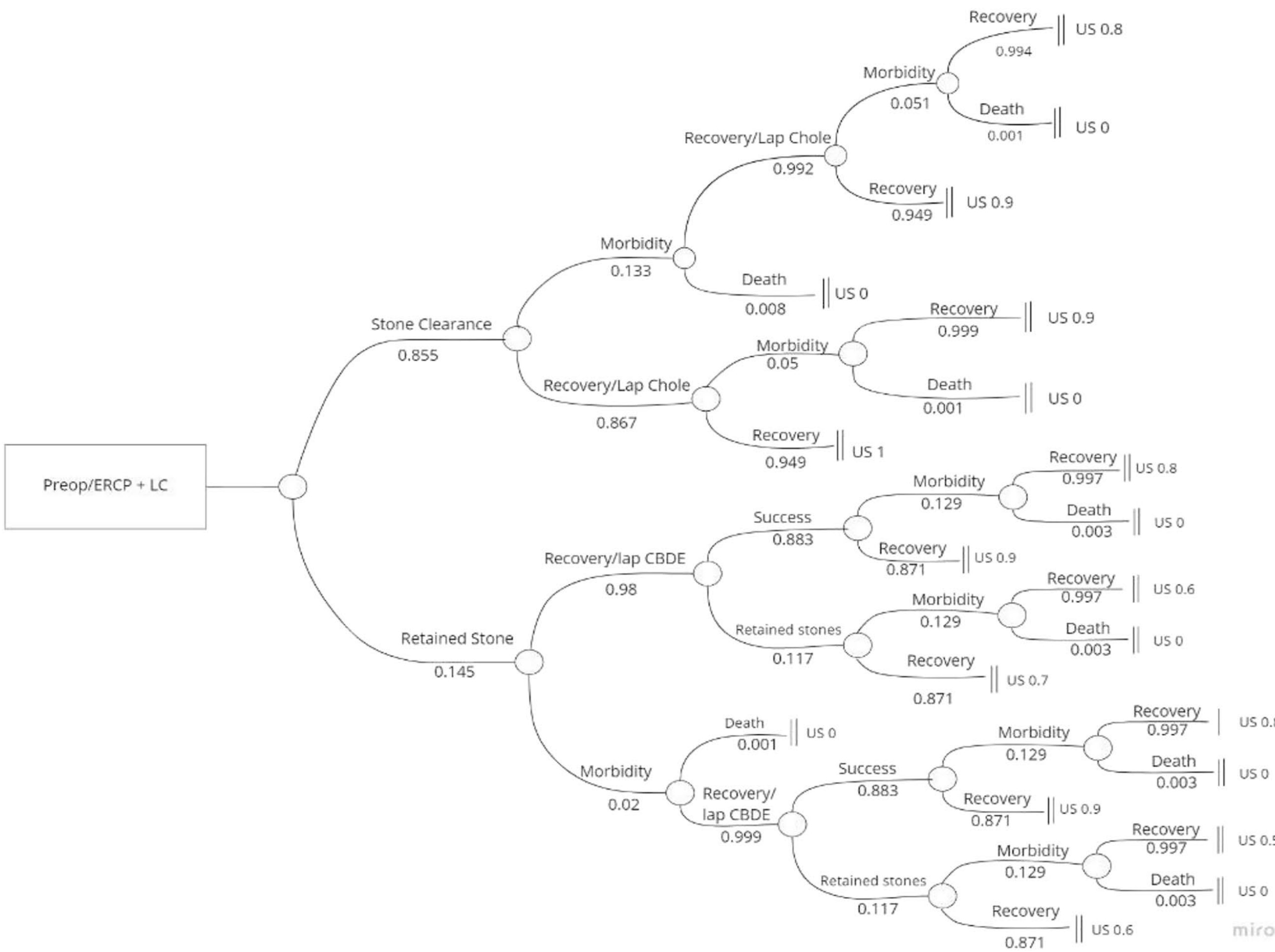

Fig. 4 The figure demonstrates the decision tree constructed for the LC + CBDE method using the utility score analysis. The final utility score for this method was 0.9629

Length of Stay

Fourteen studies included mean LOS in their analysis. Based on these results, LC + Intraop ERCP was associated with a LOS of 3.1 days, while LC + CBDE and Preop ERCP + LC were associated with a LOS of 5.27 and 7.19 days, respectively.

Operating Time

Ten studies included mean operating time in their analysis. Based on the results of these studies, Preop ERCP + LC was associated with the shortest operating time at 110 min, followed by LC + Intraop ERCP at 114 min, then LC + CBDE at 125 min.

Utility Scores and Sensitivity Analysis

The data from the systematic review was used to construct a basic decision tree, shown in Fig. 1. Next, a sub-decision tree was constructed for each of the management methods using a utility score analysis. The LC + CBDE tree is shown in Fig. 2, with a final utility score of 0.9882. The LC + Intraop ERCP tree is shown in Fig. 3, with a final utility score of 0.9919. The Preop ERCP + LC tree is shown in Fig. 4, with a final utility score of 0.9629. These utility scores are compared in graph form in Fig. 5.

The utility scores for each of the methods were then used to create a sensitivity analysis based on the percent of successful stone clearance, shown in Fig. 6. LC + Intraop ERCP was associated with the highest utility scores across all percentages.

Discussion

In this study, we have shown that Intraop ERCP is associated with the best overall outcomes when compared with either LC + CBDE or Preop ERCP + LC using the average frequencies of the various outcomes. Specifically, this

Table 1 Review of data

Study	Design	Treatment	Sample size (*N*)	Clearance rate (%)	Morbidity (%)	Mortality (%)	Recurrence rate (%)	Length of stay (days)	Operating time (min)
Lu J et al. 2012	Meta-analysis	LC + CBDE	288	87.2	19	0.6	3.7		118
		Preop/ERCP + LC	297	78.8	15.2	1.7	4.72		131
Alexakis N et al. 2012	Meta-analysis	LC + CBDE	366	69	21	0.5		4.9	
		LC + Intraop/ERCP	96	94	12.5	1		4.2	
		Preop/ERCP + LC	386	68	15	1		6.2	
Grubnik V et al. 2012	Prospective randomized trial	LC + CBDE	138	94	6.5	0		4.2	82
Gurusamy K et al. 2011	Systematic review and meta-analysis	LC + Intraop/ERCP	263	97.3	3.4	0		3	112
		Preop/ERCP + LC	269	98.1	9.3	0		5.5	98
Wang B et al. 2013	Systematic review and meta-analysis	LC + Intraop/ERCP	313	97	7	0.3			
		Preop/ERCP + LC	318	92	11	0			
Tan C et al. 2018	Meta-analysis	LC + Intraop/ERCP	313	93	6	0		3.5	
		Preop/ERCP + LC	316	92	11	0		6.1	
Bansal V et al. 2014	Randomized control trial	LC + CBDE	84	88.1	23.8	0		4.6	135.7
		Preop/ERCP + LC	84	79.8	22.6	3.6		5.3	72.4
Poh B et al. 2016	Randomized control trial	LC + CBDE	52	69	38	0		3	110
		Intraop/ERCP + LC	52	87	27	0		2	112
Zhou Y et al. 2019	Retrospective cohort Study	LC + CBDE	54	100	14.8	0	3.7		
		Preop/ERCP + LC	46	89.1	10.9	2	10.9		
Ghazal et al. 2009	Prospective observational study	LC + Intraop/ERCP	36	100	0	0	0	2.55	119
Lyu Y et al. 2019	Meta-analysis	LC + CBDE	631	89.2	11.8	0.3		5.65	
		Preop/ERCP + LC	631	84	12.9	0.8		7.95	
Singh et al. 2018	Meta-analysis	LC + CBDE	751	88.1	13.9	0.3		4.9	
		Preop/ERCP + LC	762	82.2	14.5	1		6.5	
Dasari BV et al. 2013	Meta-analysis	LC + CBDE	285	85	15.4	0.7		4.9	
		Preop/ERCP + LC	295	84	15.9	1		5.8	
Noble H et al. 2009	Randomized control trial	LC + CBDE	44	100	18	0			
		Preop/ERCP + LC	47	61	17	0			
Al-Habbal Y et al. 2020	Retrospective observational study	LC + CBDE	248	84	2.8	0	1.4		180
Pan L et al. 2018	Meta-analysis	LC + CBDE	872	94.1	7.6	0.6	1.8	4.94	112.28
		Preop/ERCP + LC	885	90.1	12	1.1	5.6	6.62	132.03
Li ZQ et al. 2020	Meta-analysis	LC + CBDE	666	91.5	14	0.16		5.27	122
		Preop/ERCP + LC	672	85.7	13.9	0.96		6.5	118
Qian Y et al. 2020	Retrospective cohort study	LC + CBDE	123	97.5	2.4	0	3.3	12	140
		Preop/ERCP + LC	137	96.3	8.8	0	16.8	18	108

Table 1 (continued)

Study	Design	Treatment	Sample size (*N*)	Clearance rate (%)	Morbidity (%)	Mortality (%)	Recurrence rate (%)	Length of stay (days)	Operating time (min)
Totals		LC + CBDE	4744	88.3	12.9	0.3	2.6	5.3	125
		Preop/ERCP + LC	5284	85.5	13.3	0.8	11.1	7.2	110
		LC + Intraop/ERCP	1073	95.5	6.3	0.2		3.1	114

This table shows stone clearance rate, morbidity, mortality, recurrence rate, length of stay, and total operating time, the compiled data from 18 studies comparing different management options for choledocholithiasis. The data is reported as it is presented in the papers. All studies included data on clearance rate, morbidity, and mortality. Only six studies included data on recurrence rate, 14 studies included data on mean LOS, and 10 studies included data on mean operating time

method was associated with higher duct clearance rates, lower morbidity and mortality, and a lower length of stay, which is why we judged it to have the best outcome by the utility score method. Furthermore, we have shown that a one-stage approach with LC + CBDE is associated with better overall outcomes than a two-stage approach with a Preop ERCP + LC in all measures except for operating time**.**

LC + Intraop ERCP was associated with the highest clearance rate (95.5%), least morbidity (6.35%) and mortality (0.2%), and with the lowest length of stay (3.1 days). The data for this method were fewer than with the other methods and were particularly favorable. The authors of these studies may be particularly well versed in this technique and thus have exceptionally good results. We would suggest that readers use the sensitivity analyses (Fig. 6) to adjust the data in a manner that reflects their judgment as to the most likely clearance rates. Recurrence rate was removed as a secondary outcome due to the minimal amount of studies that reported it in their analysis. The only outcome that Preop ERCP + LC was superior in was operating time (110 min). This makes intuitive sense as an intraoperative cholangiogram, which is required for both one-stage approaches, a timely procedure. LC + CBDE was not superior in any outcomes, but it was associated with better outcomes than Preop ERCP + LC except for operative time. The caveats to this data are that there was a significantly smaller sample size for LC + Intraop ERCP than for the other two methods. This is because only six of the 18 studies used for the systematic review included LC + Intraop ERCP in their analysis. Further studies comparing these methods may show that the data for LC + Intraop ERCP may somewhat inflated.

We used data from a variety of studies, including randomized trials, observational studies, and meta-analyses (Table 1). We used data from all available studies. As some data from existing meta-analyses were used, there may be duplicate patients in the data pool. We acknowledge the potential bias of the data, but the sensitivity analysis can mitigate such bias by allowing the reader to use the stone clearance rates they feel are more realistic. Of course, depending on the individual circumstances of the patient, one technique may be more favorable than another. The results of our study are certainly not meant to be construed that there is a "one size fits all" approach. For example, prior gastric surgery, such as a Roux-en-Y gastric bypass, may completely eliminate the option of preoperative ERCP, and only one of the one-stage approaches would be feasible.

The utility scores and sensitivity analysis further supported the data that LC + Intraop ERCP produced the highest utility score, although the utility scores for Intraop ERCP and CBDE were very near to each other (0.9910 vs. 0.9882). The use of utility scores leads to relative rankings of the outcomes, rather than specific clinical impact, like quality-adjusted life expectancies. However, the closer the utility

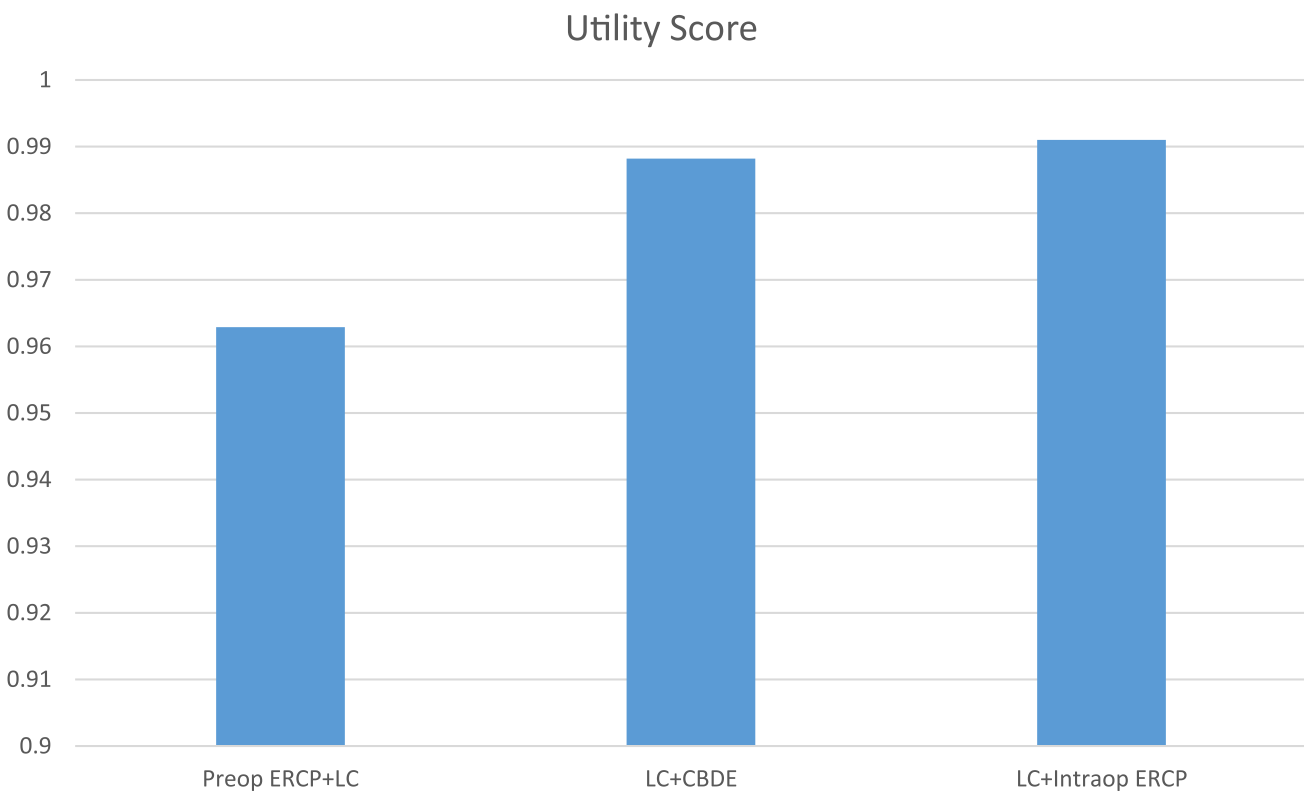

Fig. 5 This figure shows the utility scores for each of the three management methods in graphical form

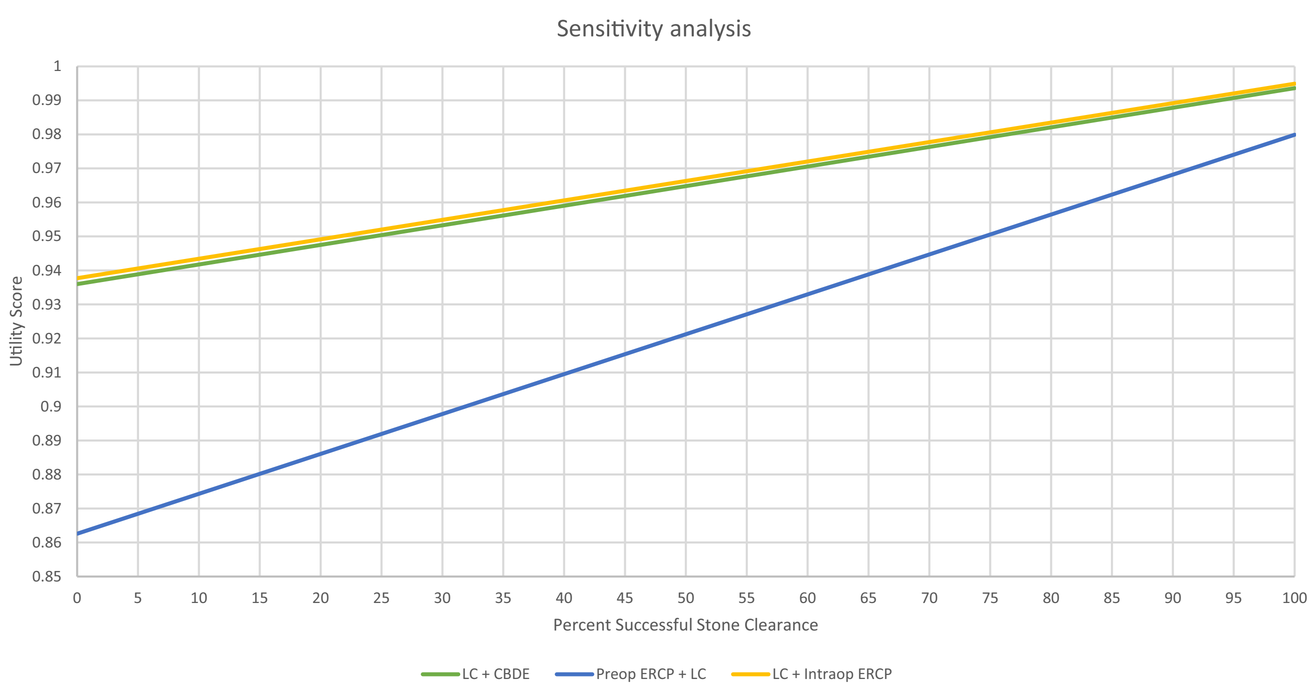

Fig. 6 This figure represents the sensitivity analysis based on the utility scores and percent stone clearance. The utility score varies as the stone clearance rate varies. LC + Intraop ERCP was associated with the highest utility scores across all percentages

score is to 1, the closer the treatment option yields a perfect health outcome. The sensitivity analysis was constructed based on the stone duct clearance rate, and the utility score varied based on the clearance rate. Figure 5 shows that even at a duct clearance rate of 100%, Preop ERCP + LC was associated with a utility score of 0.98, which was comparable to the utility score of LC + Intraop ERCP or CBDE at a clearance rate of 75%. Only below this percentage will Preop ERCP + LC have a higher utility score than a one-stage approach with either of the two methods.

Furthermore, various factors could lead to differences in these outcomes, including but not limited to center availability, physician expertise, and cost. As mentioned earlier, few studies included these measures, so they were excluded from the analysis. These factors could heavily influence the decision in determining which management method to pursue. A physician who is particularly comfortable with one management method should pursue that method as risks of complications are higher if he/she chooses to proceed with a method they are less comfortable with. Cost for the healthcare system and for the patient should also be taken into account. We also acknowledge that further studies are needed to determine the optimal management for choledocholithiasis for specific clinical settings.

Conclusion

As of today, Preop ERCP + LC remains a popular choice for the management of symptomatic choledocholithiasis. Our data has shown that between the various management options, LC + Intraop ERCP was associated with the best overall primary outcomes (stone clearance, morbidity, and mortality). We acknowledge that this is based on local expertise. We suggest that the reader uses the sensitivity analysis presented in Fig. 6 with the stone clearance rates that they judge as more likely for their institution. Furthermore, our data shows that a one-stage approach with either LC + Intraop ERCP or CBDE is associated with better primary outcomes than Preop ERCP + LC. The difference between the utility score for LC + Intraop ERCP and LC + CBD was minimal, but the difference between these one-stage approaches and a two-stage approach with Preop ERCP + LC was significant. Therefore, in the absence of other factors such as center availability and physician comfort and expertise, if the choice is readily available for a physician and he/she is comfortable with all options, a one-stage approach should be used for management. This will improve stone clearance rate, decreasing the need for additional procedures, as well as decrease morbidity and mortality resulting in improved patient outcomes. Furthermore, it will decrease the length of stay, saving time and money for the patient, hospital, and our healthcare system. While a one-stage approach may be slightly more timely to execute, this extra time is in the magnitude of minutes and is completely negligible when compared with the other advantages gained. Further studies are needed to delineate the differences between LC + Intraop ERCP and LC + CBD as well as to further support the differences between a one-stage and a two-stage approach before any major guidelines are changed. We hope that our data can be used to support future guidelines encouraging the use of a one-stage approach for the management of choledocholithiasis.

Author Contribution Obada Kattih and Vic Velanovich made substantial contributions to the conception and study design of the work, acquisition, analysis, and interpretation of the data for the work; drafting the work and revising it critically for important intellectual content; final approval of the version to be published; and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy and integrity of any part of the work are appropriately investigated and resolved.

Declarations

Conflict of Interest Obada Kattih has no conflicts of interest. Vic Velanovich is a speaker for Integra LifeSciences and a paid consultant for Innocoll Pharmaceuticals.

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