Original Article

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A Randomized Controlled Comparative Study of Laparoscopic CBD Exploration and Cholecystectomy with Endoscopic Stone Extraction and Cholecystectomy for Choledocholithiasis

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Abstract

With the advent of ERCP in 1974 it provided an alternative to CBDE. The CBD calculi could be removed endoscopically and subsequently only a cholecystectomy needed to be performed. Thus ERCP with Endoscopic sphincterotomy(ERCP-S) gained popularity as it provided an alternative to open CBDE for choledocholithiasis diagnosed preoperatively as well as intraoperatively. However, with the development of better techniques and instrumentation LCBDE is a feasible option now. Subsequent studies showed that LCBDE has similar duct clearance rates and morbidity as compared to ERCP-S followed by LC [5,6]. Therefore, a randomized prospective study with N= 56 was done to compare the efficacy of laparoscopic common bile duct exploration and cholecystectomy versus endoscopic stone extraction and laparoscopic cholecystectomy for cholelithiasis and also to compute complications of the individual procedure.In conclusion, our study shows that both LC+ LCBDE and ERCP-S+LC were equally effective in the management of choledocholithiasis and were equivalent in patient satisfaction. However, the overall duration of hospitalization was longer for LC+ LCBDE. Laparoscopic CBDE significantly reduces the risks of ERCP- associated pancreatitis, anaesthesia and another procedure. Hence, LCBDE+LC is a feasible, cost-effective, and safe procedure and ultimately should be offered as a treatment option for most patients.

Keywords: Choledocholithiasis; ERCP; Laparoscopic Bile Duct Exploration; Endoscopic Sphincterotomy.

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Background

With the advent of ERCP in 1974 it provided an alternative to CBDE [1,2]. The CBD calculi could be removed endoscopically and subsequently only a cholecystectomy needed to be performed. Thus ERCP with Endoscopic sphincterotomy(ERCP-S) gained popularity as it provided an alternative to open CBDE for choledocholithiasis diagnosed preoperatively as well as intraoperatively. However, several studies showed that preoperative ERCP with Endoscopic sphincterotomy (ERCP-S) followed by cholecystectomy was not superior to open cholecystectomy and CBDE. It was not shown that routine preoperative ERCP was not worthwhile [3,4]. However, with the development of better techniques and instrumentation LCBDE is a feasible option now. Subsequent studies showed that LCBDE has similar duct clearance rates and morbidity as compared to ERCP-S followed by LC [5,6]. Therefore, a randomized prospective study was done to compare the efficacy of laparoscopic common bile duct exploration and cholecystectomy versus endoscopic stone extraction and laparoscopic cholecystectomy for cholelithiasis and also to compute complications of the individual procedure.

Materials and Methods

Study was conducted in Department of General and Minimal Access Surgery at a tertiary care

teaching hospital in New Delhi. Patients for the study were selected from those attending the surgical OPD of with the clinical diagnosis of Choledocholithiasis.

Inclusion Criteria

Patient having Choledocholithiasis with or without jaundice but proven by USG abdomen or MRCP.

Age between 18- 70 yrs.

Exclusion Criteria

Patient unfit to undergo laparoscopic surgery.

Evidence of Cirrhosis or portal vein thrombosis on imaging.

Multiple previous laparotomies

Method of Study

Once the diagnosis of choledocholithiasis was established the patients were asked to draw envelops and accordingly they were divided into group A (LCBDE) and group B (ERCP-S+LC)

This study included 56 patients, who were divided into 2 groups:

- Group A: Included 34 patients undergoing laparoscopic CBDE and Laparoscopic Cholecystectomy (LCBDE).
- Group B: Included 22 patients undergoing endoscopic stone removal and laparoscopic Cholecystectomy (ERCP-S+LC).

A detailed proforma was filled up for each patient including history and physical examination, preoperative, operative and postoperative details. All patients underwent routine investigations including liver function test, coagulation profile, Ultrasound abdomen and MRCP. Written informed consent was taken from all the patients.

The patients in Group A underwent LCBDE and LC after confirmation of CBD stones by MRCP. Preoperatively, part preparation was done from the nipple to the mid-thigh. Patient with deranged liver function test received Inj vitamin K preoperatively. All patients were kept fasting overnight and were catheterized on table to monitor urine output. Prophylactic antibiotic (Inj. Ceftriaxone 1 gm and Metronidazole 500 mg) were given at the time of induction of anaesthesia. Operative time and other intraoperative details were recorded as per the proforma.

The evaluation parameters in each patient were as follows:

1. Size and number and position of stones (CBD or Hepatic duct stones)
2. Net Operating time
3. Postoperative analgesic requirement
4. Intraoperative and postoperative complications
5. Post ERCP-ES complications
6. Blood loss and transfusion requirements.
7. Patient acceptance
8. Incidence of hyperamylasemia and/or pancreatitis
9. Duration of postoperative hospital stay
10. Presence of residual stone indicating failure of complete clearance.
11. Conversion to open surgery

Observation and Results

A total 56 patients were included in the study, from the patient attending surgical OPD. Patients were randomized into groups A and B. The patients belonging to group A underwent LCBDE and were the test group and those of group B underwent ERCP-S followed by LC and formed the control group.

Groupwise Distribution of Patients

Table 1: Distribution of patients according to group allocated.

Types of Procedure Performed	Number of Cases	% of Total(n=28)
LCBDE	34	60.7
ERCP-S and LC	22	39.3

Number of Stones Removal

Table 2: Number of stones removed in both groups

	No. of Stones Removed		
	Laparoscopic	**Endoscopic**	**Total**
Minimum	1	0	0
Maximum	16	4	16
Mean	3.59	1.27	2.68
Standard deviation	4.244	1.104	3.528

CBD Diameter

Table 3: CBD diameter in both groups.

	CBD Diameter by MRCP/USG(mm)	
	Laparoscopic	**Endoscopic**
Minimum	9	8.8
Maximum	19	16.4
Mean	12.124	11.455
Standard Deviation	2.392	2.1

Operating Time

Table 4: Operating time in both groups

Group	N	Minimum	Maximum	Mean	Standard Deviation
LCBDE	34	130	205	170.00	21.723
ERCP-S+ LC	22	25	60	40.91	10.681
Total	56	25	205	119.29	66.663

Conversion to Open

Table 5: Conversion rates to open in both groups

		Conversion to open		Total	% Within group	
		Yes	**No**		**Yes**	**No**
Group	LCBDE	2	32	34	5.9	94.1
	ERCP-S+LC	1	21	22	4.5	95.4
	Total	3	53	56	5.3	94.7

Blood Loss

Table 6: Blood loss in both groups

	LCBDE		ERCP-S+LC	
	Blood loss (ml)	**Blood Transfusion (unit)**	**Blood Loss (ml)**	**Blood Transfusion (Unit)**
Minimum	100	0	20	0
Maximum	250	0	125	0
Mean	186.76	0	58.18	0
Standard deviation	53.120	0	27.953	0

Analgesic Requirement

Table 7: Analgesic requirement in both the groups

	Analgesic Requirement (mg)	
	LCBDE	**ERCP-S +LC**
Minimum	525	400
Maximum	850	650
Mean	604.41	486.36
Standard Deviation	84.426	73.624

Hyperamylasemia/Pancreatitis

Table 8: Incidence of Hyperamylasemia/Pancreatitis

Group		Hyperamylasemia/pancreatitis		Total
		Yes	No	
LCBDE	<25	0	2	2
	25-45	0	16	16
	45-65	0	14	14
	>65	0	2	2
ERCP-S +LC	<25	2(9.1%)	2	4
	25-45	0	10	10
	45-65	0	8	8
	>65	0	0	0
	Total	2(3.6%)	54(96.4%)	56

Post ERCP-S Complication

Table 9: Post ERCP-S complications

	No. of Patients	% within Group
Yes	4	18.2
No	18	81.8
Total	22	100

Drain Removal

Table 10: Duration of postoperative drain removal in days

Drain removal (Post-Operative day)	Group		% Within group	
	LCBDE	ERCP-S+LC	LCBDE	ERCP-S+LC
1	0	2	0	9.1
2	2	2	5.9	9.1
3	16	4	47.1	18.2
4	10	2	29.4	9.1
5	2	0	5.9	0
6	4	0	11.8	0
No Drain	0	12	0	54.5
Total	34	22	100	100

Retained Calculus in LCBDE group

Table 11: Incidence of retained calculus in group.

Retained stones	No. of Patients	% within LCBDE group
Yes	2	5.9
No	32	94.1
Total	34	100

Postoperative Complications

Table 12: Incidence of postoperative complications

Group	Postoperative complications		% within group	
	Yes	No	Yes	No
LCBDE	4	30	11.8%	88.2%
ERCP-S +LC	0	22	0%	100%
Total	4	56	7.1%	92.9%

Duration of Postoperative Stay

Table 13: Duration of postoperative stay

	Duration of postoperative stay(Days)	
	LCBDE	ERCP-S+LC
Minimum	4	1
Maximum	10	4
Mean	5.47	2.00
Standard Deviation	1.419	1.265

Return to Work

Table 14: Return to work

Group	Return to work, Net number of man-days of work lost(days)	
	LCBDE	ERCP-S + LC
Minimum	9	6
Maximum	23	16
Mean	12.37	10
Standard Deviation	3.403	2.793

Cosmesis

Table 15: Patient satisfaction of cosmetic result

Group	Cosmesis		% within group	
	Satisfied	Not satisfied	Satisfied	Not satisfied
LCBDE	30	4	88.2	11.8
ERCP-S+LC	20	2	90.9	9.1
Total	50	6	89.3	10.7

Patient Satisfaction

Table 16: Patient satisfaction

Group	Patient satisfaction		% within group	
	Satisfied	Not satisfied	Satisfied	Not satisfied
LCBDE	32	2	94.1%	5.1%
ERCP-S+LC	12	10	54.5%	45.5%
Total	44	12	78.6%	21.4%

Discussion

Both the groups were comparable with respect to the sex distribution (Chi square test, p= 0.736) as well as age (Student T test p= 0.285)

The total number of stones removed by LCBDE ranged from a minimum of 1 to a maximum of 16 while those removed by ERCP-ES ranged from 0 to 4. The p value determined by the Wilcoxon Mann Whitney test for this variable was 0.142 thus showing that the number of stones removed was not significantly different when either of the two methods were used.

The average size of the stones removed by LCBDE varied from 8-17 mm with a mean size of 11.74 mm. The size of the stones removed by ERCP-ES could not be determined, as the stones could not be extracted out completely from the patient. The stones were only pulled out into the duodenum and left there to be excluded in the stools.

The CBD diameter in the patients varied from 9 to 19 mm with a mean size of 12.12 mm in those taken up for LCBDE and the diameters taken up for LCBDE and the diameters in the patients taken up for ERCP-S varied from 8.8 to 16.4 mm with a mean size of 11.46 mm. Analysis of this data with the Student T test showed the p value 0.456 which was > 0.05 thus showing the CBD size differences to be statistically insignificant. This showed that patients in two groups

were comparable with respect to their CBD sizes.

The operating times for LCBDE were ranging from 130 to 205 minutes with an average operating time of 170 minutes. The operating times for post ERCP-S laparoscopic cholecystectomy ranged from 25 to 60 minutes with an average operating time of 40.91 minutes. Analysis showed the operating times to be significantly more in LCBDE group with a p value of <0.001. However, in this analysis the time taken for the endoscopic procedure was not taken into the total procedure times. Every ERCP-S on an average took around 35-45 minutes. In this study of 22 patients, 20 patient required one sitting of endoscopic procedure. Only two patient required two sittings. Also in study analysis of the operating times and the number of stones removed showed that there was no statistically significant relation between the two. The p value for this analysis was 0.207 analyzed by the Pearson Correlation Test.

In Group A there were 2 conversions to open, which gives a 5.9% conversion rate in the LCBDE group. In Group B there were only 1conversions to open, which gives a conversion rate of 4.5%. when analyzed by the Fisher Exact Test, it showed that the conversion rates were comparable in between the two groups with a p value of 0.482. The conversions were mainly because of dense adhesion between the colon and omentum with the gall bladder and the under surface of the liver and impacted stone at the lower end of CBD in one patient. In Group 2 the conversion to open was because markedly edematous gall bladder wall and dense adhesions between the colon and omentum with the gall bladder due to an acute inflammatory process.

Statistical analysis of the relation of the number of stones removed and the conversion rate to open in group A by the Wilcoxon Mann Whitney Test showed that there was no relation between the number of stones removed and the conversion rate to open with a p value of 0.184.

The statistical analysis of blood loss between the two groups showed that the blood loss to be significantly higher in the LCBDE group, which ranged from 100 to 250 cc with an average blood loss of 186.76 cc. The p value as determined by Student T test was < 0.001. In the post ERCP-S and LC group, the blood loss ranged from 20 cc to 125 cc with an average blood loss of 58.18 cc. However, no blood transfusion was required in either of the groups.

The analgesic requirement in group A ranged from 525 to 850 mg of Diclofenac sodium with a mean requirement of 604.41 mg. In Group B, the analgesic requirement ranged from 400 to 650 mg with a mean requirement of 486.36 mg. Statistical analysis showed that the analgesic requirement was significantly higher in patients in group A as compared to Group B with a p value of 0.001

In the LCBDE group there was no occurrence of hyperamylasemia/ pancreatitis. However, in group B there were 2 cases of hyperamylasemia without any evidence of pancreatitis. The patients develop symptoms of abdominal pain and vomiting and required admission.They responded well to conservative management and were discharged after 3 days. In this study, both the cases of hyper amylasemia occurred in the age group of < 25 years. This is consistent with the reported literature that young age group is a risk factor for hyperamy lasemia/ pancreatitis [7].

Statistical analysis of the number of stone removed by ERCP-S and the CBD diameter with the incidence of hyperamylasemia/ pancreatitis showed there to be no statistically significant association between them. The P value for these were 0.862 and 0.336 respectively.

Post ERCP-S, 4 patients out of 22 had complications in this study, a total complication rate of 18.2%. Two patients developed pain abdomen with hyperamylasemia requiring admission. Thus the incidence of hyperamylasemia was 9.1%. 2 other patients developed cholangitis which also required hospital admission. The patients were managed conservatively. Thus the incidence of cholangitis was also 9.1%.

In the LCBDE group all the drains were removed by the second to sixth day, On an average by 3.71 days. The median value was 3 days, which indicates that 50 % of the patients had all drains removed by the third postoperative day. In Group B drain was inserted in 10 patients (46.5%) and was removed between 1 to 4 days with a mean value of 2.6 days. The medial value was 3 days, which indicates that 50% of the patients had all drains removed by the third postoperative day. Statistical analysis showed no significant difference between the two groups in the duration of drain removal.

In Group A there was retained calculus in two patients with an incidence of 5.9%. Thus, LCBDE had a clearance rate of 94.1%. One patient was managed with ERCP-S and another was with open LCBDE as the consent for ERCP-S was not given. In Group B there was complete clearance of CBD after one endoscopic procedure in 20 out of 22 patients. Two patients required two endoscopic procedures at the end of which the CBD was clear. Hence, there were no retained calculi after the end of all endoscopic

procedure.

There were postoperative complications in 4 patients following LCBDE with an incidence of 11.8%. Two patients had retained stones and two patients had localized leak from the lower end of the CBD on T tube cholangiograms. Both the patients were managed conservatively. In the ERCP-S group there was no postoperative complication. However, statistical analysis showed this to be not significant with a p value of 0.505.

This was required in two patients who had retained stones in the LCBDE group in the form of open CBD exploration and ERCP-S respectively.

Following LCBDE, the postoperative stay varied from 4-10 days with a mean duration of 5.47 days and median of 5 days whereas after ERCP-S, the patient stayed for a duration ranging from 1- 4 days with a mean of 2 days and median of 1 day. Statistical analysis by the student t test showed the postoperative stay to be significantly higher in the LCBDE group as compared to the ERCP-S followed by LC group with a p value of < 0.001.

Following LCBDE the return to work ranged from 9 to 23 days with a mean value of 12.13 days. The net number of man-days of work lost in group B (including that after ERCP-S and LC together) ranged from 6 -16 days with a mean value of 10 days. Statistical analysis showed the difference in the net number of days lost between the two groups as insignificant with a p value of 0.68.

The patient satisfaction with respect to the cosmetic outcome of LCBDE was 88.2% and that after ERCP-S and LC was 90.9%. However, there was no statistically significant difference between the two groups with a p value 0.527 by the Chi Square test.

After the procedures, patient in both the groups were given a questionnaire about whether they are satisfied with the treatment given and if they would have preferred to undergo the same procedure if given an option or would they want to change to the other available option. The patient who opted for the change in the treatment modality did so because of the discomfort experienced during ERCP-S as the procedure was done only under sedation. The patient satisfaction was 94.1% in the LCBDE group as compared to 54.5% in the ERCP-S and LC group as patient had to undergo single procedure in the former group. Statistical analysis showed this to statistically significant with LCBDE group having higher satisfaction rate as compared to the two staged procedure in group B with a p value of 0.011.

Conclusion

Laparoscopic CBD exploration is a safe and reliable option for the treatment of choledocholithiasis in patients with a dilated CBD irrespective of size and number of stones, however stone impacted at lower end appears to be a relative contraindication [8]. Rigid Ureteroscope was better than flexible choledochoscope in terms of better vision and maneuverability. There was one retained calculus in this study. However, it was during early portion of the study and thus coincided with the initial learning curve of the operating surgeon. In the post ERCP-S patient undergoing Lap cholecystectomy there was a greater incidence of adhesions as compared to patients undergoing Lap Cholecystectomy for uncomplicated cholelithiasis. However, this has to be studied further as the adhesions may be due to either ERCP-S procedure or due to CBD calculi calculi causing attack of cholangitis.Postoperative analgesia requirement was more in cases of laparoscopic CBD exploration as compared to group 2 but this can be explained by presence of T- tube and greater soft tissue dissection required. Postoperative hospital stay was significantly longer after the Lap CBD exploration due to presence of drain.Postoperative complication were not statistically significant among two groups. 2 patients developed cholangitis after ERCP-S and readmitted. Patient satisfaction in term of number of procedures that have to be undergone is significantly higher in Lap CBD exploration group. Cosmetic outcome was similar in both the groups. Net Mandays of work lost were similar in both the groups.

In conclusion, our study shows that both LC+ LCBDE and ERCP-S+LC were equally effective in the management of choledocholithiasis and were equivalent in patient satisfaction. However, the overall duration of hospitalization was longer for LC+ LCBDE. Laparoscopic CBDE significantly reduces the risks of ERCP- associated pancreatitis, anaesthesia and another procedure. Hence, LCBDE+LC is a feasible, cost-effective, and safe procedure and ultimately should be offered as a treatment option for most patients.

No Disclosures.

No Conflict of interest.

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