

Research Article

Concomitant ERCP and laparoscopic cholecystectomy for management of gallstones complicated by obstructive jaundice versus two sessions procedure comparative study, Minia university hospital experience**Moatasem Mohamed El-Reedy¹, Alaa Mostafa Hassan Elsewefy¹, Adel Mohamed Shehata¹ and Ibrahim Issac Gaied Gad-Elsayed¹**¹Department of General Surgery, Faculty of Medicine, Minia University, Minia Egypt

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Abstract

Background: Choledocholithiasis is an important public health problem, since up to 18% of patients with cholelithiasis develop this complication of biliary lithiasis. Even in patients with asymptomatic choledocholithiasis, stone extraction should be performed to avoid serious complications; the aim of this study is to compare one session procedure versus sequential sessions procedure for management of Choledocholithiasis. **Methods:** This is a comparative clinical study that was done on 60 patients with combined gallbladder and CBD stones attending at Minia University Hospital of gastro enterology and hepatology between November 2021 and November 2022 surgery Patients were divided into two groups, Group A: .30 of them were managed by one session procedure group: 30 patients was managed by sequential sessions procedure. **Results:** The mean age in Group (A) and Group (B)s was 50.3± 13.5 years and 42.2± 9 years respectively(p=0,76), The incidence of males and females patients in both groups (33.3% males Vs 66.7% females), (p>0.05), as regard number of ERCP and anesthesia sessions in both groups in group A mean number was 1±0.0 in group B was 3,7±1.4 (p<0.001). In group (A), ERCP success rate (100%), lap. Cholecystectomy failure rate 13.3%. In group (B), ERCP success rate 90%. lap cholecystectomy in failure rate 20% (p=0.024). The mean duration of hospital stay in group (A) was 2.0± 1.8 days and 7.0± 3.5 days in group (B) (p<0.001). as regard post-operative complications group A reported two cases pancreatitis while 13 cases in group (B) showed postoperative complications,(p=0.003). The mean cost of operation in group (A) was 32527± 11801 L.E and 55363± 20573 L.E in group (B), (p<0.001). **Conclusion:** one session procedure was better than sequential sessions procedure as regard cost, hospital stay, and postoperative complication, but one session therapy needs specialized surgeon.

Keywords: combined gallbladder and CBD stones, laparoscopic cholecystectomy, ERCP, one session, sequential sessions, choledocholithiasis

Introduction

Choledocholithiasis is an important public health problem, since up to 18% of patients with cholelithiasis develop this complication of biliary lithiasis. Even in patients with asymptomatic choledocholithiasis, stone extraction should be performed to

avoid serious complications secondary to the presence of bile duct stones (cholestasis, ascending cholangitis or acute pancreatitis)^{[1],[2]}. The management of cholecystocholedocholithiasis in the era of laparoscopic cholecystectomy is controversial. Current guidelines state that peri-

operative endoscopic retrograde cholangiopancreatography (ERCP) and laparoscopic common bile duct exploration are equally valid treatment options [3],[4]. Conversely there has been a growing body of evidence supporting a single-stage approach with postulated benefits including reduction in hospital stay and costs. Recently, laparoscopic-endoscopic rendezvous has emerged as an alternative single-stage approach. However, in clinical practice a propensity for two-stage approach still persists [3, 5, 6].

Patients and methods

This comparative clinical study was done on 60 patients with combined gall bladder and CBD stones attending to minia university hospital of gastro enterology and hepatology, Patients were divided into two groups, Group A: managed by combined ERCP and laparoscopic cholecystectomy at one session, Group B: managed by Two sessions procedure (ERCP then laparoscopic cholecystectomy orlaparoscopic cholecystectomy then ERCP) Results were compared according to Cost and hospital stay, Post operative complications

Criteria of inclusion:

1- Inclusion criteria:

Patients with combined gallbladder and CBD stones, Age range between: 18 to70 years old, Both sexes were included

2- Exclusion criteria:

acute calcular cholecystitis more or after 7 days of disease onset, previous biliary tract surgical history,suppurative cholangitis with septic shock, acute pancreatitis, decompensated cirrhosis CBD stone More than 1.5cm diameter, malignant obstructive jaundice, unfit patient for the procedure

Randomization:

- Patients were randomly allocated by a computer-generated table into one of the two study groups, group A (30) patients, and group B (50) patients. The randomization sequence was concealed in sealed envelopes with alphabetic codes. The patients' identifiers were be attached to

the opened envelopes and secured by a dedicated person independent of randomization proceedings.

Patients were divided into two groups: group A managed by one session procedure in laparo endoscopic unit, group B managed by sequential session procedure.

3- Preoperative data:

Medical history, surgical history, laboratory investigation CBC Amylase and lipase in selected cases Liver function test) CBC Amylase and lipase in selected cases Liver function test), (radiological investigation: Abdominal us MRCP → in selected cases

Data to be evaluate

Operative data:

Success and failure rate of the procedure, Number of the procedures

Postoperative data:

All patients were followed up as regards:

Morbidity (Bile leak, Postoperative bleeding, Perforation, Cholangitis, Post-ERCP pancreatitis), Mean hospital stay (days), Total expenses

Operative technique

- ERCP was done in the operative room under C-arm machine by the Endoscopist the patient lies in supine position till he is generally anesthetized then he will be rotated to prone position figure^[1]. The side-view in duodenoscope passed through the GIT till it reaches the second part of the duodenum (figure 2) cannulation was done. Radio opaque dye was injected inside CBD and a screen-shot by the C-arm figure4 Then the guide wire was inserted through the cannula inside the CBD then the sphincterotome was inserted over the guide wire till it reaches the papilla. Sphincterotomy was done, Sphicterotome me was removed and the balloon was inserted. The balloon was inflated and multiple attempts of trawling were done till stones, mud came out of papilla (figure 5)



Figure [1]



Figure [2]

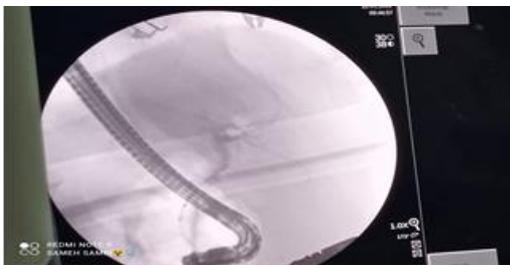


Figure [3]



Figure [4]

After successful ERCP procedure patient turned into supine position figure the skin is prepared by betadine then the operative field is draped. a 10 mm blunt trocar was placed intra peritoneal and CO2 insufflation was started to a maximum pressure 14mmHg. A two 5mm lateral Trocars were inserted in the peritoneal cavity a finger breadth below Xiphoid process A ten-mm trocar was inserted into the abdominal cavity figure 6 place the patient in reverse Trendelenburg position, By the help of the lateral grasper ,the fundus of the gallbladder will held cephalic over the dome of the liver figure. The medial grasper was used to retract the infundibulum of the gallbladder in a caudo lateral direction. Carefully the cystic duct and artery were dissected and identified in

the Calot's triangle till the critical view was obtained. Figure [7],

The cystic duct was clipped Complete cut of the duct using the scissor. The artery was clipped by 2clipses then was cut by L-hook and divided, the infundibulum was retracted cephalad and the hook will used to develop a plane in the areolar tissue between. The gallbladder was separated and held over the right upper quadrant. The gall bladder was pulled out through the umbilical port using the crocodile grasper and the final look and washing was done. In all Cases, a drain was inserte Removal of ports was done under vision. All skin incisions were closed using 3/0 non absorbable suture and nasogastric tube was removed then the patient was extubated then transferred to post anesthesia care

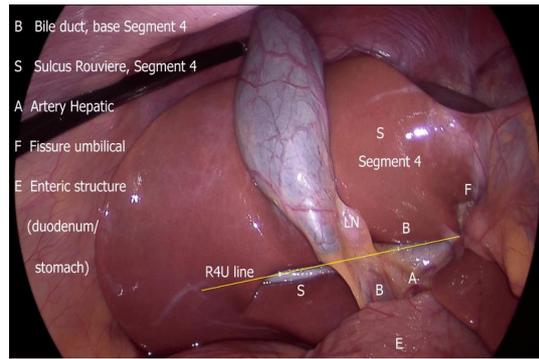


Figure [6]; M. Taberz, R Mishra, J. Chowhan published 2017 world journal of laparoscopic surgery

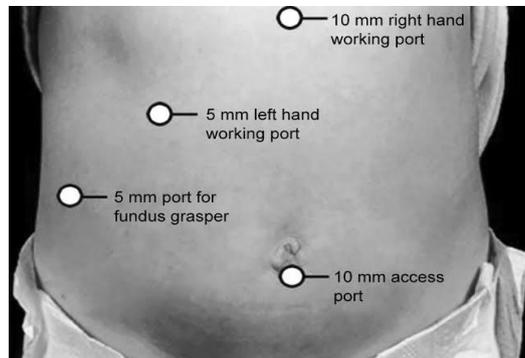


Figure [7]; (Vishal Gupta, G Jain published 27 February 2019 medicine World journal of gastroenterology

Statistical analysis

Data was collected, coded then entered as a spread sheet using Microsoft Excel 2016 for Windows, of the Microsoft Office bundle; 2016 of Microsoft Corporation, United States. Data was analyzed using IBM Statistical Package for Social Sciences software (SPSS), 21st edition, IBM, United States. The Kolmogorov-Smirnov test was used to verify the normality of distribution. Continuous data was expressed as mean \pm standard deviation, median & IQR while categorical data as numbers and percentage. Data was presented as tables and graphs. Results was considered statistically significant at a p-value of less than or equal 0.05 and highly statistically significant at a p-value of less than or equal 0.001. The used tests were

Chi-square test for categorical variables, to compare between different groups. Fisher's Exact test Correction for chi-square when more than 20% of the cells have expected count less than 5. Student T-test used for normally distributed quantitative variables, to compare between two studied groups. Mann Whitney test used for abnormally distributed quantitative variables, to compare between two studied groups

Results

Demographic data

The mean age in Group (A) and Group (B)s was 50.3 ± 3.5 years and 42.2 ± 9 years respectively. There was equal distribution of males and females patients in both (33.3% males Vs 66.7% females). No

statistically significant difference was observed between the two groups regarding age and gender ($p > 0.05$). (table 1) On comparison of comorbidities between group (A) and group (B), there was no statistically significant difference between the two groups as in group (A), 6 (20%) patients had DM, 4(13.3%) patients were both diabetic and hypertensive and 2 (6.7%) patients were asthmatic, while in group (B), 2(6.7%) patients had DM, 2 (6.7%) patients were hypertensive and 4 (13.3%) patients were both diabetic and hypertensive.(table2)

Operative data

As regard Comparison of number of procedures (ERCP and anesthesia sessions) There was statistically significant difference between the two groups regarding number of ERCP and anesthesia sessions as it was significantly higher in group (B) ($p < 0.001$). (table3), as regard): Comparison of intraoperative success and failure rate between the studied groups In group (A), all cases who underwent ERCP succeeded to complete operation (0% failure rate) while when they underwent lap. Cholecystectomy in the same session there was 13.3% failure rate as four cases turned to open cholecystectomy due to distended stomach and duodenum post ERCP procedure resulting from insufflation. In group (B), three cases who underwent

ERCP failed to complete operation due to large CBD stone and they underwent CBD exploration after multiple ERCP sessions while when they underwent lap. cholecystectomy in the same session there was 20% failure rate as six cases turned to open cholecystectomy due to multiple adhesions. There was statistically significant difference between the two groups ($p = 0.024$). (table 4),

Post-operative data

as regard Comparison of duration of hospital stay between the studied groups, The mean duration of hospital stay in group (A) was 2.0 ± 1.8 days and 7.0 ± 3.5 days in group (B)s. Group (A) showed significant decrease in duration of hospital stay compared to group (B) ($p < 0.001$) (table 5) as regard Comparison of postoperative complications between the studied groups, Two patients in group (A) had complications as they reported pancreatitis while 13 patients in group (B) showed postoperative complications. Group (B) showed statistically significant increase in postoperative complications compared to group (A) ($p = 0.003$) (table 6) as regard Comparison of cost between the studied groups, The mean cost of operation in group (A) was 32527 ± 11801.0 L.E and 55363 ± 20573 L.E in group (B)s. Group (A) showed significant decrease in cost compared to group (B) ($p < 0.001$) (table 7)

Table (1): Demographic characters among the two studied groups

Variable		Group (A) (N=30)		Group (B) (N=30)		Test value	P-value	Sig.
		No.	%	No.	%			
Gender	Male	10	33.3%	10	33.3%	$X^2 = 0.0$	1.0	NS
	Female	20	66.7%	20	66.7%			
Age (years)	Mean± SD	44.87± 15.77		45.77± 15.43		$Z_{MWU} = 0.296$	0.767	NS
	Median (IQR)	50.0 (26.0-60.0)		47.0 (33.0-55.0)				
	Range	22.0 - 66.0		23.0 - 80.0				

P value < 0.05 is significant, P value < 0.01 is highly significant, SD: Standard deviation, X^2 : Chi-Square test, Z_{MWU} : Mann-Whitney U Test

Table (2): Comparison of comorbidities between the studied groups

Variable		Group (A) (N=30)		Group (B) (N=30)		Test value	P-value	Sig.
		No.	%	No.	%			
Comorbidities	No	18	60.0%	22	73.3%	X ² = 6.40	0.171	NS
	DM	6	20.0%	2	6.7%			
	HTN	0	0.0%	2	6.7%			
	DM+HTN	4	13.3%	4	13.3%			
	Asthma	2	6.7%	0	0.0%			

P value < 0.05 is significant, P value < 0.01 is highly significant, SD: Standard deviation, X²= Chi- Square test

Table (3): Comparison of number of procedures (ERCP and anesthesia sessions) between the studied groups.

Variable		Group (A) (N=30)	Group (B) (N=30)	Test value	P-value	Sig.
Number of procedures (ERCP and anesthesia sessions)	Mean± SD	1.0± 0.0	3.70± 1.37	Z _{MWU} = 7.247	<0.001	HS
	Median (IQR)	1.0 (1.0-1.0)	3.0 (3.0-4.0)			
	Range	1.0 - 1.0	2.0 - 8.0			

P value < 0.05 is significant, P value < 0.01 is highly significant, SD: Standard deviation, Z_{MWU}: Mann-Whitney U Test

Table (4): Comparison of intraoperative success and failure rate between the studied groups

Variable		Group (A) (N=30)				Group (B) (N=30)				Test value	P-value	Sig
		ERCP		Lap. cholecystectomy		ERCP		Lap. Cholecystectomy				
		No.	%	No.	%	No.	%	No.	%			
Success rate	Succeeded	30	100.0%	26	86.7%	27	90%	21	70.0%	X ² = 6.67	0.024	S
	Failed	0	0.0%	4	13.3%	3	10%	6	20.0%			

P value < 0.05 is significant, P value < 0.01 is highly significant, SD: Standard deviation, X²: Chi- Square test

Table (5): Comparison of duration of hospital stay between the studied groups

Variable		Group (A) (N=30)	Group (B) (N=30)	Test value	P-value	Sig.
Duration of hospital stay (days)	Mean± SD	2.0± 1.78	7.0± 3.53	Z _{MWU} = 4.264	<0.001	HS
	Median (IQR)	2.0 (2.0-5.0)	7.0 (7.0-9.0)			
	Range	2.0 - 15.0	4.0 - 18.0			

P value < 0.05 is significant, P value < 0.01 is highly significant, SD: Standard deviation, Z_{MWU}: Mann-Whitney U Test

Table (6): Comparison of postoperative complications between the studied groups

Variable		One session group (N=30)		Two sessions group (N=30)		Test value	P-value	Sig.
		No.	%	No.	%			
Postoperative complications (Cholangitis, Pancreatitis, biliary leakage, bleeding)	No	28	93.3%	17	56.7%	X ² = 8.889	0.003	HS
	Yes	2	6.7%	13	43.3%			
	Cholangitis	1	3.3%	5	16.7%	X ² = 1.67	0.195 _{FET}	NS
	Pancreatitis	1	3.3%	5	16.7%	X ² = 1.67	0.195 _{FET}	NS
	Bleeding	0	0.0%	1	3.3%	X ² = 0.0	1.0 _{FET}	NS
	Biliary leakage	0	0.0%	2	6.7%	X ² = 0.52	0.492 _{FET}	NS

P value < 0.05 is significant, P value < 0.01 is highly significant, SD: Standard deviation, X²: Chi-Square test, FET: Fischer Exact Test

Table (7): Comparison of cost between the studied groups

Variable		Group (A) (N=30)	Group (B) (N=30)	Test value	P-value	Sig.
Cost (L.E)	Mean± SD	32526.7± 11801.0	55363.3± 20572.9	Z _{MWU} = 5.252	<0.001	HS
	Median (IQR)	27100 (27100-30000)	46200.0(46200-50000)			
	Range	20000 – 60000	32400 - 120300.0			

P value < 0.05 is significant, P value < 0.01 is highly significant, SD: Standard deviation, ZMWU: Mann-Whitney U Test

Discussion

Obstructive jaundice is one of the earliest symptoms of hepatobiliary dysfunction. Patients with obstructive jaundice are referred as outpatients or by ambulance to facilities providing endoscopic retrograde cholangiopancreatography (ERCP). ERCP is performed only in selected specialized centers because it is an invasive procedure that involves risks and requires teamwork, expertise and close monitoring. About 60-80% of patients with gallstones are asymptomatic (Muhammedoğlu, 2019)^[7].

The current gold standard method is laparoscopic cholecystectomy (LC) which may

be performed with or without intraoperative cholangiography (IOC). While about one-third of patients with choledocholithiasis will spontaneously clear the CBD within 6 weeks, severe adverse events of untreated CBD stones such as cholangitis and pancreatitis may develop in the remaining patients (Lim et al., 2021)^[8]. LC is now used worldwide as a treatment for cholelithiasis. Over time, the hospital stay has decreased, and patients have had an earlier recovery and return to work. Approximately 15% of patients with cholecystitis have common bile duct stones (cholecystocholedocholithiasis) (Sewefy et al., 2022)^[9]. Difficult cholecystectomy not

clearly defined because it is subjective. So many studies tried to use objective parameters to define a difficult cholecystectomy. These include: male gender, age > 60, recurrent attacks, elevated amylase, history of previous upper abdominal surgery post-ERCP, adhesion masking the gallbladder, acute inflammation and Mirizzi syndrome.

Intraoperative cholangiography, antegrade or subtotal cholecystectomy are alternatives to conversion to open in difficult cases, but these techniques are time-consuming and need skills and experiences. This study aimed to evaluate laparoscopic cholecystectomy by retrofundibular (RI) approach in comparison to SLC in difficult cases with scarred Calot's triangle (Sewefy et al., 2017)^[10]. In recent years, studies on single-stage ERCP and LC have been published in the literature. In our clinic, the single-stage approach is performed during the same surgical session for the treatment of selected patients presenting with choledocholithiasis (Muhammedoglu and Kale, 2020)^[11].

According to the Demographic characters among the two studied groups, our results showed that the mean age in Group (A) and Group (B)s was 50.25 ± 13.45 years and 42.17 ± 8.95 years respectively. There was equal distribution of males and females patients in both (33.3% males Vs 66.7% females). No statistically significant difference was observed between the two groups regarding age and gender ($p > 0.05$). According to the Comparison of comorbidities between the studied groups, our results showed that On comparison of comorbidities between group (A) and group (B), there was no statistically significant difference between the two groups as in group (A), 6(20%) patients had DM, 4(13.3%) patients were both diabetic and hypertensive and 2 (6.7%) patients were asthmatic, while in group (B), 2(6.7%) patients had DM, 2(6.7%) patients were hypertensive and 4 (13.3%) patients were both diabetic and hypertensive.

According to the operative data, there was statistically significant difference between the two groups regarding number of ERCP and anesthesia sessions as it was significantly higher in group (B) ($p < 0.001$). In contrast with our results the study of (Muhammedoglu, 2019)^[7] which was done on Of the 350 patients undergoing ERCP between 01.01.2015 and 31.12.2016, 31 patients with single-stage ERCP and LC were assigned to Group A and 25 patients with two-stage ERCP followed by LC within 6-8 weeks were assigned to Group B, reported that Total duration of anesthesia did not differ statistically significantly between the study groups (154.06 ± 53.76 min in our Group A series and 167.04 ± 75.17 min in our Group B series).

According to the Comparison of intraoperative success between the studied groups, our study showed that in group (A), all cases who underwent ERCP succeeded to complete operation (0% failure rate) while when they underwent lap. cholecystectomy in the same session there was 13.3% failure rate as four cases turned to open cholecystectomy due to distended stomach and duodenum post ERCP procedure resulting from insufflation. In group (B), three cases who underwent ERCP failed to complete operation due to large CBD stone and they underwent CBD exploration after multiple ERCP sessions while when they underwent lap. cholecystectomy in the same session there was 20% failure rate as six cases turned to open cholecystectomy due to multiple adhesions. There was statistically significant difference between the two groups ($p = 0.024$). The study of (EL-Geidie AAR et al., 2011)^[12] which was done on 98 patients they were randomized into two groups LC/LERV (N=45) and LC/ IOES (N=53) was against our results as it report that there no was no significant difference in the success and failure rate between two groups. The study of (El-Swefy et al., 2017)^[10] support our results as it reported that the sphincter of Oddi could be damaged during ERCP leading to bacterial colonization in the bile ducts furthermore

this damage may increase the difficulty of calot' triangle dissection and increase the risk of conversion to laparotomy.

According to the Comparison of duration of hospital stay between the studied groups, our study showed that the mean duration of hospital stay in group (A) was 2.0 ± 1.78 days and 7.0 ± 3.53 days in group (B)s. Group (A) showed significant decrease in duration of hospital stay compared to group (B) ($p < 0.001$). The study of (Vtoretto N et al., 2018) [13] support our results as it reported that the length of hospital stay appeared to be lowered in laparoendoscopic rendezvous group by aboutn three days, The study of (Muhammedoğlu, 2019)[7] supported our results as they reported that single-stage ERCP/LC is associated with shorter hospital stay. According to the Comparison of postoperative complications between the studied groups, our results showed that Two patients in group (A) had complications as they reported pancreatitis while 13 patients in group (B) showed postoperative complications. Group (B) showed statistically significant increase in postoperative complications compared to group (A) ($p = 0.003$). Cases with Pancreatitis and cholangitis underwent conservative management. Case with bleeding underwent abdominal exploration. The two cases with perforation: one case were on conservative management while the other one underwent abdominal exploration. The study of (Lu et al., 2012) [14] was against our results as they reported that postoperative morbidity occurred in 15.2% (54 of 355) of patients in the two-stage (ERCP/EST + LC) group vs 19.0% (65 of 343) of patients in the single-stage (LC + LCBDE) group.

The study demonstrated that there was no-statistically. The syudy of (Yan Lin et al., 2020)[15] it supports our results as it reported that the overall morbidity like post operative pancreatitis, choleangitis bleeding and biliary leakage in the in the LERV group was lower than the two-stages management, According to the Comparison of cost between the studied groups, our

results showed that The mean cost of operation in group (A) was 32526.7 ± 11801.0 L.E and 55363.3 ± 20572.9 L.E in group (B)s. Group (A) showed significant decrease in cost compared to group (B) ($p < 0.001$). The study of (Costi et al., 2014) [16] also showed that the single-stage combined tri-endoscopic approach for simultaneous cholecystolithiasis and choledo-cholithiasis was equally safe and as successful as the control group. Additionally, it was associated with a shorter hospital stay and lower cost.

Conclusion

One session procedure was better than sequential sessions procedure as regard cost, hospital stay, and postoperative complication, but one session therapy needs specialized surgeon.

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