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Original Article

Comparison of single-stage and two-stage ERCP Laparoscopic Cholecystectomy

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Abstract

Background: Gallbladder surgeries are among the commonest major abdominal operations and to continuously improve the procedure many variants have developed that need evidence-based comparison in terms of frequency common bile duct (CBD) clearance, the mean operative time and hospital stay, and rate of adverse outcomes (post-operative pancreatitis). Through this study, we aimed to compare the surgical outcome of single-stage Endoscopic Retrograde Cholangio-Pancreatography (ERCP) with LC in comparison to two-stage ERCP.

Methodology: This prospective study was conducted on a sample of 190 diagnosed patients (chosen via non-probability consecutive sampling) of cholelithiasis with choledocholithiasis, aged between 20 to 70 years who were scheduled to undergo surgery at the Ziauddin University Hospital, Karachi. The patients were divided into two equal groups (Group A: Single-stage ERCP & LC, and Group B: Two-stage ERCP followed by interval LC). After taking written informed consent, data pertaining to surgical outcome were recorded onto a pre-structured questionnaire and analyzed using SPSS Version 23.0.

Results: The demographic and clinical characteristics of both the groups were similar and so were the success rates. Adverse events free and positive outcomes were reported in 95.79% and 90.53% of the patients in groups A and B respectively. Post-operative pancreatitis was reported more often among the patients of group B. The length of hospital stay and costs were lower among Group A patients despite the longer operative times in this group.

Conclusion: Patients in group A yield better surgical outcomes, giving single-stage ERCP & LC the edge over two-stage ERCP followed by interval LC. Thus, single-stage ERCP & LC is recommended as the method of choice.

Keywords

Cholelithiasis, Choledocholithiasis, Laparoscopic Cholecystectomy (LC), Endoscopic Retrograde cholangiopancreatography (ERCP), Surgical Outcome.

Introduction

Cholelithiasis, Choledocholithiasis disease is the cause behind 16% of all reported abdominal pain complaints and accounts for up to 21% of all patients presenting to the hospital with a surgical abdomen, most the times, the ultimate cure is cholecystectomy[1]. Initially, cholecystectomy was performed by major abdominal incision, however, with the introduction of Laparoscopic Cholecystectomy in 1987, this is the preferred procedure however in some cases the surgeons are required to do the open Cholecystectomy. Laparoscopic Cholecystectomy has its advantages due to its minimal level of invasion, less trauma inflicted during surgery, decreased risk of bleeding and infection, smaller surgical scar and shortened length of stay at the hospital as compared to the open alternative[2].

The prevalence of cholelithiasis in the Pakistani population is around 10.4%[3], furthermore, 18% of the patients with cholelithiasis have associated choledocholithiasis with the incidence peaking in the Pakistani population at the age of 30 to 44 years. It has been reported by Samra et al., that out of 400 diseased gallbladder patients 320(80%) had gallstones. ERCP has become the gold standard for isolated common bile duct stones[4]. The commonly employed strategy is thus ERCP with sphincterotomy followed by extraction of common bile duct stone via Dormia basket or balloon which in turn followed by LC. The procedure can be performed in a single-stage or two stages. The other management options for CBD stones include laparoscopic exploration, open exploration, extracorporeal shock wave lithotripsy and laser lithotripsy to name a few[5].

Single-stage ERCP with LC in a single sitting is associated with higher success rates of CBD clearance and reduced hospital stay and operation time. However, the technique requires technical expertise and needs to be performed in well-equipped setups[6]. This research intends to compare the single-stage ERCP with its two-stage variant, hoping to generate evidence that shall offer greater insight regarding the better technique offering maximum patient benefit.

Methodology

This prospective analysis was conducted on a sample of 190 diagnosed cholelithiasis patients with choledocholithiasis from May 2015 and November 2019, scheduled to undergo surgery at the Ziauddin University Hospital, Karachi. The sample was collected using non-probability, consecutive sampling. After taking written informed consent, the basic sociodemographic data and details such as operative time, hospital stay, success, or failure of common bile duct clearance and postoperative complications were recorded onto a pre-structured questionnaire and analyzed using SPSS Version 23.0 & Microsoft Excel 2016.

All consenting pre-diagnosed patients of cholelithiasis with choledocholithiasis as per the American Society of Anesthesiologists (ASA) classification-ASA Class I, II and III, of either gender and aged between 20 to 70 years were included. Patients presented with comorbid conditions such as bleeding disorders or coagulopathies, carcinoma of the head of the pancreas, peri-ampullary carcinoma, acute pancreatitis or acute cholangitis and major systemic diseases such as diabetes mellitus were excluded from the study. Also excluded were the patients with ASA class IV & V and redo cases.

The included patients were then divided into two groups, Group A patients underwent ERCP along with LC in a single setting under general anesthesia. The patients first underwent ERCP in prone position followed by standard 4 port LC in the supine position. The protocol in place was that in case of failure

of ERCP to clear the stones, laparoscopic CBD exploration shall be attempted and if that also failed, the procedure will be converted to open CBD exploration followed by open cholecystectomy and placement of T-tube.

Patients in Group B first underwent ERCP with sphincterotomy and stone extraction from common bile duct by the gastroenterologist as an outdoor procedure under total intravenous anesthesia. Patients were observed for 3 hours post-procedure for any immediate complications and then discharged. Group B patients were again called for an interval LC after a period determined by the general surgeon, (maximum 14 days as soon as the inflammation subsided sufficiently and surgical field is cleared) as an elective case in the main operation theatre. Standard 4 port LC technique was employed. The protocol dictated that in cases of failure of ERCP in the two-stage group, a repeat attempt at clearance will be done after one week and if it fails again laparoscopic CBD exploration will be attempted as in single-stage group and if that also fails, the procedure will be converted to open CBD exploration followed by open cholecystectomy and placement of T-tube.

Results

Among the 190 patients enrolled in the study, 124(65%) were females while the remaining 66(35%) were males. The mean age of the sample stood at 38±7.1 years. Both procedural variants yielded similar success rates. No adverse effects were observed among the patients of both groups. The success rate was higher among the patients of group A (96.79%) as compared to 90.53% among group B patients.

Table 1: Procedural Comparison & Success rate among the participants of the two study groups; Single-stage & Two-stage ERCP

Characteristics	Group A (n=95)	Group B (n=95)
Success Rate (%)	96.79	90.53
Mean Operative Time (Mins)	57±12	41±16
Mean Hospital Stay (Hours)	110±57.6	148±27.2
Difficulty Cannulation	05(5.26)	11(11.57)
Residual CBD Stones	01(1.05)	01(1.05)
Post-Operative Pancreatitis	02(2.10)	07(7.36)
Convert to Open Procedure	01(1.05)	01(1.05)

*Values are given as Mean ± SD or n(%)
*CBD- Common Bile Duct

Discussion

Despite the climbing incidence of problems associated with gall bladder, there is a paucity of data regarding the management of common bile duct stones in Pakistan with no previous studies comparing single-stage ERCP & LC with two-stage ERCP followed by interval LC. International literature comparing similar techniques have yielded variable results[7-9].

The available evidence suggests that single-stage ERCP & LC is probably a safer and effective treatment modality but needs validation with research in our local setups. The results of this research may help establish better evidence-based practices regarding the management of choledocholithiasis in our population[8].

The results were in line with our hypothesis, Group A yielded overall better outcomes than group B. Additionally, the prevalent belief that single-stage surgery is too difficult was refuted by our results which showed that no additional difficulty was reported by operating surgeons during cannulation. A study by Selimah et al., in 2016 reported that the ERCP cannulation rate was 97.5% in both groups. Complete CBD clearance was accomplished in 82.5% of patients in the two-stage group versus 80% of patients in the single-stage group ($p>0.05$). This is synonymous with the findings of our study which yield similar CBD clearance rates in both group[9].

Morino et al., from in Italy in 2006 reported that complete CBD clearance was accomplished in 80% patients in the two-stage group versus 95.6% patients in a single-stage group ($p=0.06$). Our research also has a similarly high clearance rate. Postoperative pancreatitis occurred in 2.2% of patients versus 0% of patients between the two groups respectively which was not statistically significant. The mean hospital stay between the two groups (4.3 days in single stage versus 8 days in the two-stage group) was found to be statistically significant ($p<0.0001$)[10]. The results of our study were just as encouraging.

Sahoo et al., from India in 2014 reported that the ERCP cannulation rate was 90.2% in one stage group and 90.5% in the two-stage group ($p>0.05$). Though our results showed the two procedures to be slightly less similar in terms of outcome. Complete CBD clearance was accomplished in 71% of patients in two-stage group vs 90.5% patients in a single-stage group ($p<0.05$). In the two-stage group, post-ERCP serum amylase was raised in 22% of patients with 12% of patients having severe pancreatitis versus 0% of patients with hyperamylasaemia or pancreatitis in one stage group. The mean hospital stay was 6.8 days in a single-stage group vs 10.9 days in two-stage groups respectively ($p<0.05$). Our mean hospital stay however was much lesser[11].

Another study by Ghazal et al., from Egypt in 2009 studied one stage technique and reported that the CBD cannulation was successfully performed in 91.7% cases with a stone clearance rate of 100%, supporting our claim that no additional difficulty is attributed to this procedure than the conventional procedures[12]. There was no case of postoperative pancreatitis and the mean hospital stay was 2.55 ± 0.89 days. The mean operation time was 119.09 ± 14.4 minutes. Bansal et al., in 2010 found a successful stone clearance rate of 73.3% in two-stage technique[12,13]. Hence clearance rates are encouraging in research from other parts of the world as well. A meta-analysis by Tan et al., published in 2017 found that the success rate of CBD clearance was 93% in a single-stage group versus 92% in the two-stage group, the difference was statistically insignificant ($p=0.60$). The incidence of pancreatitis was found to be lesser (0.6%) in the single-stage group versus (4.4%) in the two-stage group ($p=0.01$)[14]. This trend was mirrored in this research as well, thus cementing this finding as applicable in different settings.

One of the major limitations of our study was the lack of research on patient satisfaction and quality of life. Furthermore, the pain examination could also be used to draw significant inferences in favor of single-stage ERCP & LC.

Conclusion

After careful consideration, it can be concluded that patients in group A may yield better

surgical outcomes giving single-stage ERCP & LC the edge over two-stage ERCP followed by interval LC. Thus, single-stage ERCP & LC may be recommended as the method of choice as it is cost-effective, decreases overall hospital stay and there are lesser chances of Post-Operative Pancreatitis with single-stage ERCP & LC as compared to two-stage.

Conflicts of Interest

None.

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