

COMPARISON OF OPEN WITH LAPAROSCOPIC COMMON BILE DUCT EXPLORATION

Kamran Safdar, Nasir Mehmood Wattoo, Qasim Butt, Talha Yasin, Muhammad Asif*

Pak Emirates Military Hospital/National University of Medical Sciences (NUMS) Rawalpindi Pakistan, *Combined Military Hospital/National University of Medical Sciences (NUMS) Rawalpindi Pakistan

ABSTRACT

Objective: To evaluate the difference in outcome of laparoscopic versus open methods for common bile duct exploration at Combined Military Hospital Rawalpindi.

Study Design: Comparative study.

Place and Duration of Study: Pak Emirates Military Hospital and Combined Military Hospital, Rawalpindi, from Jun 2018 to Apr 2019.

Methodology: A prospective study was conducted on 60 patients who underwent bile duct exploration either open or laparoscopic, for possibly benign conditions, were included in the study. Follow-up assessment regarding all the side effects was done immediately after the procedure, at 48 hours, at time of discharge and two weeks post procedure on all the participants. Demographic profile and surgical method were compared in the groups with and without the complications by using the chi-square test and binary logistic regression.

Results: Mean age of patients in our study was 45.83 ± 2.271 . Bile duct leakage was the commonest complication among the target population followed by wound infection. Open method and presence of co-morbidities had a strong correlation with presence of complications among the patients undergoing bile duct exploration in our study.

Conclusion: Laparoscopic method emerged as a safe technique for common bile duct exploration as compared to the open method in our patients. Special attention should be paid to patients with medical co morbidities and level of suspicion should be high in them for the post-operative complications.

Keywords: Bile duct exploration, Complications, Laparoscopy, Open method.

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INTRODUCTION

Hepato-biliary surgery is an emerging specialty all over the world¹. Though interventional gastroenterology has created a great impact and reduced the burden of surgeons, still the surgical aspect of hepato-biliary apparatus cannot be undermined and has its own advantages and utilities². In our part of the world, this is an emerging specialty with very few surgeons specially trained in it so it is the general surgeons who have been doing these procedures even at tertiary care hospitals. With various modalities available in recent era it is an utmost requirement for the surgeons to have an accurate knowledge of efficacy and untoward effects of all modalities so that they can give these options to the patients with

complete clarity³.

Bile duct exploration has been a common surgery performed at hepato-biliary clinics in various settings⁴. With time, the prevalence of diseases involving the hepato-biliary surgery has been increasing⁵. Common conditions for which bile duct exploration is usually performed are gall stones, bile duct stones, intractable biliary colic, bile duct obstruction leading to obstructive jaundice, acute cholangitis and acute pancreatitis⁶. A good liaison with interventional gastroenterologist is usually of great importance in order to make an accurate diagnosis before the explorative surgery⁷.

Numerous studies have been conducted on this subject in the past. A study done in Ukraine, concluded that laparoscopic method is superior to the open method in terms of complications and length of hospital stay. There was also more

Correspondence: Dr Kamran Safdar, Army Liver Transplant Unit, Pak Emirates Military Hospital Rawalpindi Pakistan

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blood loss in the open method of exploration as compared to the laparoscopic method⁸. Another recent study done in China, on cirrhotic patients with choledocolithiasis, revealed similar findings and laparoscopic method emerged as a better modality in terms of fewer short term complications and better long-term outcome⁹. Another retrospective cohort study, conducted in Lebanon, also supported laparoscopic method for bile duct exploration. Readmissions related to the procedure were also significantly high among patients undergoing open method of exploration as compared to the laparoscopic method¹⁰.

Previous studies have clearly demonstrated a better safety profile of laparoscopic procedure for bile duct exploration but many complications have been related to it as well especially if performed by unskilled surgeon without adequate facilities¹¹. Bile duct perforation, acute pancreatitis and acute renal injury are some of the few life threatening complications which can occur in the patients undergoing any type of bile duct exploration¹².

Pakistan is a developing country with most of the people having limited sources of income. Health budget, which government allocates, is also very less as compared to the burden of diseases. Therefore we need to find a balance between the available resources. Though laparoscopic method required specialized facilities and is expensive as compared to the conventional open method¹³, still the post-operative complications, hospital stay and chances of readmission should be taken into account while briefing the patient, in order to find the best option for the procedure. This study was planned with the rationale to observe and compare the outcome profile of both procedures done at Pak Emirates Military Hospital and Combined Military Hospital Rawalpindi over a time period of ten months.

METHODOLOGY

This comparative study was conducted at the surgical department of Pak Emirates Military Hospital and Combined Military Hospital Rawalpindi, from June 2018 to April 2019. Sample size

was calculated by WHO Sample Size Calculator by using population prevalence of 3.5%¹⁰. Non probability consecutive sampling technique was used to gather the sample. All patients between the age of 18 and 65 years, who underwent bile duct exploration either open or laparoscopic for a possibly benign condition, were included in the study. Patients who were referred from other military, public sector and private hospitals, who underwent bile duct exploration at our hospital, were also included in the analysis, in addition to the patients of own hospital. Exclusion criteria were the patients with less than eighteen year of age or those with uncontrolled diabetes, hypertension or any other medical illness. Patients with a known gallbladder carcinoma or any other solid or hematological malignancy were also part of the exclusion criteria. Those undergoing redo surgeries were also excluded from this study.

After gaining approval from the ethics review board committee (IREB letter no: A/29) and obtaining informed written consent from potential participants, patients who were undergoing bile duct exploration due to any reason, either open or laparoscopic, at surgical unit of PEMH and CMH Rawalpindi fulfilling the above mentioned inclusion criteria were included in the study. Routine analgesia and anti-biotic cover was given to each patient as per hospital protocol and condition of the patient. Visual Analogue Scale (VAS) score was applied to assess post-operative pain. Detailed assessment regarding all the side effects was done immediately after the procedure at 48 hours, at time of discharge and two weeks after the procedure was done on all the participants. VAS score of greater than 6 was considered as significant post-operative pain. Wound discharge and infection, bile leakage due to perforation, bleeding, collection of fluid, acute kidney injury and readmission in hospital due to primary surgery were the common short term complications noted among all the patients undergoing surgery of bile duct exploration at our hospital in the study period. Mean hospital stay was calculated for all the patients. Comorbidities in the study participants included controlled

chronic medical illnesses such as DM, IHD, HTN etc. A special proforma was designed for this

Table-I: Complications faced by patients after open or laparoscopic bile duct exploration in the study (n=60).

Medical Conditions	Frequency
Persistent post-operative pain	03 (5%)
Bile duct perforation and leakage	06 (10%)
Acute pancreatitis	01 (1.6%)
Wound discharge or infection	04 (6.6%)
Bleeding	02 (3.3%)
Hospital stay for more than a week	03 (5%)
Readmission due to consequence of primary surgery	01 (1.6%)
Others	01 (1.6%)

study including the socio demographic profile and all the possible side effects of the procedure.

Statistical analysis was performed by using

Table II: Association of the study group with the presence of post-operative complications.

Socio demographic factors	Absence of Complications	Presence of Complications	p-value
Age			
30 year or less	15 (37.5%)	10 (50%)	0.356
30-65	25 (62.5%)	10 (50%)	
Gender			
Male	25 (62.5%)	13 (65%)	0.850
female	15 (37.5%)	07 (35%)	
Pre Op Assessment			
Stones known	31 (77.5%)	11 (55%)	0.077
Not Known	09 (22.5%)	09 (45%)	
Presence of Comorbidities			
No	36 (90%)	11 (55%)	0.002
Yes	04 (10%)	09 (45%)	
Type of Surgery			
Laparoscopic	22 (55%)	02 (10%)	<0.001
Open method	18 (45%)	18 (90%)	

Table-III: Correlated factors relating to presence of complications among the patients undergoing bile duct exploration: the binary logistic regression analysis.

	p-value	Odds ratio	Confidence Interval	
			Lower	Upper
Age(ref. is 30 years or less)	0.640	0.708	0.167	3.000
Pre op assessment (reference is stones known)	0.042	6.831	1.072	43.525
Gender (ref. is male)	0.658	1.428	0.295	6.921
Surgical method (ref. is laparoscopy)	0.002	19.369	2.916	128.667
Comorbidity (ref. is no comorbidity)	0.008	17.060	2.086	139.547

Statistical Package for Social Sciences version 24.0 (SPSS-24.0). Frequency and percentages for

gender, type of surgical modality and all the complications recorded during the study were calculated. Mean and standard deviation for age and stay at hospital was also calculated for the study participants. Age, gender, findings on pre op assessment, presence of co morbidities and surgical method were compared in the groups with and without the complications by using the chi-square test and binary logistic regression.

RESULTS

A total of 66 patients were initially approached to be included in the analysis. Two had diagnosis of cancer before the surgery while four were undergoing redo surgeries. Out of 60 patients included in the final analysis, 38 (63.3%) were male and 22 (36.7%) were female. Male to female ratio was 1.7:1. Mean age of patients who underwent bile duct exploration in our study was

45.83 ± 2.271 years. Mean duration of hospital stay after the surgery was 5.73 ± 3.592 days. Bile

leak was the most common complication 6 (10%) among the target population followed by wound infection 4 (6.6%) (table-I). Other characteristics of the patients have been summarized in table-II along with the application of chi-square. With binary logistic regression, we found that open method and presence of co morbidities had a strong relationship with presence of complications among patients undergoing bile duct exploration in our study (table-III).

DISCUSSION

Laparoscopic surgery has been replacing conventional open surgery in many abdominal and gynecological procedures¹⁴. Most centers in the world have found it safer and more effective compared to the conventional method^{10,11}. Cost has been one of the issues which raises the question of making this a routine procedure in low-middle income countries like Pakistan¹³. Overall expense should be kept in mind after the evaluation of adverse effects and number of medications used, duration of hospital stay, number of redo surgeries, read-missions due to complications of the primary surgery and disability days faced by the patient¹³. This holds valid for both the private patients who must pay from their own pocket, and for insured patients for whom government organization are responsible. This matter is of great concern for a military set-up like ours, where number of disability days and patient not reaching their formation in time to join their tough duties is of utmost importance. Evaluating the cost was a complex phenomenon involving a lot of parameters so was not included in the scope of our study. The aim of this study was to look for the complications of bile duct exploration surgeries and ascertain if there is any statistical difference among the laparoscopic and open method for this procedure.

Sixty patients were included in the analysis in the given study time. Though patients were not randomized and study design was observational and not a randomized controlled trial, we still found a statistically significant difference in terms of complications among the two proce-

dures on chi-square test as well as binary logistic regression analysis. Laparoscopic method for the common bile duct exploration emerged as a safer method with comparatively better outcome than conventional open method. Studies done worldwide have documented similar findings^{9,11}, at most of these studies have been done in western countries. Our results could be generalized for low income countries if further studies analyze the overall cost and benefit ratio for both the procedures but for our patients with no issues of cost, use of laparoscopic procedure can be advocated.

Bile duct perforation was the commonest complication faced by our patients followed by wound discharge. Similar findings have been reported in studies done in other set ups involving similar patients¹⁵. Though individual complications have not been studied separately, statistical analysis clearly shows that open method had been linked with presence of these complications as compared to laparoscopic method. These finding could also be responsible for longer stay in hospital or readmission after the primary surgery. In military set up, where patient must travel to farflung areas either to their native town or formation, these findings could prove more devastating, therefore a safer procedure could save our patients from prolonged misery.

Presence of co morbidities emerged as a strong predictor of presence of complications in our target population. Even though in our study design, only stable patients with co-morbidities like diabetes, hypertension, IHD were included and unstable patients or patients with uncontrolled co-morbid illness were not included in the final analysis. It has been documented in the past as well that patients with chronic medical illnesses are at a clear disadvantage of developing post-surgical complications especially wound infections^{16,17}. Patients undergoing bile duct exploration by any method have been no exception to this and our study also reproduced these same results.

Increasing age was not a predictor of complications in our target population although previous studies have shown mixed results¹⁸. Usually, elderly have physiological immune suppression and increased chances of having chronic comorbidities which make individuals prone to surgical complications. Results in our studies were different from this expected finding. This might be due to small sample size with geriatric individuals having lesser chances of getting enrolled into the study due to our inclusion criteria.

Along with the strengths of the study in revealing the comparison of two procedures, this study had few limitations as well. Long term follow up and data of patients with redo surgeries or readmission due to primary surgery was not gathered which makes the complication rate shown in our results lesser than the prevalent rate. Further, other socio-cultural and health related factors, which could impact post-surgical recovery were not considered e.g. socioeconomic status, nutrition status and care-giving options. Studies should be done in the future, incorporating overall cost and disability days due to complications by randomizing the patients, in order to generate more generalizable results.

CONCLUSION

Laparoscopic method emerged as a safe technique for common bile duct exploration as compared to the open method in our patients. Number of complication was far less in patients undergoing laparoscopic procedure as compared to conventional open method. Special attention should be paid to patients with medical comorbidities and level of clinical suspicion should be high in them for the post-operative complications.

CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any author.

REFERENCES

- Vitale A, Lai Q. New trends and perspectives in hepatobiliary surgery: preface. *Transl Gastroenterol Hepatol* 2018; 3(1): 99-105.
- Artifon EL, Loureiro JF, Baron TH, Fernandes K, Kahaleh M, Marson FP. Surgery or EUS-guided choledochoduodenostomy for malignant distal biliary obstruction after ERCP failure. *Endosc Ultrasound* 2015; 4(3): 235-43.
- Hong KS, Noh KT, Min SK, Lee HK. Selection of surgical treatment types for intrahepatic duct stones. *Korean J Hepatobiliary Pancreat Surg* 2011; 15(3): 139-45.
- Stinton LM, Shaffer EA. Epidemiology of gallbladder disease: cholelithiasis and cancer. *Gut Liver* 2012; 6(2): 172-87.
- Di Ciaula A, Portincasa P. Recent advances in understanding and managing cholesterol gallstones. *Faculty Rev* 2018; 7(1): 1529.
- Zeng X, Yang P, Wang W. Biliary tract exploration through a common bile duct incision or left hepatic duct stump in laparoscopic left hemi hepatectomy for left side hepatolithiasis: which is better?: A single-center retrospective case-control study. *Medicine (Baltimore)* 2018; 97(46): e13080.
- Kozarek RA. The society for gastrointestinal intervention. Are we, as an organization of disparate disciplines, cooperative or competitive?. *Gut Liver* 2010; 4 (Suppl-1): S1-8.
- Gui L, Liu Y, Qin J, Zheng L, Huang YJ, He Y, et al. Laparoscopic common bile duct exploration versus open approach in cirrhotic patients with choledocholithiasis: A retrospective study. *J Laparoendosc Adv Surg Tech A* 2016; 26(12): 972-77.
- Outcomes of laparoscopic vs open common bile duct exploration: analysis of the NSQIP Database. *J Am Coll Surg* 2017; 224(5): 833-40
- Du JW, Jin JH, Hu WX, Wang ZX, Zhao HJP. Comparison of three surgical patterns for cholecysto-choledocholithiasis. *Zhonghua yi xue za zhi* 2017; 97(4): 276-79.
- Stewart L, Way LW. Laparoscopic bile duct injuries: timing of surgical repair does not influence success rate. A multivariate analysis of factors influencing surgical outcomes. *HPB (Oxford)* 2009; 11(6): 516-22.
- Palaz-Ali O, Ibis AC, Gurtekin B. Financial aspects of bile duct injuries. *Med Sci Monit* 2017; 23(1): 5264-70.
- Gupta N. Role of laparoscopic common bile duct exploration in the management of choledocholithiasis. *World J Gastrointest Surg* 2016; 8(5): 376-81.
- Platt TE, Smith K, Sinha S, Nixon M, Srinivas G. Laparoscopic common bile duct exploration; a preferential pathway for elderly patients. *Ann Med Surg (Lond)* 2018; 30(1): 13-17.
- Inokuchi M, Kato K, Sugita H, Otsuki S, Kojima K. Impact of comorbidities on postoperative complications in patients undergoing laparoscopy-assisted gastrectomy for gastric cancer. *BMC Surg* 2014; 14(1): 97.
- Everhart JS, Altneu E, Calhoun JH. Medical comorbidities are independent preoperative risk factors for surgical infection after total joint arthroplasty. *Clin Orthop Relat Res* 2013; 471(10): 3112-19.
- Joliat GR, Sauvain MO, Petermann D, Halkic N, Demartines N, Schäfer M. Surgical site infections after pancreatic surgery in the era of enhanced recovery protocols. *Medicine (Baltimore)*. 2018; 97(31): e11728.
- Bentrem DJ, Cohen ME, Hynes DM, Ko CY, Bilimoria KY. Identification of specific quality improvement opportunities for the elderly undergoing gastrointestinal surgery. *Arch Surg* 2009; 144(11): 1013-20.