Original article

Endoscopic versus open surgical management of bile duct stones

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Abstract :

Bile duct stones is one of common cause of obstructive jaundice.Endoscopic procedure less expensive open surgical approach.cross sectional study was done.Objectives to compare the therapeutic outcome of ERCPin comparison to open bile duct exploration.The study was carried out in the department of surgery in BSMMU from 1st july 2007 to june 2009.

Methods : A total of 50 patients with choledocholithiasis were evaluated in the department of surgery, BSMMU. Initial evaluation of the patients by history, clinical examination were performed .and associated with or without increased alkaline phosphates, serum bilirubin, SGOT, SGPT, and prothrombin time and common bile duct stones or a CBD diameter dilated or not on ultrasonography. Patient's prothrombin time and control time difference more than 3 were excluded due to avoid massive bleeding in ERCP and they were treated accordingly to perform ERCP. Baseline laboratory investigation were done for each patient as pre-requisite of ERCP or open cholidocholithotomy.

Results: out of 50 patients 11 were male and 14 were female in group I. In group II 12 ware male and 13 were female. The male female ratio 1:2. Post-operative jaundice was found 1 (4%) in group I, wound infection 3(12%) in group II.

Conclusion : ERCP is a safe and highly accurate diagnostic procedure in experience hands. Therapeutic potential associated with cholangiography includes endoscopic sphingterotomy, stone removal from bile ducts and placement of various kinds of stents to bridge benign and malignant stenosis. So, the management of bile duct stones and the palliation of malignant biliary stricture have largely shifted from surgery to endoscopy.

Key words : Bile duct stone, ERCP, choledocholithotomy.

Introduction :

The choice of either of the two approach is depend largely on surgeon preference and expertise. The ERCP approach is less expensive than the open surgical approach. The ERCP has a longer learning curve. Comparing these two approaches, sometimes ERCP is associated with significant morbidity and mortality. The incidence of postoperative pain is lower after procedure. Today ERCP management of ERCP choledocholithiasis is increasingly reported with the emergence of an argument to return to one stage surgical management of choledocholithiasis. Now a days ERCP is superior to open bile duct surgery in achieving CBD stone clearance.1 The advantages of endoscopic retrograde cholangiopancreatography (ERCP) over open surgery make it the predominant method of treating choledocholithiasis². The ERCP is the primary method of management in the bile duct safety of endoscopic stones. The techniques and

sphincterotomy are reviewed. After sphincterotomy, 85% to 90% CBS stones could be removed with a Dormia basket or balloon catheter². In ERCP a special side viewing Endoscopy for cannulation of the ampula to see the bile and pancreatic ducts and to obtain radiographic pictures following injection of radio opaque medium. The biliary tree can be visualized and stones can be removed with a Dormia basket. Fibreoptic Endoscopy is a safe and commonly used investigation. The morbidity and mortality associated with this procedure is extremely low. But careless and rough handling of the Endoscopy during insertion may result perforations of pharynx or esophagus⁵.

The advantages of ERCP over open surgery led to its wide spread dissemination as the predominant method treating choledocholithiasis. ERCP is required in-patients with an obstructive jaundice or in whom has suggested as abnormality of the biliary tract. A preoperative check of coagulation profile is essential, along with prophylactic antibiotics. The complications of the procedure is explained to the patient or legal guardians such as pancreatitis, cholangitis and bleeding or perforation. The therapeutic interventions are sphincterotomy, stone retrieval, balloon dilatation of strictures, endoprosthesis insertion. Bile, pancreatic juice and duodenal washing can be obtained for cytology^{6,7}.

Methodology :

A total of 50 patients with choledocholithiasis were evaluated in the department of surgery, BSMMU and others private hospital. Initial evaluation of the patients by history, clinical examination were performed and recorded in the preformed data collection sheet. Patients enrolled in the study presented with clinical symptoms which included jaundice, itching, pain, fever, anorexia, chest pain, associated with or without increased alkaline phosphates, serum bilirubin, SGOT, SGPT, and prothrombin time and common bile duct stones or a CBD diameter dilated or not on ultrasonography. Patient's prothrombin time and control time difference more than 3 were excluded due to avoid massive bleeding in ERCP and they were treated accordingly to perform ERCP. Baseline laboratory investigation such as; CBC, S. creatinine, S. electrolytes, lipid profile, RBS/ FBS, ECG, BT CT, blood grouping were done for each patient as pre-requisite of ERCP or open cholidocholithotomy.

Inclusion Criteria :

- Patients age group 20-70 years.
- Patient suffering from bile duct stone disease.

Exclusion Criteria :

• Obstructive Jaundice other than bile duct stone.

Results :

Table I: Distribution of the study patients according to age

Age Group	ge Group Group-I (n=25		Group -II (n-25		
	n	%	n	%	
20-30	4	16.0	4	8.0	
31-40	5	20.0	6	12.0	
41-50	9	36.0	7	14.0	
51-60	4	16.0	4	8.0	
61-70	3	12.0	3	6.0	
Mean ± SD Range	43.6 ± 1 (20-70	2.1 D)		45.1±15.2 (20-70)	

group (n=50).

Group I: ERCP

Group II: Open choledocholithotomy

The study included 50 Choledocolithiasis patients and they were divided into five age groups. The mean age was 43.6 ± 12.1 years with age ranged from 20 to 70 years in group I. In group II the mean age was 45.1 ± 15.2 years with age ranged from 20 to 70 years and the maximum number was found in the age group of 41-50 years in both groups.

Table II : Distribution of the study patients according to sex (n=50).

Sex	Gro (n:	Group I Group (n=25) (n=25)		Group II =25)
	n	%	n	%
Male	11	44.0	12	48.0
Female	14	56.0	13	52.0

This study was carried out in 50 patients. They were divided into male and female groups. In group I, 11(44.0%) was male and rest 14(56.0%) was female patients. In group II, 12(48.0%) was male and rest 13(52.0%) was female patients.

Table III : Distribution of the study patients according to clinical presentation. (n=50)

Complaints	Group	I (n=25)	Group I	I (n=25)
	n	%	n	%
Asymtometic	1	4.0	0	0.0
Itching	8	32.0	6	24.0
Pain	18	72.0	19	76.0
Jaundice	17	68.0	18	72.0
Fever	5	20.0	14	56.0
Lump	0	0.0	0	0.0
Weight loss	7	28.0	9	36.0
Anorexia	11	44.0	8	32.0
Vomiting	6	24.0	4	16.0
Abdominal	1	4.0	0	0.0
mass Chest pain	1	4.0	0	0.0

Regarding the complaints it was observed that pain, itching, jaundice, fever weight loss, anorexia and vomiting were most commonest clinical presentation in the both group of the patients.

Table IV : Distribution	of the	study	patients	according	to
clinical findings. (n=50)					

Clinical findings	Gre (n=	oup I =25)	Group II (n=25)	
	n	%	n	%
Anaemia				167
Mild	16	64.0	14	56.0
Moderate	7	28.0	11	44.0
Severe	0	0.0	0	0.0
Jaundice				
Mild	12	48.0	9	36.0.
Moderate	4	12.0	8	32.0
Severe	0	0.0	0	0.0
Scratch mark on				
the body				
Present	13	52.0	10	40.0
Absent	12	48.0	15	60.0

In group I, mild anaemia was found 16(64.0%), moderate 7(28.0%) and 2 patients were non anaemic. In group II, mild anaemia was found 14(56.0%), and moderate 11(44.0%). Mild jaundice was found 12(48.0%) and moderate 4(12.0%) in group I patients. In group II, mild jaundice was found 9(36.0%), and moderate 8(32.0%). Scratch mark on the body were found 13(52.0%) and 10(40.0%) in group I and group II respectively.

Table V: Distribution of the study patients according to Laboratory investigation (n=50)

Investigation	Group I (n=25)		Group	II (n=25)
N	n	%	n	%
S. Bilurubin				
$(\mu mol/L)$				
Raised level	18	72.0	22	88.0
Normal level	7	28.0	3	12.0
SGOT(IU)				
Raised level	3	12.0	8	32.0
Normal level	22	88.0	17	68.0
SGPT(IU/L)				
Raised level	9	36.0	12	48.0
Normal level	16	64.0	13	52.0
Alk. Phosphatase				
(KAU)				
Raised level	17	68.0	22	88.0
Normal level	6	24.0	3	12.0
Prothrombin time				
Abnormal	15	60.0	9	36.0
Normal	10	40.0	16	64.0

According to Laboratory investigation S. Bilurubin were raised in 18(72.0%) and 22(88.0%) in group I and group II respectively. SGOT was raised in 3(12.0%) in group I and 8(32.0%) in group II. SGPT were raised in 9(18.0%) and 12(48.0%) in group I and group II respectively. Alk. Phosphatase was raised in 17(68.0%) in group I and 22(88.0%) in group II. Abnormal prothrombin time were found 15(60.0%) and 9(36.0%) in group I and group II respectively.

Table VI: Distribution of the study patients according to operation time. (n=50)

	Group I (n=25)	Group II (n=25)	P value
	Mean±SD	Mean±SD	
Operation time (min)	52.1±3.5	104.0±5.1	0.001 ^s
Range	(40-60)	(90-120)	

S= significant

P value reached from unpaired 't' test

The mean duration of operative time was 52.1 ± 3.5 minutes with ranged from 40 to 60 minutes in group I. In group II the mean duration of operative time was 104.0 ± 5.1 minutes with ranged from 90 to 120 minutes. The mean duration of operative time difference was statistically significant (p<0.05) between two groups in unpaired t-test. The results are shown in the table VI.

Complications	Gra (n=	oup I =25)	Group II (n=25)	
	n	%	n	%
Biliary-Leakage	0	0.0	0	0.0
Chlangitis	0	0.0	0	0.0
Bile duct injury	0	0.0	0	0.0
Pancreatitis	0	0.0	0	0.0
Biliary fistula	0	0.0	0	0.0
Peritonitis	0	0.0	0	0.0
Perforation	0	0.0	0	0.0
Post operative jaundice	1	4.0	0	0.0
Hepatorenal Shutdown	0	0.0	0	0.0
Wound infection	0	0.0	3	12.0

Table VII: Complications of the study patients (n=50)

Regarding the complications post operative jaundice was found 1(4.0%) and wound infection 3(12.0%) in group I and group II patients respectively.

Table VIII: Distribution of the study patients according to outcome. (n=50)

Outcome	Group I (n=25)		Group II (n=25)	
	n	%	n	%
Uneventful post ERCP	24	96.0	22	88.0
recovery				
Satisfactory	1	4.0	3	12.0
Morality	0	0.0	0	0.0

Uneventful post ERCP recovery was found 24(96.0%) in group I and 22(88.0%) in group II patients. With satisfactory recovery it was found 1(4.0%) and 3(12.0%) in group I and group II respectively.

Discussion :

This cross sectional study was carried out with an aim to compare the therapeutic outcome of the procedure and to list the probable difficulties encountered at the time of procedure and also to recommend the scope of endoscopic management of bile duct stones. A total of 50 patients age ranging from 20 to 70 years who had bile duct stone were included in the study, in the department of surgery in BSMMU during 1st July 2007 to June 2009.

It was observed in the current study that the mean age of the patients was 43.6 ± 12.1 years and 45.1 ± 15.2 years in group I and group II respectively. The maximum number was found in the age group of 41-50 years in both groups. Suc et al. $(1998)^{27}$ have shown in their series, the mean age of the patients having choledocolithiasis was 66.8 ± 17.5 years and 66.7 ± 18.1 years in endoscopic and surgical management respectively, which is higher with the present study. The higher age range maybe due to increased life expectancy in the western country.

In this present study it was observed that 11(44.0%) was male and 14(56.0%) was female patients in group I. In group II 12(48.0%) and 13(52.0%) was male and female respectively and the male female ratio was 1:2. In a study male female ratio were observed 1:2.2 and 1.2 in group I and surgery and endoscopic management respectively is closely resemble current study²⁷, where they found the incidence was higher in female patients.

The most common presenting symptoms of the patients in the present study were pain, jaundice, itching, fever, weight loss, anorexia, vomiting frequency etc, where 72.0% complain about pain, 68.0% found jaundice, 44.0% anorexia, 32.0% itching, 28.0% weight loss, 24.0% vomiting and 20.0% had fever in group I patients. In group II, 76.0% complain about pain, 72.0% found jaundice, 32.0% anorexia, 24.0% itching, 36.0% weight loss, 16.0% vomiting and 56.0% had fever. Leese et al. (1986)²⁸ reviewed a total of 1923 sets of hospital records where the patients admitted with the criteria of acute cholangitis (temperature >38°C with a history of rigors, clinically apparent jaundice and upper abdominal pain or tenderness) or if they had frank pus in the CBD at the time of surgery, ES or post-mortem examination. Suc et al. (1998)²⁶ done a study and the patients presented with jaundice, mild acute pancreatitis (Ranson score≤211), or mild acute cholangitis4. Complications of common bile duct stones include biliary colic, jaundice, cholangitis and pancreatitis (Caddy et al. 2006)²⁸. The findings of the present study regarding the presenting symptoms of the patients are comparable with the above authors.

In the present study it was observed that the duration of operative time varied from 40 to 60 minutes in group I and 90

to 120 minutes in group II. The mean duration of operative time was 52.1±3.5 minutes and 104.0±5.1 minutes in group I and group II respectively. The mean duration of operative time was significantly (p<0.05) higher in group II. There was a median (range) operating time of 151 (80 to 300) minutes in the endoscopy arm versus 214 (115 to 420) minutes in the surgery arm observed by Stain et al. (1991)²⁹. It is, however, not apparent as to whether this refers to the combined time of endoscopy and surgery, or of surgery alone. In the other study done by Stiegmann et al. (1992)³³ mentioned that the duration of endoscopy arm was 114±78 minutes and in the surgery arm was 142±72 minutes, with significant (p<0.05) difference on tatistical test. Sgourakis et al. (2002)³⁰ reported operative time for ERCP arm, median time 90 (70 to 110) minutes and surgery median time 105 (60 to 255) minutes in the endoscopic arm. Rhodes et al. (1998)³⁴ observed the operative time (median and range) were 105 (60 to 255) minutes and 90 (25 to 310) minutes, respectively, for the endoscopy and surgical arms (p <0.05). The duration of operative time obtained in the present study was corresponds well with the above investigators.

As regards to the duration of hospital stay, a number of investigators studied and found significant (p<0.05) more duration of hospital stay in surgery with compared to endoscopy, which support the present study, where the current study found the mean duration of hospital stay was 1.1±0.7 days and 10.2±1.8 days in group I and group II respectively, which is significantly (p<0.05) higher in group II. The duration of hospital stay varied from 1 to 2 days in group I and 7 to 12 days in group II in the present study. Stain et al. (1991)²⁹, Neoptolemos et al. (1987)³¹, Bornman et al. (1992)⁴⁰ reported that the more duration days of hospital stay in surgery. In the larger trial Cuschieri et al. (1999)²³ the median (interquartile range) hospital stay for endoscopy and surgery was reported as significant by the authors. Similarly, Sgourakis et al. (2002)³⁰ also made longer duration of hospital stay in surgical arms.

Regarding the complications post operative jaundice was found 1(4.0%) in group I due to residual stones which was managed by re-ERCP and follow-up upto recovery. Wound infection was found 3(12.0%) in group II. Wound infection occurred may be due to jaundice patients were immunocompromised. After infection occurred pus send for C/S and according the C/S report they were treated. The result ⁴ obtained in the present study is similar to others studies (Halme et al. 1999; Chong et al. 2005). Complications related to endoscopic procedures included bleeding in one patient and pancreatitis in one reported by Acosta et al. (1977)²⁶ in their study and both the patients recovered after supportive therapy. In this study it was observed uneventful post ERCP recovery was found 24(96.0%) in group I and 22(88.0%) in group II patients. With satisfactory recovery it was found 1(4.0%) and 3(12.0%) in group I and group II respectively. Which were underwent open surgery and managed accordingly by Bornman et al. (1992)³² mentioned that ERCP was repeated in up to five attempts to obtain CBD stones clearance. Combined primary success rates using intention-to-treat data were 80.4% for ERCP and 93.3% for surgery (success rate potentially inflated by 4 trials involving suspicion of common duct stones Bornman et al. (1992)³². However the present study shown better outcome with the above mention study which may due to improvement of management and procedure of ERCP.

Conclusion:

ERCP is a safe and highly accurate diagnostic procedure in experience hands, being considerably superior to other diagnostic methods such as ultrasonography and CT scan. Direct cholangiography is uniformly accepted as the reference method in the diagnosis of common bile duct stones and tumors. Therapeutic potential associated with cholangiography includes endoscopic sphingterotomy, stone removal from bile ducts and placement of various kinds of stents to bridge benign and malignant stenosis. So, the management of bile duct stones and the palliation of malignant biliary stricture have largely shifted from surgery to endoscopy.

This study although conducted in a short period of time and limited number of patients with choledocholithiasis proved the superiority of ERCP over open surgery for the management of bile duct stones.

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