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ORIGINAL ARTICLE

COMPARATIVE STUDY BETWEEN DIFFERENT SURGICAL TECHNIQUES IN MANAGEMENT OF COMMON BILE DUCT AFTER EXPLORATION AND CHOLEDOCHO-LITHOTOMY.

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Aim: *a prospective study to compare different techniques in closing common bile duct after choledocho-lithotomy as T-tube drainage, intra-operative stenting, and primary closure with sphincterotomy as regard indications, operative time, hospital stay, complications, returns to work, coast, and feasibility.*
Methods: *From April 2005 to May 2006, 52 patients suffering from common bile duct (CBD) stone were selected, and operated upon for choledocho-lithotomy then randomized into group A included 19 cases were subjected to T-tube drainage, group B included 18 cases were subjected to intra-operative stenting, and group C included 15 cases were subjected to primary closure and sphincterotomy, patients were followed up for a period of 6-9 months post-operatively for evaluation.*
Results: *The three methods are effective and safe however, the hospital stay was reduced, the patients were more comfortable and rapidly return to work with CBD stents and primary closure compared to T-tube drainage, consequently the coast was reduced, however operative time was not significantly different, and also the complications was comparable.*
Conclusion: *Intra-operative stenting of CBD and primary closure with sphincterotomy are effective, safe optional techniques after choledocho-lithotomy with better patient compliance, shorter hospital stay, and costly effective, and should be considered whenever feasible.*

Keywords: *Biliary Exploration, biliary stent, sphincterotomy.*

INTRODUCTION

Management of bile duct stones requires laparotomy for extraction,[1] recent advance in radiologic, endoscopic, and surgical techniques broaden our treatment options.[2] Standard CBD exploration include choledochotomy in the supra-duodenal part,[3] then stone extraction, with confirmation of CBD clearance by passing soft catheter or dilator proximally or distally,[4] cholangiography and choledochoscopy,[5] and choledochoscopy may be preferred,[6] lastly drainage procedures is advised,[7] although it is a subject of controversy[8] with various options as:

T-shaped tube drainage is the standard practice[9,10] to decompress the biliary tree and prevent bile leakage due to edema and spasm of the sphincter of Oddi,[11,12] It has the advantages of easy post operative X-ray visualization of CBD, and the potential for T-tube tract extraction of missed stones.[9] But it carries a significant morbidity as dislodgement, associated pain, necessity of X-ray film for removal, longer hospital stay with high cost,[12] and patient's absence from work for 3-4 weeks with tube in place,[13] also associated bacteraemia necessitating antibiotic cover,[14] retention of a fragment and stricture formation,[15] and the possibility of bile leakage following extraction[16] more with plastic tubes so latex rubber is preferred.[17]

Primary CBD closure (choledochorrhaphy) was safely and effectively done provided that no evidence of pancreatitis,

cholangitis, or ampullary obstruction exists,[18] and it regains its popularity recently by the advances in endoscopic sphincterotomy and stone extraction,[8] and it is seems to be a more satisfactory technique for both surgeon and patient,[7] and should be considered.[13] Patients have a shorter hospital stay, with smooth post operative course, with lower cost,[8] post discharge X-ray is not required, with rapid return to work.[13]

Intra-operative deployment of biliary stent was done via the choledochotomy incision before its closure; it reduces operative morbidity, eliminates the complications of T-tube, and allows the patient to return to unrestricted activity quickly,[19] as the median post operative hospitalization is two days.[20] It is safe, effective, time sparing, and cost effective,[21] the stent is removed endoscopicaly after 1 month, and 6-30 months follow up demonstrates no complications.[19] However, biliary stents carries some complications as clogging that may occur in 10-30%,[22,23] by bacterial infection[24] and other component as calcium bilirubinate and calcium palmitate with protein,[25] also the risk of pancreatitis due to ductal obstruction,[26] migration proximally or distally,[27,28] cholangitis,[29] and perforation.[30]

The aim of this work is to evaluate various techniques in closing the CBD after choledocho-lithotomy either T-shaped tube drainage, implantation of biliary stent, or primary closure augmented by sphincterotomy.

PATIENTS AND METHODS

Patient population: Randomly selected sample of 52 patients from general surgery department, Assiut University hospital was included. All were diagnosed to have CBD stones.

Clinical and diagnostic work-up: all patients were subjected to:

1. Full history and examination.
2. Investigations:
   - Routine lab. tests (blood count, random sugar, serum creatinine)
   - Routine chest X-ray, ECG, etc.
   - Liver function tests.
   - Prothrombine time.
   - Abdominal ultrasonography.
   - Additional investigations were needed sometimes in some doubtful cases as CT, MRCP, and cholangiogram (5 patients had underwent previous ERCP with failure to extract the stones due to equipment deficiency or technical default with application of temporary stent, and were incorporated to group A).

Management: was done by choledocho-lithotomy using fixed surgical techniques in all steps of the procedure, with testing the CBD clearance of stones by catheter and irrigation in most of cases (a soft polyethylene catheter 8 fr. connected to 50 ml syringe is passed upwards and downwards into bile ducts with saline irrigation till the returning fluid is entirely clear, then the catheter is passed through the papilla where it can be felt in the duodenum), or by the use of intra-operative cholangiogram, then patients were divided randomly thereafter into three groups:

Group A included 19 patients in whom T-tube was used for CBD drainage, with sub-hepatic tubal drain through separate abdominal stab, and were followed up for 10-15 days until cholangiogram was done before removal of the T-tube; however sonography was needed in patients with suspected leakage.

Group B included 18 patients in whom biliary stent was inserted, usually 8.5 fr., it was manipulated till it passed through the papilla, provided that the upper end leis above the choledochotomy incision with sub-hepatic tubal drain. Those patients were followed up for 2-3 days clinically and by sonography before discharge. The stents were extracted by endoscopy after 3 months.

Group C included 15 patients in whom primary CBD closure was performed, with sphincterotomy done by simultaneous endoscopic retrograde cholangio-pancreatography (ERCP) in small number of early cases if the equipment is feasible as regard the operating radiolucent table, portable image intensifier, and portable ERCP unite (as the endoscopist proceeds to operates with the patient in the supine position though it is difficult with care for strict operative sterilization by separating the area of anesthesia and endoscopy from operative field, then CBD is cannulated by the sphincterotome where it can be visualized operatively, then sphincterotomy is done using blended current), or in most of cases sphincterotomy from choledochotomy incision that is more simple, by passing the sphincterotome downward till it pass through the papilla , then only regular fiberoptic duodenoscope is applied to guide the direction of the sphincerotome to 12 o'clock position, lastly a sub-hepatic tubal drain is applied. Patients were followed up for 2-3 days both clinically and by sonography before discharge.

Follow up: patients returned to their works if worker, or to normal pre-operative life of home working within variable periods according to the approach, and all were followed up for 6-9 months for detection of any complications, using clinical and radiologic assessment.

Ethical considerations and informed consent: The study protocol was approved by the local ethical committee, and it was explained to each patient and his/her informed consent was obtained.

Statistical analysis: The results are expressed as the mean. Statistical analysis was performed with the software statistical package for social sciences, SPSS version 8 (SPSS, Chicago, IL). A p value of less than 0.05 was considered statistically significant.

RESULTS

Age and sex incidence: This study was conducted on 52 cases, 32 females and 20 males with females: males ratio 1.6: 1, and their ages ranged from 18-66 years with mean age of 46 years.

Most of our cases presented with biliary colic (32 cases), which was the predominant complaint (61.5%), however other presentations are also encountered as jaundice in15 patients (28.8%), cholangitis in 13 patients (25%), and fatty dyspepsia in 11 cases (21.1%).

Pre-operative investigations: were done as abdominal sonography, CT or MRCP, and cholangiogram, in association to routine investigation for fitness, but the most significant was liver function tests that was disturbed to variable values pre-operatively, returned to normal values post-operatively Table 1.

Surgical management: was done for all patients for choledocho-lithotomy (Fig. 1) (no negative exploration of CBD encountered), with testing of CBD clearance of stones by catheter saline irrigation in almost all cases, or per-operative cholangiogram (only in 10 cases as the facilities is not completed with some technical difficulties to be practiced it in all cases), followed by one of the three techniques adopted; either T-tube application for 19 patients (Fig. 2) in group A (36%), per-operative biliary stent deployment for 18 cases (Figs. 4,5,6) in group B (35%), and primary closure with sphincterotomy for 15 cases in group C (29%). Sphincterotomy was done via simultaneous ERCP in 3 cases, (Fig. 3) or by applying the sphincterotome through choledochotomy incision guided by fiber-optic duodenoscope in 12 cases. However no significant difference detected in-between the three groups as regard the operative time Table 2.

Fortunately, no mortality detected, and most of our patients passed to smooth post-operative convalescence without complications (52% of group A, 73 % of group B, and 60% of group C), however some patients experienced stormy convalescence due to variable relevant causes as low grade fever due to wound infection, cholangitis or pancreatitis, or irrelevant causes as mild fever with chest infection, or patient discomfort due to the surgical wound.

The post-operative complications for each maneuver were variable; as bile leakage in 3 cases, cholangitis, pancreatitis, and minor collection in 1 case per each Table 3, fortunately, all were treated conservatively without further surgical interference.

The three groups of patients were differentiated significantly as regard Hospital stay that was 7-12 (mean 9 days) for group A patients, and 3-5 (mean 4 days) for group B cases, in comparison to 4-6 (mean 5 days) for patients in group C.

Return to work was delayed in patients of group A (3-4 weeks), compared with rapid retune in group B and C patients that was 7-10 & 7-12 days respectively, also the convalescence periods was different for each patient group but with comparable values Table 4.

Follow up: was done for all cases till discharged from the hospital, for out patient clinic follow up.

Most of our patients attended for follow up (37/52 patient constituted 71.2%), unfortunately the rest were missed during follow up, however good outcome is anticipated.

Patients attended were with good outcome; however some complications encountered as cholangitis in 2 cases of group B and 1 case in group C, and it was treated conservatively, CBD stricture was also encountered in 1 patient in group A, and managed by ERCP and stenting, lastly 1 case of incisional hernia was detected in group A treated by hernioplasty later on Table 5.

Table 1. Showed the pre-operative liver function tests.

Items	Group A	Group B	Group C
Total bilirubin (5-17µmol / L)	Mean:160	Mean:153	Mean:140
	46-279	45-260	40-240
Direct bilirubin (<5µmol / L)	Mean:135	Mean:122	Mean:115
	40-230	40-200	35-190
Alanine transaminase (ALT/SGPT)	Mean:158	Mean:140	Mean:140
(5 – 35 IU / L)	98-218	80-200	75-210
Aspartate transaminase (AST/SGOT)	Mean:125	Mean:140	Mean:125
(5 – 40 IU / L)	50-200	55-220	50-200
Alkaline phosphatase (ALP)	Mean:398	Mean:360	Mean:350
(35 – 130 IU / L)	206-590	200-500	220-480

Table 2. Showed duration of the surgical maneuvers and its significance.

Duration	Group A	Group B	Group C	P. Value
Mean (in minutes)	128	117	140	0.325 Not sig.
Range (in minutes)	90-180	80-150	95-210	

Abbreviation: Not sig., not significant.

Table 3. Showed post operative complications and its significance.

Items	Group A		Group B		Group C	
	No.	%	No.	%	No.	%
Biliary leakage	1	1.9	-	-	2	3.8
Cholangitis	-	-	1	1.9	-	-
Haemobilia	-	-	-	-	1	1.9
Wound sepsis	1	1.9	1	1.9	1	1.9
Abdominal collection	-	-	-	-	1	1.9
Pancreatitis	-	-	1	1.9	-	-

Table 4. Showed periods of hospital stay and convalescence.

Items	Group A	Group B	Group C	P. Value
Mean duration of hospital stay (in days)	9	4	5	0.0001 Sig.
Range of hospital stay period (in days)	7-12	3-5	4-6	
Convalescence period:				
Smooth	10 (52.6%)	13 (72.2%)	9 (60%)	0.467 Not sig.
Stormy (eg. Fever, discomfort)	9 (47.4%)	5 (27.8%)	6 (40%)	
Return to work after convalescence	Delayed (3-4 weeks)	Rapid (7-10 days)	Rapid (7-12 days)	

Sig.: significant Not sig.: not significant.

Table 5. Showed the follow up data in each group.

Items	Group A		Group B		Group C		Total	
	No.	%	No.	%	No.	%	No.	%
Patients attended for follow up	12	23.1	15	28.8	10	19.2	37	71.2
Good outcome	10	19.2	13	25	8	15.4	31	59.6
Cholangitis	-	-	2	3.8	1	1.9	3	5.8
CBD stricture and jaundice	1	1.9	-	-	-	-	1	1.9
Incisional hernia	1	1.9	-	-	1	1.9	2	3.8
Stent self extraction	-	-	3	5.8	-	-	3	5.8
Hospital re-admission for stent extraction	-	-	8	15.4	-	-	5	9.6

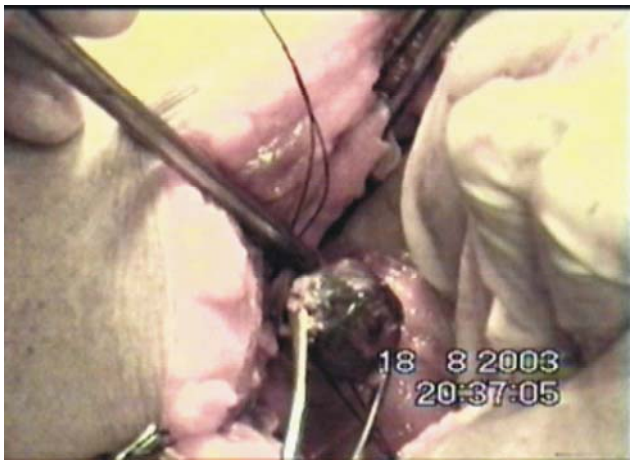

Fig 1. Choledocho-lithotomy.

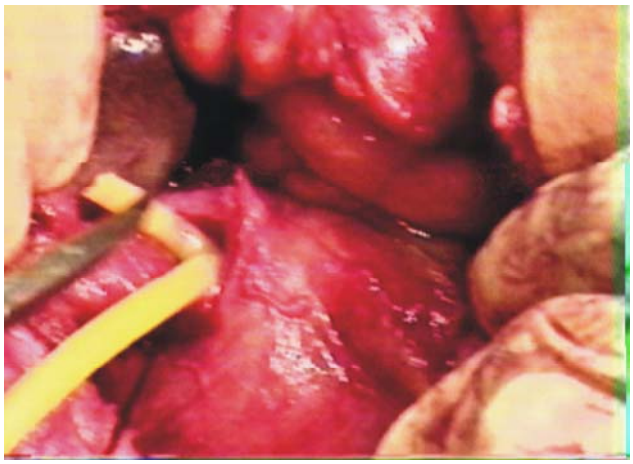

Fig 2. T-tube application.

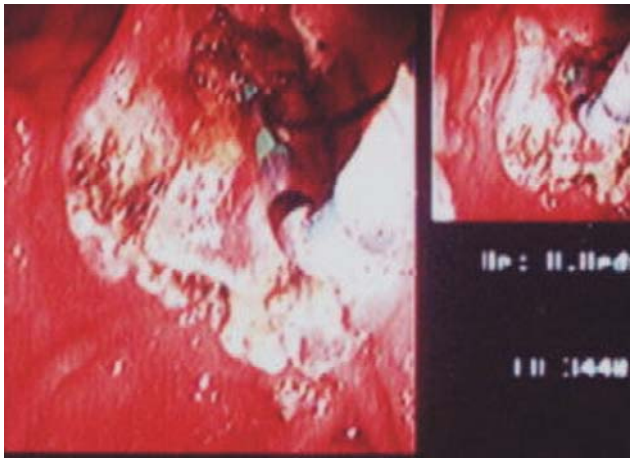

Fig 3. Endoscopic sphincterotomy

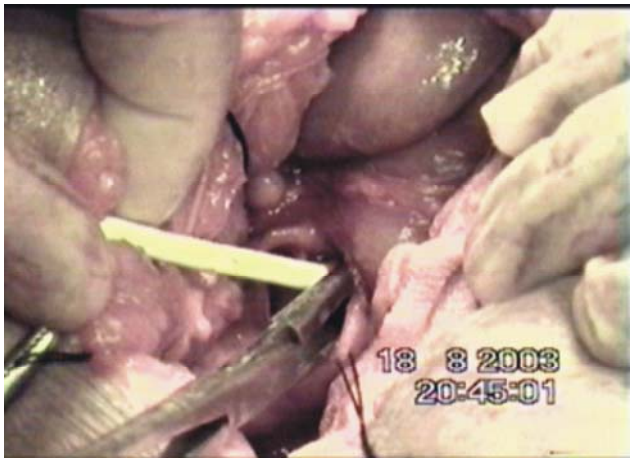

Fig 4. Intra-operative CBD stenting.

Fig 5. Intra-operative CBD stenting.

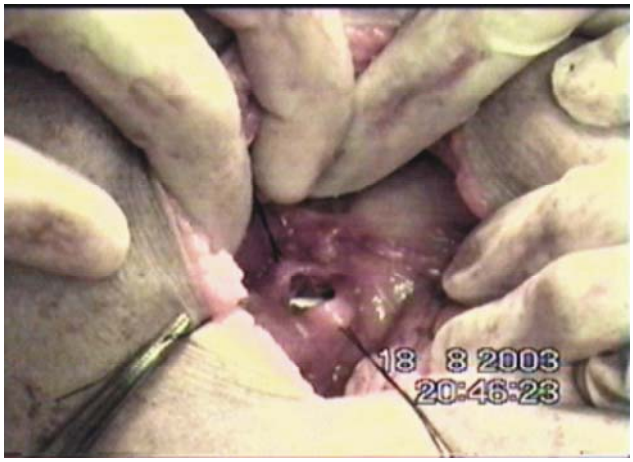

Fig 6. CBD with the stent inside before closure.

DISCUSSION

Most of patients included in this study were females (32 patients), with female to male ratio about 1.6: 1, this may reflect the higher incidence of gall stones in females as stated by many authors.[1,31]

The range of ages of patients was 18-66 years with mean age of 46 years and this is comparable with other researcher's data.[13,12,31]

The most predominant complaint was biliary colic (61.5%) in agreement with previous data,[9,8] but others deny this incidence.[31] However other complaint was also encountered and this was also reported[9,13] apart from fatty dyspepsia that was reported with a bigger incidence.[13]

None of our patients presented with biliary pancreatitis in contradistinction to others whom reported about 10% incidence of pancreatitis in their study,[9,31] and this may be explained by the high prevalence of pancreatitis and its predisposing factors in their locality.

There was marked improvement of liver function as evident by liver function tests in the three groups of our patients, and these results are similar to the other author's result.[12,31,32]

The rational of opening CBD in group C is to extract the stone, as the endoscopic guide in most of cases (12/15) is only fiber-optic duodenoscope that may be done with assistant residence not experienced in ERCP techniques and without its equipment facilities, and ERCP was done in the early cases in the study (3/15), but if the complete set and personnel of intra-operative ERCP are available, it is favored to restrict the operation for cholecystectomy only.

There was no great difference in the duration of surgery in the three groups of patients studied and it was statistically insignificant (P. value 0.325), however other authors found that there was a statistical significant difference between these three groups of patients,[9,12] and this may be attributed to better surgical circumstances, and also our operation theaters are not completely fully equipped, so transferring such equipment as portable ERCP unit with its accessories, portable duodenoscopy unit, and portable image intensifier unit, from the endoscopy center, then endoscopic intervention time, all these factors may increase the operative time that reached three hours or more in group C cases.

There was a variable difference in hospital stay period for the three groups of patients with statistical highly significant values (P. value 0.0001), and this document other authors[19,20,33] whom reported a hospital stay periods comparable to our results for the three groups with statistical significant values.

Fortunately, no peri-operative mortality detected, however some complications had occurred and all was managed conservatively without need for further interference as:

Biliary leakage that was encountered in one case in group A (1.9%), and 2 cases in group C (2.8%), and this was also reported in literatures and required puncture aspiration,[9] laparotomy, or surgery.[12]

Cholangitis was encountered in one case of group B (1.9%), and this was attributed to the high incidence of bactobilia secondary to stents, this was also reported by many authors,[24,29] and may be accused as a cause of early stent clogging and obstruction.

Wound sepsis was encountered in the three groups of patients with similar incidence (1.9% for each group), and infected bile was accused for its occurrence, however other authors reported higher incidence among their cases about 4%,[9] and also 10%,[11] and this discrepancy may be explained by the small number of cases in this study.

Retained stone was not encountered in this study in contradistinction to others whom reported of 3.8, 2.5, and 3% incidence among their cases,[8,9,34] a higher incidence was also reported equal to 6.3, and 8%,[12,35] and this may be a coincidence due to small number of patient included, or explained by good pre-operative diagnosis of the stone(s), as regard its site, number, and shape, with enthusiastic clearance of the CBD through many trials, and meticulous techniques for assurance of CBD clearance of stones, however per-operative cholangiogram was only done in 10 cases as the facilities is not completed with some technical difficulties to practiced it in all cases, so it was reserved for highly suspicious cases only.

Jaundice was not encountered in this study, in contradistinction to other author whom reported incidence of 3.5%.[12,20] This may be explained by meticulous management, and the small number of cases studied.

Abdominal collection was encountered in 1 case in group C; however it was mild and managed conservatively by aspiration, and it was also reported.[12]

Pancreatitis was encountered with 1 case in group B, and it was also reported to occur,[8] and it may be attributed to stent that may block pancreatic duct.[36]

Convalescence period and follow up: A comparable number of patients in each groups passed in smooth recovery period and a minority suffered stormy convalescence with statistical insignificant difference in

between, as reported by other data.[11] In contradistinction to return of patients to work, it was delayed in group A cases compared to other groups B&C cases whom returned rapidly to their work in agreement with other reports,[13] whom detected a similar results.

The coast effectiveness: It depends upon the materials used and the hospital stay period.

Group A: the T-tube is cheep, but in the contrary the coast may be relatively high as the period of hospital stay is prolonged and also the period of convalescence till the patient returned to work is prolonged.

Group B: the biliary stent is relatively expensive; however the short duration of hospital stay in this group and short convalescence period till the patient returned to work makes the final coast relatively low.

Group C: the addition of a simultaneous intra-operative duodenoscopy may relatively raise the expense in this group, moreover the need for 2nd endoscopic session for stent extraction by simple duodenoscopy and snaring if needed (the stent may be self extracted through stool, or in the future by using self fragmented stent), but on the other hand the short hospital stay period and the short period of convalescence till the patient returned to work makes the final coast relatively accepted.

The feasibility of the technique depends upon the center facilitation, and also the experience of the surgeons in these techniques.

To conclude choledocho-lithotomy still the gold standard treatment for CBD stone, with T-tube application afterward, however other options are also available as intra-operative stenting and primary closure with sphincterotomy, these options proved safety, and coast effectiveness, moreover it provides better patient condition post-operatively, with shorter hospital stay period, and rapid return to work

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