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REVIEW ARTICLE

A Retrospective Evaluation of Superior Efficacy in Irrigation and Flushing of Saline in Bile Duct Clearance in Open Surgery

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ABSTRACT

About 10%-18% patients[02] undergoing Cholecystectomy for Cholecystectomy for cholelithiasis also require choledocholithotomy

For choledocholithiasis. In Open cholecystectomy with choledocholithotomy common bile duct (CBD) clearance for residual stones saline Irrigation and saline flushing is required, which needs determination of superior efficacy in between.

Aims: to evaluate the efficacy of saline irrigation and saline flushing in clearance of CBD from residual calculi.

Settings and Design: A retrospectivestuy study conducted in a single centre retrieving data of 185 patients whose operations were carried out during the period between 2010 to 2022.

Methods and Material: A total of 185 patients (N=185) were categorised into two Groups. Group-A): patients (n=123) stones of CBD were extracted by milking and Desjerdin instrumentation combining saline irrigation for CBD clearance of residual stone. Group-B). patients (n=62): Instead of irrigation, CBD Clearance were obtained by saline flushing.

Statistical analysis used: In total of N=185 patients P-value is 0.05 at 95% confident limit, OR is than 1, Fisher exact test is 1,98, mann Whiteney U test is 1, t-test=0.7, Chisquare test is 1.77. Group-A): In total of 123 patients, mean age is 40.98 in Male and 39.08 in female, standard deviation is 7.04 in In male, OR is 049, P-value is 0.04. Group B): In total of 62 patients, mean age is 45'8 in Female and 48.5 in male, P-value is 0.02, OR is less Than 1~o.

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Results: In total N=185 patients clearance rate is achieved in 97.29%, Patients (n=5) had retained stone (2.70%), Group-A): In n=123 patients mean age is 40.98 in male and 39.08 in female, clearance rate is 96.74%, patients (n=4, female) had retained stone (3.25%). Group B): In n=62 patients mean age is 45.8 in female and 48.5 in male, clearance rate is 98.38%, patient (n=1, female) had a retained stone, who 23 calculi in CBD. Mortality and complications like Cholangitis, stricture are nil.

Conclusions: Both saline irrigation and saline flushing are equally safe manoeuvre in CBD clearance of residual calculous but saline flushing demonstrated superior efficacy in CBD clearance of stones.

KEYWORDS

• Saline irrigation • Saline flushing • Instrumentation • Bile Duct clearance

Key Messages: It is a study in a single centre, to validate the precision this study may be undertaken in multiple centres as this technique is crucial manoeuvre in setup without special clearance tool.

INTRODUCTION

In nonavailability of ERCP, ID USG, E USG, Intraoperative T-tube cholangigraphy choledochoscopy; open cholecystectomy with choledocholithotomy is crucial surgery. After extraction of calculi from CBD by milking and Desjerdin instrumentation, CBD clearance for residual calculi, saline irrigation or saline flushing is required, which needs determination of superior efficacy in between.

'Cars Model':[12] Step 1 Territory: with back ground and metamorph of zooming in and zooming out to address analysis and interpretation, (a) ERCP[9]: achieves 95 % success with saline irrigation and complication is 9%. (b) Laparoscopic cholecystectomy with CBD exploration (LCBDE)[02]: success rate is 96% with saline irrigation, Complication is 20%. c) Open cholecystectomy[02] with CBD exploration and T-tube drain (OCBDE): success rate is 93% with saline irrigation, Morbidity is 13%. Step 2: Nich 1—predictive superior efficacy in clearance of CBD remains as unknown back ground a scholarly research gap. Step 3: Nich 2—to fill this gap and insight the current Study is undertaken. From uncertainity idea was genereted then summarised to 'Research topic' and 'Research question' in FINER 'what is the comparative efficacy in and safety in between saline irrigation and saline flushing in achieving successful CBD clearance ?'.

Hypothesis: proposes that one of the methods will demonstrate superior efficacy in removing residual calculous from CBD contrbuting to a more efficient and successful clearance.

Primary objective: to evaluate efficacy and safety associated saline irrigation and saline flushing in CBD clearance from residual calculous. Secondary objective includes complication

MATERIALS AND METHODS

The study was conducted in single centre. A total of 185 patients from January, 2010 to 2022 were enrolled in current study. The data of patients were retrieved from OT Registers, whose operations were performed by me and our surgeon colleaques during 13 years. Operational definition-scientific Verbs i.e[14] (a) saline Irrigation means syringing of saline through infant feeding tube with a syringe inserting in CBD rent. (b) saline flushing means saline is directly flushed/inserted into CBD inserting the nozzle of a syringe in rent. (c) Instrumentation means manoeuvre of Desjerdin choledocholithotomy forcep/ Bougie in grasping, clearing patency Sample size: to calculate sample size, parameters i.e. 95% confident limit,10 interval, 20 standard deviation and Z=1.96; were used. As per formula result size was N~61. But for precision, validity, criteria based on patient with CBD diameter measuring 8 to 14mm and inclusion-exclusion criteria a total of N= 185 patients comprising of 13 years were enrolled.

Inclusion criteria: Patients with CBD measuring 8 to 14 mm diameter containing calculi were enrolled in current study.

Exclusion criteria: Patients with CBD measuring Less than 8mm or more than 15mm, with history of upper abdominal operation, neoplasm or stricture of CBD were excluded. Jaundice was not an element of selection criteria.

ERCP extraction and CBD bypass were performed for CBD measuring less than 8mm and 15mm respectively. Total patients (N=185) were categorised into two groups: Group A: patients (n=123) were treated by Opencholecystectomy with choledocholithotomy{OCBDE) with T-tube drain and saline irrigation technique was applied for CBD clearance from residul calculous after extracting stones by milking and Desjerdin instrumentation.

Group B: Patients (n=62) were treated by OCBDE and Saline flushing manoeuvre was applied for CBD clearance. Investigation: Preoperative diagnostic tests were USG, MRCP. Post operative T-tube cholangiography was conducted for all Patients. Choledochoscopy, E USG, ID USG, Intraoperative T-tube cholangiography were not available in this setup.

Common blood investigations were TC, DLC, ESR, Hb%, RBS, S. creatine, urea, LFT, Platelete count, Amylase, lipase C-reactive protein; Prothrombine time, viral marker,: Thyroid function test, ECG & CXR Chest were conducted routinely. Sometime following Pre Anaeslhetic (PAC) suggestions-Respiratory function test (PFT), Trop 1, Myocardial enzyme 2D ECHO, HRCT-Thorax, were also added.

Pre Anaesthetic checkup(PAC): All patients have undergone PAC checkup and risk factors were assessed by ASA(American Society Anaesthesiologist). 4 patients (70~80yr age) were assigned to Score ii and other 181 patients had score i.

Informed consent: All patients were taken written informed consent explaining about procedure, outcome, rare potential risk, permission of data use for Audit and Research, surgical safety check lists (WHO) were framed OT. Operative procedure; Through right kocher's incision, abdomen was opened, cholecystectomy was performed by duct first or fundus first method; tones were removed after choledocholithotomy by milking and Desjerdin instrumentation. For clearance in Group A). An infant feedingtube was inserted through choledochotomy rent into lower part and other end tube was fitted 10 ml syringe containing 10ml saline, then irrigated. Similar procedure was repeated for upper CBD.

Group B: Feeding tube was not used. 10ml Syringe containing 10ml saline, nozzle was inerted directly into CBD rent directing down, then saline was injected/flushed by optimal force/dynamic. Similar procedure was applied to upper part. Before irrigation/flushing a Bougie (3/6) was inserted into upper and lower part to know patency, grity sensation of stone. In both irrigation and flushing, procedure was repeated 5 times upper part and lower part with 10ml each time. So, total amount of saline used was 100ml. Choledochotomy was closed with catgut (3-o) by continuous suture inserting a modified Rothney smith T-tube.

RESULTS

In total of N=185 patients, clearance rate was achieved in 97.29%, total patients (n=5) had retained stones (2. 70%). Group A) In n=123 patients, Mean age is 40.98 in male and 38.08 in Female; Clearance rate is 96.74%; patients (n=4, females) had retained stone, Group B). In nsh=62 patients, Mean age is 45 in female and 48.5 in male; clearance rate is 96.38%, patient (n=1, female) had a retained stone who had 23 calculi. Mortality and complications like cholangitis, stricture are nil.

Statistical analysis used: In total of N=185 patients P-value Is 0.05 at 95% confident limit; OR is less than 1, Fisher Exact test is 1.89, Mann whiteney U test is 1, t- test=0.7, Chisquare Test is 1.77. Group A: consists of n=123 patients, mean age is 40.98 in male and 39.08 in female, standard deiation is 7.04 in male, OR (ODD RATIO) is 049, p-vaiue is 0.04. Group B: consists of 62 patients, mean age is 45.8 in Female and 48.5 in male, P-value is 0.02, OR is les than 1~0.

DISCUSSION

For discussion few literaures were also reviewed. A set of potentially useful articles were collected from Web search. A set of documents of which contents were relevant to need were analysed and developed research question. In a study of 112 patients, 1). Liang *et al*[01] achieved Clearance of 40.2% in 50 ml, 88.45% in 100 ml and 0(0%) Clearance without

Table 1: Demography and Observational characteristics

Total N= Male n= Female n=	Male: Female	Age range in year, Standard deviation (SD), Mean-x	CBD size in mm Stone size in mm	Site of stone % N= Group A +B In RHD n=1 (0.5%) In LHD n=1 (0.5%) In CHD n=n=20 (5.4%) In CBD = In upperCBD n=30(16.0%) In middleCBD n=93(47.6%) In lowerCBD n=40(21.6%) **Abbreviation** RHD=right hepatic duct LHD=left hepatic duct CHD=common hepatic duct CBD=common bile duct
N=185 M=62 F=123	1:2		CBD size = 9-14 mm Stone size = 01 –15mm	
Group-A N=123 M n=23 F n=100		Age=17-80, SD=7.04 X =40.98 Age=25-70·X =39.08		
Group-B N=62 M n=5 F n =57		Age =24-66, SD =4.28 X =25.7 Age =22-75, SD =4.28 X = 45.8		

Table 2: Observational and statistical characteristics

Total patient N=	**Saline in ml Clearance rate n= Retained rate n=**	**ODDS: RATIO P value=**	**Chisquare test x Fisher exact test**	**Mann whiteney U test**
N=185	Saline used=100ml Clearance n=180 Rate=97.2% Retained n=5 (2.7%)	O:R=0.69 P value=0.05	Chisquare test X=1.77 Fisher exact test =1.89	U=1 Student t-test=0.7 Group A=01.6 Group B=3.42 p-statstic=0.032 rankbiserial correlation r=0.016 operation time=60- 90 min 0peration blood loss =50-90ml Hospital stay=7-10 days Mortality was nil Complication was nil
Group A n=123 M=23 F=100	Saline used =100ml Clearance rate n=119(97.7%) Retained=4 (3.25%)	O:R=0.49 P value=0.04		
Group B n=62 M=5 F=57	Saline used =100ml clearancen=61(97.38% retained=1 (1.62%)	O:R=0.02 P value=0.02		

irrigation. In one study of 250 open Surgery 2), Alaa A *et al*[02] 95% clearance without mortality.

With 13% morbidity. 3). Dong-Won Ahn *et al*[03] conducted a multicentre, prospective randomised study and detected residual stones 6.8% in saline irrigation group of 73 22.7% in non saline irrigation group of 75 patients. 4). Liang Ye *et al*[1] carried out a study of 112 patients and in their study, no patient had clearance score without irrigation, 45 (40.2%) patients reached score 3 with 50 ml irrigation and 99 (88.4%) with 100ml irrigation. 5). Ye, Li[15] *et al* reported 24.0% to 40.0% clearance rate in lithotripsy which need irrigation. 6). Usman A Akbor *et al*[08] conducted a study 323 patients, 157 patients undergone saline and found that saline irrigation reduced the risk of redual stone (OR:0.22, 95% CI:o.11-0, 45) significantly. 7),Yan-Yan Ling *et al*[16] assumed a success rate of 84.5% in ERCP exstraction but success rate raised to 97% with saline irrigation. 8). Jang SE *et al*[04] conducted a study of 47 patients, clearance score were achieved in 2,4± 1.1 without irrigation, 3.5±0.7 with 50ml and 4,6 ± 0.6 score with ml saline irrigation. The literature review of a set of articles revealed that without saline irrigation clearance of CBD stone is unduly low in all lithotripsy studies. In their study irrigation was done but not flushing. Irrigation was done by flowing saline from hanging saline bottle at a height. In their open surgery, irrigation was done by injecting/pushing saline through infant feeding tube fitting the nozzle of syringe in outer end. In current study, flushing meaning is different. This is flowing of saline directly into CBD in which nozzle of 10ml syringe containing 10ml saline is fitted in CBD rent/ choledochotomy opening saline is inserted/ pushed/flushed with optimal force. So fluid velocity/flow dynamic is also optimal to wash out stone effectively and safely as constrast to irrigation in which flow dynamic is weak/ inadequate.

Followup: patients were followed up in certained schedule i.e initially 1 monthly, then 3 monthly, 6 monthly and 12 monthly. Majorty of patients turned up upto 6 months.

CONCLUSION

In present study the 'Group B' with flushing of Normal saline demonstrated superior efficacy as Compared to 'Group A' with Normal saline irrigation in clearance of residual stones in CBD. Both are equally safe manoeuvre as there was any morbidity and mortality.

Conflict of Interest: All authors declare that they have no conflict of interest.

Support: nil

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