ABSTRACT
Choledocholithiasis is the common problem that necessitates surgical intervention. It is managed either by endoscopic sphincterotomy or surgical exploration i.e. choledochotomy. The traditional surgical management of CBD stones consists of a supra-duodenal choledocotomy and insertion of a T-tube. The role of T–tube has been challenged since Thornton and Halsted described primary duct closure after CBD exploration. This study was carried out with an aim to evaluate the feasibility and safety of primary closure as compared to T-tube drainage in choledocholithiasis cases requiring CBD exploration. 70 patients in the age group of 18-60 years presenting with common bile duct stone were included after obtaining informed and written consent with exclusion of patients with malignant conditions and CBD dilation >2.5 cm. Patients fulfilling the inclusion criteria were randomly allocated into two groups of 35 patients each: Group I (Primary repair group) and Group II (T-tube repair group). In Group I duration of hospital stay ranged from 8 to 20 days (mean 12.03±2.60 days) whereas in Group II this range was 18 to 29 days (mean 22.74±3.41 days). Statistically, the difference between two groups was significant (p<0.001). The primary closure was a feasible, safe and relatively better technique as compared to T-tube drainage. It had fewer complications and a smooth and shorter duration of hospital stay which have both economic as well as psychological implications.

INTRODUCTION
Common bile duct (CBD) stones are identified in 10 to 15 percent of patients undergoing surgery for symptomatic cholelithiasis.(1-3) In all racial and ethnic groups studied, the risk of gallstones increases markedly with age. For example, gallbladder disease is found in 5% to 8% of young women but in 25% to 30% of women over the age of 50(4). In men, the prevalence also increases with age, but the increase in risk begins later in life.(5) CBD stones require extraction for management of symptoms and to prevent complications such as acute supplicative cholangitis, obstructive jaundice, hepatic abscess, and acute pancreatitis. After the common bile duct exploration is performed, the choice lies between T-tube drainage, primary duct closure with no drainage (Decker 2003)(6), or primary duct closure with biliary stent insertion (Isla 2004; Kim 2004; Gritiatsos 2005). (7) Primary closure of the common bile duct without a T-Tube has been advocated by some authors in open biliary tract surgery because of the potential complications associated with T-Tube placement. (8) Shorter operative time, and length of stay have been observed with primary closure. No increase in bile leak or peritonitis has been noted with primary closure in the “open” literature. Higher patient satisfaction has been associated with primary closure. Routine drainage of the common bile duct (CBD) following choledochotomy is unnecessary as it prolongs hospital stay and increases the postoperative morbidity.(9) The choledochotomy wound can safely be closed primarily after CBD exploration. The use of T-tube is associated with complications like bile leak, dislodgement and even breaking of the T-tube, formation of encrustations leading to difficulty in removal of tube, duct stricture, cellulitis around the T-tube, cholangitis, trauma to duct and subsequent biliary leak during tube removal and delayed healing of the CBD wound. The continuous external drainage of bile can sometimes lead to nutritional disturbances.(10) Despite its obvious advantages and various reports in literature, primary duct closure is still not being performed routinely.

As claims of advantages and implication of T-tube insertion and primary closure of CBD have been reported it was planned to compare the feasibility and safety of the two procedures in our set-up.
MATERIAL & METHODS
After obtaining the clearance from ethical committee, 70 patients in the age group of 18-60 years presenting with common bile duct stone were included in the study after obtaining informed and written consent. Exclusion criteria- patients with malignant conditions and CBD dilation >2.5 cm. Patients fulfilling the inclusion criteria were randomly allocated into two groups of 35 patients each :Group I (Primary repair group) and Group II (T-tube repair group). Patients underwent USG whole abdomen, S.bilirubin, SGOT, SGPT, S.ALP, GGT for diagnosis. CT abdomen and Magnetic Resonance Cholangiopancreatography (MRCP) wherever indicated. Pre anaesthetic investigations for fitness performed.

Laparotomy through the right paramedian transrectus epigastric vertical incision, and longitudinal incision of CBD at its anterior portion was made at the most easily-exposed area near the origin of cystic duct, through which stones were removed and operative cholangiogram or cholangiography was carried out as needed. Stone removal was made using stone forceps, Baker's dilator with saline irrigation by Nelaton tubing, and the patency of CBD to duodenum was confirmed by Nelaton catheter passed into duodenum and observing any regurgitation of saline shot through the occurrence. Choledochotomy always accompanied cholecystectomy. Choledochotomy was closed by 5-0 Vicryl suture material by continuous suturing in primary closure group, and T-tube was installed in the other group using the same material and closure method. After then, leakage of bile was performed macroscopically, or else, cholangiogram was added to ensure the remaining stone or bile leakage for the suspected cases. Negative suction drain was left from the operative area through the right flank to observe bile leakage from choledochotomy or other complications, and was usually removed around the postoperative 7th day. Stapled skin wound was undone on postoperative 7th day, which was, however, delayed till 14th day when concerned about senile age or wound conditions. Data was analyzed using Statistical Package for Social Sciences, version 15.0. The values were represented in Number (%) and Mean±SD.

RESULTS
The mean age of patients In Group I, was 40.74 years and in Group II was 44.06 years. Gender distribution in group I was, male 22.9% and female 77.1% but in group II was, male 25.7% and female 74.3% (x²=0.780; p=0.780). Statistically, the difference between two groups was not found to be significant

Statistically, there was no significant difference between two groups with respect to indications for surgery

| Indication            | Group I (n=35) | Group II (n=35) | Significance |
|-----------------------|----------------|----------------|--------------|
|                       | No. %          | No. %          | x²           | P            |
| 1. Obstructive Jaundice | 35 100         | 35 100         | 0            | 1            |
| 2. Abnormal LFT       | 31 88.6        | 33 94.3        | 0.729        | 0.393        |
| 3. Pan creatitis       | 5 14.3         | 3 8.6          | 0.565        | 0.452        |
| 4. Acute cholecystitis | 21 60.0        | 24 68.6        | 0.560        | 0.454        |

Table 1: Distribution of patients in two groups according to indications for surgery

Although proportion of patients with post-operative complications was higher in Group II as compared to Group I yet the difference between two groups was not significant.

| Indication          | Group I (n=35) | Group II (n=35) | Significance |
|---------------------|----------------|----------------|--------------|
|                     | No. %          | No. %          | x²           | P            |
| 1. Wound infection  | 6 17.1         | 7 20.0         | 0.094        | 0.759        |
| 2. Sepsis           | 2 5.7          | 3 8.6          | 0.215        | 0.643        |
| 3. Fracture of T-tube | -              | - 1            | 2.9          | 1.014        | 0.314        |
| 4. Dislodgement of T-tube | - | - 2 | 5.7 | 2.059 | 0.151 |

Table 2: Distribution of patients in two groups according to Post-Operative Complications

| Parameter                           | Group I (n=35) | Group II (n=35) | ‘t’              | ‘p’            |
|-------------------------------------|----------------|----------------|-----------------|---------------|
| 1. Mean duration of hospital stay ±SD (in days) | 12.03±2.60 (8-20) | 22.74±3.41 (18-29) | 14.80 | <0.001 |
| 2. Mean time taken for resolution from jaundice±SD (days) | 4.26±1.07 (2-6) | 3.94±2.56 (2-14) | 0.672 | 0.504 |

Table 3: Comparison of two groups according with respect to duration of hospital stay and duration for resolution from jaundice

In Group I duration of hospital stay ranged from 8 to 20
days with a mean duration of 12.03±2.60 days whereas in Group II this range was 18 to 29 days with a mean duration of 22.74±3.41 days. Statistically, the difference between two groups was significant (p=0.001).

In Group II time taken for resolution from jaundice was ranged from 2 to 6 days with a mean of 4.26±1.07 days as compared to a range of 2 to 14 days with a mean of 3.94±2.96 days Group I. Statistically, this difference between two groups was not significant (p=0.504).

DISCUSSION

Choledocholithiasis is the common problem that necessitates surgical intervention. It is managed either by endoscopic sphincterotomy or surgical exploration i.e. choledochotomy. The role of T–tube has been challenged since Thornton(11) and Halsted(12) described primary duct closure after CBD exploration more than a century ago. Others also have challenged the utility of a T-tube(13). The present study was carried out to evaluate the feasibility, safety and relative efficacy of primary closure as compared to T-tube insertion in choledocholithiasis cases undergoing choledochotomy using an unbiased randomly controlled study.

70 patients in the age group of 18-60 yrs presenting with common bile duct stone were randomly allocated to two equal groups of 35 patients each. Group I had 35 cases in whom primary closure was performed whereas Group II had 35 cases in whom T-tube placement was done for the purpose of drainage.

The Mean age of patients was 40.74±9.65 years in primary repair and 44.06±10.40 years in T-tube repair groups. In a study by Mohan et al. (2005)(14) maximum number of patients with gall stone disease were found to be aged between 31 and 40 years. Male to female ratio was 1:3.12. A higher prevalence of females with complaints of cholelithiasis has also been reported in several studies. Alwam reviewed 894 cholecystectomy specimens in 1984 reported female predominance with female; male ratio 3:1(15).

In this study, all the subjects had clinical signs and symptoms of jaundice. Abnormal liver function tests were seen in 31 (88.6%) of Group I and 33 (94.3%) patients of Group II. Pancreatitis was diagnosed in 8 patients. There were 5 (14.3%) patients of Group I and 3 (8.6%) of Group II had pancreatitis. Acute cholecystitis was indicated in 21 (60%) of Group I and 24 (68.6%) of Group II patients. The profile of complaints/indications for surgery as observed in present study was similar to that reported by Li et al. (2015)(16) who also found jaundice, abnormal liver function tests, pancreatitis and acute cholecystitis as the major indications for surgery.

On post-operative assessment for complications - Wound infection was seen in 6 (17.1%) of Group I and 7 (20%) of Group II patients. Sepsis was reported in 5.7% of Group I and 8.6% of Group II patients. These findings endorse the view expressed by Lygidakis et al.(1983) who was of the view that T-tube drainage might well provoke the exogenous acquisition of environmental microorganisms and thus promote further infection. Similar to results of present study, Saeed et al. (2012) also found the wound infection rate in primary closure and T-tube drainage group to be the same (5%). It would be pertinent to mention here that neither the present study nor any of the studies reviewed by us showed a higher infection rate in primary closure group as compared to T-tube drainage group.

The complications related with T-tube, fracture of T-tube and dislodgement of T-tube are problems restricted to group using T-tube drainage approach. The use of T-tube is associated with complications like bile leak, dislodgement and even breaking of the T-tube, formation of encrustations leading to difficulty in removal of tube, duct stricture, cellulitis around the T-tube, cholangitis, trauma to duct and subsequent biliary leak during tube removal and delayed healing of the CBD wound. In a study by Wills et al. (2002) T-tube dislodgement was the reported complication apart from other complications including sepsis. Saeed et al.(2012) also reported T-tube dislodgement in 5% of their cases. T-tube fracture is a relatively rare phenomenon and it was also seen in only 1 (2.9%) of our cases.

In present study, mean duration of hospital stay was lower in primary closure group (12.03±2.60 days) as compared to T-tube drainage group (22.74±3.41) which might mainly be attributed to additional complications in T-tube drainage group as well as additional burden of removal of drainage. In most of the study comparing the T-tube drainage and primary closure groups the duration of hospital stay in primary closure group has been cited to be significantly lower as compared to that in T-tube drainage group.

With respect to resolution of signs and symptoms of obstructive jaundice, statistically no significant difference was observed between two groups.

CONCLUSION

In present study, T-tube drainage did not offer any additional benefit including clearance of obstruction owing to choledocholithiasis. However, it posed additional complications leading to increase in overall duration of hospital stay. Primary closure was thus found to be not only safe and feasible but also proved...
to reduce the hospital stay and as such financial burden of the patient. Keeping in view these factors, primary closure should be the recommended approach in choledocholithiasis cases requiring CBD exploration.

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