A Stop-gap Procedure in the Management of High Risk Patients with Acute Biliary Tract Diseases

Mujahid Ahmad Mir¹, Shaukat Jeelani², Ishfaq Ahmad Gilkar¹, Umar Mushtaq¹, Javid Ahmad Peer¹

ABSTRACT

Introduction: Acute biliary tract diseases constitute a major portion of gastrointestinal disorders throughout the world and include acute cholecystitis and acute cholangitis. Study aimed to assess efficacy and safety of percutaneous cholecystostomy (PC) in high risk patients with acute biliary tract diseases.

Material and methods: The study was carried-out in high risk patients un-fit for general anaesthesia with acute calculus/ acalculous cholecystitis, empyema/mucocele gallbladder and patients having acute cholangitis with failed ERCP and PTC. The catheter position was established by a cholecystogram done postoperatively.

Results: 36 patients underwent ultrasound guided PC. 66.7% (24) had empyema- gallbladder, 16.7% (6) had mucocele of gallbladder and 11.1% (4) patients were diagnosed as acute calculus cholecystitis. 5.6% (2) patients had acute pyogenic cholangitis with failed ERCP. All the patients had at least one uncontrolled comorbidity and none was fit for general anaesthesia. The post-procedure hospital stay was 3 to 6 days. Rapid clinical and biochemical improvement was observed in all patients after the procedure. There was statistically significant pain relief and reduction in leukocyte count within 48 hours of procedure. 32 out of 36 procedures were done via trans-peritoneal route. Bile cultures yielded growth of E Coli in 10 (28.8%) patients, klebsella in 8 (22.86%), pseudomonas aeruginosa in 6 (17.14%) and Proteus mirabilis in 11.43% of patients. No major complication was recorded in our study. Catheter was removed after a mean of 25.25 days.

Conclusion: USG guided PC is a safe and effective stopgap procedure for treating high-risk patients with acute biliary tract diseases. Once the acute symptoms diminish or resolve, it should be followed by elective surgery.

Keywords: A Stop-gap Procedure, Management of High Risk Patients, Acute Biliary Tract Diseases

INTRODUCTION

Acute cholecystitis is caused by gallstones in 90 to 95% and a tumor obstructing the cystic duct may be the etiology in < 1% of the cases. Acute acalculous cholecystitis typically occurs in patients with other acute systemic diseases. Early laparoscopic cholecystectomy is considered as the gold standard for the treatment of symptomatic cholelithiasis and acute cholecystitis. The morbidity and mortality associated with emergent cholecystectomy in patients at high risk for surgery from comorbid conditions are 55%-66% and 14%-30% respectively. Therefore, as a stopgap procedure, high-risk patients are treated with percutaneous cholecystostomy combined with broad-spectrum antibiotics. Acute cholangitis is an ascending bacterial infection in association with partial or complete obstruction of the bile ducts. The common causes of bile duct obstruction are gallstones, benign and malignant strictures, parasites, instrumentation of the ducts, indwelling stents, and partially obstructed biliary-enteric anastomosis. The most common organisms cultured from bile in patients with cholangitis include E. coli, Klebsiella pneumoniae, Streptococcus faecalis, Enterobacter, and Bacteroidesfragilis. The initial treatment of patients with cholangitis includes intravenous antibiotics and fluid resuscitation. About 15% of patients will not respond to antibiotics and fluid resuscitation, and an emergency biliary decompression may be required which may be accomplished endoscopically, percutaneously or surgically, depending up on the level and the nature of the biliary obstruction.

Percutaneous placement of a catheter under imaging guidance in the gallbladder lumen is indicated in high risk patients with acute calculus or acalculous cholecystitis, unexplained sepsis in critically ill patients, and cholangitis following failed endoscopic retrograde cholangiopancreatography (ERCP) and percutaneous transhepatic cholangiography (PTC). Two approaches have been described: trans-hepatic and trans-peritoneal. The trans-hepatic route is preferable as it reduces the risk of biliary leak, allows the drain to be left in place for longer periods and leads to quicker maturation of a drainage tract. Ultrasound and computerized tomography (CT) scan may be used as a guidance modality. The Seldinger technique consists of inserting a pigtail catheter into the gallbladder using guide wire and dilators of increasing diameter. The “trocar” technique, allows direct insertion of a 12/14 French pig-tail catheter. PC also provides a potential route for stone dissolution and stone extraction in high-risk patients and individuals with idiosyncratic reactions to anesthesia. PC may then be followed by laparoscopic cholecystectomy in the near future after proper optimization. We aimed to study the safety and efficacy of PC as a stopgap procedure in high risk patients with acute biliary tract diseases.

Study aimed to assess efficacy and safety of percutaneous

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How to cite this article: Mujahid Ahmad Mir, Shaukat Jeelani, Ishfaq Ahmad Gilkar, Umar Mushtaq, Javid Ahmad Peer. A Stop-gap procedure in the management of high risk patients with acute biliary tract diseases. International Journal of Contemporary Medical Research 2018;5(1):10-14.
cholecystostomy in high risk patients with acute biliary tract diseases in terms of clinical improvement and complications respectively following the procedure

**MATERIAL AND METHODS**

Between June 2014 and July 2017, the study was conducted in the Postgraduate Department of Surgery Government Medical College Srinagar. High risk patients not fit for general anaesthesia with acute calculous/acalculous cholecystitis, empyema/mucocele gallbladder and patients having acute cholangitis with failed ERCP and PTC, regardless of age and gender were included in this study. Patients having un-optimised coagulopathies, suspected gall bladder malignancy, gallbladder packed with calculi preventing catheter insertion, huge intra-abdominal swellings involving right hypochondrium and massive ascites were excluded from the study. Patients were diagnosed on the basis of detailed history, physical examination with biochemical and radiological evidence of biliary disease. Ultrasound abdomen was utilised to determine size, contents and wall-thickness of gallbladder and status of hepatobiliary system. Other relevant investigations were done as routine baseline. The procedure was performed with the patient in supine position under local anesthesia in all cases. After per urethral catheterization, procedure was done using ultrasound guidance and 14-French locking pigtail catheter with trocar, under all aseptic precautions with regular monitoring of the vital signs by a suitably trained staff member. Catheter was secured to skin after attaching a gravity drainage bag (fig 1). Bile was sent for gram staining, culture and/or cell count. Patients were advised bed rest (for 2-4 hours) with regular monitoring vital signs, provision of adequate analgesia was routinely indicated in the first few hours following the procedure. Catheter was flushed and aspirated regularly with saline (6 to 8 hourly). A cholecystogram was performed when the patient was stable, to help establish satisfactory catheter position and the state of the gallbladder (fig.2).

**STATISTICAL ANALYSIS**

Microsoft office 2007 was used for the statistical analysis. Chi square test was used analysing the statistical significance.

**RESULTS**

36 patients (11 men and 25 women) with a mean age of 70.11 (SD=13.98) years and mean BMI of 31.28. (SD=3.001) underwent ultrasound guided percutaneous cholecystostomy over the study period of three years. Patients presented with chief complaints of pain in right upper quadrant abdomen (91.67%), vomiting (80.55%), and abdominal swelling/lump (94.44%). Fever and jaundice were present in 69.44% and 11.10% of patients respectively. Majority of the patients were having complicated cholecystitis. 24 (66.7%) had empyema-gallbladder, 6 (16.7%) had mucocele of gallbladder and 4(11.1%) patients were diagnosed as acute calculic cholecystitis. 2 (5.6%) patients had acute pyogenic cholangitis with failed ERCP. All the patients had atleast one comorbidity. The maximum number of comorbidities was 5(n=2). 26 (72.2%) patients were hypertensive on medication, 22 (61.1%) patients were diabetics on insulin or oral hypoglycemic agents. 20(55.5%) patients had exacerbation of COPD. 16(44.4%) patients were hypothyroid in our study. 15(41.6%) patients had CHF, 6(16.7%) had

<table>
<thead>
<tr>
<th>VAS Score</th>
<th>Number of patients</th>
<th>At admission</th>
<th>48 hours after procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absent (0)</td>
<td>0</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Mild (1-3)</td>
<td>0</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Moderate (4-6)</td>
<td>9</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Severe (7-10)</td>
<td>27</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

*Table-1: Pain score at admission and 48 hours after procedure.*
CKD, 5(13.89%) had cirrhosis, 4(11.1%) AF and one patient had anaplastic carcinoma thyroid.

Median hospital stay after performing procedure was 4 days. None of the patients in our study required to stay admitted for more than a week after the procedure was performed. Maximum and minimum hospital stay following procedures were 3 and 6 days respectively. Visual analogue score was used to assess pain preoperatively and postoperatively. Patients were advised to rate their pain depending upon their severity on the day of admission and 48 hours after the procedure. The response were graded as mild with score 1 to 3, moderate with score 4 to 6 and severe with score >7. Pain relief after 48 hours following procedure was statistically significant (table-1).

There was statistically significant reduction in mean total leukocyte count within 48 hours of procedure (table 2). Majority of the procedures 32 out of 36 were done via trans-peritoneal route. Bile cultures yielded growth of E Coli in 10 (28.8%) of patients, klebsiela in 8(22.86%), pseudomonas aeruginosa in 6 (17.14%) and Proteus mirabilia(11.43%) of patients. 7 (20%) patients did not grow any organism in their bile even after 48 hours of incubation. Most of the growth noted was sensitive to imipenem 28.56% (10), ciprofloxin 20% (7), levofloxin 20% (7) and cefuroxime 11.14% (4). Culture and sensitivity of one patient was not available and 7 bile cultures were sterile.

No major complication was recorded in any of the patients enrolled in our study. Tube displacement occurred in one patient which was removed on 4th day after the procedure and procedure was repeated. One patient died because of underlying disease. Catheter was removed after a mean of 25.25 days (range 17-35 days). One patient died with catheter in situ. All but one patient underwent definitive surgical procedure after proper optimization on elective basis. 29 (80.5%) patients underwent laparoscopic cholecystectomy, 2(5.6%) open cholecystectomy and CBD exploration, 4(11.1%) open cholecystectomy. One patient expired with catheter in situ because of underlying disease.

**DISCUSSION**

Percutaneous cholecystostomy had an immediate and beneficial effect in acute biliary tract diseases like, empyema gallbladder, acute cholecystitis/ mucocele gallbladder who were poor surgical candidates and acute suppurative cholangitis with failed ERCP/PTC and a distal bile duct stone. Patients hospitalized for other serious medical problems, when develop acute cholecystitis, are good candidates for ultrasound guided percutaneous cholecystostomy (USGPC)\(^2,1\). All 36 patients enrolled in our study who underwent percutaneous cholecystostomy showed clinical improvement within 48 hours. The level of response suggests that this procedure is an effective alternative to surgery, whether used as a stopgap measure until the patient is clinically fit for an operation or as definitive management for those with serious comorbidity or terminal disease. If a patient is not well enough to be transferred to the radiology suite, this procedure can even be done at bedside in the intensive care unit under local anaesthesia. The mean age of patients in our study was comparable to that in studies conducted by Gordon B. Werbel et al\(^14\), Van Steenbergen et al \(^15\) and Ozgur Bafiaran et al\(^16\). The sex ratio was at par with the studies conducted by JCM Li and DWH Lee et al\(^3\) and Shaista Afzal Saeed et al\(^18\). In our study patients presented with chief complaints of pain in upper abdomen and/or right upper quadrant abdomen (91.67%), vomiting (80.55%), abdominal swelling/lump (94.44%), fever (69.44%) and jaundice (11.10%) consistent with study conducted by Ozgur Bafiaran, et al (2005)\(^16\). Majority of the patients enrolled in our study were having acute cholecystitis complicated by empyema formation 24 (66.7%), 6 (16.7%) patients had mucocele of gallbladder and 4 (11.1%) patients were diagnosed as acute calcular cholecystitis. 2 (5.6%) patients had acute pyogenic cholangitis with failed ERCP. Facility for PTC was not available in at our hospital. In study by Alexander M. Eggermont et al\(^14\) the procedure was performed in six critically ill patients who had acute aloculus cholecystitis. In study by Gordon B. Werbel et al\(^14\) and Van Steenbergen et al\(^15\), critically ill patients who had acute calcular cholecystitis complicated by empyema formation were chosen as sample population. In study by Hans van Overhagen et al\(^10\), Masanori Sugiyama et al\(^12\), JCM Li et al\(^17\), patients enrolled had acute cholecystitis and an increased surgical risk. In study by Shaista Afzal Saeed et al\(^18\), 25 patients had acute calculus cholecystitis, 10 aloculus cholecystitis, 04 empyaema and 2 patients had gallbladder perforation.

All of the patients (n = 36; 100%) had at least 1 comorbidity, with a mean number of 3.2 comorbidities (median 1). The maximum number of comorbidities was 5 (n = 2). The median BMI of the patients in our study was 30.50. Most of the them were obese with only 8 patients had BMI <30. The comorbidity profile of our patients was comparable with that of the patients studied by Nicole Cheng et al\(^12\). The procedure was done under local anesthesia in all patients. Trans-hepatic approach was used for 4 patients (11.1%) and trans-peritoneal approach for 32 (88.9%) patients. The procedure was technically successful in all (36/36) patients studied, consistent with that in the study by Grinsteinos John et al.\(^23\) In our study cultures/sensitivity results of drained fluid/bile were comparable with those reported by Van Steenbergen et al\(^15\) and Ahmed Farouk Abdulaal et al\(^14\). Clinical improvement was noticed in all patients within 48 hours. Statistically significant reduction in the values of white blood cells, axillary body temperature and visual analogue score of pain were observed within 48 hours. This is at par with studies by Asgaut Viste et al\(^23\), C. Codina et al\(^26\).

Median hospital stay after performing procedure was 4 days (range3-6). Follow-up after drainage was with a median of 3 months (range 2-4 months). During that time laparoscopic cholecystectomy was performed in 29(80.55%) patients and open cholecystectomy in 4 (11.1%). 2 (5.6%) patients underwent open cholecystectomy and CBD exploration for large sized stone at distal end of CBD which could not be retrieved by ERCP. One patient died with catheter in situ.
because of metastatic carcinoma thyroid with anaplastic histopathology.
The drain was left in place for 17 – 35 days (median 6.5). No complication was seen during or after procedure in 32 (91.42%) patients. Complications occurred in 3 (8.6%) patients including hemorrhage in 2 patients which settled of its own after 2 days with no blood transfusion requirement and tube displacement in 1 patient which required removal and replacement of catheter 2 days after the initial procedure. These complications were observed in procedures performed via transperitoneal route. In literature complication rate of around 10%\(^{27}\): mainly bile leaks, nearly always after transperitoneal drainage\(^{27}\), or bleeding requiring transfusion or not\(^{27}\), drain migration (8.6%), and more rarely, digestive tract perforations or pneumothorax have been documented. One patient died because of underlying comorbidity (anaplastic carcinoma thyroid) with catheter in situ. There was no direct procedure-related mortality in our study.
The procedure may not be beneficial in all patients with cholangitis depending upon the level of obstruction. In our study, only 2 patients with acute cholangitis underwent procedure and presence of a stone in distital CBD with patent cystic duct was observed in both of them. The may not be beneficial in all cholangitis patients.
The patients were not stratified according to the technique used and the route of procedure. Moreover, the sample of patients with cholangitis was small and selective so much so that application of our results to all such patients will amount to overgeneralization.

**CONCLUSION**

Analysing various parameters of these 36 patients and post procedure interaction with them over a period of time, it was observed that ultrasound guided percutaneous cholecystostomy (USGPC) is a safe and effective procedure for treating elderly/ high-risk patients who present with acute biliary tract diseases like acute cholecystitis or acute cholangitis with failed ERCP. Once the acute symptoms diminish or resolve, USGPC should be followed by elective surgery, if possible, or by conservative management if the patients is inoperable due to systemic disease.

**REFERENCES**

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