

Efficacy of Ultrasound Guided Percutaneous Transhepatic Cholecystotomy in Management of Acute Cholecystitis among HighRisk Patients – A Record Based Cross Sectional Study

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A B S T R A C T

Introduction: Acute cholecystitis is a highly prevalent gastrointestinal emergency. There are several advances in managing this acute condition and one of the most recent technique is ultrasound guided percutaneous transhepatic cholecystotomy (PHTC). This study was carried out to assess the efficacy and safety of PHTC in the treatment of acute cholecystitis in well-defined high-risk patients and also explore its predictive role in patient's prognosis

Material and methods: A retrospective record based cross sectional study was carried out in a total of 30 patients (22 men, 8women) who underwent ultra sound guided PTHC between 2016 to 2018. All of the patients had both clinical and sonographic signs of acute calculous cholecystitis and had comorbid conditions. Parameters such as fever, C-reactive protein and lowering of white blood cell (WBC) counts were evaluated as predictive markers. SPSS was used and P value of <0.05 was considered statistically significant.

Results: All the 30 patients who underwent PTHC improved well clinically and had interval cholecystectomy later. (50.4%) of the patients who underwent PTHC had uncontrolled diabetes Mellitus while 13.3% had chronic kidney disease. Our study revealed efficacy of PTCH as there was highly significant drop seen in levels of WBC, body temperature, and C reactive protein (14.62 ± 3.057 to 7.52 ± 2.42 /1000 cells); 38.3 ± 1.1 to 37.1 ± 1.1 (°C); 218 ± 117.5 to 108 ± 52.5 (mg/L) respectively all with $p < 0.001$)

Conclusion: Percutaneous cholecystotomy is successful as a definitive treatment option in the majority of high-risk patients with acute cholecystitis with good prognosis.

Keywords: Cholecystitis, Cholecystotomy, Percutaneous, Complications, Percutaneous Transhepatic, Ultrasound, Efficacy, Safety, High Risk Patients, Gall Bladder.

INTRODUCTION

Cholecystitis is one of the most common reasons for emergency surgical admission. The majority of patients are treated with antibiotics and laparoscopic cholecystectomy is performed either as an emergency (hot cholecystectomy) or as a delayed interval procedure. Some patients are high risk for surgery and fail to respond to medical treatment, resulting in rapid clinical deterioration and uncontrolled sepsis. For this group, percutaneous transhepatic cholecystotomy (PHTC) is a very attractive treatment option to drain the source of sepsis and stabilise the patient in the acute setting. PHTC has also been used successfully as a bridge to surgery in patients who are too acutely unwell to undergo emergency laparoscopic surgery .On reviewing the literature, it is apparent that there is great variation and contrast across the board in the way PTHC is employed.¹

Percutaneous cholecystotomy (PC) can be achieved with the guidance of either computed tomography (CT) or ultrasonography (USG). PC, which was initially described by Radder in 1980, has proved to be an effective treatment for acute cholecystitis in critically ill patients, and it has low morbidity and mortality rates.² Imaging guided percutaneous catheter drainage is increasingly being performed as an alternative to early cholecystectomy. This minimally invasive radiological procedure resolves local and systemic inflammation without the risks of surgery.³ According to international guidelines, it is a valuable treatment in high risk patients and in those with moderate or severe cholecystitis.⁴ A drawback of percutaneous catheter drainage, however, is that it is not a definitive treatment since the gallbladder is not removed. This may lead to recurrent cholecystitis, and other biliary complications with severe clinical effects.^{5,6}

The most frequent imaging guide tool for PTHC is ultrasound, which provides images in real-time without the risks of radiation, and is highly economical.⁷ A few previous studies observed that when laparoscopic Cholecystotomy(LC) is preceded by PTHC, there were minimal rates of conversion and low perioperative morbidity and mortality in high-risk Acute Cholecystitis(AC) patients.^{8,9} Based on the previous studies, it was hypothesized that elderly and high-risk acute cholecystitis patients may derive significant clinical benefit from PTHC under the guidance of B-mode ultrasound and followed by laparoscopic Cholecystostomy.¹⁰ Shibasaki S et al⁸ and Kim et al⁹ and many other authors conducted studies on percutaneous transhepatic gallbladder drainage followed by elective laparoscopic cholecystectomy in patients with moderate acute cholecystitis under antithrombotic therapy and various other therapies where they did not consider high group patients. However, very few studies have been carried out in India to evaluate the outcomes of PTHC. Application of PTHC may be valid in countries like India, as a permanent treatment measure, if found effective in the acute phase of the disease, considering the socioeconomic, psychological and other clinical benefits. With this background, the aim of the present retrospective study was to investigate the efficacy of PTHC in the treatment of acute cholecystitis among high risk patients, and the clinical outcome of patients who had no further interventions following PTHC. We have retrospectively evaluated the clinical data of patients treated with PTHC for acute cholecystitis.

The aim of the study was to evaluate the efficacy and safety of ultrasound guided percutaneous transhepatic cholecystostomy in relationship to clinical outcomes among high risk patients.

MATERIALS AND METHODS

This study was carried out as a retrospective record based cross sectional study among patients admitted to the Department of General Surgery and Surgical Gastroenterology of our tertiary teaching institution for a period of two years between October 2016 and 2018.

Inclusion criteria

Records of Patients diagnosed with acute cholecystitis based on clinical features and sonographic findings of pericholecystic fluid collection and obstructed cystic duct with gall stones along with the presence of systemic complications including uncontrolled diabetes mellitus, severe anemia with congestive cardiac failure, chronic kidney disease and those with respiratory complications not fit for surgery were included in this study.

Exclusion criteria

Exclusion criteria were pregnancy, decompensated liver cirrhosis, admission to the intensive care unit at the time of cholecystitis diagnosis and psychological illness.

Sample size and sampling technique

All the patients who were admitted to our hospital during the study period and fulfilled the above criteria were selected for the study. A total of 30 case records were taken up for evaluation according to Universal sampling method for the feasibility of the study. All the cases during the study period

were selected.

Ethical approval was obtained from the Institutional Ethics Committee prior to the commencement of the study. Since this study was carried out as a secondary data analysis, informed consent was not required as per institution policies.

Data collection

Data was collected using a standardized proforma designed for this purpose. Demographic data, ASA classification, comorbid conditions and disease severity parameters like CRP, WBC count and fever were collected. Clinicians performed data collection using case record forms. The study coordinator verified all completed form in accordance with onsite source data. Follow-up took place at the outpatient clinic three weeks after discharge and CRP, WBC count and fever were collected and compared. Percutaneous catheter drainage was performed under local anaesthesia and aseptic circumstances, with image guidance using ultrasonography. The procedures were performed by, or under direct supervision of, qualified radiologists. A certain experience to undertake this procedure was not required, as percutaneous catheter drainage is reported to be a relatively easy procedure, performed by any radiologist. Gallbladder puncture was directed through the transhepatic route, depending on the preference of the radiologist and the location of the gallbladder. Patients were discharged with the percutaneous drain. The drain was left in place for three weeks. Further treatment was left to the discretion of the treating clinician. A catheter was fixed to the skin by stay sutures and was connected to a drainage bag for continuous drainage.

STATISTICAL ANALYSIS

C reactive protein, WBC count and fever were considered as primary outcome variables. Comorbid conditions were considered as Primary explanatory variable. All Quantitative variables were checked for normal distribution within each category of explanatory variable by using visual inspection of histograms and normality Q-Q plots. Shapiro-wilk test was also conducted to assess normal distribution. Shapiro wilk test p value of >0.05 was considered as normal distribution. Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean SD (Min-Max) and results on categorical measurements are presented in Number (%). Paired sample T test has been done for paired data P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.¹¹

RESULTS

A total of 30 patients of acute cholecystitis with systemic complications were recruited in the study. Out of them, 73.3% were males (n=22). The mean age of the study population was 54.52(4.28) years.

More than half (52.4%) of the patients who underwent PTHC had uncontrolled diabetes Mellitus while 8% had chronic kidney disease, 8% had cardiovascular disease, 8% had pulmonary disease and 10% had severe anemia. 11(52.4%) were in healthy state according to ASA classification, 19% were having mild systemic disease and 19% were Having

Characteristics	Summary
Mean Age (in years)	54.52 ± 4.28
Gender	
Female	8 (26.6%)
Male	22 (73.3%)
Comorbid conditions	
Chronic renal diseases	4 (13.3%)
Uncontrolled Diabetes mellitus	15 (50.4%)
Cardiovascular disease	2(8%)
Severe anemia	3(10%)
Pulmonary disease	2(6.6%)
ASA classification on admission	
I healthy status	2(6.6%)
II mild systemic disease	8(26.6%)
III severe systemic disease	15(50.4%)
IV constant threat to life	3(10%)
Disease severity (mean & SD)	
C reactive protein(mg/L)	218±117.5
White blood cell count (×10 ⁹ /L)	14.62 ± 3.057
Body temperature (°C)	37.8±1.1

Table-1: Summary of demographic parameters (N=21)

Characteristics	Pre -op	Post-op	Mean difference (95% CI)	P value
	Mean ± SD	Mean ± SD		
WBC count (*1000) (×10 ⁹ /L)	14.62 ± 3.057	7.52 ± 2.42	7.1 (5.38-8.82)	<0.001
C-Reactive Protein	218±117.5	108±52.5	105.1 (103.5-110.2)	<0.001
Body temperature (°C)	38.3±1.1	37.2±1.1	37.1 (36-37.5)	<0.001

Table-2: Comparison of disease severity parameters pre-operative and 3 weeks post-operative (N=21)

severe systemic diseases. The mean and SD of C reactive protein was (mg/L) 218±117.5, WBC count was 14.62 ± 3.057 (×10⁹/L) and for fever it was (°C) 37.8±1.1 respectively (Table 1)

After the procedure of percutaneous trans hepatic cholecystostomy, patients improved well with gross reduction of C reactive protein, white blood cell count and fever. the fall in WBC count, C reactive protein and fever was statistically significant. p<0.001 (Table 2)

DISCUSSION

In the present study we decided to evaluate the efficacy and safety of ultrasound guided percutaneous transhepatic cholecystotomy in tertiary care hospital on 21 patients. In our study, the median age of patients undergoing PC was 54 years. Almost all of the patients had comorbidities and were not fit for early laparoscopic cholecystectomy. Over 30% of patients in this series were ASA grade 2 and 3 at the time of diagnosis. These patients were at an increased risk of complications due to their co-morbidities and sepsis. There was a drop in the WBC count, fever and C-reactive protein of up to 7.1/1000 cells. 36.1(°C) and 108 ± 92(mg/L) respectively in the post procedure period.

PTHC can be easily performed under local anaesthesia with USG or CT guidance. Two ways of accessing the gall bladder were defined for the procedure. Either a transhepatic or transperitoneal approach can be used. The complications related to the procedure include bile duct injury, bile leakage

and peritonitis, portal or parenchymal vessel injury and bleeding, catheter dislodgement, colon injury, and vagal reactions. The transhepatic approach decreases the risk of bile leak, portal vessel injury, and colon injury but it carries a risk of pneumothorax and bleeding from the liver parenchyma.² In this study the transhepatic approach was preferred to access the gall bladder. All procedures were completed under local anaesthesia without any complications related to the procedure.

In the present study we have seen successful placement of the cholecystostomy drain in 100% of the study participants. This finding is in comparison with Al-Jundi et al¹² where there was 100% drain placement. The drains were placed by transhepatic route and there were no immediate complications seen in this study. In our study about 50% of our patients had uncontrolled diabetes mellitus which is in contrast to a study by Asgaut Viste et al¹³ where 50% were having cardiovascular diseases or cancer, and that about the same proportion were classified as ASA III and IV. Despite the fact that over 50% of patients were ASA grade 2 and 3, the majority of these patients survived, most likely due to successful PTHC. This is in comparison to a study by S. Aroori, et al.¹⁴ This supports the fact that PTHC can be a useful bridging procedure for future surgery and as the definitive procedure in selected group of patients.

In a systematic review on treatment of choice for ACC, Soria et al. observed that mortality among patients with ACC is 30%, and it is related to clinical severity and higher

prevalence of gangrene (50%) and perforation (10%)¹⁵ which is in contrast to present study as we have not considered this comparison of AC with ACC. Clinically, acute a calculus cholecystitis often occurs in critically ill patients, and it is especially related to sepsis, shock, trauma, surgery, burns, total parenteral nutrition, and/or pro- longed fasting. It has a high mortality (most studies, 30%; ranges between 10% and 90% with early or late diagnosis, respectively). Based on these findings, more attention should be paid to these patients.¹⁶

According to previous studies, factors such as older age, male sex, prolonged duration of symptoms, and increased inflammatory changes such as WBC and CRP are significant predictors of severe AC and treatment with PC.¹⁷ One of the major finding of the study was improved clinical and laboratory findings where there was significant reduction seen in WBC count, CRP and fever. This findings are in comparison to a study by Seong Yeol Kim¹⁸ where there was additional benefit to clinical outcomes by significant decrease in WBC count and CRP levels. The findings were in comparison to a study done by Hu YR et al¹⁹ where a significant decrease was seen in WBC and CRP count and in addition the study also seen reduction in levels of ALP, TB and CA19, bile bacteria cultures, including E.coli and other bacteria such as Klebsiella pneumoniae, Enterococcus faecium, Pseudomonas aeruginosa, which was not recorded in the present study.

As opposed to percutaneous catheter drainage, cholecystectomy is a definitive treatment for gallstone related disease, which does not require readmissions and other interventions that impact patient's quality of life and are a burden on hospital capacity for emergency and elective care. It may be clear that, in patients with a strict contraindication for surgery, percutaneous drainage is still an appropriate treatment, either as a bridge to surgery or as definite treatment.³

The disadvantage of a PTHC is that although the actual inflammatory episode will probably settle, the causative gall- bladder stones remain and the patient is at risk of future attacks of cholecystitis. For this reason, elective cholecystectomy is recommended whenever possible. Although these patients would never be fit for surgery, the repeated PCs proved efficacious and lifesaving procedures.¹² In summary, for suitable high-risk patients with AC, PTHC may be able to cure the patients in the initial treatment. However, due to limited acquisition of follow-up data in the present study, we cannot determine the initial treatment effect of PTGD on AC from the present data.

Limitations

The study is not without limitations. The major limitation being the study design. As it is retrospective in nature the relevance of data in today's scenario is difficult. Second the sample size is very low. Hence the generalizability cannot be considered and it was a single centre study. We did not recorded patients to undergo a future cholecystectomy and also the addition, indications for PTHC are not strict defined and recommendations for future use should therefore be drawn with caution. We did not document the mean number of hospitals stay and operating time for the procedure.

Though the procedure of PTHC was successful in our study, we recommend further research to be carried out using multicentric RCTs covering a large geographical area and also involving different techniques to check the efficacy.

CONCLUSION

With the findings of the present study it can be concluded that, Ultrasound-guided percutaneous cholecystostomy is a relatively safe and easy method which can help physicians and surgeons in diagnosing and treating acute cholecystitis among high risk patients at the earliest to avoid further complications. The risk of complications is low and the likelihood of success is high. The placement of a PTHC tube is an effective and simple procedure that can be used to treat severe acute cholecystitis in patients unfit for immediate surgery. Following resolution of symptoms and optimization of patients' medical conditions, laparoscopic cholecystectomy should be considered the treatment of choice. When further attacks of cholecystitis occur in unfit patients, the PTHC can be repeated.

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