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ORIGINAL RESEARCH PERIOPERATIVE MEDICINE

Comparative analysis of percutaneous gallbladder aspiration vs percutaneous cholecystostomy in acute calculous cholecystitis

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ABSTRACT

Background & objectives: Acute cholecystitis, a prevalent cause of acute abdomen pain, is primarily induced by gallstone obstruction, leading to significant inflammation and potentially severe complications. This study focuses on comparing the effectiveness and complication rates of percutaneous gallbladder aspiration versus percutaneous cholecystostomy in managing severe acute calculous cholecystitis, aiming to enhance patient care by optimizing treatment strategies.

Methodology: In this study we evaluate the efficacy and safety of percutaneous gallbladder aspiration (PGA) versus percutaneous cholecystostomy (PC) in 35 patients with acute calculous cholecystitis. Utilizing ultrasound-guided procedures, patients were either subjected to PGA, using an 18-19-gauge spinal needle for gallbladder drainage, or where an 8-12 French pigtail catheter facilitated gallbladder decompression.

Results: In this study of 35 patients with acute calculous cholecystitis, 25 underwent percutaneous gallbladder aspiration and 10 underwent percutaneous cholecystostomy. Post-procedure, 88% of the aspiration group and 80% of the cholecystostomy group reported no pain, with the majority in both groups showing a positive total response score. Analgesic demand post-procedure was low, with 76% of the aspiration group and 70% of the cholecystostomy group requiring no analgesia. Complication rates were 12% for the aspiration group and 20% for the cholecystostomy group, with overall success rates of 92% and 90%, respectively, indicating no significant difference in outcomes between the two methods.

Conclusions: This study's comparative analysis of PGA and PC offers essential insights into managing acute calculous cholecystitis in high-risk surgical candidates. With both procedures demonstrating high success rates and minimal complications, they emerge as viable alternative treatments. Future studies should focus on evaluating their long-term efficacy and optimizing patient selection criteria to enhance outcomes.

Abbreviations: PC - percutaneous cholecystostomy; PGA - percutaneous gallbladder aspiration; HIDA - hepatoimino diacetic acid scan;

Keywords: percutaneous gallbladder aspiration, percutaneous cholecystostomy, acute cholecystitis, non-surgical, radiology

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1. INTRODUCTION

Acute cholecystitis, an acute inflammatory process of the gallbladder, is a common cause of acute abdomen and a frequently encountered abdominal inflammatory process.[1] This condition is classified into two types: acute calculous cholecystitis and acute acalculous cholecystitis, depending on the presence or absence of gallbladder calculi.[1] Acute calculous cholecystitis, precipitated by obstruction of the cystic duct or gallbladder neck by a gallstone or biliary sludge, is the most common form, affecting a higher proportion of women, particularly those who are obese.[2]

The clinical presentation of acute calculous cholecystitis is characterized by constant right-upper-quadrant abdominal pain, inflammatory response, and right-upper-quadrant tenderness.[3] Severe cases may present with mild jaundice due to inflammation and edema around the biliary tract and direct compression on the biliary tract by the distended gall bladder.[4] Complications can include secondary bacterial infection, accumulation of purulent fluid leading to gall bladder empyema, perforation with widespread peritonitis with sepsis, hepatic abscess, and intra-abdominal abscess.[5]

Acute cholecystitis can also lead to other severe conditions such as gangrenous cholecystitis, cholecystoenteric fistulas, gall stone ileus, Mirizzi Syndrome, empyema of the gallbladder, gallbladder mucocele, and acute acalculous cholecystitis.[6-10] These conditions present their own unique set of symptoms and complications, further complicating the management of acute cholecystitis.

Diagnosis of acute cholecystitis is crucial for effective management and relies heavily on imaging to establish a diagnosis, identify complications, or suggest an alternative diagnosis.[11] Gallbladder scintigraphy and ultrasound are commonly used, with ultrasound being the initial test of choice due to its wide availability, speed, portability, and ability to identify complications of acute cholecystitis or alternative diagnoses.[12,13] In cases of inconclusive ultrasound results, hepatoimino diacetic acid (HIDA) scan or computed tomography (CT) may provide a definitive diagnosis.[14-16]

Management of acute cholecystitis is a critical aspect of patient care, with early cholecystectomy being the standard approach.[17] However, this procedure carries risks, particularly in high-risk patients such as the elderly and critically ill.[18] In such cases, alternative strategies such as percutaneous cholecystostomy or percutaneous gallbladder aspiration may be employed.[18-20]

The aim of the study is to determine and compare the effectiveness and incidence of complications between percutaneous gallbladder aspiration and percutaneous cholecystostomy in the management of severe acute calculous cholecystitis.

2. METHODOLOGY

2.1. Participants

The participants in this study comprised 35 patients (17 males and 18 females) who were admitted to Al Sadder Medical City, Al Najaf governorate from October 2019 to December 2020. They were specifically referred to the interventional unit of the radiology department due to a diagnosis of acute calculous cholecystitis. These patients initially entered the institution through the department of surgery. However, those who could not be immediately operated upon were selected for conservative treatment, following standard department protocols. The conservative treatment regimen consisted of fasting, administration of intravenous (IV) fluids, and a course of broad-spectrum IV antibiotics. However, a subset of these patients demonstrated no response or a poor response to the conservative medical treatment. These individuals were subsequently referred to our interventional study by a multidisciplinary team of medical professionals.

The basis for their referral was primarily their need for further intervention and their potential to benefit from the procedures being studied, namely percutaneous gallbladder aspiration and percutaneous cholecystostomy. Diagnostic criteria for acute cholecystitis included clinical and sonographic symptoms such as right upper quadrant pain, a positive Murphy sign, leukocytosis, positive C-reactive protein test results, distended gallbladder with an impacted stone, gallbladder wall thickening exceeding 3mm, or the presence of debris in the gallbladder.

The inclusion criteria for this study were well-defined. Participants qualified for the study if they were experiencing severe pain due to a thick-walled gallbladder impeding immediate laparoscopic cholecystectomy, deemed unfit for surgical procedures, or managing pre-existing medical conditions like diabetes mellitus, hypertension, heart failure, or sickle cell anemia. Inclusion was also extended to pregnant patients, those undergoing hemodialysis, and patients of advanced age. There were no specific exclusion criteria for the study, and all patients referred for gallbladder drainage were considered.

The study was conducted in adherence to Iraq's and international ethics and privacy laws. Before any involvement in the study, each participant, as well as their first-degree relatives, provided written informed consent. The ethical approval was obtained from the counsel of faculty of medicine, university of Kufa (doc. no. 10519, 5/9/2016).

The included patients were stratified into two treatment groups after consultation with surgeons: Percutaneous Transhepatic Gallbladder Aspiration (PTGBA) and Percutaneous Cholecystostomy (PTGBD). PTGBA was the preferred procedure for patients scheduled for cholecystectomy post-inflammation control of the gallbladder. Conversely, PTGBD was reserved for patients deemed unfit for surgery in the ensuing weeks

or those presenting with thick bile mixed with small stones and sludge, which were not suitable for needle aspiration.

Under ultrasound guidance, the technical success, clinical response, and complications were evaluated for each treatment group. Percutaneous gallbladder aspiration was performed using a GE LOGIQ E9 ultrasound machine, primarily employing an 18-19-gauge spinal needle. The effectiveness of each procedure was then thoroughly assessed based on these criteria. Percutaneous Gallbladder Aspiration (PGA) was utilized as a non-surgical gallbladder drainage method for select patients. This minimally invasive procedure, conducted bedside under ultrasound guidance, involved the use of an 18-19-gauge needle for puncture. The advantage of PGA lies in its safety, simplicity, cost-effectiveness, and low risk of severe complications. It is predominantly indicated for managing pain symptoms in patients with acute cholecystitis, who are planned for cholecystectomy following the control of acute inflammation. Pain severity was determined by the Numeric Pain Rating Scale (NPRS), a scale ranging from 0 (no pain) to 10 (severe pain).

Specific contraindications were identified for participants in this study. Patients diagnosed with gangrenous cholecystitis, characterized by significant irregularities in the gallbladder wall or the intraluminal membrane, were not suitable for the percutaneous interventions. Additionally, patients with emphysematous cholecystitis, a condition diagnosed by the presence of gas in the gallbladder, were also contraindicated. These patients were instead managed through emergency surgical procedures.

Percutaneous cholecystostomy was administered under local anesthesia, predominantly using ultrasound guidance via a GE LOGIQ E9. The gallbladder was punctured with an 8-12 French pigtail catheter or a thoracic drainage catheter. This procedure was typically conducted using a transhepatic approach, chosen to minimize the risk of biliary peritonitis or injury to the right colon that could occur with a transperitoneal approach. The selection of the specific method was contingent upon the judgment of the interventional specialist and patient-specific factors including body habitus, intervening bowel loops, gallbladder size, and the thickness of the liver segment. In this study, there were no absolute contraindications; however, patient conditions such as bleeding diathesis, significant ascites, presence of a gallbladder tumor, and gallbladders packed with calculi required additional scrutiny prior to the procedure. Once the cholecystostomy was performed, the catheter was ideally retained in place for at least two weeks to facilitate appropriate healing and decrease the likelihood of complications.

2.2 Statistical analysis

The collected data were processed and analyzed using the Statistical Package for the Social Sciences (SPSS), version 26, developed by IBM, US. Descriptive statistics were employed, presenting results as frequencies, proportions, and means along with standard deviations, particularly for age. Given the small categorical numbers rendering the Chi-square test inapplicable, Fisher's exact test was utilized as an alternative to compare frequencies between both treatment groups. A significance level (P-value) of 0.05 or less was deemed statistically significant in the analyses.

3. RESULTS

The study enrolled a total of 35 patients, with 25 underwent percutaneous transhepatic gallbladder aspiration (Group 1) and 10 underwent percutaneous cholecystostomy (Group 2). Baseline characteristics such as age, gender, comorbidities, fever, pain, vomiting, or analgesics received, revealed no significant differences between the two groups prior to the procedures as shown in Table 1 and Table 2.

Table 3 and Figure 1 reveals that post-procedure immediate responses were observed in 88% of group 1 and 80% of group 2, where pain absence was reported in 22 and 8 patients in these groups respectively. The remaining patients from both groups experienced mild pain. However, the difference in immediate response between the two groups did not achieve statistical significance.

In terms of the total response score post-procedure, all patients in both groups exhibited a positive response (total score of 0, 1, 2), with over two-thirds of them scoring zero: 64% in Group 1 and 70% in Group 2. Nevertheless, no significant difference was found between the groups in terms of the total response score. Regarding analgesic requirements post-procedure, 19

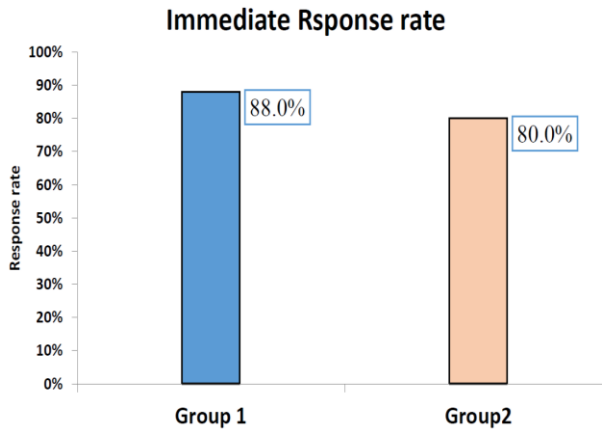


Figure 1: Bar chart for comparison of immediate response rates in both studied groups

Table 1: Age and gender distribution of the studied groups

Variables		Group 1 (n = 25)	Group 2 (n = 10)	P-value
Age (y)	≤ 50	7 (28.0)	1 (10.0)	0.351
	51 - 60	11 (4.0)	4 (40.0)	
	61 - 70	6 (24.0)	3 (30.0)	
	> 70	1 (4.0)	2 (20.0)	
	Mean (SD)	54.8 (13.7)	59.1 (11.6)	
Gender	Male	12 (48.0)	5 (50.0)	0.915
	Female	13 (52.0)	5 (50.0)	
Medical Comorbidities				
DM		12 (48.0)	5 (50.0)	0.915
HT		9 (36.0)	6 (60.0)	0.235
Sickle cell anemia		2 (8.0)	0 (0.0)	0.357
Heart failure		1 (4.0)	1 (10.0)	0.490
Others*		2 (8.0)	2 (20.0)	0.313

Data presented as n (%); DM: Diabetes Mellitus, HT: Hypertension, Others: 3 patients with CA colon and 1 was pregnant.

Table 2: History of fever, pain, vomiting and analgesia before procedure among patients in both studied groups

Clinical Sings		Group 1 (n = 25)	Group 2 (n = 10)	P-value
Fever before	No fever	5 (20.0)	1 (10.0)	0.327
	Low grade	13 (52.0)	4 (40.0)	
	Moderate	7 (28.0)	4 (40.0)	
	High grade	0 (0.0)	1 (10.0)	
Pain before	Mild	17 (68.0)	5 (50.0)	0.564
	Moderate	7 (28.0)	4 (40.0)	
	Severe	1 (4.0)	1 (10.0)	
Vomiting	None	5 (20.0)	0 (0.0)	0.311
	Single episode	14 (56.0)	7 (70.0)	
	Multiple episode	6 (24.0)	3 (30.0)	
Duration of analgesia before procedure	< 5	12 (48.0)	3 (30.0)	0.598
	5 - 10	10 (40.0)	5 (50.0)	
	> 10	3 (12.0)	2 (20.0)	

Data presented as n (%); Group 1: Percutaneous transhepatic gallbladder aspiration group; Group 2: The percutaneous cholecystostomy group

patients (76%) in Group 1 and 7 patients (70%) in Group 2 did not require any analgesia. The remaining patients required analgesia for a duration of 1-5 days. No significant difference was observed in the requirement for analgesia post-procedure between the two groups. Unfortunately, complications arose in 3 patients from Group 1 and 2 patients from Group 2. In Group 1, partial response was reported in 2 patients (8%), while in Group 2, slippage occurred in one patient (10%). Non-responsive outcomes were observed in one patient from each group. Consequently, the total complication rate (Figure 2) amounted to 12% in Group 1 and 20% in Group 2. Despite these setbacks, the overall success rate (Figure 3) remained relatively high, with Group 1 and

Table 3: Immediate response after procedure in both studied group

Pain	Group 1 (n = 25)	Group 2 (n = 10)	P- value
No pain	22 (88.0)	8 (80.0)	0.610
Mild pain	3 (12.0)	2 (20.0)	
Total	25 (100.0)	10 (100.0)	

Data presented as n (%);

Group 2 achieving success rates of 92% and 90%, respectively. However, the results demonstrated that in terms of complication and success rates there were not statistically significant.

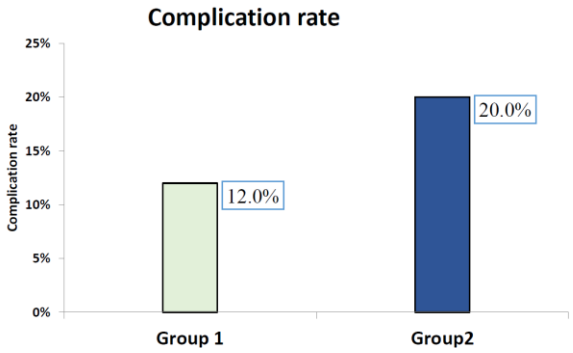


Figure 2: Bar-chart for comparison of Complication rates in both studied groups.

4. DISCUSSION

The present study evaluates the efficacy and complications of percutaneous gallbladder aspiration (PGA) and percutaneous cholecystostomy (PC) in managing acute calculous cholecystitis, a prevalent condition encountered in surgical practice. With cholecystectomy being the gold standard, especially through minimally invasive laparoscopic methods, alternatives like PGA and PC hold significance for patient's ineligible for surgery due to various contraindications, such as liver cirrhosis, advanced age, or other risk factors that elevate postoperative morbidity and mortality risks.[21-24]

4.1. Efficacy and Immediate Response

This study enrolled 35 patients, allocating 25 to PGA and 10 to PC, finding no significant preoperative differences between groups, which underscores the comparative analysis's fairness. The outcomes revealed that a majority, 88% in the PGA group and 80% in the PC group, reported immediate pain relief, with only a minor segment experiencing mild pain. These findings align with previous literature,[18] where researchers observed a 95% success rate after potential second interventions in similar procedures, and Chung et al.[25] reported success rates ranging from 82%-100% across studies. Such high efficacy rates suggest both PGA and PC are viable alternatives for symptom management in acute cholecystitis.

4.2. Complications and Success Rates

The study reports a favorable overall success rate, 92% for PGA and 90% for PC, with complications including partial response and device slippage. These rates are comparable to earlier findings by Komatsu et al.[18] and in observational studies such as that by Haas et al.[26] which reported success rates of 54.5% at single aspiration and 75.7% after repetitive aspiration, demonstrating the potential of these interventions in clinical settings.

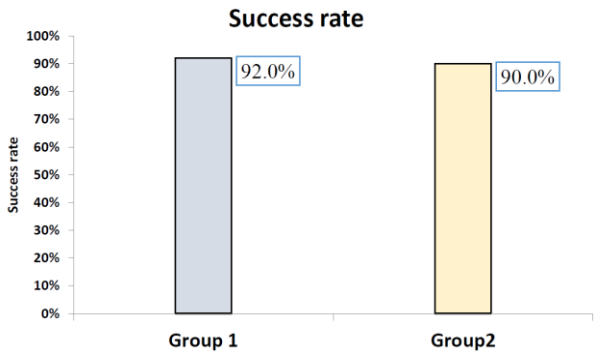
4.3. Clinical Implications and Recommendations

Given the high incidence of cholecystitis with advancing age and its prevalence in females, this study's findings underscore the need for alternative treatments for patients at high surgical risk or those with comorbid conditions. The procedures' high success and low complication rates provide strong evidence supporting

Table 4: Clinical characteristics of patients in both studied groups after procedure.

Variable		Group 1 (n = 25)	Group 2 (n = 10)	P-value*
Total score of response	0	16 (64.0)	7 (70.0)	0.594
	1	4 (16.0)	0 (0.0)	
	2	5 (20.0)	3 (30.0)	
Analgesic after aspiration	None	19 (76.0)	7 (70.0)	0.676
	One day	2 (8.0)	2 (20.0)	
	Two days	2 8.0)	1 (10.0)	
	3-5 days	2 (8.0)	0 (0.0)	
Complication of procedure	None	22 (88.0)	8 (80.0)	0.319
	Partial response	2 (8.0)	0 (0.0)	
	Slipped	0 (0.0)	1 (10.0)	
	No response	1 (4.0)	1 (10.0)	

Data presented as n (%)



PGA and PC as feasible alternatives to cholecystectomy, especially in elderly patients or those unfit for surgery. This is in line with Stanek et al.[27] and other authors[28, 29] who have also highlighted the efficacy of these minimally invasive procedures in managing acute cholecystitis.

5. LIMITATIONS

Despite the promising results, the study acknowledges limitations, such as its small sample size and the lack of a multicenter approach, partly due to constraints imposed by the COVID-19 pandemic. This limitation is critical as it might affect the generalizability of the findings. Future research should aim at larger, possibly multicenter studies to overcome these limitations and provide a broader assessment of these procedures' long-term outcomes.

6. CONCLUSION

The comparative analysis of PGA and PC in this study contributes valuable insights into the management of acute calculous cholecystitis, especially for patients where surgery poses significant risks. Both procedures exhibit high success rates with minimal complications, reinforcing their utility as alternative interventions. However, further research is needed to fully understand their long-term efficacy and to refine patient selection criteria to maximize benefits.

7. Acknowledgments

The authors thank everyone at Al Sadder Medical City, Al Najaf governorate who contributed to the data collection.

8. Ethical approval and consent to participate.

This study received approval from the Ethics Committee of the ethical approval was obtained from the counsel of faculty of medicine, university of Kufa (doc. no. 10519, 5/9/2016). The research was conducted strictly following local Iraqi and international ethical and privacy regulations. This includes but is not limited to principles outlined in the World Medical Association's Declaration of Helsinki, the Belmont Report, the CIOMS Guideline, and the International Conference on Harmonization of Good Clinical Practice. Our institutional review board is committed to maintaining the highest standards, strictly adhering to the International Guideline for Human Research Safety (ICH-GCP).

9. Declaration of interest

The authors declare that there are no financial or other relationships that might result in a conflict of interest regarding the submitted article.

10. Availability of data

The data compiled and evaluated throughout this study will be accessible through the corresponding author (MAA), provided a reasonable request is made. Please note that data availability will be ensured once the authors fully utilise it for their intended research purposes.

11. Author's contributions

Patient-related tasks and sample collection were managed by MAA. The statistical analysis was conducted by MAA and MAM. Both authors contributed to the manuscript's composition and editing. All authors participated in reviewing and approving the definitive version of the manuscript.

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