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Research Article

Evaluating Diagnostic Markers to Predict Acute Cholecystitis in Critically Ill Patients Prior to Placement of a Percutaneous Cholecystostomy

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Abstract

Purpose: We evaluate the accuracy of diagnostic markers in identifying acute cholecystitis in critically ill patients with a non-biliary admitting diagnosis. We hypothesize that the "classic" markers of acute cholecystitis including Right Upper Quadrant (RUQ) pain, elevated WBC and gallbladder wall thickening on ultrasound, have low-diagnostic yield in the Intensive Care Unit (ICU) patient population.

Methods: The study included all consecutive patients (n=62) who received a Percutaneous Cholecystostomy (PC) while admitted to the Medical (MICU) or Surgical (SICU) Intensive Care Unit during a 5-year period. The predictive value of each marker for diagnosing acute cholecystitis was evaluated.

Results: Forty-two patients had acute cholecystitis suspected upon PC placement: 8 patients had purulent or white bile, 34 patients had stones present in the cystic duct or non-visualization of the cystic duct with contrast injection. Our results confirm low sensitivities of RUQ pain (38%), elevated WBC (67%) and gallbladder wall thickening (50%) for diagnosing acute cholecystitis in the critically ill patient population. Hepatobiliary (HIDA) scans (positive predictive value 93%) were the most sensitive marker.

An ultrasound showing gallbladder wall thickening (15/20=75%) was the most common reason for PC placement in patients who did not have findings of acute cholecystitis.

Conclusion: We confirm our hypothesis that the classic markers used to diagnose acute cholecystitis are not reliable in the critically ill patient population. We propose a combination of biochemical and radiological criteria should be used to avoid missing a diagnosis of acute cholecystitis in these vulnerable patients.

Keywords: Acute cholecystitis; Critical care; Intensive care unit; Percutaneous cholecystostomy

Abbreviations

Acute Cholecystitis -AC

Percutaneous Cholecystostomy -PC

Hepatobiliary -HIDA Scan

White Blood Cell Count -WBC

Body Mass Index -BMI

Computed tomography -CT

Intensive Care Unit -ICU

Length of Stay -LOS

Background

Acute Cholecystitis (AC) affects an estimated 20 million patients annually in the United States [1,2]. The standard of care for treatment is latively straight forward, often times ambulatory Laparoscopic Cholecystectomy (LC). However, in critically ill patients the risk of general anesthesia and surgical cholecystectomy is often prohibitive. Instead, placement of a Percutaneous Cholecystostomy (PC) is preferable [3-10].

Percutaneous Cholecystostomies can serve as either a definitive procedure or bridging therapy until the patient is clinically stable for a surgical cholecystectomy [11-18]. During the course of an ICU stay, patients can develop classic signs and symptoms that are attributed to acute cholecystitis standard clinical, laboratory and radiological markers used to diagnose acute cholecystitis are by default and perhaps incorrectly, used to justify PC placement in this unique patient population.

The purpose of our study was to establish evidence-based criteria for placement of PC in critically ill patients with a non-biliary diagnosis on admission. Our goal was to evaluate diagnostic markers for acute cholecystitis and the need for a PC in ICU patients, as opposed to defining criteria for PC placement in patients who were critically ill from their gallbladder disease. Our hypothesis was that the "classic" markers of acute cholecystitis including right upper quadrant pain, elevated WBC and ultrasound findings of gallbladder wall thickening have low-diagnostic yield in the intensive care unit patient population. We further postulated that relying on classic markers results in an over-diagnosis of acute cholecystitis and unnecessary PC placement. By establishing evidence-based criteria for placement of percutaneous cholecystostomy tubes we hope to prevent unnecessary testing and procedures.

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Methods

Study population and data collection

All patients who underwent a Percutaneous Cholecystostomy (PC) placement between November 1, 2010 and October 31, 2015 in our 945-bed urban, tertiary care University hospital were identified using a procedural database maintained by our institution's Interventional Radiology Department. Two hundred and sixty five consecutive patients were identified for this time period. Patients who received their cholecystostomy tube while in a non-intensive care unit setting were excluded from the study (n=146). Of the 119 remaining critically ill patients receiving a PC, we further excluded all patients with a primary biliary reason for admission (benign biliary disease or biliary system malignancy n=57). For inclusion in our final study population (n= 62), patients had to have a non-biliary admitting diagnosis and be admitted to either the Medical (MICU) or Surgical (SICU) Intensive Care Unit at the time of the cholecystostomy tube placement (Figure 1).

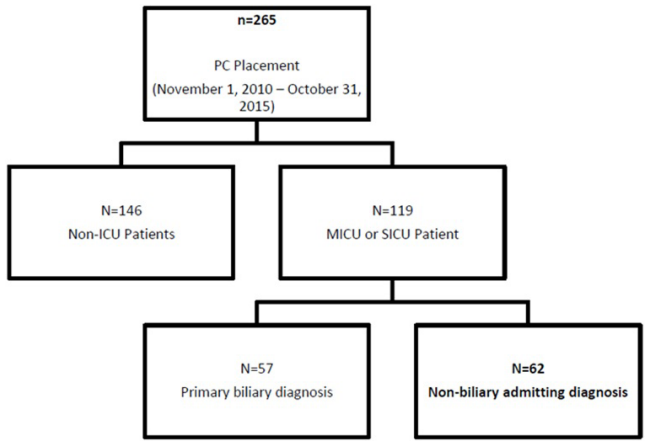

Figure 1: Inclusion Criteria of Patient Population.

This Flow chart demonstrates how patients were selected for inclusion in the study.

A retrospective chart review was conducted on the 62 patients to include pertinent history, demographics, laboratory and radiological findings and outcomes. Demographic variables including age, race, gender, Body Mass Index (BMI) and American Society of Anesthesia (ASA) score were collected. Clinical data including reason for admission and presenting symptoms of pain, fever (temperature >100.5) and jaundice were obtained from admission notes. Laboratory values utilized including White Blood Cell (WBC) (>11 B/L) or elevated liver enzymes (total bilirubin >0.9 mg/dL and direct bilirubin >0.3 mg/dL) were obtained immediately prior to Percutaneous Cholecystostomy tube placement. Imaging reviewed included Right Upper Quadrant Ultrasounds (RUQ) and Hepatobiliary (HIDA) scans. Right Upper Quadrant Ultrasounds were evaluated for abnormal findings defined as notations of gallbladder wall thickening (>4.5mm) and the presence of peri-cholecystic fluid or a sonographic Murphy's sign. For our ICU patient population, all Hepatobiliary (HIDA) scans were administered in the nuclear imaging radiology suite. Patients were positioned on their backs and a radioactive tracer (^{99m}Tc-Mebrofenin) was injected into an antecubital vein. A gamma-camera was positioned over the patient's abdomen and images were taken starting at injection and continuing for 60 minutes. A radiologist was present to observe the progression of the radiotracer and to calculate the ejection fracture of the tracer from the gallbladder. Presence of radiotracer in the small bowel was used to rule out cystic and common bile duct obstruction. Hepatobiliary(HIDA) scans were considered positive if the ejection fraction <30% or the cystic duct was not seen on Hepatobiliary (HIDA).

Procedural notes related to PC placement were reviewed for positive findings of acute cholecystitis and procedural complications at the time of PC insertion. Placement of all PC tubes was performed by the Interventional Radiology (IR) department with local anesthesia and using real-time ultrasound and fluoroscopic guidance. A 10-French Exodus multi-purpose catheter is introduced into the gallbladder and connected to gravity drainage. Contrast is injected only after decompression of the gallbladder to avoid producing septic shock. Procedural notes were reviewed for positive findings of acute cholecystitis.

Finally, operative reports for subsequent cholecystectomies, if performed, were reviewed for surgical technique (laparoscopic, converted to open, open) and any complications including blood loss (>50mL) and bile duct injury.

Outcomes

Our primary outcome was evaluation of the predictive value of each specified clinical, laboratory and radiological markers in diagnosing acute cholecystitis in the critically ill patient. The diagnosis of acute cholecystitis was established by the following findings during PC placement 1) the presence of purulent or white bile, 2) non-visualization of the cystic duct and/or presence of stones in the cystic duct 24 hours after initial drainage or 3) positive cultures (>100,000 organisms/mL) growing from the bile aspirate [19].

Statistical analysis

Patient data was first compiled in an encrypted database, before being exported as a de-identified spreadsheet. The mean, range and standard deviations were then computed for all continuous variables. For presenting symptoms and image findings, the Positive Predictive Value (PPV) and Negative Predictive Value (NPV) were calculated using cystic duct patency at the time of placement of the PC as the reference standard with GraphPad Prism version 5.00 (GraphPad Software, San Diego, CA).

Results

Demographics

Sixty-two patients met the criteria for inclusion in this study. They had an average age of 62.3 ± 18.0 years with a slight preponderance of males (56%) to females (44%). Race breakdown was primarily Caucasian (51.6%) followed by African-American (29.0%), Asian (11.3%) or Unknown/Other (8.1%). The average BMI was 30.3 ± 12.0. ASA scores reflect the severity of illness in this patient population, with all but one patient having an ASA 4 (87.1%) or ASA 3 (11.3%). Patient characteristics are given in table 1.

Primary diagnosis for patients ranged from non-biliary malignancies (21%) to neurological etiologies including strokes, seizures and changes in mental status (12.9%). Cardiac and respiratory reasons for admission were evenly distributed, 11.3% each. The remaining patients were admitted for traumas and a wide range of additional conditions including gastrointestinal bleeding and endocrine disorders (Figure 2).

Patient Characteristics	Value	Number of patients (N = 62)	Percentage of patients
Age	62.3 ± 18.0	-	-
BMI	30.3 ± 12.0	-	-
Gender	Male	35	56.0%
	Female	27	44.0%
Race	White	32	51.6%
	African American	18	29.0%
	Asian	5	11.3%
	Unknown/Other	7	8.1%
ASA Score	1	1	1.7%
	2	0	0.0%
	3	7	11.3%
	4	54	87.1%
Hospital LOS (days)	26.3 ± 19.4	-	-
ICU LOS (days)	18.8 ± 16.9	-	-
30-day Mortality	Alive at 30 days	39	63.0%
	Dead at 30 days	23	37.0%
Days between admission and C-tube placement	13.5 ± 15.4	-	-
Days until to C-tube removal	70.1 ± 64.4	-	-

Table 1: Patient Demographics.

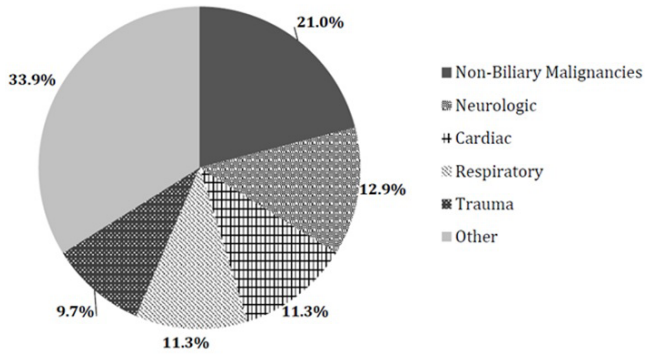

Figure 2: Reason for Admission.

This figure demonstrates the reasons for hospital admission of the included patient population.

On average, the hospital Length of Stay (LOS) was 26.3 ± 19.4 days. Intensive care unit LOS was 18.8 ± 16.9. For this critically ill patient population, 30-day mortality was high at 37%.

Cholecystostomy tubes were often placed well into admission 13.5 ± 15.4 days after admission) and often remained in place for long periods (70.1 ± 64.4 days). There were no major complications noted during PC placement. No instances of bile peritonitis, hemobilia, common bile duct injury or gallbladder perforation were noted. There were two instances of hemodynamic instability (systolic BP <90mmHg) during PC placement, which resolved with fluid resuscitation.

For clinical symptoms, 38.7% of patients presented with symptoms of pain (n=24) and 32.2% were febrile (n=20) prior to placement of the cholecystostomy tube. Jaundice was an uncommon presenting complaint (n=2). Elevated WBCs and elevated liver enzymes were more common findings in our patient population at 61.2% and 47.6% respectively. All but four patients had right upper quadrant ultrasounds and the most common finding was gallbladder wall thickening (39%). Peri-cholecystic fluid and the presence of a sonographic Murphy's sign were relatively uncommon, 41% and 18% respectively. About one third of patients (n=19) had Hepatobiliary (HIDA) scans (Table 2).

Diagnostic Markers	Number of patients (N=62)	Positive predictive value	Negative predictive value
Clinical Markers			
Pain	24	38%	60%
Fever	20	36%	75%
Jaundice	2	2.4%	95%
Laboratory Markers (on Admission)			
Elevated WBC	38	67%	50%
Elevated LFTs	30	45%	45%
Radiologic Markers			
Ultrasound: GB wall thickening	39	50%	21%
Ultrasound: Pericholecystic fluid	25	32%	58%
Ultrasound: Sonographic Murphy's sign	11	13%	95%
Hepatobiliary (HIDA) Scan	19	93%	68%

Table 2: Predictive Values of Clinical, Laboratory and Diagnostic Markers.

The Hepatobiliary (HIDA) scan had a positive predictive value of 93%. Thirteen of the nineteen patients (68%) with positive Hepatobiliary (HIDA) scans were suspected to have acute cholecystitis on percutaneous cholecystostomy placement. Of the subgroup of patients with positive Hepatobiliary (HIDA) scans, a minority had an elevated WBC (42%) or elevated LFTs (32%), respectively (Table 3).

Diagnostic Markers	Number of patients (N=19)	%
Clinical Markers		
Pain	10	53%
Fever	7	37%
Jaundice	0	0%
Laboratory Markers (on Admission)		
Elevated WBC	8	42%
Elevated LFTs	6	32%
Radiologic Markers		
Ultrasound: GB wall thickening	11	58%
Ultrasound: Pericholecystic fluid	4	21%
Ultrasound: Sonographic Murphy's sign	2	11%

Table 3: Diagnostic Markers in Patients with Positive Hepatobiliary (HIDA) Scans.

58% of these patients had gallbladder wall thickening on ultrasound, the most common associated finding.

Forty-two patients had acute cholecystitis suspected upon PC placement based on our defined criteria: 8 patients had purulent or white bile, 34 patients had stones present in the cystic duct or

non-visualization of the cystic duct with contrast injection. Additionally, one third of patients grew positive cultures from their bile aspirates (n=20) (**Table 4**).

Species	Number of Positive Cultures (N=20)	Percentage
Enteroccoccus faecalis	7	35%
Escherichia coli	3	15%
Klebsiella species	2	10%
Mixed	5	25%
Other	3	15%
Total	20	

Table 4: Positive Cultures.

Our results indicate that clinical and laboratory markers had a low positive predictive value for predicting acute cholecystitis in the critically ill patient population. The most predictive of the non-radiological markers was WBC which had a positive predictive value of 50% but a low negative predictive value of 21%. Pain and fever were sensitive only up to 38% and 36%, respectively. Ultrasound findings were relatively insensitive for predicting acute cholecystitis including gallbladder wall thickness with a positive predictive value of just 50%.

Twenty patients did not have acute cholecystitis suspected on PC placement, as evidenced by apatent cystic duct and/or negative cultures from their bile aspirate. We found that an ultrasound showing gallbladder wall thickening (15/20=75%) was the most common finding leading to an incorrect diagnosis of acute cholecystitis and an unnecessary procedure in this group of patients. However, use of the Hepatobiliary (HIDA) scan had limitations as well. Five patients were incorrectly diagnosed as having acute cholecystitis based on Hepatobiliary (HIDA) scan results. Additionally the diagnosis of acute cholecystitis was missed in one patient who was suspected to have the disease despite a normal Hepatobiliary (HIDA) scan.

Discussion

Patients presenting with acute cholecystitis have established algorithms for diagnosis and treatment [15-19]. However, development of biliary disease in critically ill patients may present atypically and therefore require a modified management approach. We retrospectively reviewed 62 critically ill patients who underwent PC placement at our institution and evaluated the clinical, radiological and diagnostic markers used to arrive at the diagnosis of acute cholecystitis. Our hypothesis was that the standard markers used to diagnose acute cholecystitis in non-critically ill patients were not diagnostic of this disease process in the critically ill patient population. To our knowledge, this is the first study specifically looking at predictive value of diagnostic markers for acute cholecystitis in intensive care unit patients without a primary biliary diagnosis.

The Tokyo Guidelines were an attempt to establish evidence-based criteria for the diagnosis of acute cholecystitis based on the presence of clinical symptoms, signs of systemic infection, and positive radiographic findings on ultrasound, Computed Tomography (CT) or Hepatobiliary (HIDA) scan. The defined clinical symptoms of AC include right upper quadrant pain, or tenderness and a positive Murphy's sign (cessation of inspiration with deep palpation in the right upper quadrant) [20]. Objective markers included an elevated White Blood Cell (WBC) count, fever or an elevated C-Reactive Protein (CRP) as well as imaging findings of AC. Characteristic findings on ultrasound or CT include gallbladder wall thickening and the presence of peri-cholecystic fluid or gallstones. An alternative diagnostic test is the Hepatobiliary scan. Hepatobiliary (HIDA) in which an ejection fraction <35% or non-visualization of the cystic duct and gallbladder after a defined time period is considered diagnostic of acute cholecystitis. while Hepatobiliary (HIDA) scans have a positive predictive value and negative predictive value of >90%, severe comorbidities, especially hepatic disease, can frequently cause false positives, rendering the test less sensitive in critically ill patients [20]. Additionally, Hepatobiliary (HIDA) scans are not bedside procedures and therefore may be impractical to administer to critically ill patients, particularly if they are ventilator-dependent and cannot be transported safely from the intensive care unit setting for imaging [21,22].

In our study, patients largely underwent RUQ ultrasounds followed by Hepatobiliary (HIDA) scans to confirm acute cholecystitis. CT scans were not included within the study because they were rarely performed in our studied patient population (n=3). Therefore positive predictive value and negative predictive value of CT scans cannot be commented on based on our available data. In our study Hepatobiliary (HIDA) scans were the most sensitive marker (positive predictive value 93%) for diagnosing acute cholecystitis. However, in the group of 20 patients who did not have acute cholecystitis suspected on PC placement, 5/19 (26.3%) did have positive Hepatobiliary (HIDA) scans. This suggests Hepatobiliary (HIDA) scan, while sensitive for predicting acute cholecystitis in ICU patients with a non-biliary diagnosis are not the most specific test for this patient population. Additionally, one patient was found to have acute cholecystitis suspected on PC placement despite a normal Hepatobiliary (HIDA) scan. Conversely, jaundice, while having a very low positive predictive value (2%), had the highest negative predictive value (95%) of any diagnostic test for acute cholecystitis in our study population.

Our findings show no single test accurately confirms acute cholecystitis in the studied patient population. Hepatobiliary (HIDA) scans had the highest positive predictive value of our tested diagnostic markers but also resulted in some false positive results. However, given the high morbidity and mortality associated with untreated acute cholecystitis or an emergent cholecystectomy, acceptance of some false positives may be necessary to avoid the risk of missing this disease process in critically ill patients. Emergent cholecystectomies in the critically ill patient population is associated with mortality as high as 14-19% [2].

Multiple studies have established the use of PC as a safe alternative therapy for acute cholecystitis. The reported recurrence of acute cholecystitis after PC varies widely in the literature with anywhere from 14%-61% of patients failing to experience a complete resolution of their symptoms [9-12]. Initial clinical improvement and resolution of symptoms is often reported to be quite high, with up to 80-90% of patients reporting an improvement of their symptoms within the first 2-5 days [11,12]. Rates of interval laparoscopic cholecystectomy after PC placement range from 30-80%, with most studies reporting between 30-60% of patients initially treated with PC subsequently requiring either an emergent or elective cholecystectomy [23-25]. Conversion rates to open cholecystectomy have been reported as high as 32% [24,25]. A study by Bickel and associates comparing the rate of conversion to open cholecystectomy after early (within 2 days of symptom onset) and late (3-6 days post symptom onset) PC placement found that the early PC group had a significantly lower conversion rate (8.3%) compared to the delayed PC placement group (33.3%) [24].

Ours was the first study to establish evidence-based criteria for the placement of percutaneous cholecystostomy in critically ill patients without a primary biliary disease. An inherent limitation exists in the specific nature of our inclusion criteria which reduces the potential study population size. Additionally, as we have no institutional algorithm in place for diagnosing acute cholecystitis, we were restricted to using conditional criteria such as positive cultures and cystic duct visualization during cholecystostomy tube placement. This limits the conclusions that can be drawn regarding the utility of individual diagnostic markers in identifying acute cholecystitis. Further research that includes a larger study population and uniform use of diagnostic markers is needed to determine if there is an optimal combination of diagnostic testing that can be used to confirm the diagnosis of acute cholecystitis and to determine which ICU patients would truly benefit from a percutaneous cholecystostomy. Additional limitations of this study include our inability to capture complications that might have been addressed at outside hospitals. Although we tracked records for patients at least 90-days after their admission for PC placement, we also cannot reliably confirm if patients underwent subsequent cholecystectomy in a large number of cases where patients if performed at an outside facility or if the surgical cholecystectomy was not mentioned in subsequent visits. Additionally, the retrospective nature of study results in incomplete data acquisition for some patients.

Conclusion

Hepatobiliary (HIDA) scans are the most sensitive test for confirming acute cholecystitis in critically ill patients. However, the Hepatobiliary(HIDA) has a low sensitivity for this patient population. Our current clinical recommendation is that a combination of biochemical criteria, as well as an ultrasound and Hepatobiliary (HIDA) scan be used to confirm acute cholecystitis in the ICU patient population. The risk of percutaneous cholecystostomy is negligibly low in comparison to the very high risk of a missed diagnosis of acute cholecystitis. As such, focus should be on avoiding a missed diagnosis and the potentially devastating sequelae of acute cholecystitis.

Compliance with Ethical Standards

Disclosure of Potential Conflicts of Interest: All authors declare no conflict of interest. Ethical approval: This article does not contain any studies with human participants or animals performed by any of the authors.

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