

Ultrasound in Emergency Medicine



THE ABSENCE OF GALLSTONES ON POINT-OF-CARE ULTRASOUND RULES OUT ACUTE CHOLECYSTITIS

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Abstract—Background: Cholelithiasis affects an estimated 20 million people in the United States yearly; 20% of symptomatic patients will develop acute cholecystitis (AC). A recent single-center study estimating test characteristics of point-of-care ultrasonography (POCUS) for the detection of AC, as defined by gallstones plus sonographic Murphy's or pericholecystic fluid or gallbladder wall-thickening, resulted in a sensitivity and specificity of 87% (95% confidence interval [CI] 66–97) and 82% (95% CI 74–88), respectively. No prior studies have been conducted to estimate the test characteristics of POCUS for the purpose of excluding acute calculous cholecystitis. **Objective:** To determine whether the finding of gallstones alone on POCUS has high sensitivity, high negative predictive value, and low negative likelihood ratio for the exclusion of AC. **Methods:** We conducted an analysis using data from a prospective cross-sectional single-center study of POCUS test to estimate the test characteristics using a simplified definition of a positive test – the presence of gallstones alone. **Clinical follow-up and pathology reports** were used as the reference standard. Test characteristics were calculated and compared to the standard definition, gallstones plus one secondary finding. **Results:** The overall prevalence of AC was 14% (23 pathology-confirmed cases of 164 included patients). The sensitivity of the simplified definition was 100% (95% CI 85.7–100), negative predictive value 100% (95% CI 92.2–100), and negative likelihood ratio was < 0.1, compared to a sensitivity of 87% (95% CI 66–97%), negative predictive value 97% (95% CI 93–99%), and negative likelihood ratio of 0.16 (95% CI 0.06–0.5).

Conclusion: Simplifying the definition of the test findings on POCUS to gallstones alone has excellent sensitivity and negative predictive value for the exclusion of AC. This finding, if broadly validated prospectively, confirms the practice of excluding acute calculous cholecystitis using POCUS in emergency department patients. © 2015 Elsevier Inc.

Keywords—cholelithiasis; acute cholecystitis; emergency ultrasound; screening; abdominal imaging

INTRODUCTION

Cholelithiasis is a highly prevalent condition, with an estimated 20 million people in the United States afflicted yearly (1). Of symptomatic patients, 20% will develop acute cholecystitis (AC), accounting for 3% to 9% of hospital admissions for acute abdominal pain (1–3). Point-of-care ultrasound (POCUS) of the gallbladder traditionally focuses on the detection of gallbladder inflammation and biliary obstruction, using the presence of gallstones plus secondary signs, including increased wall thickness > 3 mm, pericholecystic fluid, and sonographic Murphy's sign (4). The addition of a secondary sign in the definition of a positive test is important to increase the specificity of the study to accurately identify those with gallbladder inflammation. A recent prospective study by Summers et al. estimated the test

characteristics of POCUS for the diagnosis of AC, using this traditional definition of a positive test (5). When compared to the pathological reference standard, the traditional definition yielded a sensitivity and specificity of 87% (95% confidence interval [CI] 66–97) and 82% (95% CI 74–88), respectively, and had similar test characteristics to radiology-performed ultrasound (5).

It would be desirable to use POCUS as a screening test to exclude the diagnosis of acute cholecystitis rather than to rule in the diagnosis. Summers et al. reported a negative predictive value of 97% (95% CI 93–99%) and negative likelihood ratio of 0.16 (95% CI 0.06–0.5), which would suggest this as a reasonable approach (5). Prior studies of POCUS of the gallbladder have demonstrated a more modest sensitivity for AC (6–9). In a recent systematic review of point-of-care ultrasound for gallstones, the authors suggest that “a negative emergency ultrasonography result for gallstones ... implies that the emergency physician should consider another diagnosis” (10,11). However, the approach of using POCUS to exclude acute calculous cholecystitis has not been directly assessed.

We sought to estimate the test characteristics of a more simple definition of a positive test, gallstones alone, on POCUS for the presence of acute cholecystitis. We re-analyzed data from a previously published, prospective, cross-sectional study of POCUS for acute cholecystitis. We hypothesized that using a simplified definition would result in superior sensitivity, negative predictive value, and negative likelihood ratio, as compared to gallstones and the presence of a secondary sign. This would confirm the value of the POCUS as a screening test to exclude acute calculous cholecystitis.

MATERIALS AND METHODS

Study Design

We analyzed data previously collected in a prospective, cross-sectional, single-center study. Assessment of POCUS of the gallbladder for AC, as defined by gallstones plus at least one secondary sign, including sonographic Murphy’s sign, pericholecystic fluid, or gallbladder wall thickness > 3 mm, as compared to radiology-performed ultrasound, and to histopathology as the reference standard, was previously conducted. For the current study, we determined the test characteristics of POCUS when the presence of gallstones alone was considered a positive test. The study received Institutional Review Board approval.

Setting

The setting, participant selection, and interventions were previously described (5). Briefly, the study was conducted in an urban university hospital emergency department

(ED), with an annual patient census of 36,000, that supports both an emergency medicine residency-training program and an ultrasound fellowship.

Selection of Participants

A convenience sample of adult patients during business hours between May 2006 and February 2008 were enrolled. Patients 18 years or older who presented to the ED with suspected cholecystitis (right upper quadrant or epigastric pain, vomiting, or fever) were included. Subjects with risk factors for acalculous cholecystitis were not excluded.

Interventions

All subjects underwent POCUS of the gallbladder by the treating physician (attending physicians, ultrasound fellows, or residents), according to their usual practice. Of the 21 faculty, 10 are registered diagnostic medical sonographers (RDMS) certified in abdominal ultrasound. Emergency Medicine residents are required to complete 150 supervised biliary ultrasounds prior to graduation.

For the present analysis we defined POCUS as positive if gallstones were visualized, and negative if no gallstones were visualized. Secondary indicators of AC were ignored. The physicians were blinded to subsequent radiology ultrasound.

Clinical follow-up included phone calls and medical record review to identify patients who underwent a cholecystectomy within 2 weeks of the index visit. Operative and pathology reports were also reviewed as the reference standard for AC.

Outcomes

Patients were classified as positive for AC if they required a cholecystectomy during the index visit or within 2 weeks, and the pathology report was positive. Patients were classified as negative for AC if they had a negative pathology report, never underwent cholecystectomy, or if they underwent a cholecystectomy more than 2 weeks after the index visit. Cases in which pathology reported absence of gallstones, or choledocolithiasis, or cholelithiasis without cholecystitis, were also analyzed as negative.

Statistical Analysis

Primary data from the original study were obtained. Test characteristics of a simplified definition of a positive test were computed with conventional diagnostic test statistics and compared to the previously published test characteristics. Exact binomial distribution CIs were calculated for sensitivity, specificity, positive and negative predictive

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