A prospective cohort study of 200 acute care gallbladder surgeries: The same disease but a different approach

Narong Kulvatunyou, MD, Bellal Joseph, MD, Lynn Gries, MD, Randall S. Friese, MD, Donald Green, MD, Terence O'Keeffe, MD, Julie L. Wynne, MD, Andrew L. Tang, MD, *and* **Peter Rhee, MD,** *Tucson, Arizona*

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From the Division of Acute Care Surgery, Department of Surgery, University of Arizona, Tucson, Arizona.
Address for reprints: Narong Kulvatunyou, MD, Division of Acute Care Surgery, Department of Surgery, University of Arizona, 1501 N. Campbell Ave, Room 5411 PO Box 245603 Tucson, AZ 85727-5063; email: nkulvatunyou@surgery.arizona.edu.

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BACKGROUND: For patients who present to the emergency department (ED) with symptomatic cholelithiasis, surgery is indicated only if they are diagnosed of acute cholecystitis (AC). We hypothesized that, because preoperative signs and diagnostic tests are not sensitive enough to diagnose AC, coupled with the potential health care burden of non-AC gallbladder, surgery may be offered sooner.

METHODS: We prospectively evaluated 200 patients who presented to ED with clinical suspicion of gallbladder disease, including a right upper quadrant/epigastric abdominal pain and cholelithiasis, and who underwent laparoscopic cholecystectomy. We correlated the preoperative clinical findings, including ultrasonography results, with the surgeon's intraoperative assessment (OR-GB) and with the pathology report (PA-GB). A multiple logistic regression model was performed.

RESULTS: Of the gallbladders, 116 were declared AC by OR-GB but only 54 by PA-GB, ($r = 0.31$, $p < 0.001$). The median time to surgery was 17 hours; 75% of the patients underwent surgery within 24 hours. The sensitivity of ultrasonography for AC according to PA-GB was 38%, and 16% when combined all preoperative findings. Both figures dropped to 27% and 11% when correlated to OR-GB. Our regression identified persistent abdominal pain, positive ultrasonography result, and a body mass index of greater than 40 to be significant predictors of AC according to PA-GB; however, only the persistent abdominal pain remained significant according to OR-GB.

CONCLUSION: The study confirmed the lack of sensitivity of signs and diagnostic tools to diagnose AC. Because of the acute care surgery model, we believe that the approach to the patients who present to the ED with suspected gallbladder disease is to offer them surgery as soon as feasible, with or without AC. This approach will avoid an unnecessary delay as well as quickly relieve patient's pain and suffering; the health care system will benefit from a cost-effective reduction in number of outpatient referrals and repeated ED visits. (*J Trauma Acute Care Surg*. 2012;73: 1039–1045. Copyright © 2012 by Lippincott Williams & Wilkins)

LEVEL OF EVIDENCE: Diagnostic study, level II.

KEY WORDS: Acute care surgery; acute cholecystitis; gallbladder disease.

Traditionally, the general surgery approach to patients who present to the emergency department (ED) with suspected gallbladder disease (GBD) is to admit and provide "early" surgical intervention to those with acute cholecystitis (AC).[1] The "early" laparoscopic cholecystectomy is well supported by literature because it is safe and cost-effective.[2–6] However, those who do not have AC would be labeled as having symptomatic cholelithiasis and typically discharged and scheduled for later outpatient surgical follow-up.

However, this practice poses two dilemmas to our current health care environment. First, AC is not easily diagnosed and is, in fact, often underdiagnosed. The diagnosis is commonly based on the Tokyo guideline[7] using such clinical findings as right upper quadrant pain, tenderness, fever, leukocytosis, and a confirmatory test, which commonly is ultrasonography (e.g., presence of gallstones, ultrasonographic Murphy sign, thickened gallbladder wall, and pericholecystic fluid).[7–9] This preoperative diagnosis of AC is then later confirmed by the traditional criterion standard, the pathologic examination. If AC is not correctly diagnosed, patient would be labeled as mere symptomatic cholelithiasis and will often be discharged from the ED, with probability of a high likelihood of early return and/or increased morbidity.

The second dilemma is, even if patients do not have AC, the burden of non-AC (e.g., biliary colic, subacute, or chronic cholecystitis) still exists, for both patients and our health care system. It often results in recurrent abdominal pain, lost work, poor quality of life, and frequent ED visits.[10,11] The pain has already caused patients to visit the ED; by discharging such patients from the ED for outpatient follow-up will inevitably delay definitive treatment, fail to alleviate pain, and unnecessarily increase the use of healthcare resources.

Like many centers, our tertiary center has adopted the acute care surgery (ACS) practice[12–16] and thus always has an in-house surgeon readily available 24/7. Our operating rooms can accommodate most emergency and urgent cases at all hours. Our practice model has allowed us to challenge the current diagnostic and treatment algorithm for GBD. For the basis of this study, we hypothesized that neither the preoperative signs or diagnostic tests are reliable enough to diagnose AC nor do they correlate with the overall existence of GBD (AC or non-AC), using the standard pathology report (PA-GB) and the surgeon's intraoperative assessment (OR-GB).

PATIENTS AND METHODS

Our current ACS service policy has been to offer surgery during the same ED visit to any patient possibly with symptomatic from GBD—even in the absence of a clinical diagnosis of AC—so that future outpatient referrals or ED returns may be avoided. Our hospital is a tertiary care center with 73,000 ED patient visits annually. Our ACS team of surgical house officers includes a 24/7 in-house acute care surgeon (who is also responsible for all trauma activations, in-house intensive care unit coverage, and in-house general surgery consultation). Our ACS practice, established in 2009, is currently staffed by seven fully trained surgeons, all board certified in critical care.

Our study was approved by the institutional review board of the University of Arizona. From October 4, 2010, through August 9, 2011, we prospectively collected data on 200 consecutive patients who came to the ED with right upper quadrant or epigastric abdominal pain and underwent laparoscopic cholecystectomy. The data included patient demographics, body mass index (BMI), and details of the clinical findings, for example, the duration of the abdominal pain, its nature (intermittent or persistent), whether the abdominal pain was the first attack, any history of diabetes mellitus, any previous abdominal surgery, any fever (temperature > 38.5°C), and any right upper quadrant or epigastric abdominal tenderness. In addition, laboratory data included the absolute white blood cell count with evidence of leukocytosis (white blood cell count ≥ 10,500), liver function test, and ultrasonography results.

During our study, the daytime attending radiologist and the after-hours radiologist house officer both determined if ultrasonography result was read as AC, using the standard ultrasonographic findings of the presence of gallstones, ultrasonographic Murphy sign, thickened gallbladder wall (>3 mm), and pericholecystic fluid. In our study, 192 patients underwent ultrasonography; of the 8 who did not, 1 had a recent hepatobiliary iminodiacetic acid scan showing an ejection fraction of 4%, and the other had a computed tomographic scan showing gallstones with 2 read as AC. These eight patients were not included in our utility of the ultrasound correlation calculation.

We recorded the time from the patient's arrival in ED to the start of the operation. All operations were performed laparoscopically by a surgical resident (postgraduate year 2 through 6) supervised by the in-house attending surgeon. Intraoperatively, the operating surgeon assessed the gallbladder's appearance (OR-GB) as normal, acute (inflamed, edematous, with or without pericholecystic fluid or hydrops, with or without gangrene), or chronic (shrunken, with or without a thickened wall, scarring, or chronic adhesion). We later correlated OR-GB with the final pathology report (PA-GB).[17] We also recorded the hospital length of stay. All data were entered in a data form (Fig. 1).

STATISTICAL ANALYSIS

Continuous parametric data were expressed as the mean (SD), and nonparametric data were expressed as the median and interquartile range Categorical data were expressed as proportions. We performed between-group comparisons, using the Student's t test for continuous parametric data, the Wilcoxon rank-sum test for nonparametric data, and the χ^2 test for proportional data. We calculated the utility (sensitivity, specificity, negative predictive value, positive predictive value, and accuracy) for the clinical variables using the 2×2 table for both PA-GB and OR-GB. To correlate PA-GB and OR-GB findings, we used the Spearman rank coefficient statistical analysis. We then performed a stepwise multivariate logistic regression analysis to identify clinical predictors for AC, first according to PA-GB and then to OR-GB as our dependent variable. For the statistical analysis, we used STATA10 (College Station, TX); we considered a p value of ≤0.05 significant.

Clinical Predictors for Acute Cholecystitis **Date**_______

1. Age _____ 2. Sex_____ 3. MR______________ Height____Weight____
2. **Is abdominal pain persistent or intermittent?** _______________ Duration___days
   Is this the first attack….Yes…..if…..NO…..how many times___how long____(months)?
3. Diabetic Yes No 4. Previous abdominal surgery Yes No
4. Temperature:______°C
5. **RUQ Abdominal tenderness** Yes No
6. Leucocytosis: Yes No ______ Left shift: Yes No
7. Bilirubin:____
   ALP____ AST____ ALT_____
8. **Ultrasound** **Stones** Yes No **Sludge:** Yes No
   Wall thickness Yes No ___mm
   Peri-cholecystic fluid Yes No
   US Acute cholecystitis Yes No
   CT scan Wall thickness Yes No
   Peri-cholecystic fluid Yes No
   CT Acute cholecystitis Yes No
9. **OR Findings:** 0 Normal 1 Easy
   1 Chronic 2 Hard but not difficult
   2 Acute, acute on chronic 3 Difficult, close to open
   3 Acute with gangrenous (necrosis) 4 Open
10. Operating start time:___ Finished:_____ Duration____ ASA__ IOC Y / N
11. Operator: Attending PGY____

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Pathology 1 Chronic
2. Acute on chronic
3. Acute with gangrenous

Recorder:______________________

Figure 1. Data collection form.

RESULTS

Table 1 summarizes our patient demographics and clinical findings. The mean age was 38 years; the female-to-male ratio was 3:1. Interestingly, the traditional belief that only obese females in their 40s have the disease may be inaccurate: of the 155 females in our study group, 66% were younger than 40 years, and 45% were not obese (BMI < 30). Of all 200 patients, 130 (65%) had experienced more than one episode of abdominal pain. All 200 underwent attempted laparoscopic cholecystectomy; only 5% required conversion to open surgery. The median time to surgery was 17 hours; 75% underwent surgery within 24 hours; and 13% underwent surgery between midnight and 7:00 AM. Table 2 compares OR-GB and PA-GB. The Spearman correlation coefficient was 0.31 ($p < 0.001$). Of note, surgeons assessed 26 gallbladders as normal, but the final pathology report deemed all of these as abnormal. Table 3 shows the utility of the typical preoperative clinical findings to diagnose AC, correlated with the final diagnosis of AC using the standard PA-GB or the surgeon's impression, OR-GB. We did not include fever because none of our patients had a fever. Positive ultrasonography result alone showed a low sensitivity for AC according to PA-GB (38%) and lower when combined with all clinical parameters (16%). Both of those percentages dropped further when we correlated with OR-GB (27% and 11%, respectively).

Our regression analysis is summarized in Table 4 (univariate) and Table 5 (multivariate). Persistent abdominal pain, positive ultrasonography, and, in particular, BMI greater than 40 were significant predictors for AC, when we used AC according to PA-GB as the dependent variable (Table 5). However, when we adjusted to AC according to OR-GB, only persistent abdominal pain remained a significant predictor (odds ratio, 4.62; 95% confidence interval, 1.28–13.9; p = 0.019) (data not shown).

DISCUSSION

The study finding confirmed our hypothesis of the lack of sensitivity among commonly used clinical parameters in diagnosing AC, whether according to the criterion standard pathologic examination or according to surgeon's intraoperative assessment. The sensitivity of all the clinical parameters worsened when we combined all the parameters. The sensitivity of ultrasonography, in particular, was quite low (38%) according to PA-GB (and lower according to OR-GB, 27%)—a surprising and concerning finding, considering that ultrasonography is commonly used to screen for AC. We believe that the percentages we found are more realistic (as compared with other studies) of the true diagnostic value of ultrasonography for AC. The literature has traditionally reported the sensitivity of ultrasonography in diagnosing AC as ranging from 79% to 94%,[18,19] but those percentages suffer from what most researchers refer to as a "verification bias."[9] When only patients with positive ultrasonography results undergo surgery, the value of ultrasonography is falsely elevated. However, in our study, we were more likely to take patients to surgery despite ultrasonography result being negative for AC. In a study similar to ours, Bingener et al.[20] reported the sensitivity of

TABLE 1. Patient Demographics (N = 200)

Age, mean (SD), y	38 (16)
Sex (female: male)	3.4: 1
BMI, mean (SD)	32 (7)
Duration of abdominal pain, median (95% CI), d	1 (1–2)
More than one episode of pain, n (%)	135 (65)
History of diabetes mellitus, n (%)	20 (10)
Abdominal tenderness, n (%)	166 (83)
Time from ED to surgery, median (95% CI), h	17 (12–25)*
ASA classification, median (95% CI)	2 (2–2)
Intraoperative cholangiogram, n (%)	17 (9)
Conversion to open surgery, n (%)	10 (5)
Length of stay , median (95% CI), d	2 (1–2)

*150 patients (75%) underwent surgery within 24 hours; 26 patients underwent surgery between midnight and 7:00 AM.
ASA, American Society of Anesthesiologists; CI, confidence interval.

TABLE 2. Intraoperative Assessment (OR-GB) Versus Pathology Report (PA-GB)

	N = 200	
	OR-GB	PA-GB
Normal gallbladder	26	0
AC	116	54
Gangrene	8	7
Chronic cholecystitis	58	146

TABLE 3. Utility of Clinical Findings for Diagnosing AC Using Pathology (PA-GB) or Surgeon's Intraoperative Assessment (OR-GB)

Per Pathology AC Finding (PA-GB) (n = 54)					
	Sensitivity, %	Specificity, %	PPV, %	NPV, %	Accuracy, %
Persistent abdominal pain	80	49	36	87	57
Abdominal tenderness	91	20	30	85	39
Leukocytosis	61	62	38	81	62
US	38	90	59	81	77
Leukocytosis + US	24	94	60	78	76
All combined	16	97	67	77	76
Per intraoperative AC assessment (OR-GB) (n = 116)					
	Sensitivity, %	Specificity, %	PPV, %	NPV, %	Accuracy, %
Persistent abdominal pain	71	57	69	59	65
Abdominal tenderness	88	24	61	59	61
Leukocytosis	52	68	68	50	58
US	27	96	100	50	57
Leukocytosis + US	17	99	95	47	52
All combined	11	100	100	45	49

NPV, negative predictive value; PPV, positive predictive value; US, ultrasonography.

TABLE 4. Univariate Analysis of Clinical Variables as a Predictor of AC Per Pathology Report (PA-AC)

	Non-AC (n = 146)	AC (n = 54)	p
1. Age, mean (SD), y	37 (1.3)	42.0 (2.2)	0.08
2. Sex, male	0.18	0.33	0.026
3. BMI, mean (SD)	31 (0.5)	34 (1.1)	0.027
4. Duration of abdominal pain, median (95% CI), d	1 (1–3)	1 (1–2)	0.98
5. First attack	0.33	0.39	0.45
6. History of diabetic mellitus	0.08	0.17	0.056
7. Persistent abdominal pain	0.51	0.80	<0.001
8. Abdominal tenderness	0.8	0.9	0.076
9. Leukocytosis	0.4	0.6	0.003
10. Left shift	0.4	0.6	0.0158
11. Elevated bilirubin	0.1	0.09	0.83
12. Elevated ALP	0.12	0.06	0.20
13. Elevated AST	0.38	0.19	0.008
14. Elevated ALT	0.32	0.13	0.008
15. US positive for AC	0.09	0.38	<0.001
16. ASA classification, median (95% CI)	2 (1–2)	2 (2–3)	0.01
17. Duration of surgery, mean (SD), min	84 (3)	99 (5)	0.007

ALP, alkaline phosphatase; ALT, alanine transaminase; ASA, American Society of Anesthesiologists; AST, aspartate transaminase; CI, confidence interval; US, ultrasonography.

ultrasonography for AC to be 52%; it was higher (60%) when adjusted for AC according to OR-GB. In contrast, Al-azawi et al.[21] reported the sensitivity of ultrasonography to be only 27%, with a much higher sensitivity (73%) using clinically based diagnoses.

Several studies[22–24] suggested that the value of any diagnostic test (Bayes' theorem) depended on the likelihood ratio (LR) of the test. In our study, the LR for positive ultrasonography finding in diagnosing AC with leukocytosis was 4; and without leukocytosis, 4.3. The rule of any diagnostic test to be of clinical value is that it should have LRs greater than 10 so that it can change the pretest probability significantly, especially when the pretest probability is low. However, when the diagnostic test has LRs between 2 and 5, the clinical diagnostic significance is less because it generates only small changes in the pretest probability.[22]

Most AC studies always diagnosed AC according to the pathology (PA-GB) as a criterion standard. We however found significant discrepancy in AC between PA-GB and OR-GB. There were some previous studies[20,25] that agreed with our notation. Our correlation coefficient was 0.31; that of Bingener et al.[20] was 0.6. Fitzgibbons et al.[25] also concluded that pathology reports poorly correlate with OR-GB and expressed uncertainty about using pathology reports to identify which patients really need surgery. We certainly think that OR-GB provide a different perspective in assessing the presence of GBD. Even when patients turn out not to have AC, the presence of chronically inflamed, scarring, and adhesive gallbladder certainly explains why some patients have recurrent symptoms.

In our regression model using AC according to PA-GB as the dependent variable, we found that persistent abdominal pain, positive ultrasonography result, and BMI greater than 40 were significant predictors of AC. Several other studies[26–28] found that older age (>60 years), comorbidities (e.g., diabetes, cerebrovascular accident, and coronary artery disease), and male sex were risk factors for AC. Lee et al.[28] found that BMI of 25 or lower was a risk factor for AC. However, we do not believe that those studies are comparable. First, in most of those studies, the population was homogeneously Asian; ours was mostly whites and Hispanics. Second, in most of those studies, the population was older, mostly male, with a nonspecified clinical setting; ours was younger and mostly female, with the clinical setting specified as the ED. When we adjusted the model to AC according to OR-GB, we found that only persistent abdominal pain remained significant. Thus, in this situation where our patients had significant abdominal pain that caused them to come to ED and not wait for a clinic visit and when most clinical findings are not reliable for diagnosing AC, the symptom of persistent abdominal pain coupled with the presence of gallstones may alert surgeons to the likelihood of AC, at least by OR-GB, and that surgical intervention is warranted.

We emphasized our outcome analysis focusing on AC, yet we also want to emphasize the burden of non-AC GBD. As we have alluded in our introduction, this group of patients also deserves surgery to alleviate their pain. Most contemporary gallbladder studies[29–34] analyzed factors that would predict the severity of AC gallbladder, but none looked at severity of non-AC GBD. A conversion to an open surgery is certainly one way to gauge the severity and chronicity of the GBD. In our study, of the 10 patients who received conversion to an open surgery, 3 were from non-AC, while 7 were from AC (3 gangrenous). Our 5% conversion rate is well within 3% to 11% often reported in the contemporary literature for AC.[35–38]

We had no significant delay to surgery in our patient population. Because of our ACS setup, we were able to take the patients to surgery sooner. Our median time to surgery was 17 hours, and 75% of them underwent surgery within 24 hours. The most recent population-based study by Banz et al.[6] on AC concluded that delaying surgery for patients with AC will only increase the conversion rate, the rate of postoperative complications, and the length of hospital stay. Interestingly, in the study of Banz et al., only 35% of the patients underwent surgery within 24 hours, compared with 75% in ours.

Most of the current literature[2–6,35–39] supports hospital admission and early surgery for AC because it is safe[2–6,37–38] and cost-effective.[39] However, we have shown that the clinical findings are not sensitive at diagnosing AC. Many patients would be underdiagnosed. At the same time, there is no

TABLE 5. Multivariate Analysis of Independent Variables as a Predictor of AC

	OR	p
1. BMI > 40, OR (95% CI)	5.81 (1.95–17)	0.002
2. Persistent abdominal pain, OR (95% CI)	2.48 (1.03–6.0)	0.043
3. US, OR (95% CI)	4.39 (1.68–11.4)	0.003

CI, confidence interval; OR, odds ratio; US, ultrasonography positive for AC.

current standard to diagnose the existence and the severity of non-AC GBD. Greiner et al.[40] in their study of the value of diagnostic test concluded that in dealing with any disease that is so prevalent, in this case a GBD, a false-negative result can be costly (the cost is increased complication, persistent abdominal symptoms, unnecessary and frequent ED visits, time loss from work, etc.), and a really sensitive diagnostic test is needed. Currently, of course, we have no such sensitive diagnostic test for GBD, especially AC. A hepatobiliary iminodiacetic acid scan might improve diagnostic sensitivity for AC, but neither the test is practical and readily available nor it can assist with identifying the existence or the severity of non-AC GBD.

Assuming patients did not have AC, we would label them as having symptomatic cholelithiasis, give them pain medication and discharge them from the ED, and refer them for a later elective surgery. Certainly, this was a viable option in the past or maybe the only option in some setting. However, the situation is inefficient and costly to our health care system.[10,11] That additional office visit to arrange for an elective cholecystectomy can accrue significant monetary and time losses. At our facility, the physician fee normally charged for a new clinic visit, using Coding Procedure Terminology 99204, is $428. Our hospital charges a facility fee of $138. The total cost for our non-AC patients—supposedly 146 in our study—for a repeated office visit would have been an additional $82,636 (not even counting other added costs, like laboratory fees, parking fees, etc.). We agree with David B. Hoyt, MD, the executive director of the American College of Surgeons, regarding the future delivery of health care. He stated that, "Future healthcare services and products should have proven benefits for patients and [be] cost-effective" and that "the overall objectives should be not only improving quality but [also] reduce cost."[41] The application of our acute care gallbladder surgery model to ED patients with possible GBD would definitely improve the quality of care as well as reduce the costs.

There are some exploring the advantages and disadvantages and the need for regionalized ACS service. This study would probably argue in favor because it improves efficiency of health care delivery. Patients can get their surgery faster and safely through the night than having to wait the next day or be rescheduled as an elective. The efficiency on not having to add on cases to the next day busy operating room schedule has been a reason for our hospital to adopt this policy. Before the development of ACS service, symptomatic patients who wanted surgery had to wait until the next day to be added on at the end of the day when there was operating room availability. In addition, since the anesthesia department deemed these cases as being nonurgent, patients were frequently delayed for days awaiting availability of the operating room. Moreover, not being able to diagnose these patients with symptomatic cholelithiasis as having AC often meant that the anesthesia staff often refused to do these cases in the middle of the night when it was non–life threatening. The development of ACS toward GBD meant that we now have support from the anesthesia staff to allow non–life-threatening cases to be done in the middle of the night (13% in our study), and the hospital has supported this idea wholeheartedly as operating room staff and anesthesiologists who are already in the hospital covering trauma could be used instead of them sleeping.

The main strengths of our study are its prospective nature and the minimization of any aspects of "verification bias" of the diagnostic tests. Our study however has some weaknesses. First, our justification for surgical intervention was based on patient's symptom, later confirmed by pathologic or intraoperative assessment. Despite having no normal gallbladder based on pathologic examination, the true benefit of surgical intervention can only be confirmed by patient extended follow-up, in which we do not have. Any claims we made based on OR-GB would be subjective and subjected to variation among the assessors. Moreover, we only focused on treating AC; we did not discuss other postoperative complications; however, we think that these have been extensively discussed previously.[35–38]

In conclusion, neither the available diagnostic tools are sensitive enough to identify patients with AC according to pathology nor are they predictive of what surgeon may find intraoperatively. Thus, we believe that when patients present to ED with suspected GBD, early surgery is warranted. Not only this approach will relieve patient from symptoms and other possible complications of AC but also the health care system will benefit from a cost-effective reduction in outpatient referrals and in multiple repeated ED visits.

AUTHORSHIP

N.K and P.R designed this study. N.K. searched the literature and collected data, which were analyzed by N.K., B.J., L.G., and P.R. All authors participated in data interpretation and article preparation.

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DISCLOSURE

The authors declare no conflicts of interest.

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