

A Prospective Randomized Study of Clinical Assessment versus Computed Tomography for the Diagnosis of Acute Appendicitis

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ABSTRACT

Background: The objective of this study was to determine if routine use of computed tomography (CT) for the diagnosis of appendicitis is warranted.

Methods: During a one-year study period, all patients who presented to the surgical service with possible appendicitis were studied. One hundred eighty-two patients with possible appendicitis were randomized to clinical assessment (CA) alone, or clinical evaluation and abdominal/pelvic CT. A true-positive case resulted in a laparotomy that revealed a lesion requiring operation. A true-negative case did not require operation at one-week follow-up evaluation. Hospital length of stay, hospital charges, perforation rates, and times to operation were recorded.

Results: The age and gender distributions were similar in both groups. Accuracy was 90% in the CA group and 92% for CT. Sensitivity was 100% for the CA group and 91% for the CT group. Specificity was 73% for CA and 93% for CT. There were no statistically significant differences in hospital length of stay (CA = 2.4 ± 3.2 days vs. CT = 2.2 ± 2.2 days, $p = 0.55$), hospital charges (CA = $\$10,728 \pm 10,608$ vs. CT = $\$10,317 \pm 7,173$, $p = 0.73$) or perforation rates (CA = 6% vs. CT = 9%, $p = 0.4$). Time to the operating room was shorter in the CA group, 10.6 ± 8.4 h vs. CT, 19.0 ± 19.0 h ($p < 0.01$).

Conclusions: Clinical assessment unaided by CT reliably identifies patients who need operation for acute appendicitis, and they undergo surgery sooner. Routine use of abdominal/pelvic CT is not warranted. Further research is needed to identify sub-groups of patients who may benefit from CT. Computed tomography should not be considered the standard of care for the diagnosis of appendicitis.

THE DIAGNOSIS OF APPENDICITIS remains a clinical dilemma. Reliance on clinical examination with complimentary use of laboratory tests is a time-honored means of diagnosing acute appendicitis. Traditionally, surgeons have operated with a degree of uncertainty, tol-

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Presented at the 112th Annual Session of the Southern Surgical Society, December 5, 2000.

erating a number of nontherapeutic appendectomies because of the increased morbidity and mortality associated with delay in diagnosis and consequent perforation [1,2]. This approach has yielded accuracy rates between 80% and 87% [3-5]. Lower accuracy has been reported in women of childbearing age, and at both extremes of age regardless of gender [6-9]. The use of computed tomography (CT) has been studied [10-16], with some series reporting the accuracy of appendiceal CT to be more than 95% [17-19]. Studies have concluded that CT assists in the diagnosis of appendicitis in patients with atypical or nonspecific findings on clinical examination [6,20,21]. Rao et al. advocate routine use of CT for diagnosis in all patients suspected of having acute appendicitis [19].

These studies compared accuracy rates before and after introduction of appendiceal CT in a retrospective manner, or characterized prospectively how clinical decision-making was improved by the routine use of appendiceal CT. To date there have been no prospective randomized studies directly comparing clinical assessment (CA) alone to CT for the diagnosis of appendicitis. In our study, we hypothesized that use of CT for the diagnosis of acute appendicitis would not benefit all patients, but may improve accuracy in certain patients, specifically, women of childbearing age.

MATERIALS AND METHODS

Study population

All patients presenting to the Emergency Department with a possible diagnosis of acute appendicitis between November 1998 and October 1999, at the University of Miami/Jackson Memorial Hospital, were evaluated for inclusion in the study. The institutional review board approved the experimental protocol. All patients were at least 18 years old and gave informed consent. Patients were excluded if they were awaiting interval appendectomy, were unable to receive intravenous contrast, were HIV-seropositive, were pregnant, or had unreliable clinical examinations (e.g., taking

steroids, known inflammatory bowel disease, sickle cell disease).

Experimental design

All patients were evaluated by the surgical team, consisting of junior (R2) and senior (R3 or R4) surgical residents overseen by an in-house surgical attending physician, prior to diagnostic work-up. Each patient was assigned a score by an attending, fellow, chief, or senior resident using the Alvarado scoring system [22] (Table 1).

Utilizing the Alvarado score, we categorized patients in one of three groups based on the patients probability of having appendicitis (Table 2).

All patients were admitted to the surgical service and monitored with serial physical and laboratory examinations until there was resolution of symptoms, another diagnosis was confirmed (e.g., pelvic inflammatory disease, pyelonephritis, cholecystitis), or appendectomy was performed. Those patients who were discharged without appendectomy were followed at one week with a telephone call.

CT technique

Computed tomographic scans were performed on a helical GE Hi-Speed Advantage Scanner (GE Medical Systems, Milwaukee, WI) after oral administration of 30 mL of diatrizoate meglumine/diatrizoate sodium solution (Gastrografin®; Amersham Health, Piscataway, NJ) diluted in three cups of water. No rectal contrast was administered. All patients received a 125-mL intravenous bolus of 68% ioversol in-

TABLE 1. ALVARADO SCORE FOR THE DIAGNOSIS OF ACUTE APPENDICITIS [22]

	Score
Symptoms	
Migration	1
Anorexia	1
Nausea/vomiting	1
Signs	
Tenderness (right lower quadrant)	2
Rebound	1
Elevated temperature (>38.5°C)	1
Laboratory	
Leukocytosis	2
Left shift (polymorphonuclear leukocytes)	1
Total	10

TABLE 2. STRATIFICATION OF PATIENTS INTO RISK CATEGORIES FOR PURPOSES OF STUDY ENROLLMENT

1. Score >8 : High probability of having appendicitis. These patients had no further work-up, but proceeded to surgery, with pathological confirmation of appendicitis.
2. Score 2–8: Intermediate probability of having appendicitis. These patients were randomized to either CT or CA.
3. Score <2 : Low probability of having appendicitis. These patients had no further surgical evaluation, except for telephone follow-up to confirm the absence of appendicitis.

jection (Optiray®320, Mallinckrodt Inc, St. Louis, MO) injected at 2 mL/sec with a 40-sec delay. Axial images were obtained from the diaphragm through the pubic symphysis with a 7-mm collimation at a 1.5:1 pitch.

CT interpretation

Scans were interpreted by a senior radiology resident (PGY-3 or PGY-4) or a radiology attending. In some cases, the resident's interpretation of a "positive" scan was used to make the decision to operate during the night. Criteria for a "positive" study included pericecal fat stranding, a dilated appendix (>6 mm) with an enhancing rim, or pericecal soft tissue prominence. Scans were considered "negative" if there was an alternative diagnosis or none of the above findings.

Outcomes measures

The primary endpoint was the presence (confirmed by pathology) or absence of appendicitis; or confirmation for non-operative patients by lack of symptoms at one-week follow-up. We also noted the presence of gangrene, perforation, abscess, or phlegmon. We recorded the time from initial presentation to diagnosis, and to operation, as well as length of stay (LOS) for patients in both arms of the study. A cost analysis was performed based on the laboratory charges, CT charges, and LOS.

Statistical analysis

A target enrollment of 100 patients with an intermediate probability of having appendicitis (50/arm) was calculated based on estimates of

a 20% false-positive rate for CA, and a false-positive rate of 10% for CT to show statistically significant differences between groups (alpha error = 0.05, beta error = 0.20, Student's *t*-test power analysis formula). We also planned a subset analysis of women of childbearing age. Ultimately, one full year of data was collected prior to analysis, with a total of 182 patients randomized. Differences in means were evaluated using Student's *t*-test, and categorical variables were compared by Chi-square test. The data were analyzed on an IBM-PC computer using a STATISTICA software package (Statsoft, Tulsa, OK), with significance determined at $p < 0.05$.

RESULTS

Between November 1998 and October 1999, 102,000 patients were seen in our Emergency Department; 316 of these patients presented with right lower quadrant pain. One hundred thirty-four patients had an Alvarado score >8 and did not meet inclusion criteria (Table 3). These patients were taken to surgery without further diagnostic work-up. Two of these patients did not have appendicitis. There were no patients with a score <2 who presented to the surgical service for evaluation for appendicitis. One hundred eighty-two patients had Alvarado scores between 2 and 8. Ninety-seven patients were randomized to CT and 85 to CA. In the CT arm, 19 of 97 patients were excluded for various protocol violations, listed in Figure 1. Seventy-eight patients were available for final analysis. The mean time from presentation to the time CT scan was performed was 11.8 ± 10.1 h.

Of the 85 patients randomized to CA, 17 were excluded for protocol violations, listed in Figure 1. Sixty-eight patients were included in the final analysis. There were no statistically significant differences between the characteristics of the two groups (Table 4). The numbers of patients, sensitivity, specificity, and accuracy of CT and CA are listed in Table 5. The accuracy of CA and CT were 90% and 92%, respectively. Three patients randomized to CT had scans initially read as negative but were taken to surgery based on clinical judgement and had appendicitis. Three other patients had CT scans interpreted as positive for appendicitis: Two of those patients did not require surgery, and the

TABLE 3. INCLUSION/EXCLUSION CRITERIA

Inclusion criteria	Exclusion criteria
Admissions to ED presenting with possible acute appendicitis	Age <18 years
≥18 years of age	HIV-seropositivity
Alvarado score of 2–8	Awaiting interval appendectomy
Informed consent	Inability to receive IV contrast
	Pregnancy
	Unreliable clinical exam (e.g., steroid administration, known inflammatory bowel disease, sickle cell disease)

other had a negative laparotomy. The characteristics of these patients are shown in Table 6. The mean length of time from initial presentation to surgery for patients who received an appendectomy was 10.6 ± 8.4 h in the CA group compared with 18.7 ± 18.8 h in the CT group ($p < 0.01$). Hospital LOS was similar in both groups; being 2.4 ± 3.2 days for the CA group, compared to 2.2 ± 2.2 days in the CT group ($p = 0.55$). Mean hospital charges were $\$11,409 \pm 10,578$ for CA and $\$10,589 \pm 7,065$ for

CT ($p = 0.59$). One patient randomized to CA incurred charges of \$135,000 from a hospital stay of 30 days due to surgical wound complications after appendectomy. This patient was not included in the final cost and LOS analysis.

One-week telephone follow-up was attempted for the "negative" patients in both the CT and CA groups. Of 34 negative patients in the CT group who required telephone follow-up, 28 could not be reached. Six patients in this group reported no new abdominal pain. Of the

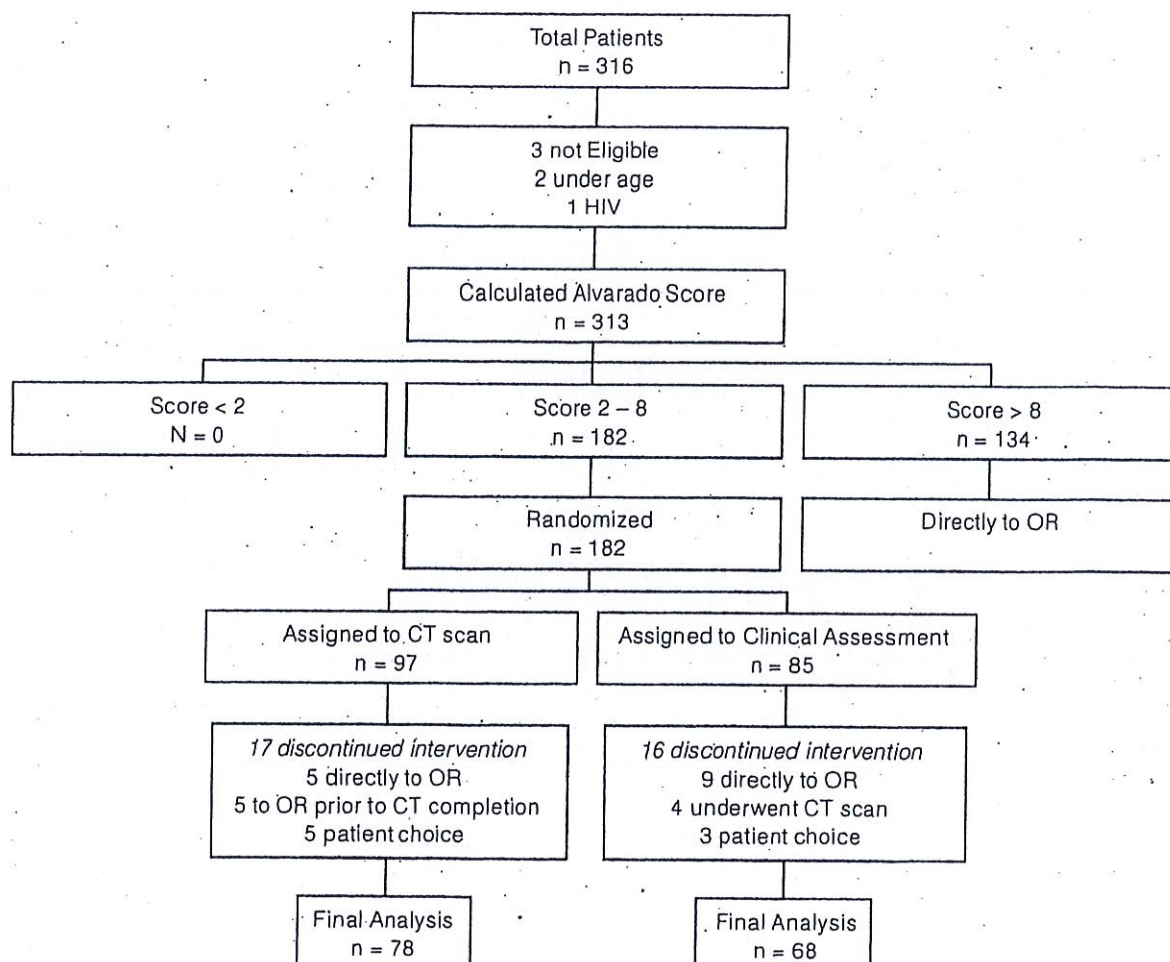


FIG. 1. Consort diagram.

TABLE 4. COMPARISON OF CHARACTERISTICS BETWEEN CT AND CA GROUPS

	CA (n = 68)	CT (n = 78)	p value
Age (years)	35 ± 14	34 ± 11	0.88 ^a
Male (%)	68%	51%	0.05 > p > 0.01 ^b
Alvarado score	6.2 ± 1.5	6.1 ± 1.6	0.57 ^a
Perforations	4 (6%)	7 (9%)	0.4 ^b
White blood cell count	13.9 ± 4.5	12.9 ± 4.6	0.21 ^a

^aby Student's *t*-test.^bby Chi-square for population proportions.

19 true-negative patients in the CA group, 10 could not be reached, seven were found to be without symptoms, and two were admitted with other diagnoses (upper GI bleeding and pancreatitis). None of the patients who could not be contacted returned to our emergency center.

A planned subset analysis was performed for the forty-eight women in the study who were of childbearing age (defined as ages 18 to 45 years). Twenty-nine patients were randomized to CT and 19 to CA. There was no difference in sensitivity and specificity in the two groups (Table 7). There were no statistically significant differences in charges between CT and CA (\$9,433 ± 7,700 vs. \$12,922 ± 11,621, *p* = 0.21) or mean LOS (2.0 ± 2.1 days vs. 2.3 ± 2.3 days, *p* = 0.68). In the women who went to the operating room, there was no statistical difference in time to surgery (27.4 ± 34.1 h vs. 10.8 ± 6.4 h, *p* = 0.12).

DISCUSSION

The diagnostic challenges posed by patients presenting with acute abdominal pain remain

an ongoing problem for the clinician. The surgeon is caught between the dangers of missing or delaying the diagnosis of appendicitis, and the risks of nontherapeutic surgery. If CT truly improves accuracy, it would be the solution to this clinical dilemma. Our study, the first prospective randomized comparison of clinical assessment versus CT, shows that CT did not increase the accuracy of clinical examination for the diagnosis of acute appendicitis. We found no benefit for the entire study population, even for the subset of women of childbearing age. These results are markedly different from other studies [9,21], none of which were randomized trials.

This discrepancy requires critical review of this study. We did not randomize all patients presenting with possible appendicitis. We did not include young children; they are not seen in our Emergency Department. Exclusion of very young children from our study, in whom the diagnosis is notoriously difficult, may have increased the accuracy of clinical examination. We did not include patients with known inflammatory bowel disease or HIV-seropositiv-

TABLE 5. SENSITIVITY, SPECIFICITY, AND ACCURACY IN BOTH GROUPS

Diagnostic test	Findings				p ^a	95% CI ^a
	(+)	(-)				
CT						
(+)	30	3	Sensitivity (30/33)	91%	0.165	-18 to -0.1%
(-)	3	42	Specificity (42/45)	93%	0.049	3-37%
Totals	33	45	Accuracy (72/78)	92%	0.895	-7 to 12%
CA						
(+)	42	7	Sensitivity (42/42)	100%		
(-)	0	19	Specificity (19/26)	73%		
Totals	42	26	Accuracy (61/68)	90%		

^ap values and confidence intervals comparing CT with CA.

TABLE 6. CHARACTERISTICS OF PATIENTS WITH FALSE-NEGATIVE AND FALSE-POSITIVE CT SCANS

False-negative CTs

1. 30-year-old male presented with right lower quadrant pain with anorexia, nausea, and vomiting. WBC was 6,000 on admission, and neutrophil differential was 60%. This patient was randomized to CT, which was read preliminarily as negative. Patient was taken to the OR based on the clinical assessment. Patient had acute appendicitis, confirmed by pathology.
2. 36-year-old male presented with right lower quadrant pain, anorexia, nausea, and vomiting. WBC was 13,000, and neutrophil differential was 82%. He was randomized to CT, which was read as negative for acute appendicitis. Patient was taken to the OR based on clinical assessment and had acute appendicitis confirmed by pathology.
3. 29-year-old male presented with right lower quadrant pain with rebound, anorexia, and vomiting. WBC was 10,000, and neutrophil differential count was 76%. He was randomized to CT, which was read as negative for appendicitis. He was taken to OR based on clinical assessment. He had acute appendicitis confirmed by pathology.

False-positive CTs

1. 51-year-old female presented with right lower quadrant pain, nausea, and vomiting. WBC was 13,000, and neutrophil differential was 85%. She was randomized to CT, which revealed fat infiltration around a distended, thick-walled appendix. Symptoms in the interim resolved and patient improved with no treatment. Patient discharged home without surgery and had no complaints at one-week follow-up telephone call.
2. 34-year-old female who presented with right lower quadrant pain, anorexia, nausea, vomiting, and fever. WBC was 12,000 and the neutrophil differential was 85%. She was randomized to CT, which was read by a senior resident at night to be positive for appendicitis. Patient was taken to the operating room based on reading. Attending radiologist revised reading as "adnexal cystic changes with some fat stranding." A normal appendix was found in the operating room—confirmed by pathology.
3. 31-year-old female, 10 days postpartum, who presented with right lower quadrant pain, rebound, and fever. WBC was 15,000, with a 92% differential count. She was randomized to CT scan, which revealed a questionable appendicolith. Patient was taken to the OR and found to have a normal appendix; the final diagnosis was puerperal sepsis.

ity, patients taking steroids, patients in sickle cell crisis, or patients with an unreliable clinical examination. We did not believe it was ethical to randomize these patients, for whom CT may be the only reliable means for diagnosis. In fact, one HIV-seropositive patient was screened for randomization, but was excluded. As part of our study design, we did not randomize patients who presented with the classic signs and symptoms of acute appendicitis (i.e., an Alvarado score of 9 or 10). We did not

believe these patients needed a CT scan to confirm the diagnosis; they were taken to surgery. By excluding this group of patients, we may have decreased the accuracy of clinical examination alone, while not affecting the accuracy of CT. We did not include patients with an extremely low likelihood of appendicitis (Alvarado score <2); they were not triaged for surgical evaluation. There was a disproportionate number of males in the CA group: 68% of patients in the clinical observation group were

TABLE 7. SENSITIVITY, SPECIFICITY, AND ACCURACY IN WOMEN OF CHILDBEARING AGE (18-45 YEARS)

Diagnostic test	Findings			
	(+)	(-)		
CT				
(+)	5	2	Sensitivity (5/5)	100%
(-)	0	22	Specificity (22/24)	92%
Totals	5	24	Accuracy (27/29)	93%
CA				
(+)	11	1	Sensitivity (11/11)	100%
(-)	0	7	Specificity (7/8)	88%
Totals	11	8	Accuracy (18/19)	95%

male, as compared to 51% in the CT group. This could potentially improve the accuracy of CA if difficult-to-evaluate females were predominantly in the CT group. Furthermore, our subset analysis demonstrated no difference in accuracy rates for CA and CT in women of childbearing age. Five patients randomized to have appendiceal CT were taken for surgery prior to the scan having been performed. Four patients randomized to CA erroneously had CT scans. These nine patients crossed-over between study groups, and may have potentially biased the study even though they were removed from analysis.

The results of our CT scans are based on scanning the abdomen and pelvis after oral and intravenous contrast with a 7-mm slice thickness. This yielded a 92% accuracy, comparable to other series [16,18,24]. We scan the entire abdomen and pelvis because there are many pathological conditions that mimic appendicitis which are not in the pelvis [18,20,21]. Including abdominal cuts has been shown to increase the overall sensitivity and the sensitivity for cases needing surgery (82–96%) [20]. The 7-mm slice collimation affords adequate coverage of the entire abdomen and pelvis. However, a narrower slice collimation could improve the detection of various structures such as the appendix and increase the sensitivity and accuracy of CT scans [20]. These results may also be biased by the fact that we did not use rectal contrast, which has a reported 100% sensitivity and accuracy for the detection of appendicitis [23]. However, we believe that the increased time and technical assistance necessary to perform CT with rectal contrast in our busy emergency/trauma center is not worthwhile. Many centers use unenhanced CT with variable results, with sensitivities ranging from 84% to 96% [18,24]. Our use of oral and intravenous contrast provides increased tissue discrimination, allowing for the diagnosis of diseases that may mimic appendicitis (e.g., pyelonephritis, ureteral colic, ovarian cysts, diverticulitis, and pelvic inflammatory disease). Such diagnoses can be found in almost 22% of patients initially evaluated for appendicitis [18,25].

The most common CT findings in patients with proven appendicitis are fat stranding (88–100%) and dilated appendices (47–100%)

[15,16,18,20,21,23,24]. An appendicolith (57%) and cecal changes (46–80%) are less common [15,20,23]. The absence of pericecal fat stranding does not always exclude appendicitis, especially if there is a dilated appendix. The evaluation of fat stranding is also difficult in patients with a paucity of intraperitoneal fat [18]. Review of the three false-negative CT scans demonstrated that none had fat stranding. One patient had no intraperitoneal fat, and thus the evaluation for fat stranding and an abnormal appendix was limited. Another patient had a normal-appearing appendix on CT. In the third case, a dilated appendix without associated fat stranding was noticed on review by the attending radiologist. The three false-positive cases included a scan with well-visualized fat stranding and a dilated appendix, and one scan with only a dilated appendix. Another case was read initially as a periappendiceal phlegmon by the resident. Upon attending review, a normal appendix was visualized along with the correct diagnosis of a right ovarian cyst, proven at surgery.

One-week telephone follow-up served to confirm true-"negative" appendicitis for both groups of patients. Because of the demographics of the patient population, few patients who are doing well, but who have not had surgery, return for follow-up clinic appointments. Sixty patients (41 in the CT group, 19 in the observation group) were discharged without appendectomy. Definitive follow-up was obtained in only 15 of these 60 patients. One could postulate that some of the remaining 45 "true"-negative patients had appendicitis, which was missed by CT or by clinical observation. However, none of them returned to our hospital, and we doubt they were seen elsewhere, as the majority of our patients use only our facility for emergency care.

One could legitimately comment on the length of time required to have a CT, 11.8 ± 10.1 h, as well as the length of time to have surgery, 10.6 ± 8.4 h vs. 18.7 ± 18.8 h for CA and CT, respectively. These figures represent reality at a major urban center. Fortunately, these delays did not translate into increased morbidity. The rates of perforation were unexpectedly low in both groups, 6% and 9% for observation and CT patients, respectively, much

lower than has been reported in other studies [2,3,14,15]. A likely explanation is that those patients with perforation had Alvarado scores >8 and were therefore taken to the operating room without randomization.

The hospital charge for both groups (approximately \$10,000) is substantially higher than reported previously [19]. We did not compare simple costs for emergency department evaluation (using CT) to costs for such things as hospital observation or unnecessary appendectomy to calculate projected savings. We recorded actual total hospital charges incurred for both groups because these charges were readily quantifiable. If we had attempted to use actual hospital cost, we would have had to resort to estimates.

A study that finds no difference between groups may always be accused of inadequate power (Type II error). We continued this study beyond the numbers initially dictated by our power analysis specifically to reduce potential beta error. We planned a subset analysis of women of childbearing age—the group we believed would most likely demonstrate benefit from use of routine CT—at the outset. Confirmation of the null hypothesis in this particular subset of patients warrants further study. This does not, however, diminish the identified lack of statistically significant difference between the two groups in our study population as a whole. Even with continuation of the study beyond the numbers dictated by the initial power analysis, there were minimal differences between CA and CT.

Clinical assessment yielded a 90% accuracy for the diagnosis of acute appendicitis, compared to 92% for CT. The greater sensitivity of clinical assessment (100% vs. 91%) makes it the ideal screening modality; the greater specificity of CT (93% vs. 73%) makes CT a useful diagnostic tool when CA is inadequate. Computed tomography is invaluable for patients with known diagnoses such as endometriosis, neutropenia, acquired immunodeficiency syndrome, and sickle cell crisis, and for patients taking high-dose steroids. The judicious use of CT scans has decreased the rate of negative appendectomy in several reports [13–16,19,26]. However, to state that appendiceal CT should be done routinely in

all patients with possible appendicitis is another matter [27]. The danger inherent in routine use of CT is that it rapidly becomes regarded as the criterion standard for the diagnosis of appendicitis. To insist that an otherwise healthy young male patient with the classic signs and symptoms of acute appendicitis must always have a CT to confirm the diagnosis prior to surgery is problematic. To imply that not obtaining a CT in that situation falls below the standard of care is incorrect. Our study suggests that, even when the presentation is equivocal, use of CT is not always indicated for the evaluation of right lower quadrant pain.

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