ORIGINAL ARTICLE

Ultrasonography versus Computed Tomography for Suspected Nephrolithiasis

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ABSTRACT

BACKGROUND

There is a lack of consensus about whether the initial imaging method for patients with suspected nephrolithiasis should be computed tomography (CT) or ultrasonography.

METHODS

In this multicenter, pragmatic, comparative effectiveness trial, we randomly assigned patients 18 to 76 years of age who presented to the emergency department with suspected nephrolithiasis to undergo initial diagnostic ultrasonography performed by an emergency physician (point-of-care ultrasonography), ultrasonography performed by a radiologist (radiology ultrasonography), or abdominal CT. Subsequent management, including additional imaging, was at the discretion of the physician. We compared the three groups with respect to the 30-day incidence of high-risk diagnoses with complications that could be related to missed or delayed diagnosis and the 6-month cumulative radiation exposure. Secondary outcomes were serious adverse events, related serious adverse events (deemed attributable to study participation), pain (assessed on an 11-point visual-analogue scale, with higher scores indicating more severe pain), return emergency department visits, hospitalizations, and diagnostic accuracy.

RESULTS

A total of 2759 patients underwent randomization: 908 to point-of-care ultrasonography, 893 to radiology ultrasonography, and 958 to CT. The incidence of high-risk diagnoses with complications in the first 30 days was low (0.4%) and did not vary according to imaging method. The mean 6-month cumulative radiation exposure was significantly lower in the ultrasonography groups than in the CT group ($P<0.001$). Serious adverse events occurred in 12.4% of the patients assigned to point-of-care ultrasonography, 10.8% of those assigned to radiology ultrasonography, and 11.2% of those assigned to CT ($P=0.50$). Related adverse events were infrequent (incidence, 0.4%) and similar across groups. By 7 days, the average pain score was 2.0 in each group ($P=0.84$). Return emergency department visits, hospitalizations, and diagnostic accuracy did not differ significantly among the groups.

CONCLUSIONS

Initial ultrasonography was associated with lower cumulative radiation exposure than initial CT, without significant differences in high-risk diagnoses with complications, serious adverse events, pain scores, return emergency department visits, or hospitalizations. (Funded by the Agency for Healthcare Research and Quality.)

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Pain from nephrolithiasis is a common reason for emergency department visits in the United States.[1,2] Abdominal computed tomography (CT) has become the most common initial imaging test for suspected nephrolithiasis because of its high sensitivity for the diagnosis of urinary stone disease.[3] However, CT entails exposure to ionizing radiation with attendant long-term cancer risk,[4-7] is associated with a high rate of incidental findings[8,9] that can lead to inappropriate follow-up referral and treatment,[10] and contributes to growing annual care costs for acute nephrolithiasis, which are currently approximately $2 billion in the United States.[1,2] No evidence has shown that increased CT use, despite its higher sensitivity, is associated with improved patient outcomes.[11,12] To assess the effect of diagnostic imaging techniques on patient outcomes, we conducted a multicenter, randomized trial comparing ultrasonography with CT.

Methods

Study Design and Randomization

Study patients were recruited in 15 geographically diverse academic emergency departments, four of which were safety-net hospitals (Table S1 in the Supplementary Appendix, available with the full text of this article at NEJM.org). Patients with suspected nephrolithiasis were randomly assigned, in a 1:1:1 ratio, to one of three imaging groups: ultrasonography performed by an emergency physician (point-of-care ultrasonography), ultrasonography performed by a radiologist (radiology ultrasonography), or abdominal CT. Patients were randomly assigned only during hours when all three imaging techniques were feasible. Randomization was performed with the use of the RANUNI function in SAS software at the study website. After assignment, the patients' care during the emergency department visit at the time of enrollment was managed at the discretion of the treating physicians, including decisions about further imaging and the treatment and disposition of the patients. The protocol and statistical analysis plan are available at NEJM.org.

Study Population

We enrolled patients from October 2011 through February 2013. Patients were identified according to their report of symptoms as recorded on the patient tracking board in the emergency department. Patients 18 to 76 years of age who reported flank or abdominal pain were eligible for entry into the study if the treating emergency physician decided to order imaging to establish or rule out a primary diagnosis of kidney stones. Patients whom the treating physician considered to be at high risk for serious alternative diagnoses, such as acute cholecystitis, appendicitis, aortic aneurysm, or bowel disorders, were not eligible, nor were pregnant women. Men weighing more than 129 kg (285 lb) and women weighing more than 113 kg (250 lb) were excluded, since the accuracy of imaging may be reduced in obese patients. Patients who had a single kidney, who had undergone renal transplantation, or who were undergoing dialysis were ineligible. The University of California, San Francisco, Committee on Human Research and the institutional review board at each participating site approved the study. All participants gave written informed consent.

Initial Imaging

Point-of-care ultrasound examinations were performed by emergency physicians who had had training as recommended by the American College of Emergency Physicians. Radiology ultrasound examinations were performed in radiology departments according to the guidelines of the Society of Radiologists in Ultrasound or the American Institute of Ultrasound in Medicine. CT was performed according to local standards. Patients and providers were aware of the imaging method to which the patients had been assigned.

Outcomes

The study had three primary outcomes: high-risk diagnoses with complications that could be related to missed or delayed diagnoses, cumulative radiation exposure from imaging, and total costs (not reported here). There were numerous secondary outcomes, which are described below. Patients were contacted at 3, 7, 30, 90, and 180 days after randomization to assess study outcomes and were surveyed with the use of a detailed structured interview regarding their health and all encounters they had with health care providers after randomization. Utilization of health care services, radiation exposure, and diagnoses were confirmed by means of a review of the medical records, performed by research coordinators at the participating sites.

High-risk diagnoses with complications were prespecified and were defined as any of the following diagnoses within 30 days after the emer-

gency department visit: abdominal aortic aneurysm with rupture, pneumonia with sepsis, appendicitis with rupture, diverticulitis with abscess or sepsis, bowel ischemia or perforation, renal infarction, renal stone with abscess, pyelonephritis with urosepsis or bacteremia, ovarian torsion with necrosis, or aortic dissection with ischemia.[13]

Cumulative radiation exposure was defined as the sum of the effective doses from all imaging that was performed within 6 months after randomization. We calculated the radiation dose from CT examinations on the basis of the dose-length product reported for each CT scan, which we converted to an effective dose using conversion factors,[14] with the results reported in millisieverts. When the dose-length product was not available (which was the case for 53 scans [2.2% of the 2369 CT examinations]), we used the average radiation dose on the basis of trial data. For the other types of imaging examinations, we estimated effective doses using a previously created map of doses for each type of examination.[15]

Analyses of costs, which are ongoing, are based on national Medicare reimbursements for costs associated with the emergency department visits.

Secondary outcomes were serious adverse events, serious adverse events related to participation in the study, return emergency department visits and hospitalizations after discharge from the emergency department, self-reported pain scores (as assessed on an 11-point visual-analogue scale, with higher scores indicating more severe pain), and diagnostic accuracy for nephrolithiasis. Serious adverse events were defined according to Food and Drug Administration standards as untoward medical occurrences that resulted in death, were life-threatening, required hospitalization, caused persistent or clinically significant disability, or required medical, surgical, or other intervention to prevent permanent impairment.[16] Events that occurred at the time of the emergency department enrollment visit were not counted as serious adverse events. Related serious adverse events, a subset of all serious adverse events, included events that were attributable to study participation — that is, randomization to one of the groups was deemed to have contributed to a delayed diagnosis or to have contributed to the event by altering management. These diagnoses included acute cholecystitis, appendicitis, and bowel obstruction. Three persons — the site principal investigator, the study principal investigator, and the chair of the data and safety monitoring board — adjudicated all 466 serious adverse events and independently rated each one as definitely, probably, or possibly related, unlikely to be related, or not related to the initial randomization; any differences among the adjudicators were resolved by discussion. Events that were classified as definitely, probably, or possibly related to the study assignment were considered to be related serious adverse events.

We assessed diagnostic accuracy for nephrolithiasis by comparing the baseline diagnosis at the time of discharge from the emergency department with the reference standard of confirmed stone diagnosis, with confirmation either by the patient's observation of the passage of the stone or by the patient's report that the stone had been removed surgically. We also assessed the accuracy of the first imaging test the patient underwent, according to the interpretation of the physician performing the test, who prospectively recorded whether the examination was consistent with nephrolithiasis.

STATISTICAL ANALYSIS

Statistical analyses were performed according to the intention-to-treat principle, except for the alternative method for calculating accuracy, which was limited to the first test a patient underwent. Continuous data are summarized as means and standard deviations. Baseline characteristics and outcomes were compared across study groups with the use of chi-square tests (for sex, age distribution, race or ethnic group, serious adverse events, hospital admission, emergency department readmission, sensitivity, and specificity), Fisher's exact test (for high-risk diagnoses with complications and related serious adverse events), and the Kruskal–Wallis test (for pain score, radiation exposure, and emergency department length of stay). Distributions for radiation exposure were right-skewed; therefore, we truncated at the 99th percentile before calculating means and standard deviations. Accuracy statistics were calculated according to standard definitions of sensitivity and specificity. As an additional analysis, outcomes were calculated with stratification according to status with respect to a history of nephrolithiasis. We included all patients in the primary analyses and, as a sensitivity analysis, calculated outcomes limited to patients for whom complete follow-up data were available. The study was designed to have 80% power to detect differences among study

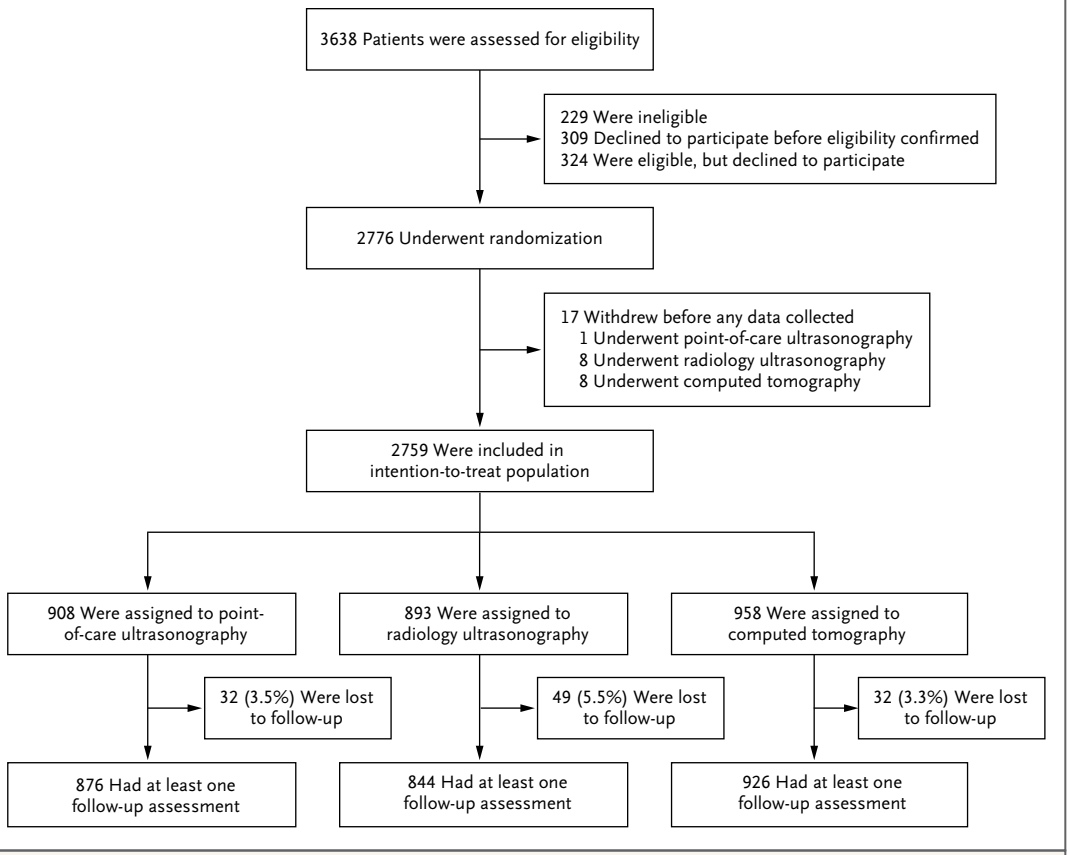

Figure 1. Screening, Randomization, and Follow-up.

groups of 5% for events with a prevalence of 10%, 0.34% for events with a prevalence of 0.5%, and 0.14 SD for radiation exposure. Our target sample size was 2500 patients. We used SAS software, version 9.4, for all the analyses.

RESULTS

PATIENTS

We screened 3638 patients, of whom 3100 were considered to be eligible. A total of 2776 patients underwent randomization; however, 17 of those patients were excluded before the baseline data collection (Fig. 1), with the result that data were collected for 2759 patients (89% of eligible patients). We randomly assigned 908 patients to point-of-care ultrasonography, 893 to radiology ultrasonography, and 958 to CT (Fig. 1). The baseline characteristics of the study population are shown in Table 1. The mean pain scores at enrollment and the proportion of patients admitted directly to the hospital from the emergency department did not differ significantly among the groups, suggesting that the severity of illness was similar in the three groups. A total of 113 patients (4.1%) were lost to follow-up, with no significant variation according to study group (Fig. 1).

The medical history, laboratory values, and physical examination findings for the enrolled patients and the emergency department physicians' assessment of the likelihood of various diagnoses are shown in Table 2. There were no significant differences according to study group. Overall, 41.6% of the patients had a history of kidney stones, 63.3% had hematuria, and 52.5% had costovertebral-angle tenderness, whereas a small minority had physical examination findings suggestive of acute cholecystitis (1.3%) or appendicitis (3.6%) or were judged by the enrolling physician to be at high risk for aortic aneurysm (0.8%), appendicitis (3.1%), or bowel obstruction or ischemia (3.6%).

Table 1. Baseline Characteristics of the Study Participants.*

Characteristic	Point-of-Care Ultrasonography (N=908)	Radiology Ultrasonography (N=893)	Computed Tomography (N=958)
Female sex — no. (%)	443 (48.8)	416 (46.6)	472 (49.3)
Age			
Mean — yr	40.1±12.4	40.4±12.8	40.7±12.8
Distribution — no. (%)			
18–30 yr	250 (27.5)	240 (26.9)	253 (26.4)
31–40 yr	222 (24.4)	223 (25.0)	231 (24.1)
41–50 yr	223 (24.6)	217 (24.3)	225 (23.5)
51–64 yr	197 (21.7)	191 (21.4)	221 (23.1)
65–76 yr	16 (1.8)	22 (2.5)	28 (2.9)
Race or ethnic group — no. (%)†			
Non-Hispanic white	369 (40.6)	369 (41.3)	390 (40.7)
Black	236 (26.0)	213 (23.9)	241 (25.2)
Asian	35 (3.9)	39 (4.4)	51 (5.3)
Native American	12 (1.3)	8 (0.9)	18 (1.9)
Pacific Islander	1 (0.1)	1 (0.1)	4 (0.4)
Hispanic	218 (24.0)	224 (25.1)	226 (23.6)
Mixed or other	32 (3.5)	33 (3.7)	23 (2.4)
Data missing	5 (0.6)	5 (0.6)	5 (0.5)
Self-reported pain score‡	8.3±2.0	8.0±2.4	8.1±2.2
Hospital admission directly from emergency department — no. (%)	73 (8.0)	77 (8.6)	86 (9.0)

* Plus–minus values are means ±SD. The data exclude the 17 patients who withdrew from the study after randomization but before any baseline data were collected. There were no significant differences among the groups in any characteristic listed here.
† Race or ethnic group was self-reported.
‡ Pain was assessed on an 11-point visual-analogue scale, with higher scores indicating more severe pain.

HIGH-RISK DIAGNOSES WITH COMPLICATIONS

High-risk diagnoses with complications during the first 30 days after randomization were recorded in 11 patients (0.4%) — 6 patients (0.7%) assigned to point-of-care ultrasonography, 3 (0.3%) assigned to radiology ultrasonography, and 2 (0.2%) assigned to CT — with no significant difference according to study group (P=0.30) (Table 3). Additional information on the patients who had high-risk diagnoses with complications is provided in Table S2 in the Supplementary Appendix.

RADIATION EXPOSURE

Over the course of the 6-month study period, the average cumulative radiation exposures were significantly lower in patients assigned to point-of-care ultrasonography and radiology ultrasonography than in those assigned to CT (10.1 mSv and 9.3 mSv, respectively, vs. 17.2 mSv; P<0.001). This difference is attributable to the imaging performed at the baseline emergency department visit (Table 3).

SERIOUS ADVERSE EVENTS

There were no significant differences among the study groups in the number of patients with serious adverse events (Table 3): 113 of 908 patients (12.4%) assigned to point-of-care ultrasonography, 96 of 893 (10.8%) assigned to radiology ultrasonography, and 107 of 958 (11.2%) assigned to CT (P=0.50). A total of 466 serious adverse events occurred in these 316 patients; 426 (91.4%) were hospitalizations during the follow-up period, and 123 (26.4%) involved surgical treatment or complications of urinary stone disease.

Table 2. Clinical Data and Provisional Diagnosis by Emergency Department Physician.*

Variable	Point-of-Care Ultrasonography (N=908)	Radiology Ultrasonography (N=893)	Computed Tomography (N=958)
		number (percent)	
Medical history			
History of kidney stones	377 (41.5)	385 (43.1)	387 (40.4)
History of cancer	62 (6.8)	48 (5.4)	58 (6.1)
Diabetes	72 (7.9)	94 (10.5)	100 (10.4)
Hypertension	236 (26.0)	219 (24.5)	270 (28.2)
Hematuria	562 (61.9)	591 (66.2)	593 (61.9)
Physical examination findings†			
Costovertebral-angle tenderness	463 (51.0)	478 (53.5)	507 (52.9)
Right-lower-quadrant tenderness	216 (23.8)	238 (26.7)	270 (28.2)
Left-lower-quadrant tenderness	238 (26.2)	217 (24.3)	257 (26.8)
Murphy's sign, suggestive of cholecystitis	9 (1.0)	13 (1.5)	14 (1.5)
McBurney's sign, suggestive of appendicitis	31 (3.4)	39 (4.4)	29 (3.0)
Patient described as guarding, suggestive of acute abdomen	43 (4.7)	48 (5.4)	51 (5.3)
Enrolling physician's estimate of diagnosis†			
Highly suggestive of appendicitis	24 (2.6)	33 (3.7)	28 (2.9)
Highly suggestive of abdominal aorta abnormality	5 (0.6)	10 (1.1)	7 (0.7)
Highly suggestive of bowel abnormality	35 (3.9)	26 (2.9)	37 (3.9)
Estimated likelihood of kidney stones			
0–5%	26 (2.9)	24 (2.7)	26 (2.7)
6–25%	126 (13.9)	121 (13.5)	126 (13.2)
26–50%	184 (20.3)	164 (18.4)	159 (16.6)
51–75%	227 (25.0)	195 (21.8)	244 (25.5)
76–100%	320 (35.2)	370 (41.4)	366 (38.2)
Likelihood of kidney stones not known	25 (2.8)	19 (2.1)	37 (3.9)

* These data exclude the 17 patients who withdrew from study after randomization but before any baseline data were collected. There were no significant differences among the three study groups for any comparison (P values ranged from 0.10 to 0.84).
† The categories are not mutually exclusive.

There were 12 related serious adverse events (0.4%), which occurred in 3 patients (0.3%) assigned to point-of-care ultrasonography, 4 (0.4%) assigned to radiology ultrasonography, and 5 (0.5%) assigned to CT (P=0.88) (Table 3). Additional information regarding patients with related serious adverse events is provided in Table 4.

The total number of serious adverse events included 5 deaths. These deaths occurred between 38 and 174 days after randomization, and none were considered to be related to participation in the study.

EMERGENCY DEPARTMENT LENGTH OF STAY, READMISSIONS, AND PAIN SCORES

The median length of stay in the emergency department was 6.3 hours in the point-of-care ultrasonography group, 7.0 hours in the radiology ultrasonography group, and 6.4 hours in the CT group (P<0.001 for the comparison of radiology

Table 3. Primary and Secondary Study Outcomes According to Study Group.*

Outcome	Point-of-Care Ultrasonography (N=908)	Radiology Ultrasonography (N=893)	Computed Tomography (N=958)	P Value
Primary Outcomes				
High-risk diagnosis with complication — no. of patients (%)	6 (0.7)	3 (0.3)	2 (0.2)	0.30
Radiation exposure — mSv	10.1±14.1	9.3±13.4	17.2±13.4	<0.001
During emergency department enrollment visit	6.5±9.4	4.7±8.4	14.1±9.6	<0.001
From enrollment to 30 days	1.2±4.4	1.8±5.4	1.0±3.9	0.19
30–180 days	1.5±5.5	2.1±6.8	1.2±4.8	0.08
Secondary Outcomes				
Serious adverse events — no. of patients (%)	113 (12.4)	96 (10.8)	107 (11.2)	0.50
Related serious adverse events — no. of patients (%)†	3 (0.3)	4 (0.4)	5 (0.5)	0.88
Emergency department length of stay — hr‡				
Median	6.3	7.0	6.4	<0.001
Interquartile range	4.5–9.0	5.4–9.9	4.7–9.0	
Return emergency department visit — no. of patients/total no. (%)§				
Within 1 wk	86/835 (10.3)	77/816 (9.4)	99/872 (11.4)	0.43
Within 1 mo	136/835 (16.3)	121/816 (14.8)	143/872 (16.4)	0.62
Within 6 mo	231/835 (27.7)	231/816 (28.3)	255/872 (29.2)	0.77
Hospital admission after emergency department discharge — no. of patients (%)§				
Within 1 wk	27/835 (3.2)	25/816 (3.1)	17/872 (1.9)	0.21
Within 1 mo	44/835 (5.3)	48/816 (5.9)	34/872 (3.9)	0.16
Within 6 mo	87/835 (10.4)	84/816 (10.3)	83/872 (9.5)	0.80
Self-reported pain score¶				
At discharge from the emergency department	3.2±2.9	3.0±2.9	3.3±2.9	0.05
At 3-day follow-up	3.0±3.1	2.8±2.9	3.0±3.0	0.42
At 7-day follow-up	2.0±2.9	2.0±2.8	2.0±2.8	0.84
Accuracy for diagnosis of nephrolithiasis‖				
Sensitivity — % (95% CI)	85 (80–89)	84 (79– 89)	86 (82–90)	0.74
Specificity — % (95% CI)	50 (45–54)	53 (49–57)	53 (49–58)	0.38

* Plus–minus values are means ±SD.
† Related serious adverse events were those that were deemed by three raters to have contributed to a delayed diagnosis or to have contributed to the event by altering management.
‡ The length of stay includes the time in the emergency department or observation unit as part of the baseline emergency department visit.
§ The total number includes patients who were initially discharged home directly from the emergency department.
¶ Pain was assessed on an 11-point visual-analogue scale, with higher scores indicating more severe pain. At the time of discharge from the emergency department, data on pain scores were available for 579 patients in the point-of-care ultrasonography group, 569 patients in the radiology ultrasonography group, and 615 patients in the CT group; at the 3-day follow-up, data were available for 623 patients, 579 patients, and 633 patients in the three groups, respectively; and at the 7-day follow-up, data were available for 680 patients, 650 patients, and 709 patients in the three groups, respectively.
‖ The analysis for the accuracy of diagnosis of nephrolithiasis was limited to patients with at least a 30-day follow-up. Data were available for 777 patients in the point-of-care ultrasonography group, 766 patients in the radiology ultrasonography group, and 839 in the CT group.

ultrasonography with each of the other two groups) (Table 3). No significant differences were observed among the groups with respect to the proportion of patients who had a return visit to the emergency department within 7 or 30 days or who were admitted to the hospital within 7, 30, or 180 days or with respect to self-reported pain scores at any assessment; data on the assessments at the time of discharge from the emergency department, at 3 days, and at 7 days are shown in Table 3.

Among patients who underwent only a single imaging examination, the median length of stay in the emergency department was significantly shorter in the point-of-care ultrasonography group than in the other two groups: 5.1 hours (interquartile range, 3.7 to 7.4) in the point-of-care ultrasonography group vs. 6.4 hours (interquartile range, 4.9 to 8.5) in the radiology ultrasonography group and 6.2 hours (interquartile range, 4.6 to 8.7) in the CT group (P<0.001).

DIAGNOSTIC ACCURACY FOR NEPHROLITHIASIS

The proportion of patients with a confirmed stone diagnosis within 6 months after randomization was similar in the three study groups (34.5% in the point-of-care ultrasonography group, 31.2% in the radiology ultrasonography group, and 32.7% in the CT group; P=0.39). On the basis of the diagnosis at the end of the emergency department visit, the sensitivity and specificity for the diagnosis of nephrolithiasis were similar in the three study groups in the intention-to-treat analysis (i.e., regardless of the imaging performed) (Table 3).

Patients in the ultrasonography groups were more likely than those in the CT group to undergo additional diagnostic testing during the initial emergency department visit; 40.7% of the patients in the point-of-care ultrasonography group and 27.0% of the patients in the radiology ultrasonography group underwent CT, whereas 5.1% of the patients in the CT group underwent ultrasonography (P<0.001). Despite the additional imaging tests ordered for the patients assigned to ultrasonography, the mean total costs for the emergency department visit were slightly lower among patients assigned to ultrasonography than among those assigned to CT (a difference of $25 between CT and radiology ultrasonography, P<0.001.)

An analysis of diagnostic accuracy for nephrolithiasis that was performed on the basis of the result of the first imaging test patients underwent showed that ultrasonography had lower sensitivity and higher specificity than CT: the sensitivity was 54% (95% confidence interval [CI], 48 to 60) for point-of-care ultrasonography, 57% (95% CI, 51 to 64) for radiology ultrasonography, and 88% (95% CI, 84 to 92) for CT (P<0.001), and the specificity was 71% (95% CI, 67 to 75), 73% (95% CI, 69 to 77), and 58% (95% CI, 55 to 62), respectively (P<0.001). There was no significant difference in results between those with and those without complete follow-up.

RESULTS STRATIFIED ACCORDING TO HISTORY OF NEPHROLITHIASIS

There were no significant differences among the groups with respect to high-risk diagnoses with complications when the results were stratified according to whether patients had a history of

Table 4. Details of Related Serious Adverse Events in 12 Enrolled Patients, According to Imaging Method.*

Emergency Department Discharge Diagnosis	Final Diagnosis	Diagnostic Delay
		days
Point-of-care ultrasonography		
Nonspecific pain	Acute renal insufficiency, pyelonephritis, urosepsis	1
Nephrolithiasis	Small-bowel obstruction, bowel ischemia and resection	3
Nephrolithiasis	Acute cholecystitis	65
Radiology ultrasonography		
Nonspecific pain	Appendicitis	1
Ruptured ovarian cyst	Ovarian torsion	2
Nonspecific pain	Acute cholecystitis	5
Nonspecific pain	Diverticulitis	26
Computed tomography		
Urinary tract infection	Acute allergic reaction requiring hospital admission	0
Nonspecific pain	Acute cholecystitis	3
Nonspecific pain	Pulmonary embolism	3
Nonspecific pain	Acute cholecystitis	25
Nonspecific pain, ovarian cyst	Acute cholecystitis	64

* Related serious adverse events, a subset of all serious adverse events, included events that were attributable to study participation — that is, randomization to one of the groups was deemed by three raters (the site principal investigator, the study principal investigator, and the chair of the data and safety monitoring board) to have contributed to a delayed diagnosis or to have contributed to the event by altering management. ED denotes emergency department.

nephrolithiasis (Table S3 in the Supplementary Appendix). The mean radiation exposure was significantly lower in the ultrasonography groups than in the CT group among patients with and those without a history of nephrolithiasis (Table S3 in the Supplementary Appendix). There were few differences in secondary outcomes according to group when the results were stratified according to status with respect to a history of nephrolithiasis, and the results paralleled the overall results (Table S3 in the Supplementary Appendix). Patients in the ultrasonography groups were less likely to undergo additional diagnostic testing with CT when they reported a history of nephrolithiasis (31% vs. 36%, P<0.001).

DISCUSSION

In the current study, patients in the ultrasonography groups were exposed to a lower total amount of radiation than were patients in the CT group, with no significant difference in high-risk diagnoses with complications, total serious adverse events, or related serious adverse events. The important secondary outcomes of pain scores, hospital admissions, and emergency department readmissions during follow-up also did not differ significantly among the groups.

Our results do not suggest that patients should undergo only ultrasound imaging, but rather that ultrasonography should be used as the initial diagnostic imaging test, with further imaging studies performed at the discretion of the physician on the basis of clinical judgment. Some patients in each study group — but more in the ultrasonography groups — underwent additional imaging. However, most patients in the ultrasonography groups did not undergo CT, and still there was no increase in any category of serious adverse events among patients assigned to ultrasonography. Since some patients in the ultrasonography groups ultimately underwent CT, the radiation exposure in the ultrasonography groups was more than zero. However, despite additional CT imaging, the mean radiation exposure in the ultrasonography groups was about half that in the CT group.

The reasons that the physicians managing the care of the study participants had some participants undergo CT after ultrasonography is unknown, and this practice varied across study sites. However, the strategy of starting the evaluation with ultrasonography and obtaining additional imaging when needed on the basis of the judgment of the emergency department physician led to decreased exposure to radiation. Patients with nephrolithiasis frequently undergo repeat imaging over time; our results showed that replacing initial CT with ultrasonography for this often-recurring disease reduced overall radiation exposure.

When the accuracy of imaging was analyzed according to the first imaging test (rather than all the imaging tests) a patient underwent, CT had greater sensitivity than ultrasonography, a finding that was consistent with prior research.[17,18] The specificity for CT was lower than in prior research, probably because we used a stringent reference standard of stone diagnosis, which did not depend on the CT results. Yet the higher sensitivity of CT for nephrolithiasis did not translate into better patient outcomes.

Patient outcomes and diagnostic accuracy were similar in the two ultrasonography groups. Radiation exposure was slightly higher in the point-of-care ultrasonography group because of greater use of subsequent CT, possibly because emergency room physicians may have less confidence than radiologists in performing ultrasonography and interpreting the results. The length of stay in the emergency department was slightly but significantly shorter (0.7 hours) in the point-of-care ultrasonography group than in the radiology ultrasonography group, perhaps reflecting the fact that patients did not need to leave the emergency department to undergo imaging. When we assessed length of stay among participants who underwent only a single imaging test, the difference was even larger; those who underwent point-of-care ultrasonography had a significantly shorter length of stay of 1.3 hours.

The strengths of our study include its large size, diverse emergency departments, and a randomized design that assessed clinically relevant outcomes beyond diagnostic accuracy alone. Our high follow-up rate suggests that the incidence of missed serious adverse events was probably low. A limitation of our study is that we could not blind the investigators, patients, or physicians to the study group assignment. However, we prespecified high-risk diagnoses with complications and used independent review to characterize serious adverse events related to trial participation. We used a stringent reference standard of stone diagnosis to calculate diagnostic accuracy, which had the advantage of being unbiased with respect to imaging method, as evidenced by the equal

diagnosis of stones across the three groups. The disadvantage of this standard was that some participants might have had a stone they did not remember passing. Finally, the emergency departments were all staffed by emergency physicians with training and certification in conducting point-of-care ultrasonography, and this may not be true of all emergency departments.

The use of CT for the diagnosis of suspected renal stones has increased by a factor of 10 over the past 15 years in the United States,[11] probably because of its greater sensitivity and because it can be performed at will in most emergency departments in the United States.[12] Few studies of advanced imaging have assessed patient outcomes beyond diagnostic accuracy, and our trial, with a pragmatic trial design, confirms the feasibility of assessing diverse patient outcomes. We found that although ultrasonography was less sensitive than CT for the diagnosis of nephrolithiasis, using ultrasonography as the initial test in patients with suspected nephrolithiasis (and using other imaging as needed) resulted in no need for CT in most patients, lower cumulative radiation exposure, and no significant differences in the risk of subsequent serious adverse events, pain scores, return emergency department visits, or hospitalizations.

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APPENDIX

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