Accuracy of Patient Reported Stone Passage for Patients With Acute Renal Colic Treated in the Emergency Department

Andrew C. Meltzer, Pamela Katzen Burrows, Ziya Kirkali, Judd E. Hollander, Michael Kurz, Patrick Mufarrij, Allan B. Wolfson, Cora MacPherson, Scott Hubosky, Nataly Montano, and Stephen V. Jackman

OBJECTIVE To study patients who initially presented to the Emergency Department with acute renal colic to determine if patient-reported stone passage detects stone expulsion as accurately as follow-up computed tomography (CT) scan.

METHODS This is a secondary analysis of a multi-center prospective trial of patients diagnosed by a CT scan with a symptomatic ureteral stone <9 mm in diameter. Patient-reported stone passage, defined as capture or visualization of the stone, was compared to CT scan-confirmed passage performed 29-36 days after initial presentation.

RESULTS Four-hundred-three patients were randomized in the original study and 21 were excluded from this analysis because they were lost to follow-up or received ureteroscopic surgery. Of the 382 remaining evaluable patients, 237 (62.0%) underwent a follow-up CT scan. The mean (standard deviation) diameter of the symptomatic kidney stone was 3.8 mm (1.4). In those who reported stone passage, 93.8% (91/97) demonstrated passage of the symptomatic ureteral stone on follow-up CT. Of patients who did not report stone passage, 72.1% (101/140) demonstrated passage of their stone on follow-up CT.

CONCLUSIONS For patients who report capture or visualization of a ureteral stone, a follow-up CT scan may not be needed to verify stone passage. For patients who do not capture their stone or visualize stone passage, imaging should be considered to confirm passage. UROLOGY 136: 70−74, 2020. © 2019 Elsevier Inc.

In the United States, urinary stone disease affects nearly 1 in 11 people over a lifetime, with an estimated annual medical cost of $5 billion.[1] The prevalence and rate of emergency department visits for urinary stone disease has nearly doubled over the past 15 years.[2-4] Initial management of an acute episode of urinary stone disease often occurs in the emergency department. Following initial treatment of symptoms, CT scan is often performed to verify the diagnosis and the size and location of the stone. Current practice is to order repeat imaging after a reasonable time to confirm passage of a symptomatic stone.[5] Repeat imaging can include an abdominal x-ray, renal ultrasound, or CT scan. CT scan is the most accurate imaging modality and is considered the standard for stone diagnosis.[6] Ultrasound is highly sensitive to hydronephrosis, a secondary finding of stone obstruction in the ureter, but ultrasound is not sensitive to the stone itself. When patients are discharged from the emergency

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Trial Registration: *Parent study was registered at https://clinicaltrials.gov (NCT00382265).*

From the Department of Emergency Medicine, George Washington University School of Medicine & Health Sciences, Washington, DC; the The George Washington University Biostatistics Center, Washington, DC; the Department of Emergency Medicine, University of Pittsburgh School of Medicine, Pittsburgh, PA; the Department of Emergency Medicine, Thomas Jefferson University, Philadelphia, PA; the Department of Emergency Medicine, University of Alabama at Birmingham School of Medicine, Birmingham, AL; the National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Bethesda, MD; the Department of Urology, George Washington University School of Medicine & Health Sciences, Washington, DC; and the Department of Urology, University of Pittsburgh School of Medicine, Pittsburgh, PA

Address correspondence to: Andrew C. Meltzer, M.D., M.S., Department of Emergency Medicine, The George Washington University School of Medicine & Health Sciences, 2120 L Street NW, Suite 450. Washington, DC 20037.

E-mail: ameltzer@mfa.gwu.edu

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department, they are encouraged to attempt to visualize or capture a passed stone to confirm passage and make it possible to determine its composition. Visualization is important because cessation of pain does not necessarily mean that a ureteral stone has been expelled.[7] Prolonged retention of a ureteral stone may lead to permanent renal damage, and thus may require surgical intervention.[8] In a study of 358 patients with prolonged ureteral obstruction, 27% demonstrated impairment of renal parenchymal function and 7% had renal impairment up to 17 months after passing stone.[9] In patients with ureteral calculi larger than 4 mm in diameter, 28% exhibited asymptomatic loss of renal function at presentation as measured by radioisotope renography.[10] Published meta-analyses, as well as the current American Urological Association Guidelines on Surgical Management of Stones, provide a strong recommendation that clinicians should offer follow-up scans because a change in stone position may influence treatment approach.[5,11] It is unknown whether patient report of stone passage is sufficiently accurate to make it possible to forgo further imaging.

METHODS

After an initial phase assessing feasibility, participants were enrolled in the second phase of the Study of Tamsulosin for Urolithiasis in the Emergency Department (STONE), conducted from 2013 to 2016 at 6 emergency department recruiting sites.[12] Eligibility criteria for both phases of the study have been previously published in detail.[13] Briefly, adults at least 18 years of age were eligible if they presented to the emergency department with a symptomatic stone determined by CT scan to be less than 9 mm in diameter and located in the ureter.[13] Stone size was calculated by the largest dimension on axial view of CT scan. Hydronephrosis was determined by the attending radiologist's review of the CT scan. Eligible patients were randomized to take either active tamsulosin or matching placebo for 28-days. Study participants were contacted by telephone at 2, 7, 15, 20, 29, and 90 days after enrollment to determine if they had visualized or captured a stone, the study definition of stone passage. Participants were also asked to undergo a follow-up CT scan at 29 to 36 days after randomization to confirm whether their stone had passed.

For this analysis of the follow-up CT scans, both treatment groups were combined. Patient-reported passage was considered the index test and CT scan of the abdomen was considered the reference standard.[6] Participants who did not have the follow-up CT scan performed were asked to give a reason for refusal. Follow-up CT scans were evaluated by attending radiologists at participating institutions who were unaware of the patient's symptoms, stone status or treatment group. In cases where passage was equivocal, an outcome review committee composed of 3 urologists from recruiting sites determined whether there had been passage of the symptomatic stone by majority opinion.

To assess for potential bias, baseline characteristics were compared between the participants who did and did not undergo a follow-up CT scan. Categorical variables were compared using the chi-square test, and continuous variables using the Wilcoxon test. For all outcomes, a nominal P value of less than .05 was considered to indicate statistical significance, without adjustment for multiple comparisons. SAS version 9.4 (SAS Institute Inc, Cary, NC) was used in the data analysis.

RESULTS

Of the 403 participants enrolled in phase 2 of the STONE study, 382 were eligible for this analysis; 13 participants were lost to follow-up without a follow-up scan being performed, and 8 underwent ureteroscopic surgery to remove the stone before follow-up CT scan. Of the 382 included, 237 (62.0%) underwent a follow-up CT scan (Fig. 1). For those 237, the mean age was 39.7 years,

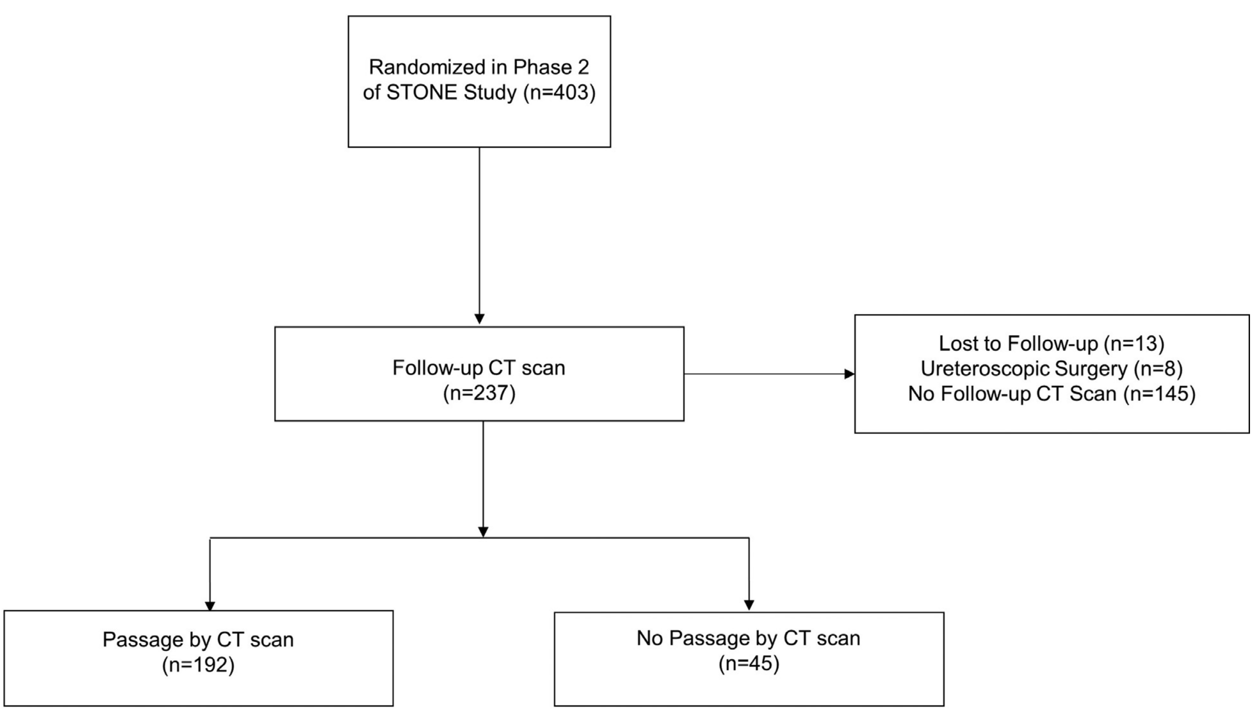

Figure 1. Participant flow diagram.

Table 1. Baseline characteristics of study participants per follow-up CT scan status

	Follow-up CT	No Follow-up CT	*P* Value
Average age at screening	39.7 ± 13.4	41.6 ± 14.2	.23
Gender			.65
Female (n = 103)	62 (60.2)	41 (39.8)	
Male (n = 279)	175 (62.7)	104 (37.3)	
Race			.02
Non-white (n = 84)	61 (72.6)	23 (27.4)	
White (n = 273)	159 (58.2)	114 (41.8)	
Ethnicity			.24
Hispanic (n = 26)	19 (73.1)	7 (26.9)	
Non-Hispanic (n = 355)	218 (61.4)	137 (38.6)	
Family history of urinary stone disease			.26
Yes (n = 86)	49 (57.0)	37 (43.0)	
No (n = 295)	188 (63.7)	107 (36.3)	
Past history of urinary stone disease			.45
Yes (n = 110)	65 (59.1)	45 (40.9)	
No (n = 272)	172 (63.2)	100 (36.8)	
Location of symptomatic stone*			.04
Upper ureter (n = 116)	81 (69.8)	35 (30.2)	
Lower ureter (n = 266)	156 (58.6)	110 (41.4)	
Median diameter of symptomatic stone (mm)	4.0 (3.0 – 5.0)	3.5 (3.0 – 5.0)	.60
Diameter of symptomatic stone			.83
1-2 mm (n = 70)	42 (60.0)	28 (40.0)	
3-4 mm (n = 209)	130 (62.2)	79 (37.8)	
5-6 mm (n = 88)	57 (64.8)	31 (35.2)	
7-8 mm (n = 15)	8 (53.3)	7 (46.7)	
Stones on baseline CT scan			.54
Single (n = 247)	156 (63.2)	91 (36.8)	
Multiple (n = 135)	81 (60.0)	54 (40.0)	

Data presented n (%) unless noted as an average (±SD) or median (25%-75%).
* The level of sacroiliac vessels was considered the landmark to define "upper" and "lower" ureter.

26.2% were female, and 27.7% were non-white (Table 1). The mean (SD) diameter of the symptomatic stone was 3.8 mm (1.4). The most common reason for lack of CT follow-up was patient refusal. Of the 145 participants who did not return for a CT scan, 31.0% noted that the reason was they had already seen or captured a stone. Less than 1% of those who did not return reported the reason to be concern about the radiation exposure of a repeat CT scan. As was reported in a prior manuscript, there was no difference in passage rates in tamsulosin vs placebo groups.[12]

There was a significant difference between the rates of confirmed stone passage on CT scan in those who reported passage and those who did not report passage (93.8% vs 72.1%; relative risk 1.30, 95% confidence interval 1.16 − 1.46; $P < .001$). Of those who reported stone passage, 6.2% had evidence of the original stone on the follow-up CT scan; whereas of those who did not report stone passage, 27.9% had evidence of the original stone on the follow-up CT scan. Patient-reported capture or visualization of the symptomatic stone had a sensitivity of 47.4% (95% confidence interval 40.3%-54.5%), a specificity of 86.7% (95% confidence interval 76.7%-96.6%), a false positive rate of 6.2% and a false negative rate of 72.1% (Table 2). Median days to passage (25%-75%) was 3.0 days (1.0-8.0).

The 6 participants who reported passing the symptomatic stone but did not pass that stone on the follow-up CT are not different on baseline demographics and stone characteristics from the others who underwent a follow-up CT scan.

We analyzed the cohort who did not think they passed the stone and compared those that actually had confirmed passage by CT scan (72.1%) and those that accurately predicted no passage by CT scan (27.9%) (Table 3). Patients who did not pass stone were more likely to have a stone in upper ureter and more likely to have a larger stone. No other differences in baseline demographics and characteristics were detected.

DISCUSSION

Patients with urinary stone disease often receive multiple CT scans and are potentially exposed to dangerous cumulative levels of radiation.[14] Our study suggests that patient-reported passage is highly predictive of actual passage of stone, as defined by CT scan. A persistent stone was evident on follow-up CT scan in only 6 of 97 (6.2%) patients who reported stone passage. In contrast, a

Table 2. Stone passage by patient report and CT scan

	Passage by Scan	NO Passage by Scan	Relative Risk* (95% Confidence Interval)
Passage by report	91/97 (93.8)	6/97 (6.2)	1.30 (1.16–1.46)
NO passage by report	101/140 (72.1)	39/140 (27.9)	
All patients	192/237 (81.0)	45/237 (19.0)	

Data presented as n/N (%).
* Relative risk that patient reported passage corresponds to CT passage.

Table 3. Participants who did not report stone passage

	Passage by Scan (n=101)	NO Passage by CT Scan (n=39)	*P* Value
Location of symptomatic stone*			<.001
Upper ureter (n = 57)	32 (56.1)	25 (43.9)	
Lower ureter (n = 83)	69 (83.1)	14 (16.9)	
Diameter of symptomatic stone (mm)	4.0 (3.0–4.0)	5.0 (4.0–6.0)	<.001
Average Age at Screening	40.2 ± 13.0	41.5 ± 14.5	.63
Gender			.27
Female (n = 42)	33 (78.6)	9 (21.4)	
Male (n = 98)	68 (69.4)	30 (30.6)	
Race			.29
Non-white (n = 46)	36 (78.3)	10 (21.7)	
White (n = 85)	59 (69.4)	26 (30.6)	
Ethnicity			.77
Hispanic (n = 16)	11 (68.8)	5 (31.3)	
Non-Hispanic (n = 124)	90 (72.6)	34 (27.4)	
Family history of urinary stone disease			.22
Yes (n = 30)	19 (63.3)	11 (36.7)	
No (n = 110)	82 (74.6)	28 (25.5)	
Past history of urinary stone disease			.50
Yes (n = 34)	23 (67.7)	11 (32.4)	
No (n = 106)	78 (73.6)	28 (26.4)	
Location of symptomatic stone*			<.001
Upper ureter (n = 57)	32 (56.1)	25 (43.9)	
Lower ureter (n = 83)	69 (83.1)	14 (16.9)	
Median diameter of symptomatic stone (mm)	4.0 (3.0–4.0)	5.0 (4.0–6.0)	<.001
Diameter of symptomatic stone			.002
1-2 mm (n = 18)	17 (94.4)	1 (5.6)	
3-4 mm (n = 75)	59 (78.7)	16 (21.3)	
5-6 mm (n = 42)	22 (52.4)	20 (47.6)	
7-8 mm (n = 5)	3 (60.0)	2 (40.0)	
Stones on baseline CT scan			.55
Single (n = 95)	70 (73.7)	25 (26.3)	
Multiple (n = 45)	31 (68.9)	14 (31.1)	

Data presented n (%) unless noted as an average (±SD) or median (25%-75%).
* The level of sacroiliac vessels was considered the landmark to define "upper" and "lower" ureter.

persistent stone was present in 39 out of 140 (27.9%) patients who did not report passage. The clinical significance of 6.2% being incorrect should inform the decision to order a follow-up CT scan to confirm stone passage. The fact that 72.1% did not capture or visualize the stone but actually had CT confirmation of stone passage underlies the need for mechanisms to improve the ability of patients to visualize or capture stones.

The most accurate follow-up imaging test for stone passage is abdominal CT scan, which has high accuracy but exposes patients to radiation doses that are potentially carcinogenic[15,16] and increases the rate of incidental findings.[17] It has an unknown impact on rates of unnecessary surgeries to retrieve stones that may otherwise have passed on their own. A reduction in the use of follow-up CT scans may be beneficial for patients with kidney stones and reduce overall healthcare expenditures. The use of ultrasound to confirm stone passage is a common strategy to reduce patient radiation exposure. However, in 5 out of the 6 patients who thought they had passed their stone but had a retained stone on follow-up CT scan, the initial hydronephrosis was found to have resolved at follow-up. Thus, ultrasound appears to have a limited ability to determine stone passage in this group of patients.

The most significant limitation of our study is that the patients who underwent a follow-up CT scan were different from those who did not get a follow-up CT scan in some ways. Several findings suggest that the study may be susceptible to both selection bias and work-up bias. Patients who underwent a follow-up CT scan were less likely to report stone passage when contacted, less likely to have distal stones and less likely to be white than those who did not return for a follow-up CT scan. This suggests that patients who returned for the follow-up CT scan were different from the general population of stone patients. We postulate that patients who reported passage of their stones were less likely to return for a repeat CT scan because they felt that imaging was not needed if they believed that the stone had passed. Likewise, we hypothesize that patients with distal stones were more likely to have passed their stones or have no symptoms and would be less likely to return for the scan. The reasons for the racial differences in the rate of follow-up CT remain unclear.

Our study has several strengths. First, we recruited participants from the emergency department, where most patients first present for renal colic. Second, we had a diverse sample with respect to race (23% non-white) and ethnicity (7% Hispanic), making our results more generalizable. Third, we encouraged all patients to return for a follow-up CT scan and ultimately obtained it in a majority (62%) of our patients. Finally, we included patients who had stones in any part of the ureter in order to increase the generalizability of our study.

In conclusion, we found that patient-reported stone passage was strongly associated with stone passage on follow-up CT scan. Routine follow-up CT imaging of patients with ureteral stones who have visualized or captured their stone thus may not be necessary.

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