**Date:** 4/12/17  
**Presenter Name:** Andrew Fried


**Country(ies):** USA

**Funding Source(s):** Grant from the Agency for Healthcare Research and Quality  
☐ None Stated

### Purpose

**Research Question(s):**  
What is the best initial imaging test for suspected nephrolithiasis?  
☐ None Stated

**Hypotheses:**  
Patients who have their initial imaging by point of care US, radiology performed US, and CT, will have different amounts of high-risk diagnoses, cumulative radiation exposure, and total costs.  
☐ None Stated

**Study Purpose:**  
To find the optimal initial imaging test for these patients.

### Methods

**Study Design:** Randomized, multicenter, pragmatic, comparative effectiveness trial

**Outcome(s) [or Dependent Variable]:**  
Primary outcome:

1.) High risk diagnoses with complications that could be related to missed or delayed diagnoses.  
2.) Cumulative radiation exposure from imaging.  
3.) Total cost (which was not reported)

Secondary outcomes:

1.) Serious adverse events  
2.) Serious adverse events related to participation in the study (acute chole, appendicitis, bowel obstruction)  
3.) Return emergency department visits and hospitalizations after discharge from ED  
4.) Self-reported pain  
5.) Diagnostic accuracy of nephrolithiasis as measured by the reference standard of confirmed stone diagnosis which is the patient reporting passing the stone or surgical removal.
**Intervention [or Independent Variable]:**

Initial imaging study: POCUS, Radiology preformed US, CT

**Ethics Review:** IRB Review  
**Committee:** University of California San Francisco Committee on Human Research

**Research Setting:**

15 geographically diverse academic emergency departments

**Study Subjects:**

Pts 18-76

**Inclusion Criteria:**

Patients presenting with flank or abdominal pain in which the treating physician decided to order imaging to establish or rule out nephrolithiasis.

**Exclusion Criteria:**

- If the treating physician thought they were at high risk for alternative dx such as acute chole, appendicitis, AAA, bowel disorders.  
- Men weighing > 129 kg  
- Women weighing > 113 kg  
- Patients with single kidney, s/p renal transplant, or undergoing dialysis

**Study Interventions:**

- POCUS performed by EM physicians with training as recommended by ACEP  
- Radiology US exams  
- CT according to local standards

**Study Groups:**

POCUS/Rads/CT in a 1:1:1 fashion

**Instruments/Measures Used:** US, CT, follow up data, SAS software

**Data Analysis:** Intention to treat

**A priori sample size calculation?** Not Described

**Statistical analyses used:** chi-square, Fisher’s exact, Kruskal-Wallis

**Adjustment for potential confounders?** No
## Results

### Study participants:

- 2759 included in intention to treat
- 908 to POCUS
- 893 to Rads US
- 958 to CT

No significant differences regarding history, physical exam, labs, and ED physician’s assessment of the likelihood of various diagnosis.

### Brief answers to research questions [key findings]:

**Primary:**

1. **High risk diagnoses with complications within 30 days:** POCUS (6 patients, 0.7%)  Rads US (3 patients, 0.3%)  CT (2 patients, 0.2%) \( p=0.3 \)

2. **Radiation exposure:** POCUS (10.1 mSv)  Rads US (9.3 mSv)  CT (17.2 mSv)  Attributable to baseline ER visit \( p<0.001 \)

**Secondary:**

1. **Serious adverse events:** POCUS (12.4%)  Rads US (10.8%)  CT (11.2%)  with \( p=0.5 \)
   - a) 91% of these “serious adverse events” were hospitalizations
   - b) 26.4% involved surgical treatment or complications of urinary stones

2. **Related serious adverse events:** \( p=0.88 \)
   - a) POCUS (3 pts) - 1 pyelo, 1 SBO requiring resection, and 1 chole (65 days later?)
   - b) Rads US (4 pts) - 1 appendicitis, 1 ovarian torsion, 1 chole, 1 diverticulitis
   - c) CT (5 pts) - 3 choles, 1 PE, 1 allergic reaction requiring admission

3. **Length of stay:** \( P < 0.001 \)
   - a) POCUS: 6.3 hours  5.1 hours if only study
   - b) Rads: 7 hours  6.4 hours if only study
   - c) CT: 6.4 hours  6.2 hours if only study

4. **Diagnostic accuracy** \( p<0.001 \)
   - a) POCUS: 54% sensitive  71% specific
   - b) Rads US: 57% sensitive  73% specific
   - c) CT: 88% sensitive  58% specific

5. **Additional diagnostic testing:** \( p<0.001 \)
   - a) POCUS: 40.7 %
   - b) Rads US: 27 %
   - c) CT: 5.1 %
6) Confirmed stone diagnosis within 6 months: P=0.39
   a) POCUS: 34.5%
   b) Rads US: 31.2%
   c) CT: 32.7%

Additional findings:
Patients in the US groups were less likely to undergo additional imaging with CT if they reported a history of nephrolithiasis (31% vs 36% p<0.001)

Limitations:
No blinding of groups for anyone involved.

Very strict definition of positive diagnosis of kidney stone making the sensitivity and specificity data minimally useful. CT was only ~50% specific because if it saw a stone that the patient did not recall passing or did not need a procedure to remove, it was deemed a false positive. CT was likely able to find small stones that may not have caused hydro visible on US and therefore made US look more specific. This may, however, be useful information as this is a more patient centered outcome.

“Primary outcome” was three separate outcomes.

Clinical Implications

Applicable? YES

Feasible? OF COURSE

Clinically relevant? ABSOLUTELY

Comments:
There has been some criticism about this paper aimed at pointing out that US is not the best test for nephrolithiasis and that a 40% CT rate after an initial US is a failure. This paper does not tell us that US is the BEST test for nephrolithiasis. It does teach us that it is the best FIRST test. This was designed as a pragmatic study to look at how we can start these workups. It shows us that by employing US as the first test we are not hurting patients or causing worse outcomes. In fact, we are speeding up visits and decreasing radiation exposure without any worse outcomes.

Level of evidence generated from this study
Ia: evidence obtained from meta-analysis of randomized controlled trials
Ib: evidence obtained from at least one randomized controlled trial
IIa: evidence obtained from at least one well-designed, controlled study without randomization
IIb: evidence obtained from at least one other type of well-designed quasi-experimental study
III: evidence obtained from a well-designed, non-experimental study
IV: expert committee reports; expert opinion; case study; case report

Additional Comments/Discussion/Notes