Author's response to reviews:

Title: CT Imaging History for Patients Presenting to the ED with Renal Colic–Evidence from a Multi-Hospital Database

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Author’s response to reviews:

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Michael D Repplinger, MD, PhD
BMC Emergency Medicine

Dear Dr. Repplinger:

Thank you for the extension. We are pleased to resubmit our manuscript with revisions for your review and appreciate your continued interest in our work. We have addressed the reviewer's comments point by point below, and we have highlighted with yellow changes within the manuscript. Our responses are below the closing of this letter.

Thanks for your time and consideration. We believe the reviewer's comments were helpful to markedly improve the quality of the manuscript, and we look forward to its possible publication in your journal.

Sincerely yours,

Peter B Richman MD MBA
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We have addressed each point of Kaji et al. either by adding to study design description and/or discussing methodological flaws in the limitations. To simplify the description of our study design, we have changed it to a retrospective cohort.

2. Please clarify if patients were consented (mentions verbal consent in study design, but waiver of consent under population).

We have clarified consent issue (waived) in the setting section.

In addition, please correct/amend the following:

1. Tables 1 and 3 are completely redundant with the text. The most logical course of action would be to simply delete the tables and keep the text.

We have removed those tables and reduced the amount of tables changing those numbers accordingly.

2. "Data" is the plural form of "datum" and therefore should always be adjoined with the plural form of verbs (e.g. - data were, data are, etc).

We have corrected this throughout the manuscript.

3. How closed is the health care environment where you reside? The data point of "70.6% of all ED visits within a twelve-county region" is pretty specific. Please explain where that statistic is coming from.

We have provided additional narrative in the setting and changed our number to an estimate as the 70.6% is somewhat dated and now harder to determine with the growth of freestandings.


The reference has been changed.

Reviewer reports:
Michael Ward, M.D. (Reviewer 1): Page 1
28: "6-hospital" should be written out six-hospital

changed
33: CT written twice. Delete.

changed
Page 3
42-49: Awkward sentence. Probably put "historically the preferred...condition" in parentheses.

Page 4
4,11: Write out your numbers less than 10.

changed

16: I would remove "Unfortunately." Some offering of opinions is certainly OK but probably better suited in your discussion if anywhere. Where possible, leave the interpretation of the results and previous lit to the reader and otherwise just list the facts.

deleted “unfortunately”

Page 5
This needs to be clearer. It sounds like a priori study where data was obtained via retrospective chart review. Confusing to read that "Subjects were verbally consented" and later to read "a waiver of consent for data." If this was a chart review process, then how you selected the patients is paramount. Specific ICD 10 codes? Was there a different search method? I am guessing you did not have research assistants at 6 different sites enrolling patients 24/7 for 10 months.

Our study protocol clarifies that patients were identified prospectively even though ultimately this study is essentially a chart review. So final diagnosis provided by clinician at point of care.

Page 6
You need to include additional information in how your research assistants were trained and whether there was any quality control completed, intra/inter-rater calculations done. Becoming important in chart reviews. If not, should be noted as a limitation.

As per prior reviewer comments, we have extensively addressed this in the protocol and limitations.

16: Can you provide how you came up with the number 70.6%? Excluding the peds and pregnant patients. Did you somehow tabulate the number of ED visits outside of your system in a 12-county region?

We have provided additional narrative in the setting and changed our number to an estimate as the 70.6% is somewhat dated and now harder to determine with the growth of freestandings. We now estimate 2/3.

Page 7
26-28: Not really the intention of your study but would be interesting to look at bounceback rate for the 14% of patients without imaging. Could bolster your argument? Same for US group. The issue with US is that we cannot always determine size/location, etc.
We have discussed this as a future study in the future studies/limitations section.

Page 8
4: Can you better clarify how you determined the previous CT data? I am guessing CTs obtained only through your hospital system. Any attempt to determine if previous imaging noted in history, etc. Likely not and just a limitation as you list.

This was already addressed in the original submission quite clearly at the beginning paragraph of the limitations.

Page 9
18-26: sentence should be less definitive. Saying "not resulted in" sounds like we can definitively say CT does not benefit. These results were from retrospective studies in which we can draw causal conclusions. Only investigative/exploratory...may be better to say 'likely,' or 'observed,' or 'showed'

changed

55: "Disturbingly" may be a little strong for a original study. Would probably leave that kind of language for an editorial, etc. Do not want to show your hand too much as retrospective studies are notorious for being subject to bias.

deleted

James Svenson (Reviewer 2): I don't think the introduction makes the case for doing this study. I do not think they really emphasize the multihospital aspect and how this is different and more important than previous. Nor, do they really discuss the differences in scan rates across hospitals or patient flow between the hospitals.

We respectfully disagree with this reviewer regarding the introduction. We especially disagree that the Introduction does not focus on the novel multi-center opportunity to evaluate patients as this is the entire focus of the objective paragraph at the end of the section. We believe the logic of the Introduction flows as follows:

• Rapid growth of overall CT utilization despite significant radiation exposure concerns

• CT for renal colic as diagnostic modality of choice and marked increase in use over past two decades

• Renal colic patients at high risk for recurrence and, thus, recurrent imaging

• Prior studies evaluating recurrent imaging from CTs for renal colic limited in single center “look back” data.
Our study is relatively novel in its multi-center “look back” to assess the question of CT exposures for renal colic evaluation

Introduction:
The authors state that x-ray was the preferred imaging when in fact IVPs were utilized. Plain x-rays are notoriously insensitive and difficult to read.

Deleted

Methods:
This is not a prospective study. This is a retrospective study from a prospectively enrolled patient population.

As noted previously, we have changed this description.

The setting does not really describe the hospital system. What area do the six hospitals encompass. How many other hospitals and medical centers are there in the area that provide care.

We have added significant description of the hospital system and geographic area.

The inclusion criteria seem rather narrow. What about people who are diagnosed with nephrolithiasis, or kidney stone, or ureteral colic. Are those all missed.

We clarified that we included all of these final diagnoses as study eligible.

How far back did the chart reviews go. Just to where e records had been implemented or further?

January 1, 2017, now noted in methods section

Results:
Should have a patient flow chart. How many patients were screened. How many med inclusion criteria, included in final data, etc.

We did not track for patients screened but ineligible. This is now noted in the Study Protocol section.

Table one doesn't add anything since all the data are summarized in the first paragraph.

Table deleted.

One of the reasons for the study is to look at prior CT use across a system, but none of those data are really presented. How many patients with multiple scans were seen at multiple hospitals, how many seen at a single hospital.
It was not the purpose of this study to collect data about different hospital site visits but solely to focus on recurrent imaging. Practitioners had access to all imaging records at each facility if they chose to address that concern prior to selecting CT or other modality.

Table 3 likewise adds nothing to what is summarized in the paragraph.

Deleted

For those with negative CTs how was the diagnosis of renal colic made.

The determination of diagnoses eligible for patient inclusion was at the discretion of the treating physician. This is now clarified in the protocol section.

Table 4 95 had no prior CT scan. I think the authors need to distinguish those with prior history of stones and those without. Are these patients who had no CTs who had no prior history of kidney stones. Of the patients with no prior CT history did they all get CTs on their current visit, or was there a different distribution of US/CT.

You state "Patients with a prior stone were more likely than those with no history to receive a CT" yet several places after say the opposite.

Table 4 has been renumbered as Table 2. The purpose of this table is solely to present the overall study group prior exposure in summary. We think this has some value considering the large number of patients with very high exposures.

We agree that there are so many data points presented that some of the data can appear conflicting, yet we do not believe that such conflicts are reality. We have clarified again our abbreviation EDCV within the results section to make it clear that these are statistics related to the current ED visit when EDCV appears. We also think part of the confusion was the ambiguous way we reported the results of the “ultrasound only”, which might have implied a greater number of patients receiving ultrasound only. We have made it clear that the denominator for the % for “only US” is 56 and that the comparisons for this subgroup are based on that number.

The organization of the results paragraphs follows this logic:
• P1—Overall study group characteristics
• P2—Imaging type for EDCV (current visit) and results
• P3—comparison of characteristics of those who received vs. didn’t receive a CT during EDCV
• P4—CT Imaging history review, relationship between prior CT imaging/patient and EDCV use of CT and US respectively; relationship between patient characteristics/stone history and EDCV imaging
• P5—relationship of patient characteristics and imaging history with respect to US utilization

Here are the key points presented in the results about CT that might seem conflicting with some commentary in italics—

• Patients with a prior stone history were more likely than those with no history to receive an EDCV CT (88% vs. 16%; p < 0.001). This is related to current visit only and we do not believe it is ambiguously written. This is data point does not include any comment on the US status of the patient at EDCV. If you have a prior history of stone more like to get a CT. We reviewed this data point consistently in our discussion.

• Patients who did not receive a CT at the current visit had a significantly higher mean prior number of CTs than those who had current visit CT (5.1+/-7.7 vs 2.2+/-4.9; p < 0.001). This seems logical and may suggest that physicians were cognizant of higher numbers of CT exposures. This is a comparison of number of CTs not prior stone history per se. This again is reiterated in our discussion without conflict to prior statements/data review.

• Patients who received an US at their current visit also had a significantly higher mean number of prior CTs (4.9+/-7.6 vs 2.8+/-5.6; p<0.001). Again, physicians utilized US for patients with higher number of CTs and may suggest that they were aware of the higher prior exposure.

• Characteristics associated with positive prior CT history included: female gender (42% vs. 28%; p=0.02), flank pain (40% vs. 13%; p < 0.001), and prior renal stone by history (48% vs. 10%; p < 0.001). Patients more likely to have prior CT history if prior history of renal stone. This does not related specifically to likelihood of receiving CT on current visit.

• Patients with a reported prior stone were more likely to receive a renal ultrasound as the only imaging study during the EDCV (33% vs. 15%; p=0.003). Patients with a history of one or more CT scans were also more likely to undergo only an ultrasound compared to those with no prior CT (35% vs. 22%; p=0.046). This is an analysis of the

Discussion:
The discussion really doesn't highlight the results of this study until the end. The results should be emphasized first and their implications later.

The authors put a lot of results (with p values or CI) in the discussion. These should be discussed in the results section.

We have moved discussion of the results forward and removed some data as suggested.

First paragraph might be nice to discuss the rates of alternative dx and whether they would be found with US. Some studies find as high as 6% with many not being considered.
We added such a statement about this and a reference [17]

Again, the authors emphasize the multi-hospital aspect of this study, but do not really explore this.

** maybe we can de-emphasize the multi-hospital aspect, he seems distracted by this but I don’t think it was the point

Why do the authors think that those with a prior history of stones were more likely to undergo a repeat scan. There is no discussion of this finding except to say it seems disturbing. Also it seems to contradict the fact that those with previous high number of CT had US. Why that discrepancy.

Also in the results section they state "Patients with a reported prior stone were more likely to receive a renal ultrasound as the only imaging study…” that seems contradictory.

**this was already mentioned by him above, anything you can add to paper might help clarify.

References:
Seem relatively dated. I am sure there are newer studies that could be cited.

We repeated our literature search and added a reference (reference 18).