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Does unenhanced computerized tomography as imaging standard post-retrograde intrarenal surgery paradoxically reduce stone-free rate and increase additional treatment for residual fragments? Outcomes from 5395 patients in the FLEXOR study by the TOWER group

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Abstract

Background: Assessment of residual fragments (RFs) is a key step after treatment of kidney stones.

Objective: To evaluate differences in RFs estimation based on unenhanced computerized tomography (CT) *versus* X-rays/ultrasound after retrograde intrarenal surgery (RIRS) for kidney stones.

Design: A retrospective analysis of data from 20 centers of adult patients who had RIRS was done (January 2018–August 2021).

Methods: Exclusion criteria: ureteric stones, anomalous kidneys, bilateral renal stones. Patients were divided into two groups (group 1: CT; group 2: plain X-rays or combination of X-rays/ultrasound within 3 months after RIRS). Clinically significant RFs (CSRFs) were considered RFs $\geqslant$ 4 mm. One-to-one propensity score matching for age, gender, and stone characteristics was performed. Multivariable logistic regression analysis was performed to evaluate independent predictors of CSRFs.

Results: A total of 5395 patients were included (1748 in group 1; 3647 in group 2). After matching, 608 patients from each group with comparable baseline and stone characteristics were included. CSRFs were diagnosed in 1132 patients in the overall cohort (21.0%). Post-operative CT reported a significantly higher number of patients with RFs $\geqslant$ 4 mm, before (35.7% *versus* 13.9%, $p < 0.001$) and after matching (43.1% *versus* 23.9%, $p < 0.001$). Only 21.8% of patients in the matched cohort had an ancillary procedure post-RIRS which was significantly higher in group 1 (74.8% *versus* 47.6%, $p < 0.001$). Age [OR 1.015 95% confidence interval (CI) 1.009–1.020, $p < 0.001$], stone size (OR 1.028 95% CI 1.017–1.040, $p < 0.001$), multiple stones (OR 1.171 95% CI 1.025–1.339, $p = 0.021$), lower pole stone (OR 1.853 95% CI 1.557–2.204, $p < 0.001$) and the use of post-operative CT scan (OR 5.9883 95% CI 5.094–7.037, $p < 0.001$) had significantly higher odds of having CSRFs.

Conclusions: CT is the only reliable imaging to assess the burden of RFs following RIRS and urologist should consider at least one CT scan to determine the same and definitely plan reintervention only based on CT rather than ultrasound and X-ray combination.

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Introduction

Many studies focus on several variables like demographic factors,[1] stone parameters,[2] and intraoperative technical steps and technology used[3] to predict stone-free rate (SFR) and outcomes of retrograde intrarenal surgery (RIRS) in adults and children alike. Similarly, preoperative computerized tomography (CT) imaging for endourological intervention is ideal for kidney stones and to estimate stone parameters like Hounsfield units (HU),[4] and its ability to influence decision-making for RIRS has been well documented.

There is no definite consensus on which is the best post-operative imaging modality and time of imaging to determine real SFR post-RIRS in adults. The use of CT scans in diagnosis and post-procedure assessment by virtue of better resolution has indeed led to better evaluation of residual fragments (RFs) after surgical interventions. It has led to a decrease in the reported SFR after RIRS, virtually questioning the validity of the concept of obtaining a 'stone-free' intervention.[5]

Ultrasound and X-rays alone or in combination are the easiest and perhaps cheapest way of doing the follow-up, but their sensitivity for stones smaller than 5 mm is poor, and hence their limitations to determine clinically insignificant residual fragments (CIRFs), which are often cited as between 2 and 5 mm.[6] The issue also persists if CIRFs could become symptomatic and become a nucleus for eventual regrowth; hence, the advocacy that CT is the best tool for post-surgical intervention. Danilovic *et al.*[7] suggested that endoscopic evaluation may be the better tool to assess when and what type of imaging needs to be planned post-operatively.

From another perspective, one could argue about the clinical relevance of very small fragments that may be missed by ultrasound and perhaps overdetected by CT, while keeping in mind that the quality of life may decrease when actively pursuing treatment of RFs.[8]

The aim of this study is to evaluate if CT is indeed preferred in real-world practice, and, if so, how non-CT imaging fares in terms of reporting the true number of RFs and its impact on ancillary treatment.

Material and methods

Included patients

A retrospective analysis was performed on the FLEXOR database created as a TOWER group (Team of Worldwide Endourological Researchers, research wing of the Endourological Society) endeavor.[9] Briefly, this register incorporated data from 20 centers of 6669 adult patients who had RIRS for renal stones from January 2018 to August 2021. Patients with ureteric stones, anomalous kidneys, bilateral renal stones, and planned endoscopic combined intrarenal surgery were excluded. Patients with missing data were also excluded. RIRS was performed as per surgeons' preferences and available resources and protocols in their place of practice including the way they perform RIRS for various stone sizes, numbers, and locations.

For the present analysis, patients were divided into two groups based on the reported post-operative imaging used to determine RFs. The choice of follow-up protocols was entirely up to each center; the choice of imaging was entirely based on the surgeon's own preference and available resources in their place of practice. Assessment of RFs was performed within 3 months after surgery. Patients who had an unenhanced CT scan were included in group 1, while those who had either plain X-rays or a combination of X-rays and ultrasound were in group 2. Clinically significant residual fragments (CSRFs) were considered RFs $\geqslant$ 4 mm since the sensitivity of either plain X-rays and ultrasound for stones smaller than 5 mm is poor[6,10] and patients with fragments larger than 4 mm should primarily be offered reintervention instead of follow-up.[11]

Statistical analysis

The Shapiro–Wilk test was used to assess for normality. Categorical variables are reported as absolute numbers and percentages, while continuous variables are reported as median and interquartile range. Differences between the two groups were analyzed using chi-square test or Fisher exact test for categorical parameters and the Mann–Whitney *U* test for continuous variables. To reduce confounding and selection bias in the statistical comparisons, propensity score matching (PSM) was applied. Propensity scores were calculated using a logistic regression model, and one-to-one nearest-neighbor matching for the following baseline and intraoperative variables was performed: age, gender, being a recurrent stone former, pre-stenting, stone parameters (multiple stones, stone diameter, stone location), HU, general anesthesia, use of reusable scope, semirigid ureteroscopy before RIRS, Holmium laser, and stone basketing, and total operation time. To ensure optimal matching of covariates, caliper width was set at 0.2 according to empirical guidelines in literature,[12] and the absolute standardized mean difference (ASMD) was checked to ensure that all covariates were <0.1.[13] All statistical comparisons were then repeated for the PSM cohort similar to the overall cohort.

A multivariable logistic regression analysis was performed to predict RFs $\geqslant 4$ mm, using age, gender, stone size, multiplicity, HU, and lower pole stones as covariates. Data are presented as odds ratio (OR) and 95% confidence interval (CI). All statistical tests were done using R Statistical language, version 4.3.0 (R Foundation for Statistical Computing, Vienna, Austria). A p value < 0.05 was considered to be statistically significant.

Results

A total of 5395 patients were included. There were 1748 patients in group 1 and 3647 patients in group 2. Table 1 shows baseline characteristics for the unmatched and matched cohort. Patients in group 2 were younger [47 (35–60) *versus* 50 (39–60) years, ASMD 0.163]. The distribution for gender, stones located in upper and middle poles, and recurrent stone formers was similar in both groups. A higher percentage of pre-stented patients (51.1%) was present in group 1 (51.1% *versus* 41.6%, ASMD 0.190). A greater proportion of patients with a lower pole (55.4%) and pelvis stones (37.9%) underwent a CT scan post-RIRS. Patients in group 2 had harder stones [1033 (800–1249) *versus* 945 (656–1170) HU, ASMD 0.304]. After matching, 608 patients from each group were included. The baseline demographics and stone characteristics input into the propensity score model were comparable in the matched cohorts, being all covariates matched to an ASMD of <0.1. Table 2 shows intraoperative characteristics and incidence of RFs after surgery.

An equal distribution of patients on whom general anesthesia, reusable scopes, semirigid ureteroscopy, and Holmium or Thulium fiber laser was used for RIRS was seen in both groups before and after matching. Surgical time was significantly longer in group 1 before [70 (55–90) *versus* 46 (35–65) min, $p=0.017$] and after matching [67 (55–90) *versus* 60.5 (40, 110) min, $p=0.013$]. Overall, RFs $\geqslant 4$ mm were diagnosed in 1132 patients (21.0%). Post-operative CT reported a significantly higher number of patients with RFs $\geqslant 4$ mm, before (35.7% *versus* 13.9%, $p<0.001$) and after matching (43.1% *versus* 23.9%, $p<0.001$). Only 21.8% of patients in the matched cohort had an ancillary procedure post-RIRS, which was significantly higher in group 1 (74.8% *versus* 47.6%, $p<0.001$).

Age (OR 1.015 95% CI 1.009–1.020, $p<0.001$), stone size (OR 1.028 95% CI 1.017–1.040, $p<0.001$), multiple stones (OR 1.171 95% CI 1.025–1.339, $p=0.021$), lower pole stone (OR 1.853 95% CI 1.557–2.204, $p<0.001$) and the use of post-operative CT scan (OR 5.9883 95% CI 5.094–7.037, $p<0.001$) had significantly higher odds of having RFs $\geqslant 4$ mm at multivariable analysis (Table 3).

Discussion

The European Association of Urology guidelines quote that patients with fragments <4 mm could be offered surveillance for up to 4 years, since intervention rates range between 17% and 29%, disease progression between 9% and 34%, and spontaneous passage between 21% and 34% at 49 months.[11] Conversely, patients with larger RF should be offered definitive intervention, since intervention rates are high (24–100%).[11] The proposed imaging consists of plain X-rays and/or ultrasound, based on stone characteristics and clinicians' preferences. However, there is no recommendation on the need for CT alone as imaging for follow-up.[11] This study attempts to detect fragments $\geqslant 4$ mm and how this may contribute to early reintervention by urologists performing RIRS in real-world practice. Of 5395 patients, only a third had a post-operative CT scan. Does this disparity beg the question of why CT is not

Table 1. Baseline characteristics of the unmatched cohort, and after PSM.

Charateristics	Entire cohort			After PSM		
	Group 1 Unenhanced CT (*N* = 1748)	Group 2 X-rays/ ultrasound (*N* = 3647)	ASMD	Group 1 Unenhanced CT (*N* = 608)	Group 2 X-rays/ ultrasound (*N* = 608)	ASMD
Age, median [IQR]	50 [39–60]	47 [35–60]	**0.163**	49 [39, 60]	49 [36, 60]	0.067
Female, *n* (%)	588 (33.6)	1231 (33.8)	0.002	225 (37.0)	217 (35.7)	0.027
Recurrent stone former, *n* (%)	442 (25.3)	796 (21.9)	0.081	220 (36.2)	214 (35.2)	0.021
Pre-stented, *n* (%)	893 (51.1)	1518 (41.6)	**0.190**	291 (47.9)	295 (48.5)	0.013
Multiple stones, *n* (%)	879 (50.8)	1380 (38.8)	**0.242**	246 (40.5)	226 (37.2)	0.068
Stone diameter (mm), median [IQR]	12 [8.0–17]	11 [9.0–15]	**0.192**	13 [9.0–18]	12 [9.0–17]	0.003
Stone location (s), *n* (%)						
Upper pole	428 (24.8)	832 (22.9)	0.044	155 (25.5)	139 (22.9)	0.061
Middle pole	490 (28.4)	978 (26.9)	0.032	143 (23.5)	130 (21.4)	0.051
Lower pole	956 (55.4)	1537 (42.4)	**0.262**	303 (49.8)	291 (47.9)	0.039
Pelvis	657 (37.9)	1186 (32.6)	**0.111**	203 (33.4)	192 (31.6)	0.039
HU, median [IQR]	945 [656–1170]	1033 [800–1249]	**0.304**	970 [730–1190]	952 [681–1200]	0.014

Bold value: ASMD ⩾0.1.
ASMD, absolute standardized mean difference; CT, computerized tomography; HU, Hounsfield Unit; IQR, interquartile range; PSM, propensity score matching.

the standard imaging protocol in adults? Perhaps this is multifactorial, and while we did not specifically query this, we postulate the reasons are:

(1) Not a standard recommendation in all guidelines.[11,14]
(2) Cost could preclude surgeons as ultrasonography and X-rays are significantly cheaper, faster, and easier to do.[15]
(3) On table intraoperative assessment and absence of significant RFs may obviate postoperative need for CT.[7]
(4) Preference to minimize radiation dose.[16]
(5) Nonavailability of CT on premises.[17]
(6) Noncompliance of patient for CT scan.[18]

Currently, there is no standard recommendation between different guidelines, and perhaps this is the main reason for the variability in our study which reports data from different health systems worldwide. Our analysis showed that CT picked up a larger number of RF ⩾ 4 mm even after well-matching baseline patient and stone characteristics.

Bhojani *et al.*[19] observed that in comparison to endoscopic evaluation, a CT scan underreports the number of stones as it is unable to detect multiple small stones lying in close proximity to one another. This is in line with the current knowledge that CT is the most reliable imaging tool, reaching 95% sensitivity,[20] but when measuring stones <3 mm; however, these could be very well missed mostly due to image slicing.[21] Conversely, ultrasound has a sensitivity of 45% for the detection of both ureteral and renal calculi.[22] Yet, its sensitivity drops further for stones <3 mm.[22] A plain radiography has a sensitivity of 37.0% for stones <5 mm.[20] Therefore, stone detection can be improved by combining X-rays with ultrasonography, but wide variations exist in sensitivity (58–100%) and specificity (37–100%).[15,20] Moreover, care should be taken when measuring stone size using ultrasonography as

Table 2. Intraoperative characteristics and post-operative outcomes of the unmatched cohort, and after PSM.

Charateristics	Entire cohort			After PSM		
	Group 1 Unenhanced CT (*N* = 1748)	Group 2 X-rays/ ultrasound (*N* = 3647)	*p* Value	Group 1 Unenhanced CT (*N* = 608)	Group 2 X-rays/ ultrasound (*N* = 608)	*p* Value
General anesthesia, *n* (%)	1454 (83.2)	2373 (65.1)	0.423	449 (73.8)	429 (70.6)	0.073
Reusable scope, *n* (%)	952 (54.5)	2912 (79.8)	0.561	396 (65.1)	381 (62.7)	0.051
Semirigid ureteroscopy before lithotripsy, *n* (%)	1141 (65.3)	1855 (50.9)	0.295	299 (49.2)	323 (53.1)	0.079
Holmium laser, *n* (%)	1309 (74.9)	2365 (64.8)	0.220	447 (73.5)	438 (72.0)	0.33
Stone basketing, *n* (%)	480 (28.7)	1181 (34.2)	0.119	269 (44.2)	258 (42.4)	**0.037**
Total operation time (min), median [IQR]	70 [55–90]	46 [35–65]	**0.017**	67 [55–90]	60.5 [40, 110]	**0.013**
RFs ⩾4 mm, *n* (%)	624 (35.7)	508 (13.9)	<**0.001**	262 (43.1)	145 (23.9)	<**0.001**
Reintervention, *n* (%)*	445 (71.3)	216 (42.5)	<**0.001**	196 (74.8)	69 (47.6)	<**0.001**

Bold value: statistically significant *p* value.
**n* = patients with RFs ⩾4 mm.
CT, computerized tomography; IQR, interquartile range; PSM, propensity score matching; RF, residual fragments.

the width of the ultrasound beam and resolution are similar to the size of some small stones, especially when <4 mm with an overestimation of true stone size.[6] Reportedly, up to 50% of kidney stones <5 mm in size were measured as ⩾5 mm.[22] Our results confirm this. In fact, we found that CT scan was able to detect a significantly larger proportion of patients having RFs ⩾ 4 mm in the matched cohort despite the fact that all variables were well-balanced at baseline. This also accounts for a higher number of patients who underwent an ancillary procedure in group 1. We speculate that maybe this reflects that urologists using post-operative CT scans were more decisive for the need for additional intervention when patients had larger RFs. It is also possible that if urologists were unsure of being on table stone-free or suspecting multiple RF they asked for an early CT to plan additional intervention. As larger and multiple RFs are indeed associated with more stone-related events over time,[23] this reflects that urologists were able to act decisively on which intervention would benefit their patients within 3 months itself.

Table 3. Multivariable analysis of factors affecting detection of residual fragments ⩾4 mm.

Factors	OR (95% CI)	*p* Value
Age (years)	1.015 (1.009–1.020)	<0.001
Stone Size (mm)	1.028 (1.017–1.040)	<0.001
Multiple stones (reference: single stone)	1.171 (1.025–1.339)	0.021
Lower pole stone (reference: other locations)	1.853 (1.557–2.204)	<0.001
Post-operative CT scan (reference: X-rays/ultrasound)	5.988 (5.094–7.037)	<0.001

CI, confidence interval; CT, computerized tomography.

Another important decision-making in endourology intervention is in which patients can be offered observation for their RF. In a global survey,[24] there was considerable variability in the cut-off definition of CIRF, and the authors concluded that it seemed to be associated with the type of lithotripter used for percutaneous nephrolithotripsy used and the post-operative imaging modality to assess treatment success. Indeed, RF post-endourological interventions continue to remain a thorny problem.

To better identify a subset of patients with RF on whom further intervention may not be required, the term CIRF was coined that refers to any RF smaller than 4 mm in the absence of symptoms, obstruction, and infection.[5] Currently, it is fixed between 2 and 5 mm.[5] We used <4 mm as a threshold and found that group 1 had significantly higher CSRFs. Undoubtedly, a drawback of using a CT scan to assess RFs is the exposure to radiation, and with many patients suffering from frequent recurrences, radiation exposure would be greatly increased if we rely solely on CT. Therefore, CT scan should be reserved after surgery for symptomatic patients.[11]

Indeed, the recommended dose limit for occupational exposure by the International Commission on Radiological Protection (ICRP) is <100 mSv in 5 years (i.e., average < 20 mSv/year for 5 years) with the further provision that no annual exposure be >50 mSv.[25] No such threshold has been established for medical imaging and radiation-induced risk is more controversial at doses between 10 and 100 mSv, the dose range relevant to CT.

Consistent with the as low as reasonably achievable radiation principle, some centers have introduced low-dose and ultra-low-dose CT protocols. These CT protocols have been compared to standard dose CT and have been shown to maintain high diagnostic accuracy, sensitivity, and specificity while significantly reducing radiation dose.[26] Cheng *et al.*[27] studied ultra-low-dose CT use in ureteral stones and reported that 38% of stones not associated with hydronephrosis and detected by ultra-dose CT lacked visibility on plain X-rays. The limitation is that they may not be as effective in detecting stones <3 mm in size or in patients with a body mass index of >30 kg/m^2.[28]

As seen from our study, group 1 had much higher numbers of CSRFs, and non-CT methods were unreliable to show them accurately. Therefore, it might be ideal to propose that CT could indeed be advocated as the first imaging for follow-up post-RIRS in case of suspicious larger fragments. Paradoxically, this also led to a significantly higher reintervention (74.8% *versus* 47.6%) within the 3 months post-RIRS, and all these were asymptomatic patients on follow-up. Perhaps it is important to focus on developing such protocols and consider low-dose and ultra-low-dose CT as a step forward. By using CT, our results indicate that urologists can identify those RF which definitely need further intervention and time their intervention appropriately, while also identifying CIRF and reassuring the patients that in the latter observation is a choice. Conversely, we feel that without CT imaging, no reintervention should be done as other imaging is not accurate and has lesser specificity in detecting RFs of different sizes. In our study, CT scan was associated with almost sixfolds of detecting CSRFs, which irrefutably justifies its appropriate use as a post-op imaging tool.

Study limitations

This study has some limitations, starting from its retrospective nature. Secondly, we did not have details on what type of CT was used. Neither did we collect data on the exact timing of post-operative imaging except that they were all done within the first 3 months of intervention. This could affect the reporting of RFs in both groups as a scan done too early may show more RFs, and perhaps many of these might have been observed to avoid reintervention. The reasons for choosing post-operative CT over ultrasound/X-rays most likely rely on multiple unidentified or unreported confounders, such as stone complexity, stone composition, visibility during the procedure, history of urinary tract infections, consideration of accumulated radiation dose prior to this event, and more, this is a real-world multicenter study in which the numbers and data provided reflect a true practice for imaging preferences post-RIRS. Perhaps to be cost-effective and to minimize radiation, even if urologists chose an ultrasound/X-rays initially to document RIRS outcomes, a CT scan should definitely be offered before a final decision for reintervention or observation, and this could be a low or ultra-low-dose CT scan if feasible. However, as Streeper *et al.*[8] have demonstrated, health-related quality of life does not rely on the stone-free status of the patient, and this puts into question the risk of overdetection of small RFs using CT. Interestingly, the patients who underwent a secondary procedure for RFs had a worse quality of life than those observed. This brings up what we term the 'CT paradox' whereby to minimize further interventions and render a patient image-proven stone-free, we intentionally over-investigate and over-treat, which is counterproductive to the actual intent.

Future directions

We believe that in the future, low and ultra-low-dose CT scans can change the landscape of imaging follow-up in managing patients post-RIRS, but the definitive answer of which imaging would be most suitable may be elusive as urolithiasis is such a widely varying disease in which standardization may not suit all patients. While there is no doubt that CT has a higher accuracy for identifying RFs, all variables should be considered when choosing the most suitable post-operative imaging modality. This is indeed the ideal way to have standardized reporting for publishing comparative studies. Until we can establish clear protocols on ideal timing and a consensus on how these imaging protocols can be adapted globally within the constraints and limitations, ultrasound and X-rays may be the next best alternative. Knowing these imaging limitations, urologists should defer final reintervention or observation-only protocols without a CT scan. The nomograms,[29] clinical effectiveness protocols for imaging post-RIRS,[30] and even radiomics[31] could play an influential role in streamlining imaging pre- and post-RIRS, and perhaps different imaging platforms can be integrated for a personalized and tailored approach.

Conclusion

Our study reconfirms that CT scan has the best probability of detecting RFs $\geqslant$ 4 mm. In our real-world study, paradoxically, this led to a significantly higher early reintervention within 3 months just based on imaging. Hence, we advocate that while urologists must be vary of using imaging alone as a yardstick for reintervention, we do advocate performing at least one CT scan to confirm no RFs and before any definite ancillary reintervention as X-rays and ultrasound combination maybe unreliable to determine the accuracy of RF burden.

Declarations

Ethics approval and consent to participate

The study was approved by the ethics board of the Asian Institute of Nephrology and Urology, Hyderabad, India (#AINU 08/2022). Each institution obtained its own ethics board approval before contributing and provided anonymized data.

Consent for publication

All patients provided signed informed consent to gather their anonymized data.

Author contributions

Vineet Gauhar: Conceptualization; Investigation; Methodology; Writing – original draft.

Daniele Castellani: Conceptualization; Investigation; Methodology; Writing – original draft.

Ben Hall Chew: Investigation; Methodology; Writing – review & editing.

Daron Smith: Investigation; Methodology; Writing – original draft.

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Competing interests

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Availability of data and materials

Due to the possibility of compromising the privacy of research participants, the data supporting this study are not publicly available. However, they can be obtained from the corresponding author at daniele.castellani@ospedaliriuniti.marche.it upon reasonable request.

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