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The 2023 Stone-Free CT Mandate: Addressing the Two Sides of the Debate

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Abstract

To the editors of the *Journal of Endourology*, we write to express our reservations in the recent announcement that starting in 2023 all reporting of stone-free rates be based on CT.

Keywords: stone-free rate, postoperative imaging, radiation exposure, patient-reported outcomes

Introduction

Recently, the editors of the *Journal of Endourology* announced new instructions for authors submitting urolithiasis articles that stone-free rates are not only going to be required but must be based on noncontrast CT scans with 2 to 3 mm cuts. This announcement, the first of its kind for a urology focused journal, was made in the spirit of improving the quality and consistency of stone-related research. This bold decision is certain to have a substantial impact for the articles presented in this journal.

At the same time, the influence of this decision could have far-reaching effects with the potential to change how urolithiasis studies are designed and perhaps ultimately even change clinical practice when it comes to stone treatment and postoperative imaging. The ramifications of this decision are considerable, and perspectives are undoubtedly variable from one clinician to the next and one medical center to another. Herein we provide a split view on the subject from neighboring academic urology practices that more typically than not share common points of view.

Point

Dusting or basketing, sheath or no-sheath, thulium or holmium, prone or supine? Every year thousands of journal articles are added to the enormous body of literature that encompasses endourology, a field that is constantly innovating and evaluating new technologies and techniques. For the urologist, sifting through these numerous studies can be overwhelming enough. The difficulties get worse when considering the heterogeneity of defined outcomes.

Stone-free status is a fundamental criterion used to guide patient counseling and the measuring stick to which emerging technologies are compared with standard of care. However, there is extensive variability in the literature in determination of ''stone-free'' status. Lack of standardized stone-free reporting limits the ability to make meaningful comparisons across studies and leads to selection bias.[1,2] Stemming from this need for standardization, the editors of the *Journal of Endourology* will start to require urolithiasis articles report stone-free status based on noncontrast CT scans and with specific criteria defining what is ''stone-free.'' We commend the editors for their decision to foster high-quality research that will advance the field.

Clinical trials for surgical techniques and technologies are challenging to perform. Many factors such as patient demographics, disease characteristics, and surgeon discretion lead to confounding even in the best designed trials. However, stone-free status, if well defined, is one outcome we have the tools to measure reliably and with little variability.

Postoperatively, methods for assessing stone-free status include plain film kidney, ureter, and bladder radiograph (KUB), ultrasonography, or CT. Among these, CT is the gold standard with a sensitivity of 98% and specificity of 97%.[3] Ultrasound has a lower sensitivity (52%–75%) for renal stones and KUB has an even lower sensitivity for stones <5 mm[4] and cannot detect radiolucent stones. Despite its

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limitations, KUB has been found to be the most common imaging modality used to determine stone-free status in urolithiasis research studies. Even more troubling, however, is the fact that according to Deters et al a third of articles failed to define stone-free status whatsover.[5] Although this underutilization of postoperative imaging and preferential utilization of a clinically suboptimal imaging test mirrors national clinical practice[6] one would certainly hope that well-designed research studies in the field could do better.

Urolithiasis research findings should be compared with the same predefined outcomes and the recent decision by the editors to include and define stone-free status will allow urologists to do just that. In addition, having standardized outcomes will enable combining data over time and from varied patient populations in the form of meta-analyses that provide the highest standard of evidence to compare technologies and techniques. Given the explosion of technology in urolithiasis, the need for standardization is essential to help urologists and patients choose the right approach for their stone. It will also help guide intellectual and monetary resources to promote and advance technology/techniques that are of true benefit.

Concern of radiation exposure with the use of noncontrast CTs is undoubtedly relevant when considering postoperative CT use. However, modern low-dose and ultralow CT protocols have shown reduction in radiation dose up to 78% to 89% while maintaining high sensitivity.[7] And although KUBs should be lower exposure than CT, Kuebker et al demonstrated that in the current population of stone formers, only a quarter of KUB had effective dose <1 mSv and in ~20% of patients, the effective radiation exposure form KUB was similar to a low-dose CT.[8]

CTs are also expensive having been estimated as being double that of a renal ultrasound and ~10× the cost of KUB.[3,9] However, these are charges that depend on market factors and the payer rather than the actual cost of the resources and time needed. One study reporting a 7.5-fold difference in CT cost based on the plan type.[10] We can only hope that the editorial support for CTs as a more accurate and useful test for stones might ultimately help lower the cost for this useful study. In the meantime, for studies exploring the use of more expensive technologies for treatment of patients, should not they be compared in the most rigorous manner, even if it costs more?

Another potential concern in routine use of postoperative CTs is the sentiment that the small residual fragments that may be more likely to be seen are clinically insignificant. However, a mounting body of literature supports the idea that there is no such thing as a clinically insignificant residual fragment or small stone. Rebuck et al reported that patients with ≤4 mm fragments detected by CT after ureteroscopy had ~20% of experiencing a stone event in the following 1.6 years.[11] A recent meta-analysis found aggregate intervention rate for ≤4 mm fragments to be 19%.[12] Portis et al even showed that the presence of residual fragments of <2 mm in size had a 33% long-term retreatment rate compared with those who were stone free.[13] With the editors standardizing the definition of ''stone-free'' for published research, we can finally compare the clinical significance of residual fragments with greater scientific rigor.

Endourology and urolithiasis care is continually driven forward by ingenuity and innovation of its leaders since the first percutaneous nephrolithotomy.[14] However, comparing these innovations has always been imperfect because of differing definitions. With the proposed changes by the editors, we will finally hold the field accountable for equitable assessments of both devices and techniques. The benefits of consistency are obvious and allow us to compare studies based on differences in intervention rather than the various ways in measuring outcome. Achieving this consistency will not happen spontaneously but requires guidelines and adherence, which is what the editors of this journal propose. To those in opposition, we ask, if we as endourologists do not hold ourselves to the highest standard, then who and if not now, then when?

Counterpoint

Although we applaud the pursuit of rigorous scientific inquiry and standardization of the term ''stone-free,'' we feel that the potential clinical applications of this decision may have negative consequences for patients and future studies.

From a patient perspective, we must acknowledge inherent radiation exposure of CT as well as its associated cost. Although most centers have standardized low dose (<4 mSV) CT, a 2015 study by Smith-Bindman et al found that <8% of patients undergoing CT for urolithiasis were imaged using a low-dose protocol, and that some patients received 200× the amount of radiation of their peers.[15] Moreover, since urinary stones are often a chronic condition, with a disease course marked by frequent recurrences, radiation exposure for patients with additional stone events and those on surveillance would be greatly increased were we to rely solely on CT.

Although we acknowledge there are little data to support that doses <100 mSv demonstrate an increased risk of malignancy, chronic stone formers who undergo multiple scans over their lifetime may approach this threshold.[16] Special consideration must be given to the population of pediatric stone formers, who are more sensitive to radiation exposure and exhibit heightened risks of secondary malignancy.[17] Guidance for these more susceptible populations was notable absent from the journal's recent announcement. Beyond radiation exposure risks, CT ($1160) is substantially costlier than renal ultrasound ($571) or plain radiography ($384).[18] Although some of this change in cost may be absorbed by insurance companies, without significant billing reform, the lion's share of this expense will be passed down to patients.

On another level, the patient perspective is all presumed based upon the sentiments of physicians. There has yet to exist a nationwide advocacy group for patients with kidney stones, outside of those with cystinuria and pediatric kidney stones. Organizations such as Pediatric KIDney Stone Care Improvement Network (PKIDS) have demonstrated that partnering with patients and their caregivers to help define the future urinary stone research agenda ensures alignment of investigators and stakeholders.[19] That said, this effort is relatively novel, as supported by a recent review, published in this journal, which reported that only 15% of randomized controlled trials within the nephrolithiasis space included *any* disease-specific patient-reported outcomes.[20]

The decision of the editors will also have consequences for investigators and future studies. There is no doubt that CT represents the gold standard imaging modality after urinary stone surgery to assess stone-free status. However, we must

acknowledge that imaging in general is performed infrequently after stone surgery, and CT represents the vast minority of such studies. For example, using data from the MUSIC ROCKS (Michigan Urological Surgery Improvement Collaborative Reducing Operative Complications from Kidney Stones) registry (a statewide cohort of 33 urology groups in Michigan aiming to improve outcomes after ureteroscopy and extracorporeal shockwave lithotripsy), we have reported that only 36.3% of patients undergo imaging within 60 days of ureteroscopy and 13.7% had CT as a primary imaging modality.[21]

Similar results have also been published on a national scale based on claims data.[6] Although there are limitations associated with observational studies based on large clinical registries, they do provide broadly generalizable data owing to the diverse nature of included practices. Were the recommendations of the editors of this journal adopted, future studies from real-world practice clinical registries such as ours and others[22,23] would be severely handicapped.

Conclusion

In closing, although we support the intent of the editors' statement, which undoubtedly will improve the rigor and quality of future studies, we must acknowledge the potential unintended consequences associated with widespread adoption of CT imaging for patients with urinary stones. We jointly agree on the following three points:

1. CT is the gold standard for kidney stone detection and should be used when vetting new technologies: It is paramount that we use the most sensitive detection tools to determine their efficacy as measured by stone-free rate when assessing new technologies such as thulium lasers, improved dusting techniques, and vacuum devices. Standard CT protocols must be established to ensure that the CTs patients are receiving are true ''low-dose'' CTs. Furthermore, the timing of these studies should be standardized, particularly as stone-free rates may be different 1 week after dusting as compared with 4 weeks.
2. Guidance is needed to determine modality and frequency of surveillance imaging: Notably absent from the American Urological Association (AUA), European Association of Urology (EAU), and the Endourological Society are formal guidelines regarding how often and what imaging study should be used to follow chronic stone formers. When making such a decision, access to testing, radiation exposure, and cost must all be considered. We challenge the Endourological Society as a leader in this space to provide guidance to urologists everywhere.
3. Patient experience must be considered in all future outcomes research projects: As surgeons, we consider the efficacy, safety, and patient experience whenever we decide to go to the operating room. The journal's new stone-free policy is a bold stance to strengthen our knowledge on the efficacy of the surgeries we perform. One could even argue that this will make surgeries safer as less efficacious surgeries will be abandoned. However, it does not address the silent stakeholder in the decision: the patient. Will a patient understand the clinical implications of a 2 mm fragment after a ureteroscopy? Will they care? Perhaps adopting composite outcome measures such as ''symptomatic stone recurrence rates'' or ''re-operation rates'' may be more clinically meaningful to urologists and their patients. With the stated lack of patient-reported outcomes in randomized controlled trials in the field of nephrolithiasis research, it may be time that we reframe what is really important when it comes to patient outcomes that matter.

As the definitive reference in this field, the *Journal of Endourology* should continue to foster rigorous, novel, and high-impact science while balancing such pursuits against the impact on patients. We look forward to how this policy change will drive future research.

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Abbreviations Used
CT = computed tomography
KUB = kidney, ureter, and bladder radiograph