CLINICAL EFFECTIVENESS PROTOCOLS FOR IMAGING IN THE MANAGEMENT OF URETERAL CALCULOUS DISEASE: AUA TECHNOLOGY ASSESSMENT

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Approved by the AUA Board of Directors May 2012

Authors' disclosure of potential conflicts of interest and author/staff contributions appear at the end of the article.

The Panel would like to acknowledge James Robert White, Ph.D., for his methodological expertise and invaluable contributions to the evidence review and analysis.

Introduction

Imaging for urinary calculous disease accounts for a significant portion of the total imaging performed by urologists.[1] Patients with suspected ureteral calculi often undergo repeated imaging studies before, during and after treatment, and patients with urinary calculous disease are at high risk for recurrence[2]. Imaging accounts for 16% of the total expenditure for each episode of care in the management of urinary calculous disease.[3]

The EAU-AUA Clinical Guidelines for the Management of Ureteral Calculi cover the evidence for clinical management of ureteral calculous disease.[4] The American College of Radiology Appropriateness Criteria™ documents the performance characteristics of various imaging studies for a given clinical scenario.[5] However, neither document addresses the critical questions about how imaging technology should be employed to maximize its effectiveness in a given clinical scenario. The technology assessment led to the development of clinical effectiveness protocols to address this need.

Non-contrast computed tomography (CT) has emerged as the most sensitive and specific modality for detecting ureteral calculi. Consequently, CT is frequently used in the initial diagnosis of ureteral calculous disease[6] and in the follow-up of known ureteral calculi before and after treatment. Protocols guiding imaging use in the management of ureteral calculous disease are desirable because of the potentially harmful cumulative effects of radiation exposure to patients and the increased cost of high-resolution axial imaging modalities.

Protocols, in the form of decision tree algorithms, and the associated discussions are meant to address the following specific questions: (1) What imaging study should be performed for suspected ureteral calculous disease? (2) What information should be obtained? (3) Once a ureteral calculus has been diagnosed, what imaging modality should be employed? and (4) After treatment of a ureteral calculus, what follow-up imaging studies are necessary?

Current research fails to provide objective evidence to support the answers to some of these questions about imaging. When objective evidence does not exist, the most "effective" course of action is the one that (1) has a reasonable probability of answering the clinical questions at hand, (2) causes the least potential harms and (3) has the least resource utilization in terms of cost.

This Technical Assessment was developed to complement the EAU-AUA Clinical Guideline for the Management of Ureteral Calculi.[4] Methodology similar to that used in the development of AUA Guidelines was used in the development of this technical assessment. Unlike the Guidelines, these protocols are based on clinical outcomes and consideration of the potential harms and cost-effectiveness of each approach. The clinical judgment of the physician and the preferences and expectations of the patient should always be the main determinants regarding the management of ureteral calculous disease. Practical considerations regarding the availability of imaging modalities in a given environment informs the choice of imaging study to be performed. Imaging is merely a tool to support and inform these clinical decisions.

To assist the clinician, a decision tree algorithm has been developed to select the most effective imaging study for a given clinical scenario. The scenarios are divided as follows: (1) Initial presentation, (2) Follow-up or surveillance of a known ureteral calculus and (3) Follow-up after treatment or passage of a ureteral calculus. Exceptions are addressed in the associated discussion of each algorithm.

In summary, the protocols were developed specifically to support clinicians in decision-making regarding the wise use of limited resources in managing a very common clinical condition. These protocols are intended to enhance the effective utilization of imaging by urologists, emergency physicians and primary care physicians for suspected or proven ureteral calculous disease.

Methodology Protocol and Literature Search

To assist in the development of these clinical effectiveness protocols, the panel crafted 31 Guiding Questions (GQs) classified by index patient, specific modality and other factors (see Table 4). A comprehensive search of the literature related to these GQs was performed for full-text-in-English articles published between January 1990 and July 2011 and was targeted toward major subtopics associated with imaging of ureteral calculi including unenhanced (non-contrast) CT, conventional radiography, ultrasound, intravenous urography (IVU), magnetic resonance imaging (MRI), nuclear medicine studies, hydronephrosis, extravasation and follow-up imaging. For a full explanation of methodology and findings, see Appendix A.

Initial Presentation

Patients who are suspected of having a ureteral stone frequently experience severe flank and occasionally abdominal pain. They desire to have a diagnosis made quickly, receive therapy to relieve symptoms and be informed about the most appropriate management strategies. Therefore, non-contrast CT (NCCT) is the preferred initial imaging study for the index patient **(Level A Evidence)**. This selection is based on the reported median sensitivity and specificity for NCCT in the detection of ureteral calculi as 98% and 97%, respectively, far superior to other imaging modalities (See Table 1). Based on a review of the literature, there appears to be consensus that the upper threshold for low-dose CT is 4mSv. Low-dose CT is preferred for patients with a Body Mass Index (BMI) ≤ 30 as this imaging study limits the potential long term side effects of ionizing radiation while maintaining both sensitivity and specificity at 90% and higher. However, low-dose CT is not recommended for those with a BMI > 30 due to lower sensitivity and specificity.[7-9]

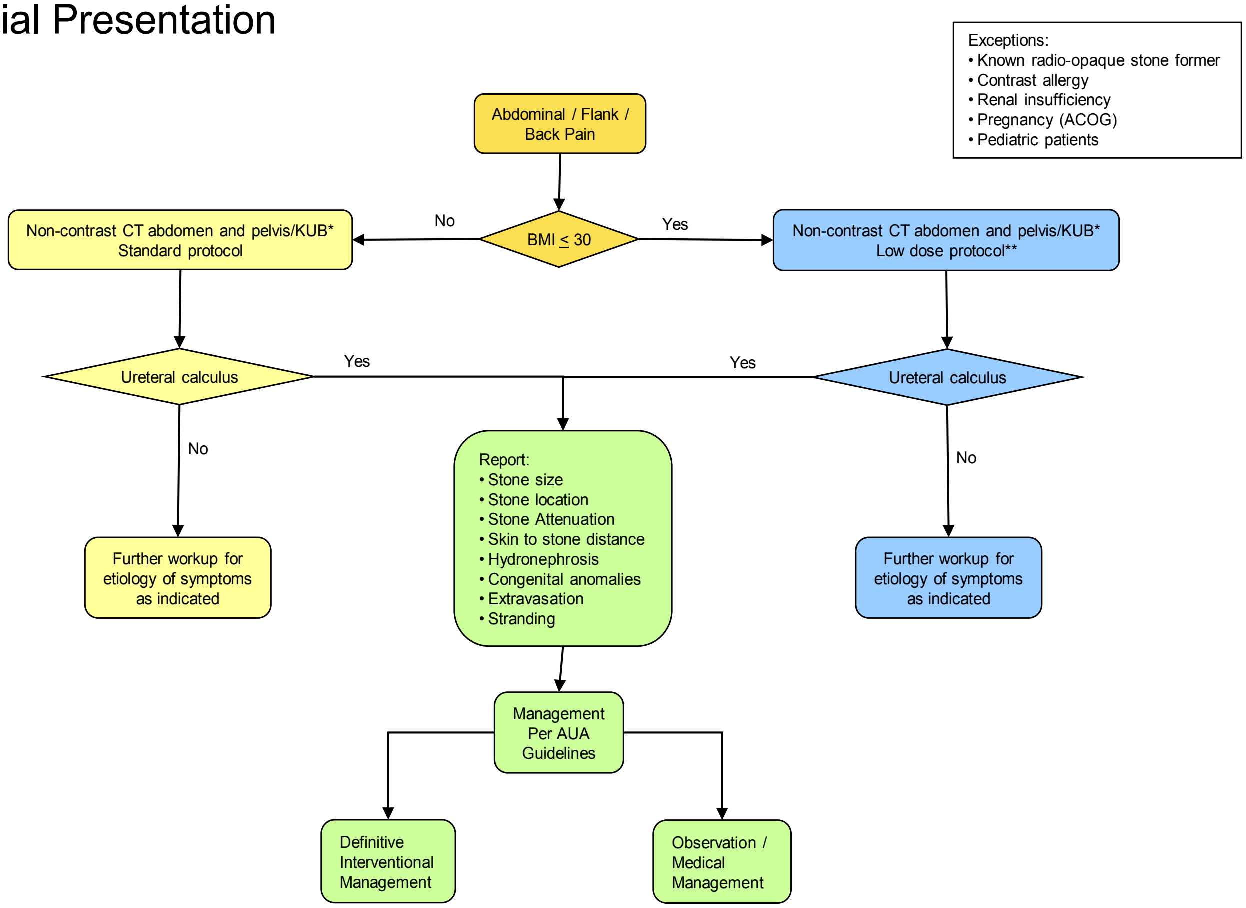
Table 1. Median reported SN/SP for modalities of interest in studies relative to non-contrast CT (based on the evidence report).

Modality	Median SN	Median SP
Conventional radiography	57%	76%
Ultrasound	61%	97%
Intravenous pyelography	70%	95%
MRI	82%	98.3%
CT (not as gold standard)	98%	97%

When a ureteral calculus is demonstrated on a CT scan, the stone is also visualized on the CT scout approximately 50% of the time.[10] A CT "scout" film is performed at a lower mA than a standard kidney, ureter, bladder (KUB) film, accounting in part for the decreased sensitivity in detecting stones. A standard KUB X-ray should be performed in cases where the stone is not demonstrated on the CT scout as the stone will be seen in 10% of these patients.[10-11] Follow-up KUB X-rays are obtained in those who are candidates for observation and in whom the stone was identified on either the CT scout or initial KUB. Follow-up imaging with KUB serves as an indicator of stone progression. A follow-up KUB X-ray is also considered in those in whom the stone was not seen on the initial CT scout or KUB X-ray but was positioned in the sacroiliac area limiting its visualization. Oblique films may also be considered in such cases, either at the time of the original CT or at follow-up, as these images may further facilitate stone visualization. **See decision tree diagram 1.**

Certain parameters and findings should be assessed on CT imaging to facilitate subsequent management decisions. The majority of patients with ureteral stones will have some degree of hydronephrosis, a mean of 83% based on our review of 48 studies. (See evidence report in Appendix B available on the AUA website). However, the presence of hydronephrosis does not predict the need for intervention.[12] The presence or the degree of hydronephrosis has been shown to influence results with shock wave lithotripsy (SWL) of ureteral stones, but this has less impact on ureteroscopic (URS) removal.[13-19] Stone size and location are predictive of spontaneous passage and successful stone removal.[12, 20-22] Secondary signs of ureteral stones such as peri-ureteral and renal stranding, ureteral edema (tissue rim sign) and peri-renal fluid have not been shown to consistently influence the likelihood of stone passage.[22-24] While skin-to-stone distance and stone attenuation

(1) Initial Presentation



* KUB is obtained if stone is not seen on CT scout film
**Low dose protocol not recommended for patients with BMI>30

have been shown to impact results of SWL treatment in patients harboring renal stones, these parameters have not been reported consistently for ureteral stones.[25-30]

Alternative imaging modalities are considered for specific patient groups. Renal ultrasonography (sono) and KUB are a viable option for a known stone former who has previously had radio-opaque stones. Sensitivities of 58-100% and specificities of 37.2-100% have been reported for this combination of modalities.[31-37] (See Table 1; **Level C Evidence)**

Renal ultrasonography, in spite of its lower sensitivity, is the preferred initial imaging modality for children because of radiation concerns.[38] Low-dose CT should be considered if renal ultrasonography is not diagnostic for children in whom a ureteral stone is still suspected.[39-40] Renal ultrasonography is the initial imaging modality of choice for pregnant patients with suspected colic.[41-47] If the diagnosis is not established with this study during the first trimester, MRI without contrast should be considered as second-line imaging as the fetus is most susceptible to potential radiation-induced injury in the first trimester. MRI without contrast usually defines the level of obstruction and, in some cases, provides an estimate of stone size.[48-51] Women in the second and third trimesters are candidates for low-dose CT if ultrasonography is not diagnostic.[52] An American Congress of Obstetricians and Gynecologists (ACOG) committee on obstetric practice endorses the utilization of low-dose CT when clinically indicated and notes that an exposure of less than 5 rads, a threshold well above the average for a low-dose CT, is not associated with the development of fetal anomalies or fetal loss.[53]

Observation of Known Ureteral Calculus

The chance of spontaneous passage of a known ureteral calculus is based primarily on stone size and location. Perhaps the best study performed to date, which

Observation

investigated the "natural history" of a known ureteral calculus, demonstrated that 83% of patients will pass their stone without the need for intervention.[54] One of the more important aspects of the 1999 Miller and Kane study was their observation that among the stones that passed spontaneously, 95% passed within six weeks of follow-up.

Interestingly, while initial diagnosis of a ureteral calculus was performed using CT or IVU in this study, follow-up imaging of these known calculi consisted of plain radiography in most cases or limited IVU if the stone was not easily visualized on X-ray. Yet, with more widespread use of CT imaging and the introduction of low-dose CT protocols, the Panel was charged with making recommendations on the most current imaging options, taking into account sensitivity/ specificity, as well as radiation dose and the cost of follow-up imaging.

The EAU-AUA Guidelines on the Management of Ureteral Calculi suggest as an Option that medical expulsive therapy (MET) should be considered as first-line treatment for most patients with ureteral stones whose symptoms are controlled. As a Standard, the Guidelines recommend that patients "should be followed with periodic imaging studies to monitor stone position and to assess for hydronephrosis."[4] Therefore, our charge was to better define which imaging options would allow effective assessment of stone position and the presence or absence of hydronephrosis during follow-up in order to assist one in determining if intervention is warranted.

The Panel sought to validate the reliability of hydronephrosis as a proxy for the degree of obstruction in patients with suspected ureteral calculi. In particular, if hydronephrosis is present with a known ureteral calculus, what is the best way to assess obstruction or loss of renal function? Unfortunately, the quality of this body of evidence was moderate (level B), and no clear recommendations could be gleaned from the literature. The majority of these studies suggested that IVU should be considered the gold standard in assessing renal obstruction/function. (See evidence report in Appendix B.) Yet, the threshold for classifying obstruction from non-obstruction results in variability in the reported sensitivity and specificity. Seven studies utilized a combination of conventional radiography (i.e. KUB) and ultrasound (X-ray+US) in diagnostic trials to assess the presence of hydronephrosis while documenting that the ureteral calculus (if radio-opaque) remained in the ureter. However, there is significant variability in reported sensitivity and specificity results with sensitivities ranging from 58 to 100%, and specificity ranging from 37.2 to 100%. (See Evidence Report in Appendix B)

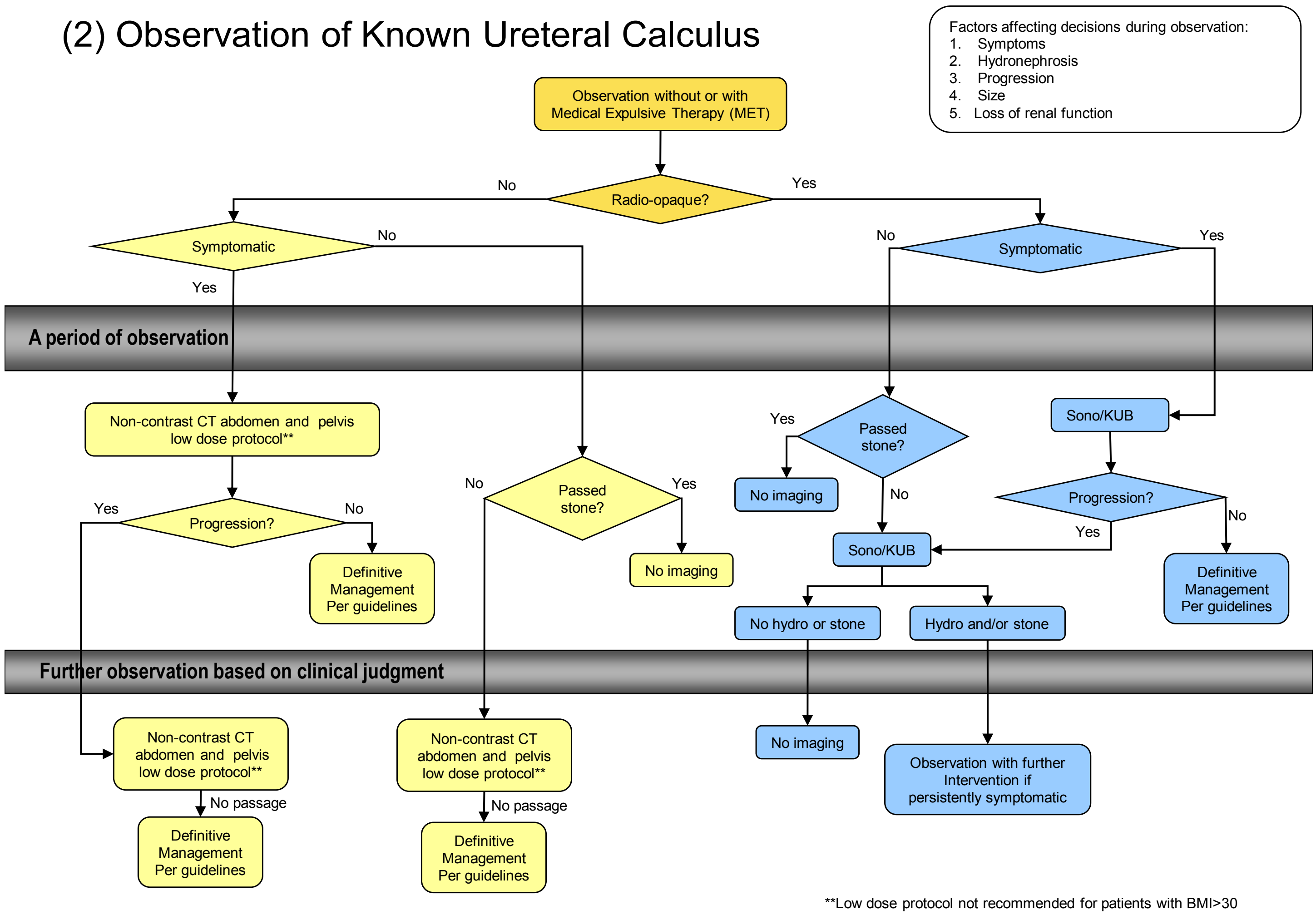
Two articles[55-56] recommended the use of repeated CT scans to follow patients with ureteral calculi. NCCT offers the most sensitive and specific imaging modality for following ureteral calculi; however, patient radiation exposure is increased as compared to other imaging studies. Two recent studies showed that some patients received high radiation doses when NCCT was used for follow-up of ureteral stones.[57-58] Both studies suggest that every effort should be made to use low-dose NCCT for follow-up imaging. In fact, there have been a number of recent studies demonstrating excellent sensitivity (95%) and specificity (97%) for detecting stones with a low-dose CT protocol (30 mAs) compared to a standard dose protocol (180 mAs) in patients with a BMI of <30.[59-60]

The quality of the body of evidence regarding the follow-up of a ureteral calculus is low **(level C).** Based on the limited information in the retrieved articles, there is high variability in determining the choice of imaging protocols for follow-up either to observe progression of ureteral calculi or to assess the degree of clinically significant obstruction (i.e. hydronephrosis that might ultimately lead to renal injury). The Panel took into account not only the sensitivity/specificity of various imaging modalities in determining their ability to follow known ureteral calculi, but also assessed the impact of radiation exposure and costs of the imaging studies when making their recommendations. Based on these studies and expert Panel opinion, the following decision tree diagram and recommendations are offered. **See decision tree diagram 2.**

After a period of MET in a patient with a known radio-opaque ureteral calculus < 10 mm in diameter with minimal to moderate associated hydronephrosis and no evidence of renal damage, assuming the symptoms are well controlled, the Panel believes that a combination of ultrasonography combined with plain KUB offers the best combination of sensitivity/specificity with minimal radiation exposure and significantly reduced cost as compared to NCCT imaging. Of course, straining one's urine to identify spontaneous stone passage during MET will avoid the need for repeat imaging studies. In patients who continue to have symptoms, without evidence of stone passage, the sono/KUB combination can assess stone progression, as well as an ongoing hydronephrosis. However, if sono and KUB fail to demonstrate hydronephrosis or persistent stone, further imaging, with oblique plain radiographs or low-dose NCCT limited to the area of interest, may be warranted to definitively determine if the stone is still present.

In those patients who have a radiolucent stone, a low-dose NCCT can assess stone progression and the degree of hydronephrosis. Clinical acumen combined with new findings on imaging studies will assist the

Follow-Up



clinician in determining whether continued observation combined with MET or surgical intervention is warranted. It may be reasonable to consider confirmatory radiographic imaging prior to surgical intervention.

Follow-Up of Ureteral Calculus After Treatment

After spontaneous passage or definitive surgical intervention for a ureteral calculus, follow-up imaging is obtained to assure complete stone removal and/or the absence of obstruction. Few would argue against the position that with a stone in hand and relief of symptoms, follow-up imaging after spontaneous passage is generally unnecessary. On the other hand, ureteral instrumentation and particularly stone fragmentation warrants post-operative imaging to document (1) clearance of the stone/fragments, (2) resolution of hydronephrosis and/or (3) the development of unanticipated obstruction such as that from ureteral stricture. Although the incidence of ureteral stricture after ureteroscopy is low (1-4%), its occurrence is not entirely predictable.[4] Ureteral stricture formation after SWL is distinctly uncommon (0 -2%)[4] and in most reports is likely the result of adjunctive instrumentation (ureteral catheterization, stone push-back) or stone impaction. After SWL, however, passage of fragments and resolution of associated obstruction should be confirmed.

Although the need for an imaging study to confirm stone/fragment clearance after SWL or ureteroscopy with lithotripsy is widely accepted, the need for follow-up studies in asymptomatic patients to assess for obstruction is subject to debate. At the center of the controversy is the reliability with which symptoms predict obstruction. Several investigators have addressed this issue by way of retrospective evaluation of patients who have undergone ureteroscopy for renal and/or ureteral calculi and were evaluated with post-operative imaging studies aimed at detecting obstruction (i.e., renal ultrasound, IVU, CT). Weizer and colleagues reviewed 241 patients at a mean of 5.4 months post-ureteroscopy using NCCT, renal ultrasound, IVU, diuretic renography or retrograde pyelogram.[61] Among 188 patients with no pain at post-operative follow-up, seven patients (3.7%) were nonetheless found to have obstruction on post-operative imaging studies. Bugg and co-workers also reviewed 118 patients who underwent 143 ureteroscopic procedures and were evaluated with IVU, renal ultrasound or CT at a mean of seven months post-operatively.[62] Among 77 patients with complete follow-up who were treated for renal or ureteral calculi, one out of 25 patients (4%) without pre-operative obstruction who reported resolution of their symptoms post-operatively was found to have persistent obstruction. Of note, the incidence of silent obstruction in the larger subgroup of patients without pain but who did or did not have pre-operative obstruction was not reported. Karadag and associates identified silent obstruction in only one patient out of 228 asymptomatic patients (0.4%) in their review of 268 patients undergoing ureteroscopy for calculi who were imaged with intravenous urography at three months post-ureteroscopy.[63] Finally, Karod and co-workers found no cases of silent obstruction among 183 patients who underwent ureteroscopy and were evaluated radiographically at a mean of 73 days post-procedure.[64]

From the above studies, it is clear that the incidence of post-operative obstruction in asymptomatic patients is decidedly low (Level C). Imaging all ureteroscopy patients to detect the rare case of silent obstruction is not cost-effective. According to Bugg and colleagues, among the select group of patients without post-operative pain or pre-operative obstruction, 25 radiographic studies would be required to diagnose one case of persistent obstruction.[62] Although seemingly a small price to pay to avoid loss of one renal unit, this need-to-treat value is hardly justifiable from a strictly economic viewpoint. Nonetheless, the Panel believes that the relatively low cost and lack of ionizing radiation associated with renal sonography justifies its use in routine follow-up of patients treated for ureteral calculi.

Obstruction with or without associated symptoms after ureteroscopy is generally due to either obstructing stone fragments or ureteral stricture. With the low incidence of stricture (<2% in most series), obstructing fragments are likely to comprise the more common etiology overall and may be detectable with KUB, thereby providing a means to identify patients who require further functional imaging and/or further treatment. In the future, perhaps with further subgroup analysis, peri-operative patient or stone characteristics can be identified in those patients without obvious persistent stones who should undergo a functional imaging study. Based on current data and panel opinion, we offer the following decision tree diagram for the follow-up of ureteral calculi after treatment with either MET or surgical intervention (SWL and ureteroscopy). **See decision tree diagram 3**.

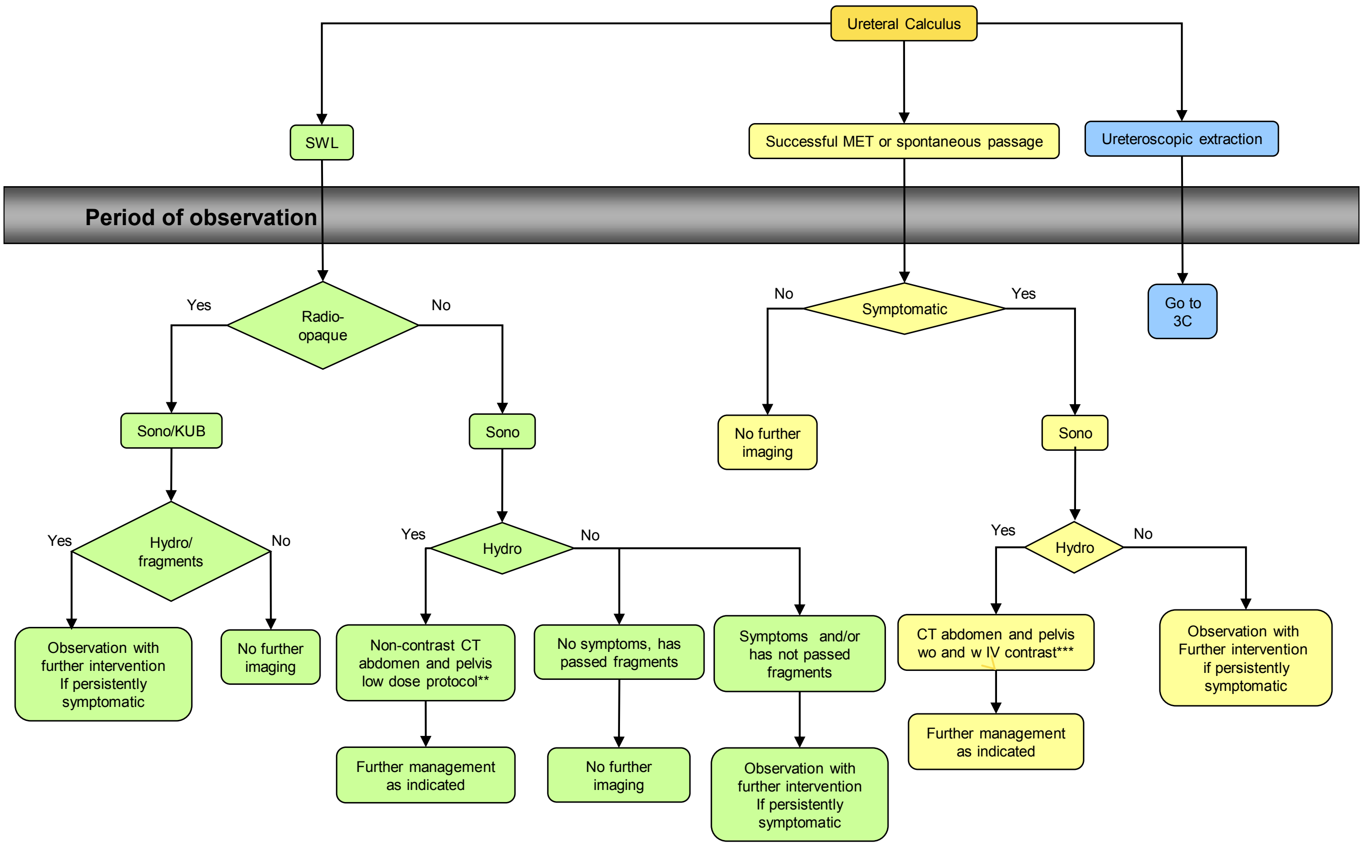
For patients undergoing MET for a ureteral calculus in whom there is documented stone passage (stone in hand) and resolution of symptoms, no further imaging is necessary. If the patient remains symptomatic despite documented passage, evaluation with a renal sonogram will demonstrate whether persistent obstruction is present and will indicate the need for further imaging to identify an additional stone, residual edema or obstruction.

For patients undergoing SWL, follow-up renal sonogram with KUB for radio-opaque stones or without KUB for radiolucent stones will document stone clearance and demonstrate the presence or absence of hydronephrosis (Figure 3). If the patient is asymptomatic and KUB/sonogram shows no stones or hydronephrosis, no further imaging is required. If KUB/sonogram demonstrates hydronephrosis and/or residual fragments, further observation with repeat imaging or secondary treatment is indicated. Patients with radiolucent stones and no hydronephrosis who remain symptomatic and/or have not passed fragments should be further observed with repeat imaging or intervention as indicated. **See decision tree diagram 3C.**

For patients undergoing ureteroscopy, the decision tree diagram distinguishes patients who undergo intact stone removal from those requiring stone fragmentation because of differing imaging requirements for documenting residual stones. For patients who undergo intact stone removal and whose symptoms have resolved, a renal sonogram is sufficient to document resolution of hydronephrosis (Figure 3C). For symptomatic patients without hydronephrosis or asymptomatic patients with hydronephrosis on renal sonogram, a CT of the abdomen and pelvis with contrast will determine the presence and/or site of obstruction, with further management dictated by the findings.

For patients who underwent ureteroscopy with stone fragmentation and are asymptomatic, follow-up imaging with a sonogram (radiolucent stones) or a sonogram/KUB (radio-opaque stones) will document the presence of residual fragments and/or hydronephrosis (**Figure 3C1**). A radiolucent stone is one that cannot be detected with standard radiographic plain film imaging whereas radio-opaque stones are demonstrated. In the absence of hydronephrosis and residual fragments, no further imaging is indicated. However, in patients with radio-opaque stones, if residual fragments and/or hydronephrosis are documented, further observation or intervention is pursued at the discretion of the practitioner. For patients with non-opaque stones, hydronephrosis on sonogram should prompt further evaluation with a low-dose NCCT to identify obstructing residual fragments.

(3) Follow-Up of Ureteral Calculus after Treatment



REV. 05/07/12 FlowChart_CER_UCD_050712

** Low dose protocol not recommended for patients with BMI>30
*** Assuming normal renal function and no contrast allergy

In symptomatic patients with radio-opaque stones, a sonogram and KUB also provide sufficient initial imaging to guide the need for further observation, interval imaging or secondary treatment as indicated. For those with radiolucent stones, however, low-dose NCCT will optimally identify residual fragments or obstruction. If either is present, continued observation or secondary intervention is dictated by the severity of symptoms and/or obstruction. In persistently symptomatic patients without hydronephrosis or residual fragments further management is left to the discretion of the practitioner based on suspicion of urinary pathology.

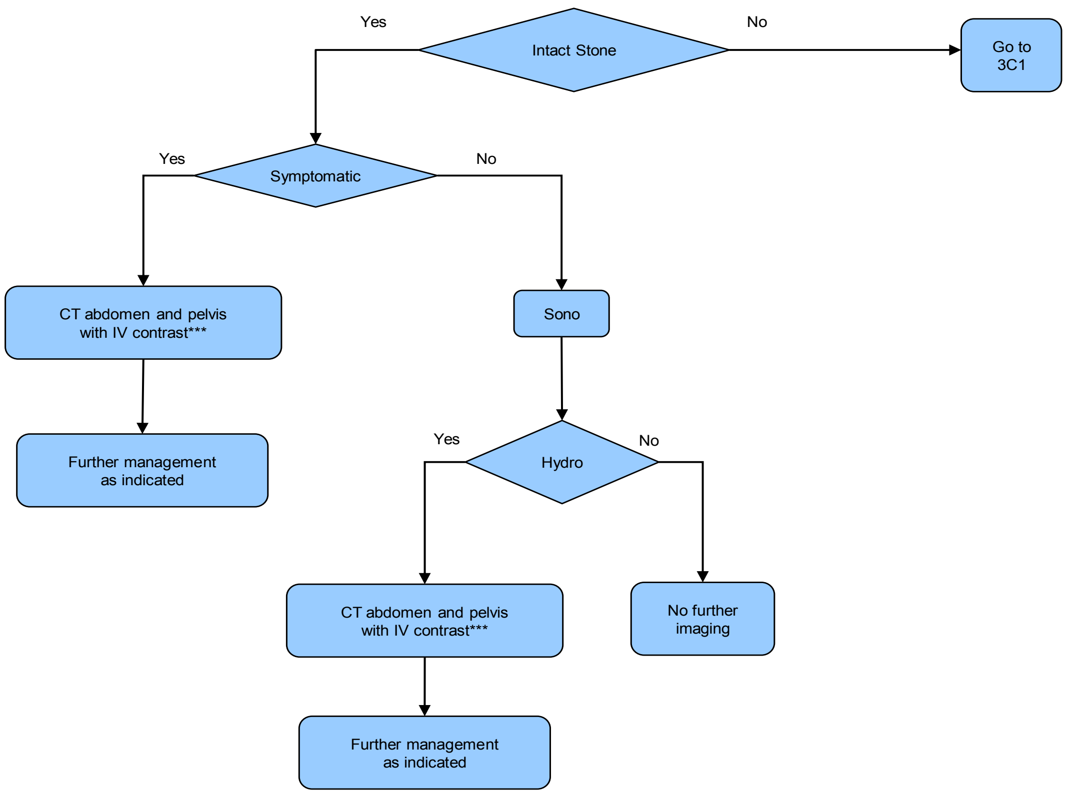
The role of IVU in the follow-up of patients with ureteral calculi who have been treated surgically is limited. However, IVU or diuretic renography may be used in lieu of CT with contrast in patients who underwent ureteroscopic intact stone removal and have persistent symptoms or hydronephrosis on sonogram or in whom additional or residual ureteral stones are not suspected, but there is concern for obstruction. In many institutions, IVU is no longer performed.

Finally, the timing of follow-up imaging studies or need for secondary intervention is left to the discretion of the treating physician. Based on inconsistent and limited animal data and anecdotal clinical data, the optimal timing to obtain imaging studies post-procedure in order to identify obstruction and avoid irreversible loss of renal function is unknown. Furthermore, since the degree of hydronephrosis does not necessarily correlate predictably with the degree of obstruction, the level of concern of the practitioner must dictate the need for and timing of further functional studies or definitive secondary intervention.

Risks and Resource Utilization Associated with Ureteral Imaging

The performance characteristics of imaging modalities used in the management of ureteral calculous disease are well documented.[5] There is no question that NCCT of the abdomen and pelvis provides the most sensitive and specific information about the size and location of ureteral calculi.[65-66] However, the superb performance characteristics of CT must be balanced against its potential harms.

(3C) Follow Up After Ureteroscopic Extraction, Intact Stone



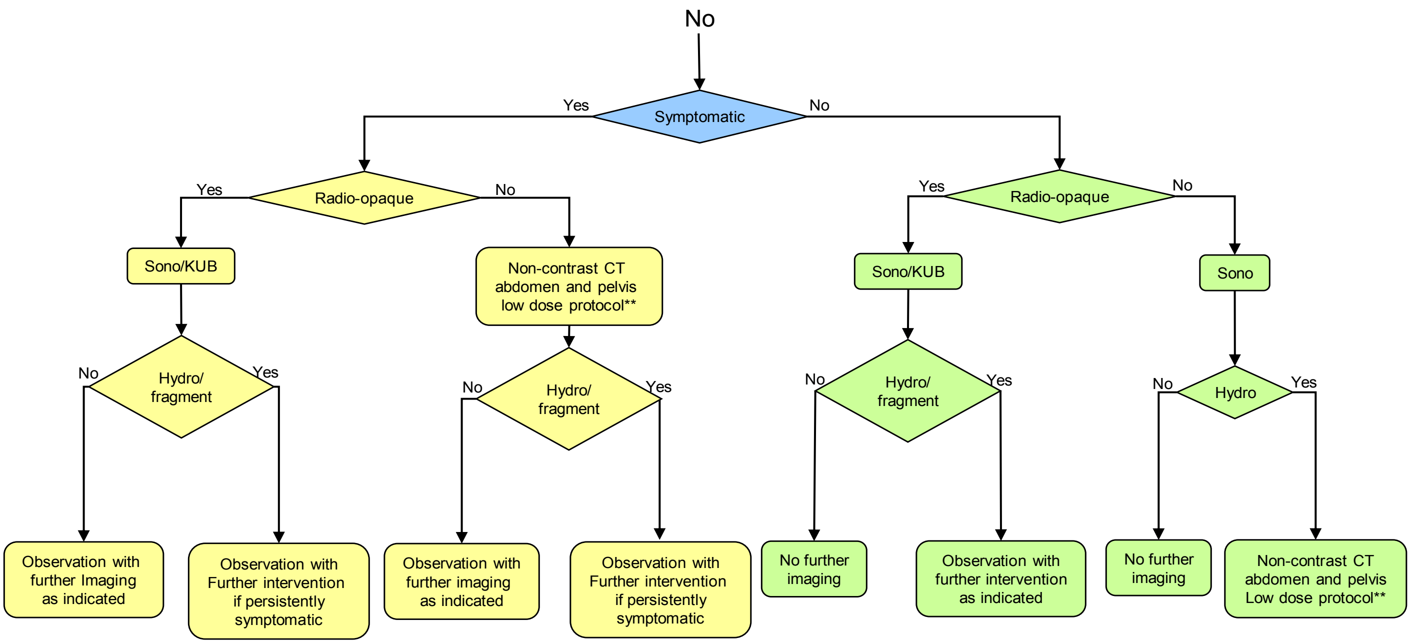
*** Assuming normal renal function and no contrast allergy

Risks Associated with Ureteral Imaging
All forms of conventional radiography and CT scanning depend on ionizing radiation to create an image. Ionizing radiation is known to potentially harm through deterministic and stochastic effects. ***Deterministic effects*** (e.g., erythema of the skin and generation of cataracts) occur at a given threshold, and the effect is proportionate to the dose. ***Stochastic effects*** (e.g., the induction of secondary cancers or hereditary defects) may occur at any dose. The probability that a stochastic effect will occur increases with the dose, but the severity of the effect is independent of the dose. Deterministic effects are rarely encountered with diagnostic radiation doses associated with the management of ureteral calculous disease. Stochastic effects are currently believed to be low-threshold events linearly correlated with dose.[67] In general, younger patients, patients with genetic instability and pregnant patients are at higher risk of suffering long-term harms as the result of radiation exposure.[68]

It is useful to quantify the risk of radiation exposure to patients and healthcare providers using "effective dose." ***Effective dose*** (in mSv) estimates the potential adverse biologic effect of the sum of the equivalent doses of radiation to exposed organs; therefore, radiation exposure from various types of diagnostic imaging studies can be compared in terms of relative biologic risk. Effective dose cannot be equated to the actual absorbed dose for any individual. The actual absorbed dose for an individual will depend on the scanning protocol and the equipment with which it is performed. There is compelling evidence of wide variability in the effective dose produced during the same kind of examination (e.g., CT of the abdomen and pelvis) within an imaging facility and between imaging facilities.[69] Average effective doses for imaging studies commonly performed in the evaluation and management of ureteral calculous disease are given in Table 2. Actual doses in clinical practice may be considerably higher owing to a number of factors.[69]

In addition to the harms associated with radiation exposure, imaging studies utilizing intravenous contrast (iodine or gadolinium) have associated risks. Adverse reactions including severe allergic reactions, impaired renal function, nephrogenic systemic fibrosis and death have been reported.[70]

(3C1) Follow Up After Ureteroscopic Extraction, Requiring Fragmentation



**Low dose protocol not recommended for patients with BMI>30

Table 2. Estimated Effective Dose (mSv) by Type of Exam

Type of Exam	Effective dose (mSv)	Reference
Ultrasound (US)		
Abdomen and pelvis US	0	
Magnetic Resonance Imaging (MRI)		
Abdomen and pelvis MRI	0	
Conventional Radiography (CR)		
KUB	0.7	A
KUB with tomograms	3.9	B
IVU	3.0	A, C
Computed Tomography (CT)		
Non-contrast CT, abdomen and pelvis	10.0	D,E
Without and with contrast CT, abdomen and pelvis (2-phase)	15.0	F
Without and with contrast CT, abdomen and pelvis (3-phase)	20.0	A
Non-contrast CT, abdomen and pelvis (low-dose protocol)	3.0	G

Table 2 References:
A. Mettler FA, Huda W, Yoshizumi TT et al: Effective doses in radiology and diagnostic nuclear medicine: a catalog. Radiology 2008; **1**: 254.
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Minimizing Risks

All imaging studies using ionizing radiation should aspire to the ALARA principle (As Low As Reasonably Achievable),[71] attempting to expose the patient to the least ionizing radiation that will answer the clinical question at hand. Thus, when two or more imaging studies have equal or nearly equal clinical effectiveness, the study with the least ionizing radiation should be selected. A non-contrast study should be selected over one using contrast when it would be equally effective to do so.

Optimization of selected studies should be pursued. For example, the sensitivity of abdominal ultrasound or KUB for the detection of a ureteral calculus may be optimized by withholding food and fluid prior to the examination to reduce the adverse effects of bowel gas on sensitivity and specificity.[72] Similarly, optimization of conventional radiographs used to identify ureteral calculi may be accomplished by the aforementioned measures to decrease bowel gas or by adding oblique studies or tomograms to reduce missed detection from underlying or overlying structures.

Optimization of CT scans includes limited scanning protocols confined to an anatomic region of interest (e.g., pelvic CT) for evaluation of the distal ureter, adjustments of CT parameters for tissue thickness and body habitus and limitation of phases (e.g., non-contrast only or combined injection and delayed phases) to reduce total radiation exposure. Specific protocols to reduce radiation exposure for the detection of ureteral calculous disease have been successful in lowering the effective dose for a standard abdominal and pelvic CT scan from 10 mSv to 3 mSv.[60]

Specific scanning protocols for imaging facilities may vary significantly based on the wide range of estimates of effective dose found in the literature for a given exam. Clinicians will need to understand which scanning protocols are being used in imaging their patients.

Resource Utilization

The best interests of the patient are paramount when imaging is performed for any clinical problem. The study is justified when the benefits of the information obtained outweigh the potential physical and economic harms to the patient. It is reasonable to consider the cost of an imaging study both to the individual patient and to the healthcare system. Healthcare resources are finite. Therefore, cost effectiveness becomes the third factor (along with performance characteristics and risks) in considering the overall clinical effectiveness of an imaging study.

Costs of Imaging

The costs of imaging vary widely and are dependent in part on market-related factors and who is responsible for payment. One surrogate for relative cost is the maximum allowable charges assigned to the study by the Centers for Medicare and Medicaid Services (CMS). Table 3 demonstrates the ratio of the national allowed charges for imaging procedures commonly used for the diagnosis and management of ureteral calculous disease. Actual charges by imaging providers for each study may be considerably higher than the CMS allowed charge. By looking at relative charges, it is possible to have a sense of "costs." For example, NCCT has charges that are twice as high as ultrasound, while MRI charges are three-fold higher than CT. However, it is important to keep in mind that charges are artificial and may not correspond proportionately to cost, i.e., the actual cost of resources required to provide a given service. In fact, the allowable charge for CT has been aggressively cut by CMS in an attempt to limit utilization.

Table 3. Average Medicare Allowable by Type of Exam

Type of Exam	Approximate Relative Values (KUB=1)
Ultrasound (US)	
Abdomen and pelvis US	5
Magnetic Resonance Imaging (MRI)	
Abdomen and pelvis MRI (without contrast)	30
Conventional Radiography (CR)	
KUB	1
KUB with tomograms	
IVU	5
Computed Tomography (CT)	
Non-contrast CT, abdomen and pelvis	10
Without and with contrast CT, abdomen and pelvis (2-phase)	20
Without and with contrast CT, abdomen and pelvis (3-phase)	20
Non-contrast CT, abdomen and pelvis (low-dose protocol)	10

Reference: CMS charge data national average 2012

Summary

While medical decision making should not be compromised by cost, it is often possible to make rational medical decisions without additional imaging studies or with a lower-cost option. In those cases where the information may be obtained by two equally sensitive or nearly equally sensitive imaging modalities, the lower cost option should be favored. When a clinical question can be answered equally or nearly equally by two or more imaging modalities, it is the modality with the least harm and lowest overall resource utilization that should be selected. This Technology Assessment has produced clinical effectiveness protocols which attempt to summarize information about the (1) performance characteristics, (2) risks and (3) costs of imaging studies to provide a rational approach to imaging in the management of ureteral calculous disease.

Appendix A: Methodology

Inclusion and exclusion criteria considered during the abstract and full text review process were as follows:

Population

Included: Patients satisfying one or more of the four following scenarios: (i) primary flank pain or renal colic with no previous history of stone, (ii) flank pain with known history of renal calculous disease, (iii) follow-up of known ureteral stone and (iv) follow-up after treatment of ureteral stone. An age threshold of 14 years was selected for separating pediatric and adult patient populations. This threshold was determined after initial assessment of the available literature and recommendations by the panel. Articles that focused on the pediatric population were selected for separate assessment. Given the lack of gender specific studies retrieved, male and female patients were not distinguished in the evidence synthesis, with the exception of pregnant female patients, who were assessed independently.

Excluded: Patients representing unique and infrequent challenges for imaging modalities (e.g., morbidly obese subjects, patients with anatomical abnormalities that preclude standard imaging techniques).

Interventions

Included: non-contrast and contrast computed tomography, conventional radiography, intravenous pyelography, ultrasound, magnetic resonance imaging, nuclear medicine or any combination of the above.

Excluded: All other imaging techniques were excluded.

Study design

Included: Given the diagnostic nature of the topic and the unknown size of the body of literature, there were no restrictions on study design. Included studies were randomized controlled trials (RCTs); controlled clinical trials (CCTs) and observational studies including cohort studies with and without comparison group, case-control studies, case series, as well as more general prospective and retrospective diagnostic accuracy studies.

Excluded: Studies of non-living humans, animals or artificial systems.

Sample size

Studies with fewer than 10 patients were excluded from data extraction given the unreliability of the statistical estimates that can be derived from them.

Articles selected for full-text review were classified according to several factors including study design, sample size, index patient scenario, general patient characteristics, imaging modalities, and related Guiding Questions. A separate analysis was conducted for each Guiding Question in which at least one relevant study met the inclusion criteria. A qualitative assessment of all included studies was performed, including examination of the heterogeneity of populations, interventions and outcomes. Finally for each Guiding Question, the body of evidence was assessed for each relevant outcome (benefits and harms), study design, methodological quality, volume of data (number of studies and subjects), consistency and precision. The body of evidence for each outcome across studies will be rated using the AUA system of A, B or C.

A = well-constructed RCTs or extremely strong and consistent observational studies

B = RCTs with weaknesses of procedures or applicability or moderately strong and consistent observational studies

C = observational studies yielding inconsistent findings or that have other problems

Upon completion of the abstract review and systematic prioritization of topics, 411 articles were selected for full-text review, which formed the basis of the evidence report. Table 4 displays the number of articles found to be directly related to each Guiding Question and the corresponding rating of the body of evidence.

Table 4. Guiding questions and associated evidence from literature review (based on review of the literature, the panel determined that age 14 was typically reported as the cutoff between pediatric and adult patients)

Guiding Questions	Total relevant articles from literature search	Strength of evidence
Index Patients		
1. In **adult patients** (14 years and older) with {suspected renal colic with no previous history of stone/ suspected renal colic with known history of renal calculous disease} what is the most appropriate and effective imaging modality for diagnosis and management of ureteral calculous disease?	145	High (level A)
2. In **pediatric patients** (younger than 14 years) with {suspected renal colic with no previous history of stone/suspected renal colic with known history of renal calculous disease} what is the most appropriate and effective imaging modality for diagnosis and management of ureteral calculous disease?	15	Low (level C)
3. In **pregnant patients** with {suspected renal colic with no previous history of stone/flank pain with known history of renal calculous disease} what is the most appropriate and effective imaging modality for diagnosis and management of ureteral calculous disease?	12	Low (level C)
4. In **adult patients** (14 years and older), what is the most appropriate and effective imaging modality for {follow-up of a known ureteral stone/follow-up after treatment of ureteral stones}?	28	Low (level C)
5. In **pediatric patients** (younger than 14 years), what is the most appropriate and effective imaging modality for {follow-up of a known ureteral stone/follow-up after treatment of ureteral stones}?	4	Low (level C)
6. In **pregnant patients**, what is the most appropriate and effective imaging modality for {follow-up of a known ureteral stone/follow-up after treatment of ureteral stones}?	0	N/A
Modalities		
7. What is the diagnostic accuracy (sensitivity/specificity) of **non-contrast CT** in identifying ureteral calculi?	37	High (level A)
8. What is the diagnostic accuracy (sensitivity/specificity) of **conventional radiography** (low KV, MA films) relative to non-contrast CT in identifying ureteral calculi?	21	Low (level C)
9. What is the diagnostic accuracy (sensitivity/specificity) of **ultrasound** relative to non-contrast CT in identifying ureteral calculi?	21	Low (level C)
10. What is the diagnostic accuracy (sensitivity/specificity) of **intravenous pyelography (IVU)** relative to non-contrast CT in identifying ureteral calculi?	19	Low (level C)
11. What is the diagnostic accuracy (sensitivity/specificity) of **magnetic resonance imaging (MRI)** relative to non-contrast CT in identifying ureteral calculi?	3	Low (level C)
12. What is the accuracy of nuclear medicine studies for identification of ureteral obstruction or renal damage?	6	Moderate (level B)

Table 4 Continued...

Conditions		
13. Of what value are **location** and **duration** of pain in predicting imaging findings for {non-contrast CT/conventional radiography/ultrasound/IVU/MRI/nuclear imaging}?	3	Low (level C)
14. What is the diagnostic significance of **hydronephrosis** for {non-contrast CT/conventional radiography/ultrasound/IVU/MRI/nuclear imaging}?	56	Moderate (level B)
15. What is the significance of **extravasation** in predicting clinical outcome?	0	N/A
16. What is the significance of secondary signs on CT (e.g. perinephric or renal stranding, renal edema, enlargement, density) in predicting clinical outcome?	25	Moderate (level B)
17. To what extent and for how long can ureteral obstruction be tolerated in an {adult/pediatric/pregnant} patient without risk of permanent renal damage/loss of function?	1	Low (level C)
18. What is the diagnostic accuracy (sensitivity/specificity) of {non-contrast CT/conventional radiography/ultrasound/IVU/MRI} based on stone location?	14	Moderate (level B)
19. What is the reliability of **hydronephrosis** as indicator of degree of obstruction and potential for loss of renal function? (If hydronephrosis is confirmed and calculus is suspected, what is the best way to assess obstruction/potential loss of renal function? (Resistive indices, IVU etc.))	24	Moderate (level B)
20. Does the **lack of hydronephrosis** properly exclude clinically important obstruction after ureteroscopy or *extracorporeal shock wave lithotripsy* (*SWL*)?	2	Low (level C)
Consequences		
21. What **harms** are associated with utilization of non-contrast CT imaging for ureteral calculous disease?	26	Low (level C)
22. What **radiation-based risks or harms** are associated with utilization of nuclear medicine imaging for ureteral calculous disease?	2	Low (level C)
23. What are additional **risks or harms** associated with utilization of non-contrast CT imaging for ureteral calculous disease?	26	Low (level C)
24. What are additional **risks or harms** associated with utilization of conventional radiography imaging for ureteral calculous disease?	2	Low (level C)
25. What are additional **risks or harms** associated with utilization of intravenous pyelography for ureteral calculous disease?	11	Low (level C)
26. What are additional **risks or harms** associated with utilization of ultrasound imaging for ureteral calculous disease?	1	Low (level C)
27. What are additional **risks or harms** associated with utilization of magnetic resonance imaging for ureteral calculous disease?	0	N/A
28. What are additional **risks or harms** associated with utilization of nuclear medicine imaging for ureteral calculous disease?	2	Low (level C)
29. What are the economic consequences of {non-contrast CT/conventional radiography/ultrasound/IVU/MRI/nuclear medicine/some combination of the prior}?	6	Low (level C)
Epidemiology		
30. What is the current **utilization** of {non-contrast CT/conventional radiography/ultrasound/ IVU/MRI/nuclear medicine/some combination of the prior} in management of the initial episode of ureteral colic?	8	High (level A)
31. After diagnosis of ureteral calculous disease, what is the **frequency of follow-up imaging** utilizing {non-contrast CT/conventional radiography/ultrasound/ IVU/MRI/nuclear medicine/some combination of the prior}?	27	Moderate (level B)

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Conflict of Interest Disclosures

All panel members completed COI disclosures. Relationships that have expired (more than one year old) since the panel's initial meeting, are listed. Those marked with (C) indicate that compensation was received; relationships designated by (U) indicate no compensation was received.

Consultant/Advisor: Dean Assimos, Oxalosis and Hyperoxaluria Foundation (OHF) (U)

Scientific Study or Trial: Dean Assimos, National Institute of Health (NIH) (C)

Other-Investment Interest: Pat F. Fulgham, Urology Clinics of North Texas (C)

Other -Health Publishing: Dean Assimos, Med Review in Urology (C), Urology Times ©
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We are grateful to the persons listed below who contributed to the Imaging Pilot Project by providing comments during the peer review process. Their reviews do not necessarily imply endorsement of the Guideline.

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Disclaimer

This document was written by the Imaging Pilot Panel of the American Urological Association (AUA) Education and Research, Inc., which was created in 2011. The Practice Guidelines Committee of the AUA selected the panel chair. Panel members were selected by the chair. Membership of the panel included urologists, with specific expertise in this area. The mission of the committee was to develop guidance that is analysis-based or consensus-based, depending on Panel processes and available data, for optimal clinical practices in the use of imaging for the management of ureteral calculus.

Funding of the committee was provided by the AUA, and Committee members received no remuneration for their work. Each member of the committee provides an ongoing conflict of interest disclosure to the AUA.

While this clinical effectiveness protocol does not necessarily establish the standard of care, AUA seeks to recommend and to encourage compliance by practitioners with current best practices related to the condition being treated. As medical knowledge expands and technology advances, the document will change. Today, this guidance represents not absolute mandates but provisional proposals for treatment under the specific conditions described. For all these reasons, this document does not pre-empt physician judgment in individual cases. Treating physicians must take into account variations in resources, and patient tolerances, needs, and preferences. Conformance with any clinical effectiveness protocol does not guarantee a successful outcome.

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