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American Urological Association (AUA)

Endourological Society Guideline

SURGICAL MANAGEMENT OF STONES: AMERICAN UROLOGICAL ASSOCIATION/ ENDOUROLOGICAL SOCIETY GUIDELINE

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Purpose

The purpose of this Guideline is to provide a clinical framework for the surgical management of patients with kidney and/or ureteral stones.

Methods

A systematic review of the literature using the Medline In-Process & Other Non-Indexed Citations, MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and Scopus databases (search dates 1/1/1985 to 5/31/15) was conducted to identify peer-reviewed studies relevant to the surgical management of stones. The review yielded an evidence base of 1,911 articles after application of inclusion/exclusion criteria. These publications were used to create the guideline statements. If sufficient evidence existed, then the body of evidence for a particular treatment was assigned a strength rating of A (high quality evidence; high certainty), B (moderate quality evidence; moderate certainty), or C (low quality evidence; low certainty). Evidence-based statements of Strong, Moderate, or Conditional Recommendation, which can be supported by any body of evidence strength, were developed based on benefits and risks/burdens to patients. Additional information is provided as Clinical Principles and Expert Opinions when insufficient evidence existed.

Guideline Statements

Imaging, pre-operative testing:

1. **Clinicians should obtain a non-contrast CT scan on patients prior to performing PCNL. *Strong Recommendation; Evidence Level Grade C***
2. **Clinicians may obtain a non-contrast CT scan to help select the best candidate for SWL versus URS. *Conditional Recommendation; Evidence Level Grade C***
3. **Clinicians may obtain a functional imaging study (DTPA or MAG-3) if clinically significant loss of renal function in the involved kidney or kidneys is suspected. *Conditional Recommendation; Evidence Level Grade C***
4. **Clinicians are required to obtain a urinalysis prior to intervention. In patients with clinical or laboratory signs of infection, urine culture should be obtained. *Strong Recommendation; Evidence Level Grade B***
5. **Clinicians should obtain a CBC and platelet count on patients undergoing procedures where there is a significant risk of hemorrhage**

or for patients with symptoms suggesting anemia, thrombocytopenia, or infection; serum electrolytes and creatinine should be obtained if there is suspicion of reduced renal function. *Expert Opinion*

6. **In patients with complex stones or anatomy, clinicians may obtain additional contrast imaging if further definition of the collecting system and the ureteral anatomy is needed. *Conditional Recommendation; Evidence Level Grade C***

Treatment of adult patients with ureteral stones:

7. **Patients with uncomplicated ureteral stones ≤10 mm should be offered observation, and those with distal stones of similar size should be offered MET with α-blockers. (Index Patient 3) *Strong Recommendation; Evidence Level Grade B***
8. **Clinicians should offer reimaging to patients prior to surgery if passage of stones is suspected or if stone movement will change management. Reimaging should focus on the region of interest and limit radiation exposure to uninvolved regions. *Clinical Principle***
9. **In most patients, if observation with or without MET is not successful after four to six weeks and/or the patient/clinician decide to intervene sooner based on a shared decision making approach, clinicians should offer definitive stone treatment. (Index Patients 1-3) *Moderate Recommendation; Evidence Level Grade C***
10. **Clinicians should inform patients that SWL is the procedure with the least morbidity and lowest complication rate, but URS has a greater stone-free rate in a single procedure. (Index Patients 1-6) *Strong Recommendation; Evidence Level Grade B***
11. **In patients with mid or distal ureteral stones who require intervention (who were not candidates for or who failed MET), clinicians should recommend URS as first-line therapy. For patients who decline URS, clinicians should offer SWL. (Index Patients 2,3,5,6) *Strong Recommendation; Evidence Level Grade B***
12. **URS is recommended for patients with suspected cystine or uric acid ureteral stones who fail MET or desire intervention. *Expert Opinion***
13. **Routine stenting should not be performed in patients undergoing SWL. (Index Patients 1-6) *Strong Recommendation; Evidence Level Grade B***
14. **Following URS, clinicians may omit ureteral stenting in patients meeting all of the following criteria: those without suspected ureteric injury during URS, those without evidence of ureteral stricture or other anatomical impediments to stone fragment clearance, those with a normal contralateral kidney, those without renal functional impairment, and those in whom a secondary URS procedure is not planned. (Index Patients 1-6) *Strong Recommendation; Evidence Level Grade A***
15. **Placement of a ureteral stent prior to URS should not be performed routinely. (Index Patient 1-6) *Strong Recommendation; Evidence Level Grade B***
16. **Clinicians may offer α-blockers and antimuscarinic therapy to reduce stent discomfort. (Index patients 1-6) *Moderate Recommendation; Evidence Level Grade B***
17. **In patients who fail or are unlikely to have successful results with SWL and/or URS, clinicians may offer PCNL, laparoscopic, open, or robotic assisted stone removal. (Index patient 1-6) *Moderate Recommendation; Evidence Level Grade C***
18. **Clinicians performing URS for proximal ureteral stones should have a flexible ureteroscope available. (Index Patients 1, 4) *Clinical Principle***
19. **Clinicians should not utilize EHL as the first-line modality for intra-ureteral lithotripsy. (Index patients 1-6,13,15) *Expert Opinion***

20. **In patients with obstructing stones and suspected infection, clinicians must urgently drain the collecting system with a stent or nephrostomy tube and delay stone treatment. *Strong Recommendation; Evidence Level Grade C***

<u>Treatment of adult patients with renal stones:</u>

21. **In symptomatic patients with a total non-lower pole renal stone burden ≤ 20 mm, clinicians may offer SWL or URS. (Index Patient 7) *Strong Recommendation; Evidence Level Grade B***
22. **In symptomatic patients with a total renal stone burden >20 mm, clinicians should offer PCNL as first -line therapy. (Index Patient 8) *Strong Recommendation; Evidence Level Grade C***
25. **In patients with total renal stone burden >20 mm, clinicians should not offer SWL as first-line therapy. (Index Patient 8) *Moderate Recommendation; Evidence Level Grade C***
27. **Clinicians may perform nephrectomy when the involved kidney has negligible function in patients requiring treatment. (Index Patients 1-14) *Conditional Recommendation; Evidence Level Grade* C**
28. **For patients with symptomatic (flank pain), non-obstructing, caliceal stones without another obvious etiology for pain, clinicians may offer stone treatment. (Index Patient 12) *Moderate Recommendation; Evidence Level Grade C***
29. **For patients with asymptomatic, non-obstructing caliceal stones, clinicians may offer active surveillance. *Conditional Recommendation; Evidence Level Grade C***
30. **Clinicians should offer SWL or URS to patients with symptomatic ≤ 10 mm lower pole renal stones. (Index Patient 9) *Strong Recommendation; Evidence Level Grade B***
31. **Clinicians should not offer SWL as first-line therapy to patients with >10mm lower pole stones. (Index Patient 10) *Strong Recommendation; Evidence Level Grade B***
32. **Clinicians should inform patients with lower pole stones >10 mm in size that PCNL has a higher stone -free rate but greater morbidity. (Index patient 10). *Strong Recommendation; Evidence Level Grade B***
33. **In patients undergoing uncomplicated PCNL who are presumed stone-free, placement of a nephrostomy tube is optional. *Conditional Recommendation; Evidence Level Grade C***
34. **Flexible nephroscopy should be a routine part of standard PCNL. *Strong Recommendation; Evidence Level Grade B***
35. **Clinicians must use normal saline irrigation for PCNL and URS. *Strong Recommendation; Evidence Level Grade B***
39. **In patients not considered candidates for PCNL, clinicians may offer staged URS. *Moderate Recommendation; Evidence Level Grade* C**
40. **Clinicians may prescribe α-blockers to facilitate passage of stone fragments following SWL. *Moderate Recommendation; Evidence Level Grade B***
43. **SWL should not be used in the patient with anatomic or functional obstruction of the collecting system or ureter distal to the stone. *Strong Recommendation; Evidence Level Grade C***
44. **In patients with symptomatic caliceal diverticular stones, endoscopic therapy (URS, PCNL, laparoscopic, robotic) should be preferentially utilized. *Strong Recommendation; Evidence Level Grade C***
45. **Staghorn stones should be removed if attendant comorbidities do not preclude treatment. *Clinical Principle***

Treatment for pediatric patients with ureteral or renal stones:

46. **In pediatric patients with uncomplicated ureteral stones ≤10 mm, clinicians should offer observation with or without MET using α-blockers. (Index Patient 13)** ***Moderate Recommendation; Evidence Level Grade B***
47. **Clinicians should offer URS or SWL for pediatric patients with ureteral stones who are unlikely to pass the stones or who failed observation and/or MET, based on patient-specific anatomy and body habitus. (Index Patient 13)** ***Strong Recommendation; Evidence Level Grade B***
48. **Clinicians should obtain a low-dose CT scan on pediatric patients prior to performing PCNL. (Index Patient 13)** ***Strong Recommendation; Evidence Level Grade C***
49. **In pediatric patients with ureteral stones, clinicians should not routinely place a stent prior to URS. (Index Patient 13)** ***Expert Opinion***
50. **In pediatric patients with a total renal stone burden ≤20mm, clinicians may offer SWL or URS as first -line therapy. (Index Patient 14)** ***Moderate Recommendation; Evidence Level Grade C***
51. **In pediatric patients with a total renal stone burden >20mm, both PCNL and SWL are acceptable treatment options. If SWL is utilized, clinicians should place an internalized ureteral stent or nephrostomy tube. (Index Patient 14)** ***Expert Opinion***
52. **In pediatric patients, except in cases of coexisting anatomic abnormalities, clinicians should not routinely perform open/laparoscopic/robotic surgery for upper tract stones. (Index Patients 13, 14)** ***Expert Opinion***
53. **In pediatric patients with asymptomatic and non-obstructing renal stones, clinicians may utilize active surveillance with periodic ultrasonography. (Index Patient 14)** ***Expert Opinion***

Treatment for pregnant patients with ureteral or renal stones:

54. **In pregnant patients, clinicians should coordinate pharmacological and surgical intervention with the obstetrician. (Index Patient 15)** ***Clinical Principal***
55. **In pregnant patients with ureteral stones and well controlled symptoms, clinicians should offer observation as first-line therapy. (Index Patient 15*) Strong recommendation; Evidence Level Grade B***
56. **In pregnant patients with ureteral stones, clinicians may offer URS to patients who fail observation. Ureteral stent and nephrostomy tube are alternative options with frequent stent or tube changes usually being necessary. (Index Patient 15)** ***Strong Recommendation; Evidence Level Grade C***

Treatment for all patients with ureteral or renal stones:

23. **When residual fragments are present, clinicians should offer patients endoscopic procedures to render the patients stone free, especially if infection stones are suspected. (Index Patient 11)** ***Moderate Recommendation; Evidence Level Grade C***
24. **Stone material should be sent for analysis.** ***Clinical Principle***
26. **Open/ laparoscopic /robotic surgery should not be offered as first-line therapy to most patients with stones. Exceptions include rare cases of anatomic abnormalities, with large or complex stones, or those requiring concomitant reconstruction. (Index Patients 1-15)** ***Strong Recommendation; Evidence Level Grade C***
36. **A safety guide wire should be used for most endoscopic procedures. (Index Patients 1-15)** ***Expert Opinion***
37. **Antimicrobial prophylaxis should be administered prior to stone intervention and is based primarily**

on prior urine culture results, the local antibiogram, and in consultation with the current Best Practice Policy Statement on Antibiotic Prophylaxis. *Clinical Principle*

38. **Clinicians should abort stone removal procedures, establish appropriate drainage, continue antibiotic therapy, and obtain a urine culture if purulent urine is encountered during endoscopic intervention. (Index Patients1-15) *Strong Recommendation; Evidence Level Grade C***

41. **If initial SWL fails, clinicians should offer endoscopic therapy as the next treatment option. (Index Patient 1-14) *Moderate Recommendation; Evidence Level Grade C***

42. **Clinicians should use URS as first-line therapy in most patients who require stone intervention in the setting of uncorrected bleeding diatheses or who require continuous anticoagulation/antiplatelet therapy. (Index Patients1-15) *Strong Recommendation; Evidence Level Grade C***

INTRODUCTION

Background

Kidney stones are a common and costly disease; it has been reported that over 8.8% of the United States population will be affected by this malady, and direct and indirect treatment costs are estimated to be several billion dollars per year in this country.[1-3] The surgical treatment of kidney stones is complex, as there are multiple competitive treatment modalities, and in certain cases more than one modality may be appropriate. Proper treatment selection, which is directed by patient- and stone-specific factors, remains the greatest predictor of successful treatment outcomes. The Panel used information from the literature to formulate actionable guideline statements to assist clinicians in providing the best care for their patients requiring stone elimination.

This Guideline includes revisions of the previously published AUA Guidelines titled 'Staghorn Calculi (2005)'[4] and 'Ureteral Calculi (2007)'[5] and is expanded to incorporate the management of patients with non-staghorn renal stones. The Update Literature Review (ULR) process for AUA Guidelines was used to determine that updates were warranted for both the Staghorn Calculi and Ureteral Calculi Guidelines. A guideline for the management of non-staghorn renal stones had previously not been generated by the AUA. The AUA and the Endourological Society felt that a single, all-encompassing guideline document would provide the greatest value to the clinician for patient management. This Guideline also compliments the AUA Guideline on 'Medical Management of Kidney Stones' published in 2014.[6]

The surgical management of patients with various stones is described below and divided into 13 respective patient profiles. Index Patients 1-10 are non-morbidly obese; non-pregnant adults (≥ 18 years of age) with stones not thought to be composed of uric acid or cystine; normal renal, coagulation and platelet function; normally positioned kidneys; intact lower urinary tracts without ectopic ureters; no evidence of sepsis; and no anatomic or functional obstruction distal to the stone(s). Index Patients 13 and 14 are children (<18 years if age) with similar characteristics to Index Patients 1-10. Index Patient 15 is a pregnant female with symptomatic renal or ureteral stone(s) with normal renal function without urinary tract infection (UTI). The proximal ureter is defined as the segment distal to the ureteropelvic junction (UPJ) and above the upper border of the sacroiliac joint. The middle ureter is that which overlies the sacroiliac joint and the distal ureter that lies below it.

Index Patients

Index Patient 1: Adult, ≤10mm proximal ureteral stone

Index Patient 2: Adult, ≤10mm mid ureteral stone

Index Patient 3: Adult, ≤10mm distal ureteral stone

Index Patient 4: Adult, >10mm proximal ureteral stone

Index Patient 5: Adult, >10mm mid ureteral stone

Index Patient 6: Adult, > 10 mm distal ureteral stone

Index Patient 7: Adult, ≤20mm total non-lower pole renal stone burden

Index Patient 8: Adult, >20mm total renal stone burden

Index Patient 9: Adult, ≤10mm lower pole renal stone(s)

Index Patient 10: Adult, >10mm lower pole renal stone(s)

Index Patient 11: Adult, with residual stone(s)

Index Patient 12: Adult, renal stone(s) with pain and no obstruction

Index Patient 13: Child, not known to have cystine or uric acid ureteral stone(s)

Index Patient 14: Child, not known to have cystine or uric acid renal stone(s)

Index Patient 15: Pregnant female, renal or ureteral stone(s)

Methodology

Process for Initial Literature Selection

Consistent with the published AUA Guideline methodology framework,[7] the process started by conducting a comprehensive systematic review. The AUA commissioned an independent group to conduct a systematic review and meta-analysis of the published literature on various options for the surgical

management of stones.[8] The protocol of the systematic review was developed *a priori* by the methodology team in conjunction with the expert panel. A systematic review was conducted to identify published articles relevant to the surgical management of renal or ureteral stones. Literature searches were performed on English-language publications using the Medline In-Process & Other Non-Indexed Citations, MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and Scopus from 1/1/1985 to 5/31/2015. Preclinical studies (e.g., animal models), commentary, and editorials were excluded. Studies on patients with lower tract stones were excluded (including bladder stones and diversions). Bibliographies of review articles were checked to ensure inclusion of all possibly relevant studies. Multiple reports on the same patient group were carefully examined to ensure inclusion of only non -redundant information. The systematic review yielded a total of 1,911 studies. The Panel and methodology group continued to monitor the literature for relevant randomized trials thereafter and added several newer trials published through 2015.

The Panel judged that there was a sufficient evidence base from which to construct the Guideline. Data on study type (e.g., randomized controlled trial [RCT], controlled clinical trial [CCT], observational study), perioperative testing, treatment parameters (e.g., type of treatment), patient characteristics (e.g., age, stone size and location), outcomes (e.g., stone-free rate, residual fragments, quality of life [QoL]) and complications were extracted.

Almost all the studies that reported on preoperative testing (99 computed tomography [CT] scan, 10 renal scan, 128 renal ultrasound [US], 188 KUB, 156 intravenous pyelogram [IVP], 68 complete blood count [CBC], 29 stone analysis and 112 urine culture) did not report the purpose of performing these tests. There were no reliable data on the utility or incremental value of testing. The procedures of interest were percutaneous nephrolithotomy (PCNL), ureteroscopy (URS), laparoscopy, shock-wave lithotripsy (SWL), open surgery, robotic surgery, ureteral stent, or nephrostomy. Comparison of any of these active treatments against each other or against medical management was done when possible. Medical expulsive therapy (MET) was evaluated in terms of efficacy against placebo. Outcomes included stone-free rate (as determined by KUB, US, IVP, nephrotomogram, CT, endoscopy); residual fragments (by size); secondary procedures needed (stone-removing versus ancillary); QoL; pain; analgesic requirements; length of hospitalization; comparative recurrence rates; renal function; and procedure complications (e.g., death, sepsis/sirs, transfusion, loss of kidney, readmission rates, overall rates). When multiple studies evaluated the same outcome and had similar population, intervention, and comparison, meta-analysis was conducted using the random effects model, when appropriate.[8] Stone-free rate was stratified based on stone size and location.

The methodology team independently rated the methodological quality of the studies and provided an overall judgment of the whole body of evidence based on confidence in the available estimates of effect.

The methodology team summarized the data with explicit description of study characteristics, methodological quality, main findings, and quality of the evidence (confidence in the estimates). The methodology team attended panel meetings and facilitated incorporation of the evidence into the Guideline.

Quality of Individual Studies and Determination of Evidence Strength

The quality of individual studies that were either RCTs or CCTs was assessed using the Cochrane Risk of Bias tool.[9] The quality of CCTs and comparative observational studies was rated using the Newcastle-Ottawa Quality (NOQ) Assessment Scale.[10] Because there is no widely-agreed upon quality assessment tool for single cohort observational studies, the quality of these studies was not assessed.

The categorization of evidence strength is conceptually distinct from the quality of individual studies (the latter is also called the risk of bias). Evidence strength refers to the body of evidence available for a particular question and includes not only individual study quality but consideration of study design; consistency of findings across studies; adequacy of sample sizes; and generalizability of samples, settings, and treatments for

the purposes of the Guideline. The AUA categorizes body of evidence strength as Grade A (well-conducted and highly-generalizable RCTs or exceptionally strong observational studies with consistent findings), Grade B (RCTs with some weaknesses of procedure or generalizability or moderately strong observational studies with consistent findings), or Grade C (RCTs with serious deficiencies of procedure or generalizability or extremely small sample sizes or observational studies that are inconsistent, have small sample sizes, or have other problems that potentially confound interpretation of data). By definition, Grade A evidence is evidence about which the Panel has a high level of certainty, Grade B evidence is evidence about which the Panel has a moderate level of certainty, and Grade C evidence is evidence about which the Panel has a low level of certainty.[7]

AUA Nomenclature: Linking Statement Type to Evidence Strength

The AUA nomenclature system links statement type to body of evidence strength, level of certainty, magnitude of benefit or risk/burdens, and the Panel's judgment regarding the balance between benefits and risks/burdens (see Table 1). Strong Recommendations are directive statements that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be undertaken because net benefit or net harm is substantial. Moderate Recommendations are directive statements that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be undertaken because net benefit or net harm is moderate. Conditional Recommendations are non-directive statements used when the evidence indicates that there is no apparent net benefit or harm or when the balance between benefits and risks/burden is unclear. All three statement types may be supported by any body of evidence strength grade. Body of evidence strength Grade A in support of a Strong or Moderate Recommendation indicates that the statement can be applied to most patients in most circumstances and that future research is *unlikely to change confidence*. Body of evidence strength Grade B in support of a Strong or Moderate Recommendation indicates that the statement can be applied to most patients in most circumstances but that better *evidence could change confidence*. Body of evidence strength Grade C in support of a Strong or Moderate Recommendation indicates that the statement can be applied to most patients in most circumstances but that better evidence is likely to *change confidence*. Body of evidence strength Grade C is rarely used in support of a Strong Recommendation. Conditional Recommendations also can be supported by any body of evidence strength. When body of evidence strength is Grade A, the statement indicates that benefits and risks/burdens appear balanced, the best action depends on patient circumstances, and future research is *unlikely to change confidence*. When body of evidence strength Grade B is used, benefits and risks/burdens appear balanced, the best action also depends on individual patient circumstances and better evidence *could change confidence*. When body of evidence strength Grade C is used, there is uncertainty regarding the balance between benefits and risks/burdens, alternative strategies may be equally reasonable, and better evidence is *likely to change confidence*.

For some clinical issues, particularly diagnosis, there was little or no evidence from which to construct evidence-based statements. Where gaps in the evidence existed, the Panel provides guidance in the form of Clinical Principles or Expert Opinions with consensus achieved using a modified Delphi technique if differences of opinion emerged.[11] A *Clinical Principle* is a statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature. *Expert Opinion* refers to a statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence.

Panel Selection and Peer Review Process

The Surgical Management of Stones Panel was created in 2013 by the American Urological Association Education and Research, Inc. (AUA). The Practice Guidelines Committee (PGC) of the AUA selected the Panel Chair who in turn appointed the additional panel members with specific expertise in this area. The Endourological Society also nominated two representatives to serve on the panel. Once nominated,

TABLE 1: AUA Nomenclature Linking Statement Type to Level of Certainty, Magnitude of Benefit or Risk/Burden, and Body of Evidence Strength			
	Evidence Strength A (High Certainty)	**Evidence Strength B (Moderate Certainty)**	**Evidence Strength C (Low Certainty)**
Strong Recommendation (Net benefit or harm substantial)	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is substantial Applies to most patients in most circumstances and future research is unlikely to change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is substantial Applies to most patients in most circumstances but better evidence could change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) appears substantial Applies to most patients in most circumstances but better evidence is likely to change confidence (rarely used to support a Strong Recommendation)
Moderate Recommendation (Net benefit or harm moderate)	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is moderate Applies to most patients in most circumstances and future research is unlikely to change confi-	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is moderate Applies to most patients in most circumstances but better evidence could change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) appears moderate Applies to most patients in most circumstances but better evidence is likely to change confidence
Conditional Recommendation (No apparent net benefit or harm)	Benefits = Risks/Burdens Best action depends on individual patient circumstances Future research unlikely to change confidence	Benefits = Risks/Burdens Best action appears to depend on individual patient circumstances Better evidence could change confidence	Balance between Benefits & Risks/Burdens unclear Alternative strategies may be equally reasonable Better evidence likely to change confidence
Clinical Principle	A statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature		
Expert Opinion	A statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence		

all panel members were asked to record their conflict of interest (COI) statements, providing specific details on the AUA interactive web site. These details are first reviewed by the Guidelines Oversight Committee (GOC), a member sub-committee from the PGC consisting of the Vice Chair of the PGC and two other members. The GOC determines whether the individual has potential conflicts related to the guideline. If there are conflicts, then the nominee's COI is reviewed and approved by the AUA Judicial and Ethics (J&E) committee. A majority of panel members may not have relationships relevant to the Guideline topic.

The AUA conducted a thorough peer review process. The draft guidelines document was distributed to 109 peer reviewers, 54 of whom provided comments. The Panel reviewed and discussed all submitted comments and revised the draft as needed. Once finalized, the Guideline was submitted for approval to the PGC and Science and Quality Council (S&Q). Then it was submitted to the AUA Board of Directors and the Endourological Society Board of Directors for final approval. Funding of the panel was provided by the AUA, with support from The Endourological Society; panel members received no remuneration for their work.

Limitations of the Literature

Evidence to guide perioperative diagnostic evaluation was sparse and of low quality, affecting recommendations on laboratory testing and imaging. Data on stone-free rate (lithotripsy, URS and PCNL) when stratified by location and stone size were also limited in clinical trials; therefore, rates were also derived from large registries that provided precise, although likely biased, estimates. Comparative effectiveness of MET was derived from a large number of trials that overall has a moderate risk of bias. Only a very small number of studies were available to provide comparative effectiveness inferences in children.

GUIDELINE STATEMENTS

1. **Clinicians should obtain a non-contrast CT scan on patients prior to performing PCNL. *Strong Recommendation; Evidence Level Grade C***

Neither randomized trials nor comparative studies have specifically addressed the role of preoperative CT prior to PCNL. Nevertheless, the use of CT for preoperative assessment in those with nephrolithiasis has gained widespread acceptance, as it defines stone burden and distribution, and provides information regarding collecting system anatomy, position of peri-renal structures and relevant anatomic variants. It may also be used to predict operative outcomes and, in some instances, stone composition.[12-21]

CT protocols have been developed and evaluated utilizing radiation doses approximating those of plain film radiography. These "low-dose protocols" continue to allow excellent differentiation of calculi from surrounding tissues while minimizing radiation exposure.[22] Three dimensional reconstructive techniques are additionally available and are advocated by some for their perceived utility in improving preoperative PCNL planning.[23]

2. **Clinicians may obtain a non-contrast CT scan to help select the best candidate for SWL versus URS. *Conditional Recommendation; Evidence Level Grade C***

Neither randomized trials nor comparative studies have specifically addressed the role of preoperative CT for treatment selection between SWL and URS. Furthermore, the Panel recognizes that multiple imaging modalities, including renal US, IVP or intravenous urogram (IVU), and KUB (kidneys, ureters, and bladder) plain radiography, may be used to preoperatively assess candidates for SWL and URS.[24] However, in light of the breadth of information provided by CT, the Panel feels that CT can be useful to help determine whether SWL or URS is better suited for a given patient.

Non-contrast CT imaging is the most sensitive and specific imaging investigation in the diagnosis of upper urinary tract stone disease.[25] Despite CT's diagnostic superiority over other imaging tests, it is incumbent on urologists to be cognizant of the potential risks/harms of the investigations they select for their patients to accurately diagnose and plan appropriate therapies. Concerns regarding the long-term cancer risks associated with ionizing radiation have led to calls for the use of US in the initial diagnosis of acute flank pain. While the initial diagnostic use of US instead of CT

imaging in a randomized trial among patients presenting to the emergency department with suspected nephrolithiasis has not been associated with serious adverse outcomes,[26] a reliance on US alone to formulate surgical planning is a different situation entirely. The use of US alone to direct SWL or URS treatment planning should be discouraged as US is inherently inaccurate in determination of stone size, and it provides no information on stone density.

Although the combined use of KUB and US will provide information on stone size and location better than either modality alone, there are recognized drawbacks to this approach as well. CT has demonstrated improved accuracy in determination of these parameters and may also provide information regarding skin-to-stone distance and stone attenuation. Individually, each of these factors may be used to assess likelihood of successful SWL treatment. Renal stone attenuation should be obtained; <900-1000 Hounsfield units can help predict success with SWL.[27,28] Additionally, skin-to-stone distance, which is best measured by CT, may also predict treatment outcome;[29,30] <10 cm is favorable for renal stones. Thus, clinicians can use CT information to select which patients are reasonable candidates for SWL. If the parameters are not favorable, URS is preferred as excellent results are achievable with these procedures even in a morbidly obese cohort.

Furthermore, using a group of CT-based parameters, predictive models have been developed to estimate stone-free rates for SWL.[31,32] The use of preoperative CT to assess such factors individually or combined in predictive models may aid the clinician in estimating success rates for each modality and ultimately result in a more informed decision in which the risks and benefits of each modality are weighed.

3. **Clinicians may obtain a functional imaging study (DTPA or MAG-3) if clinically significant loss of renal function in the involved kidney or kidneys is suspected.** ***Conditional Recommendation; Evidence Level Grade C***

Kidney stone disease can affect renal function. If a clinician suspects compromise of renal function, obtaining a functional imaging study (DTPA or MAG-3) can help guide treatment for stone disease. Nuclear renography can provide the differential function of the two kidneys in addition to assessing for urinary tract obstruction. It should be noted that the ability of nuclear renography to assess obstruction may be limited in cases of moderate to severe chronic kidney disease.

Although parenchymal thickness can occasionally allow a clinician to estimate renal function, there are settings, such as in the case of chronic kidney disease or staghorn/complex stones, where renal function is compromised and function cannot be adequately assessed without a nuclear renal scan or another contrast-enhanced imaging study, such as CT urography, magnetic resonance (MR) urography, or IV urography.[33-37] Decreased renal function of the involved kidney may lead to a decision to consider other therapeutic options, which may range from observation to nephrectomy.

Additionally, establishing baseline renal function can be useful in following treatment outcomes for upper urinary tract stone disease. The assessment of renal function may be limited in the setting of obstruction; therefore, alleviation of the obstruction with a nephrostomy tube or ureteral stent may be required in order to appropriately assess renal function in the affected renal unit before selecting therapy.

4. **Clinicians are required to obtain a urinalysis prior to intervention. In patients with clinical or laboratory signs of infection, urine culture should be obtained.** ***Strong recommendation; Evidence Level Grade B***

It is critical that clinicians obtain a urinalysis prior to stone intervention in order to minimize the risks of infectious complications. A urine culture should be obtained if UTI is suspected based on the urinalysis or clinical findings. If the culture demonstrates infection, the patient should be prescribed appropriate antibiotic therapy based on sensitivity results in an attempt to sterilize the urine prior to intervention.

Clinicians should also be aware that there can be discordance between preoperative voided urine cultures or those from indwelling urethral catheters compared to urine proximal to an obstructing stone. Intraoperative urine cultures should be obtained, if technically

feasible, from urine proximal to the stone if infected urine is suspected at the time of intervention.[38-42]

Additionally stone cultures may be obtained, especially in cases of suspected infection-related stones, in order to help guide postoperative therapy. There is also potential discordance between stone cultures and preoperative voided urine cultures.[39-41]

5. **Clinicians should obtain a CBC and platelet count on patients undergoing procedures where there is a significant risk of hemorrhage or for patients with symptoms suggesting anemia, thrombocytopenia, or infection; serum electrolytes and creatinine should be obtained if there is suspicion of reduced renal function. *Expert Opinion***

There are neither randomized trials nor comparative studies upon which one may base preoperative laboratory evaluation prior to surgical management of urinary tract stones. The American Society of Anesthesiologists (ASA) released an updated practice advisory for preanesthesia evaluation in 2012. Overall, ASA recommends against routine ordering of preoperative CBC and serum chemistry testing, suggesting this be obtained on a selective basis.[43] The meta-analysis shows that in non-selected/ asymptomatic patients, abnormal CBCs were reported in 2.9-9%, whereas in selected high-risk patients, abnormalities were noted in 6.3-60.8%, leading to change in clinical management in 14.9%. Among non-selected patients, abnormal sodium was noted in 1.9%, abnormal potassium in 0.2-16%, and abnormal glucose in 0.9-40% (changes in clinical management were not reported). ASA concluded that *routine* preanesthesia hemoglobin was not indicated but should be obtained as indicated by clinical characteristics. Similarly, evaluation of serum chemistries and renal function tests should be based upon clinical characteristics, including pertinent preoperative medications and therapies, endocrine disorders, and risk of renal dysfunction. As patients with urolithiasis may be at risk for renal dysfunction, the Panel recommends consideration of preoperative creatinine to assess baseline renal function. In patients undergoing procedures where there is a significant risk of hemorrhage, such as PCNL, open/ laparoscopic or robotic assisted nephrolithotomy, the Panel recommends that a CBC be obtained. In addition, this test should be ordered if the patient has signs or symptoms suggesting anemia, thrombocytopenia or infection. An assessment of serum electrolytes, creatinine and BUN should be checked if reduced renal function is suspected, such as in those with hydronephrosis, parenchymal thinning or co-morbid conditions associated with renal dysfunction and electrolyte disturbances.

There are no randomized trials to inform those circumstances in which preoperative coagulation studies should be obtained prior to surgical management of urologic stone disease. The Society of Interventional Radiology (SIR) Standards of Practice Committee addressed periprocedural assessment of coagulation status prior to image-guided interventions, categorizing percutaneous nephrostomy placement as a procedure with "significant bleeding risk, difficult to detect or control."[44] Based on this designation, SIR advises routinely obtaining pre-procedural international normalized ratio (INR) to assess standardized prothrombin time (PT) in all patients before undergoing nephrostomy tube placement, although there was no consensus on obtaining pre-procedural partial thromboplastin time (PTT).

In contradistinction, the ASA Committee on Standards and Practice Parameters issued an overarching practice advisory for pre-surgical anesthesia evaluation. ASA discourages routine preoperative testing in unselected patients. Rather, coagulation studies should be selectively obtained specifically based upon clinical characteristics, including documented or suspected bleeding disorders, hepatic dysfunction, and renal dysfunction. Those on anticoagulant medications may require coagulation studies preoperatively to assess degree of perioperative anticoagulation, noting that anticoagulated patients may present additional perioperative risk.[43]

The Panel, concurring with the ASA, concludes that in the absence of clinical indications (e.g., the aforementioned systemic anticoagulation, relevant hepatic dysfunction, hematologic disease or bleeding disorders, clinical history suggestive of a coagulation disorder) coagulation studies should not be routinely obtained prior to surgical management of urinary stone

disease. These recommendations are separate from blood product ordering, which should be based upon perceived risks of operative bleeding and perioperative requirements for transfusion. Published institution-specific maximum surgical blood order schedules have suggested preoperative type and screen for PCNL.[45]

6. **In patients with complex stones or anatomy, clinicians may obtain additional contrast imaging if further definition of the collecting system and the ureteral anatomy is needed.** ***Conditional recommendation; Evidence Level Grade C***

When treating a complex stone burden or patient with complex anatomy, a clinician may obtain additional contrast-enhanced imaging with urographic phases to help determine the best treatment approach.[46,47] Complex urinary tract anatomy can be related to both renal/ureteral anatomy and patient body habitus.

Situations in which complex urinary tract anatomy may require further imaging include ectopic kidneys (e.g., horseshoe kidney, pelvic kidney, cross-fused ectopia), other congenital kidney conditions (e.g., UPJ obstruction, duplicated collecting system, caliceal diverticulum, ureteral stricture, megaureter, ureterocele), renal transplant grafts, kidneys with prior surgery or complex stone anatomy/conditions (e.g., staghorn stones, nephrocalcinosis). Further imaging may be required in certain patients (e.g., neurologic disorders, including spinal dysraphism; unusual body habitus; presence of urinary diversion or prior kidney/ureteral surgery).

CT and IVU are the most useful IV contrast studies. Additionally, MR urography can be useful in defining anatomy during pregnancy (without contrast) and in the setting of IV contrast allergy, although stones are typically not well visualized directly with MR imaging.

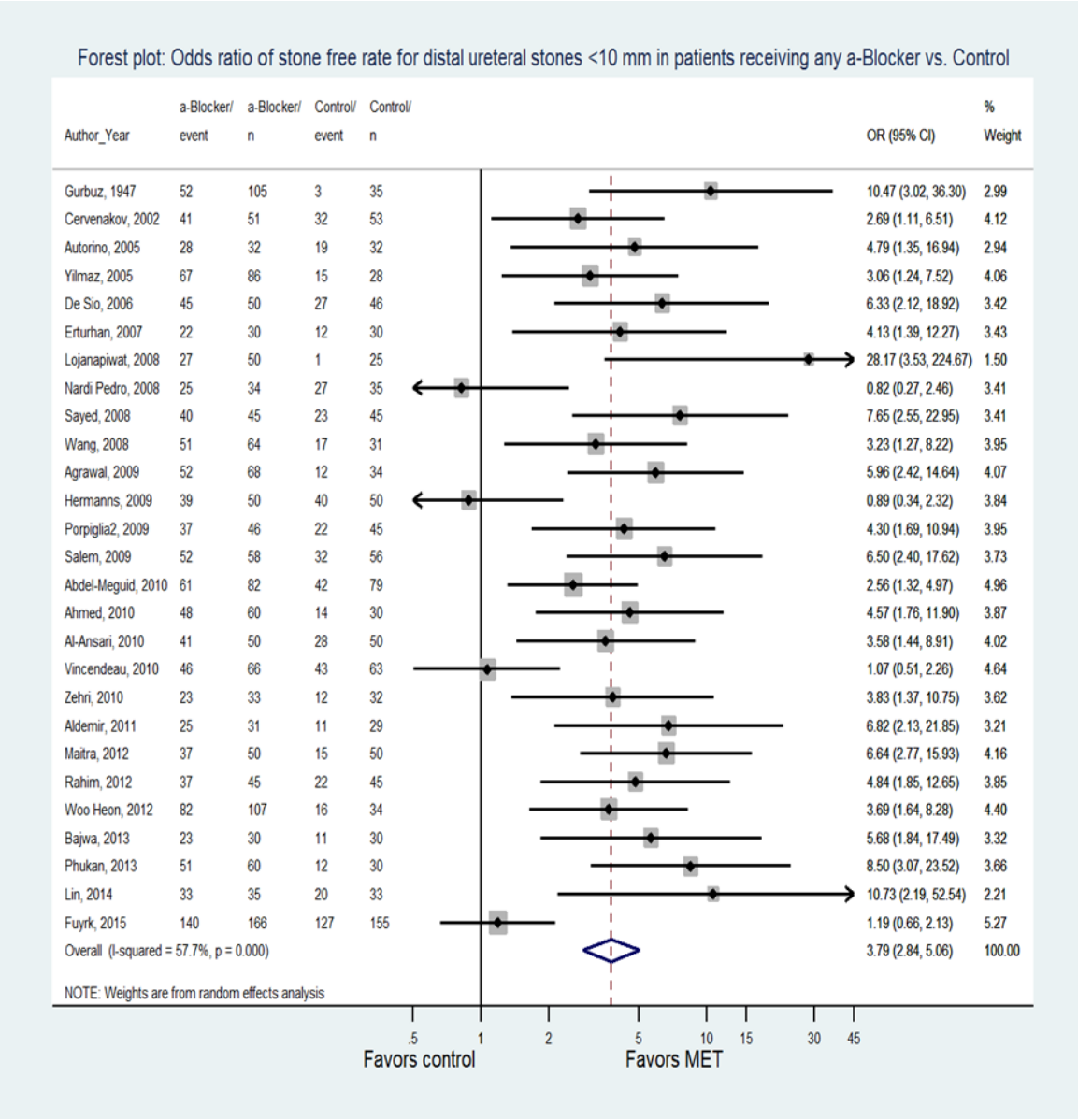
Finally, contrast imaging studies can also include retrograde or antegrade pyelography, which can define the collecting system anatomy and help to determine the optimal treatment approach.

7. **Patients with uncomplicated ureteral stones ≤10 mm should be offered observation, and those with distal stones of similar size should be offered MET with α-blockers. (Index Patient 3)** ***Strong Recommendation; Evidence Level Grade B***

Natural history studies have shown that the likelihood of spontaneous stone passage correlates with stone size and stone location.[48] The smaller the stone and the more distally in the ureter the stone is located, the greater the likelihood of spontaneous passage. Furthermore, smaller stones are likely to pass more quickly than larger stones.[49] The control arms of RCTs evaluating tamsulosin as MET show that about half of patients with distal ureteral calculi <10 mm in size will spontaneously pass their stones (Figure 1). Consequently, there is ample evidence that a trial of spontaneous passage is reasonable in patients amenable to conservative therapy with <10 mm distal ureteral stones in whom pain is well controlled and there are no signs of infection or high grade obstruction. While there is less evidence for those harboring middle and distal ureteral stones, the panel also feels that observation should be offered to those with uncomplicated stones of similar size in these ureteral areas.

Several pharmacologic agents have recently been tested for their ability to change the natural history of ureteral calculi by increasing spontaneous passage rates. Ureteral contractility is mediated by both alpha and beta adrenoreceptors in the ureteral wall. Stimulation of α_1-receptors promotes contraction of ureteral smooth muscle, leading to more vigorous and frequent peristalsis.[50,51] As such, α_1 receptor antagonists have the potential to inhibit ureteral spasm and uncontrolled contraction, theoretically reducing pain and promoting spontaneous stone passage. The Panel's meta-analysis[8] showed superior spontaneous stone passage rates in patients with <10 mm distal ureteral stones treated with α-blockers (77.3%) compared to placebo or no treatment (54.4%) (RR 3.59, 95% CI 2.900-4.125). This effect was largely accounted for by trials in which tamsulosin 0.4 mg was administered daily in patients with <10 mm distal ureteral calculi (Figure 2). Calcium channel blockers, which also suppress smooth muscle contraction by inhibiting the influx of extracellular calcium into smooth muscle cells. One trial showed a benefit of nifedipine, a calcium channel blocker, in patients with <10 mm distal ureteral stones while another did not. Therefore, due to

Figure 1:



insufficient supporting data, the Panel does not endorse the utilization of this agent for MET. (Figure 3).

A recent large trial of 316 patients with <10 mm distal ureteral calculi randomized to tamsulosin 0.4 mg daily or placebo found a benefit of therapy only in patients with larger stones (>5mm, 83% stone passage in the tamsulosin group versus 61% in the placebo group, 95% CI 3.1%-41.6%, p=0.03), but no difference in stone passage rates between treatment and control groups in patients with smaller stones (<5 mm).[52] The already high rate of spontaneous stone passage with smaller stones may account for the lack of effect of tamsulosin seen in patients with smaller stones in this trial. The Panel's meta-analysis found no improvement in stone passage rates in patients with <5 mm distal ureteral stones treated with tamsulosin (OR 1.23, 95% CI 0.61-2.47)[8] but did confirm a benefit of therapy in patients with >5 mm distal ureteral stones (OR 4.53, 95% CI 2.90-7.07). However, given the more limited data available for subgroup analysis, the Panel elected to include all patients with <10 mm distal ureteral stones in the recommendation supporting MET.

Of note, a recent large 3-way RCT from the United Kingdom compared tamsulosin (0.4 mg daily), nifedipine (30 mg daily) and placebo (1:1:1) in patients with ≤10 mm ureteral calculi.[53] Unlike most other MET

Figure 2:

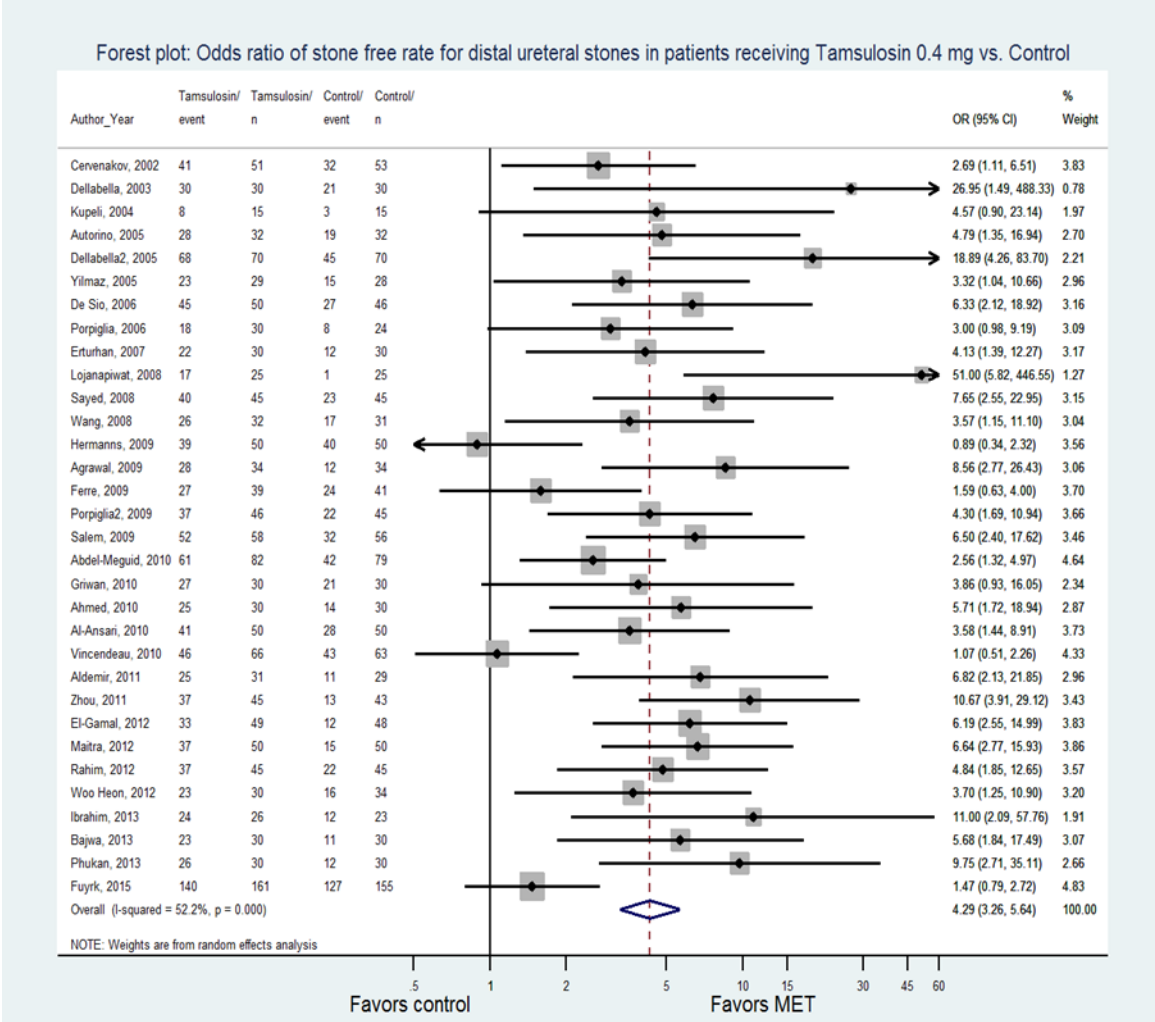
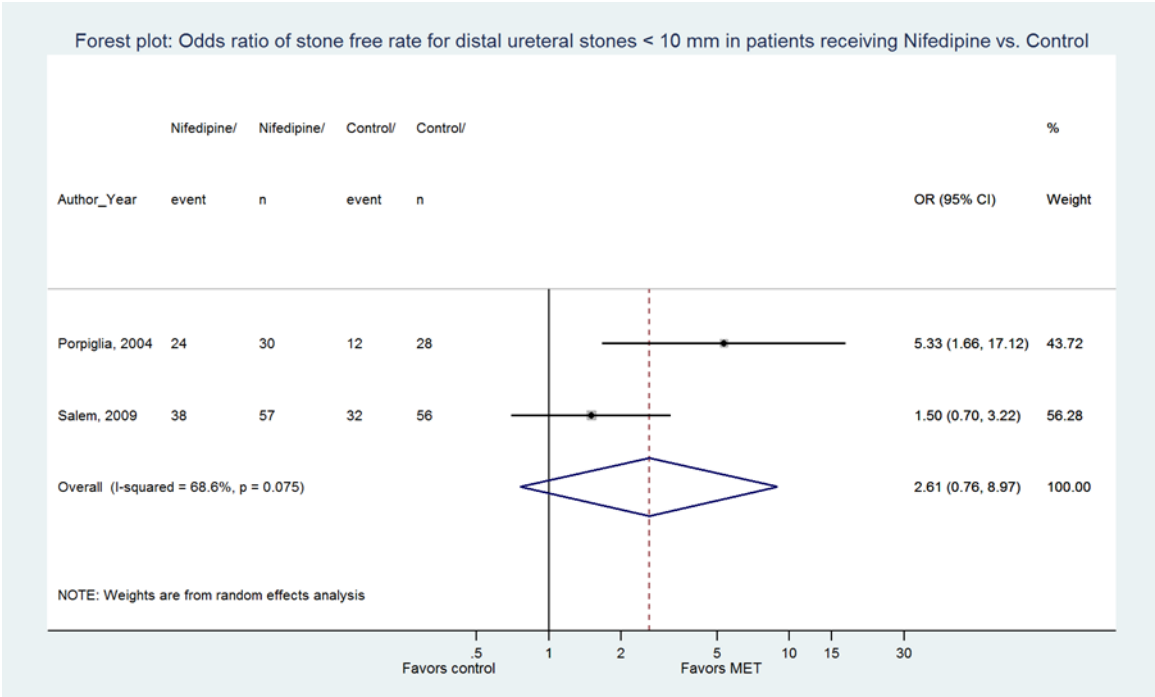


Figure 3:



trials, the primary outcome parameter in this trial was absence of need for additional intervention at four weeks rather than radiographic evidence of stone passage. These investigators found no difference between either of the active treatment groups and the placebo group regarding the absence of need for further intervention (81% for tamsulosin versus 80% for placebo, adjusted risk difference 1.3%, 95% CI -5.7 to 8.3, p=0.73; 80% nifedipine versus 80% placebo, adjusted risk difference 0.5%, 95% CI -5.6 to 6.5, p=0.88). Furthermore, subgroup analysis evaluating the effect of stone size and location failed to reveal subgroups of patients who would benefit from therapy. Although this well-designed trial, which is much larger than any of the other published MET trials that showed a benefit of therapy, raises concern about the validity of the recommendation in favor of MET, this trial is not necessarily comparable to the others because of the difference in outcome parameters. The absence of need for intervention rates is much higher (80%) in the UK trial than in the pooled control arms of the other α-blocker MET trials for which the radiographic spontaneous passage rate for <10mm stones in all locations in the ureter was 53%. Therefore, the results of this trial were not incorporated into this Panel's meta -analysis, and the recommendation for MET in properly selected patients still stands until further compelling studies suggest otherwise.

Finally, most of the trials evaluating the efficacy of α-blockers and calcium channel blockers in promoting spontaneous stone passage in patients with ureteral stones either exclusively enrolled patients with distal ureteral stones or were largely dominated by such patients. Based on the few α-blocker trials that included patients with middle and proximal ureteral calculi, the Panel's analysis found no benefit of therapy (Figures 4 and 5), and there were no trials evaluating nifedipine in patients with middle and proximal ureteral stones. Consequently, the Panel could not specifically endorse MET for stones in these locations. However, because of the low side effect profile of α-blockers and the demonstrated efficacy of α-blockers in patients with <10 mm stones in any location of the ureter, the Panel feels that a trial of these agents in this patient population, despite the lack of demonstrable benefit, can be considered an option until larger scale trials are available to provide more definitive direction.

Patients should be informed that medications for MET are prescribed for an off label indication.

8. **Clinicians should offer reimaging to patients prior to surgery if passage of stones is suspected or if stone movement will change management. Reimaging should focus on the region of interest and limit radiation exposure to uninvolved regions. *Clinical Principle***

If a patient is in the process of ureteral stone passage, clinicians should offer repeat imaging prior to stone intervention if symptoms have changed because a change in stone position may influence treatment approach (URS versus SWL versus continued observation), particularly if passage of the stone is suspected. Repeat imaging can include KUB x-ray, renal/bladder US, or CT. If feasible, a tailored approach should be utilized to limit radiation exposure.

A change in ureteral stone position can influence SWL success. It may also affect the decision to change intervention modality (e.g., from SWL to URS if a stone has advanced from the proximal ureter to the mid-ureter overlying the bony pelvis) or to defer intervention if the stone has advanced to the distal ureter and continued observation is reasonable.

Kreshover et al. found an approximately 10% risk of negative URS for ureteral stones smaller than 4 mm in size in a distal ureteral location.[54] Other factors that influence the decision to re-image a patient include pain, time interval since prior imaging, and presence of obstruction/hydronephrosis.

9. **In most patients, if observation with or without MET is not successful after four to six weeks and/or the patient/clinician decide to intervene sooner based on a shared decision making approach, the clinicians should offer definitive stone treatment. (Index Patients 1-3) *Moderate Recommendation; Evidence Level Grade C***

Should MET be selected as a management strategy for the patient with a ureteral stone that has the potential for spontaneous passage, the clinician must have a clear understanding of the indications to alter this

Figure 4:

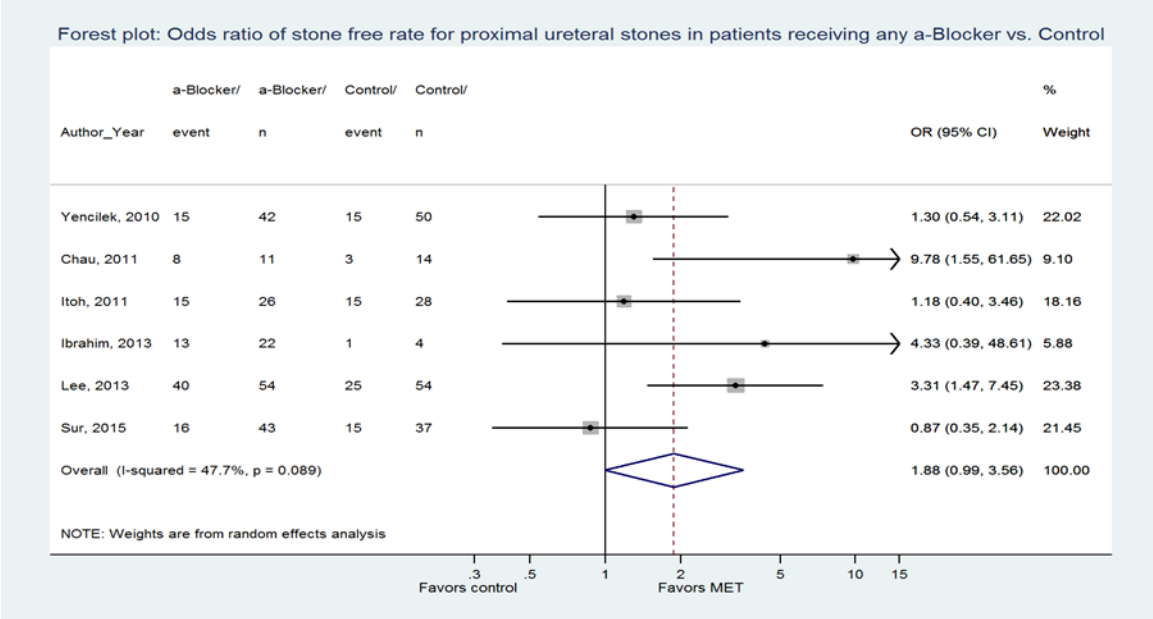
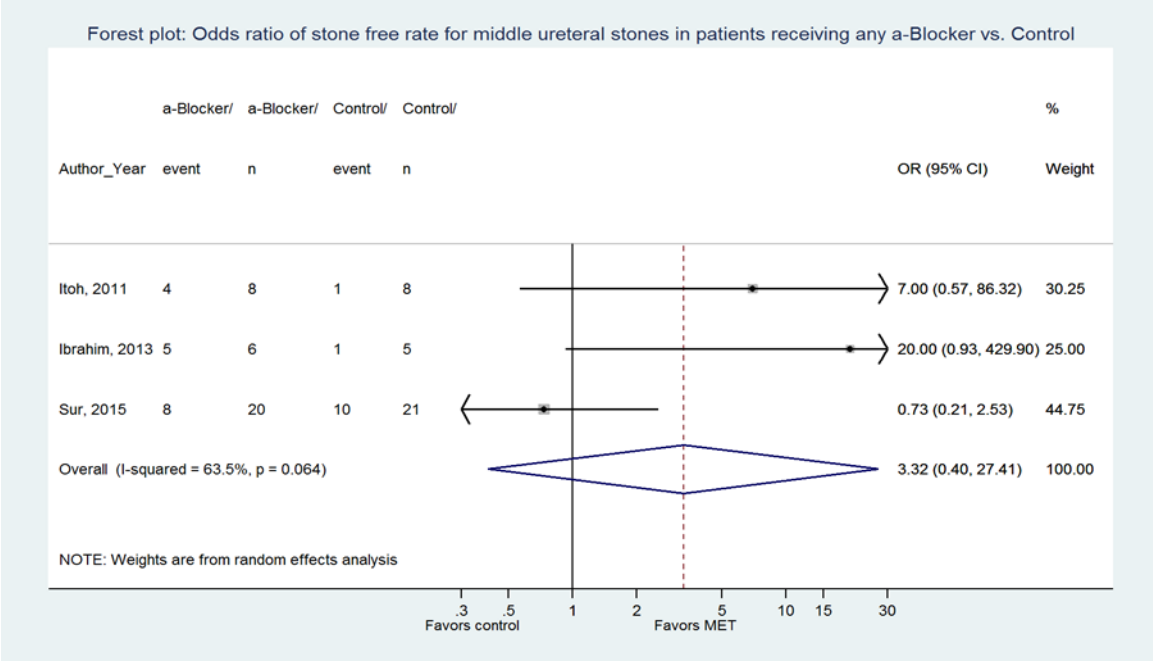


Figure 5:



approach and proceed with definitive intervention.

It is the Panel's opinion that recurrent renal colic requiring repeated visits to the emergency department or hospital admission for parenteral analgesia, worsening renal function, or evidence of urinary tract sepsis are all indications to proceed with surgical intervention.

While the maximum time duration for a trial of MET has not been clearly elucidated, experimental data on the effects of complete unilateral ureteral obstruction on renal function suggest the interval of conservative therapy should not exceed six weeks from initial clinical presentation in order to avoid irreversible kidney injury.[55] While admittedly not all ureteral stones cause complete obstruction, the Panel recommends a six week interval to reduce the potential for permanent damage. A previous study has also indicated that most stones destined to pass spontaneously will do so within six weeks.[49] As such, there seems little benefit in

continuing MET beyond this time interval. Moreover, a shared decision making approach between patient and clinician should be adopted in that the choice to change from a conservative to interventional approach should take into account social factors, such as work obligations, travel plans, and family care issues.[56]

10. **Clinicians should inform patients that SWL is the procedure with the least morbidity and lowest complication rate, but URS has a greater stone-free rate in a single procedure. (Index Patients 1-6)** ***Strong Recommendation, Evidence Level Grade B***

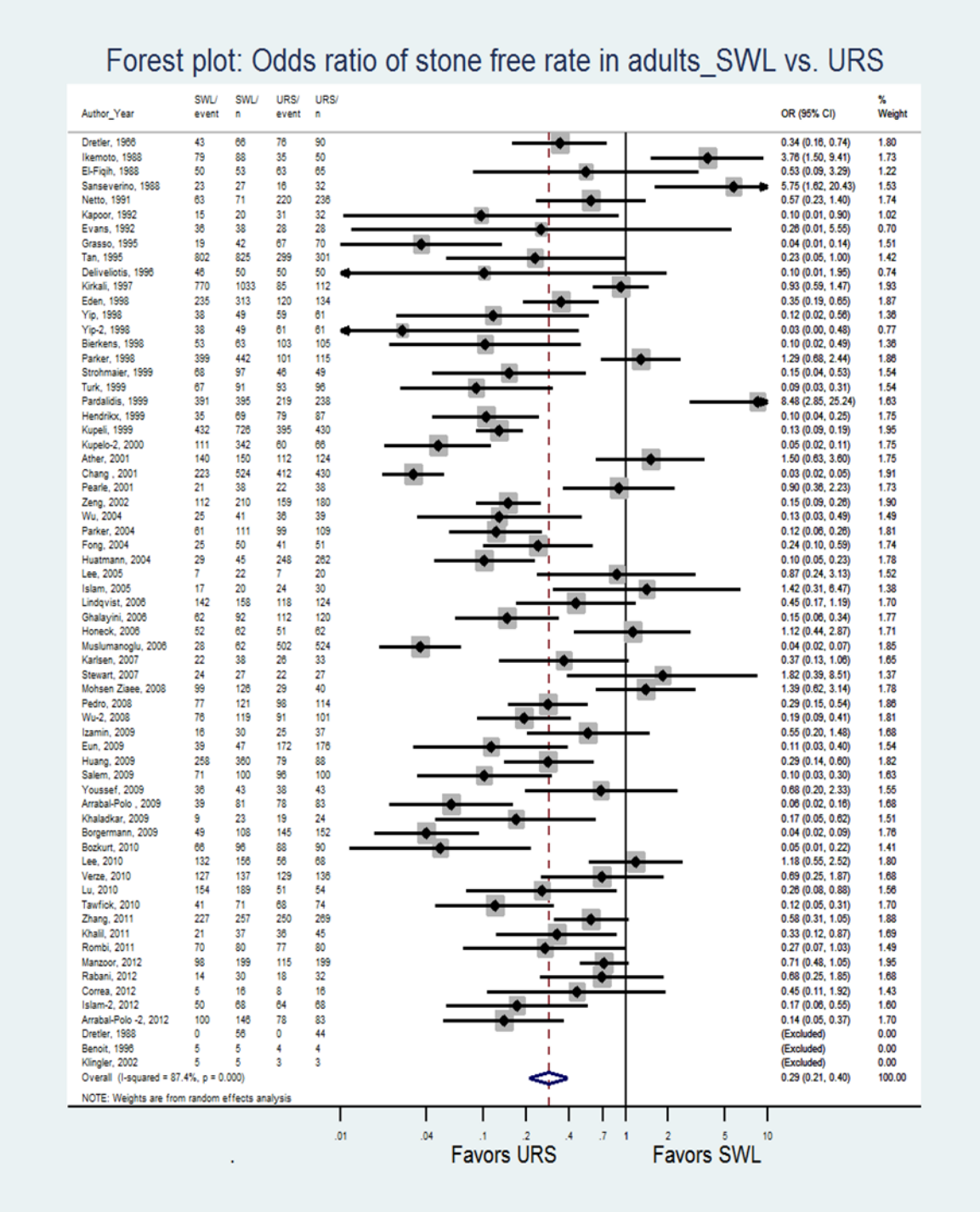
For the patient requiring definitive treatment of a ureteral stone, URS and SWL are the two most commonly used treatment modalities. (Figure 6) The present Panel's analysis revealed no statistically significant differences between SWL and URS with regard to UTI (median 4.5% versus 2.9%, respectively), sepsis (median 1.2% versus 0.3%, respectively), ureteral stricture (median 0% versus 0.2%, respectively), or ureteral avulsion (median 0% versus 0.1%, respectively). However, ureteral perforation occurred significantly more frequently during URS than SWL (median 3.2% versus 0%, respectively, $p<0.01$). The 2012 Cochrane Review comparing SWL and URS identified 7 RCTs reporting complication rates and found a significantly lower complication rate for SWL compared to URS (RR 0.53, 95% CI 0.33-0.88, $p=0.01$).[57] Likewise, the 2007 EAU/ AUA Guideline for the Management of Ureteral Calculi found a higher complication rate for URS compared to SWL for stones in all locations in the ureter: 11% versus 4%, respectively, for proximal ureteral stones; 14% versus 4%, respectively, for middle ureteral stones; and 7% versus 1%, respectively, for distal ureteral stones.[5] While stone-free rates are reportedly high for both modalities, URS stone-free rates have been shown to be superior to SWL stone-free rates in contemporary series. The Panel's analysis of studies comparing URS and SWL for treatment of ureteral calculi showed superior stone-free rates for URS over SWL (90% for URS versus 72% for SWL, RR SWL/URS 0.294, 95% CI 0.214-0.404, $p<0.001$). For stones ≤10 mm in size stratified by stone location, median stone-free rates remained superior for URS over SWL at all locations in the ureter (85% versus 66.5%, respectively, for proximal ureteral stones; 91% versus 75%, respectively, for middle ureteral stones; and 94% versus 74%, respectively, for distal ureteral stones) (Table 2). However, for stones >10 mm in size, stone-free rates were comparable for SWL and URS (74% versus 79%, respectively) in the proximal ureter, while stone-free rates for stones in the mid and distal ureter favored URS over SWL (82.5% versus 67%, respectively, for mid ureteral stones; and 92% versus 71%, respectively, for distal ureteral stones).

Furthermore, URS is more likely than SWL to successfully treat patients with a ≤10 mm ureteral stone in a single procedure. According to the 2007 EAU/ AUA Guideline for the Management of Ureteral Calculi, the mean numbers of primary URS procedures required to treat stones in the proximal, middle and distal ureter were 1.01, 1.00 and 1.00, respectively.[5] In contrast, the corresponding mean numbers of primary SWL procedures for stones in these locations were 1.34, 1.29, and 1.26, respectively. Consequently, since most successful URS require only a single procedure and stone-free rates are higher for URS than SWL for all ureteral stones except proximal ureteral stones >10 mm in size, URS has an advantage over SWL with regard to a higher success rates and need for fewer procedures.

11. **In patients with mid or distal ureteral stones who require intervention (who were not candidates for or who failed MET), clinicians should recommend URS as first-line therapy. For patients who decline URS, clinicians should offer SWL. (Index Patients 2,3,5,6)** ***Strong Recommendation; Evidence Level Grade B***

The Panel's meta-analysis demonstrated that URS is associated with significantly higher stone-free rates in a single procedure than SWL for patients with ureteral stones.[8] The disparity in stone-free outcome was particularly notable for patients with < 10 mm mid and distal ureteral calculi (Table 2). Based on studies comparing SWL versus URS for distal ureteral stones, the overall success rate of SWL for distal ureteral stones was reported to be approximately 65% (2,260/3,488) compared to a 92% success rates for URS (2539/2751) ($p<0.001$).[8] Therefore, URS should

Figure 6:



be recommended as first-line therapy. Nonetheless, patients should be counseled that SWL is an acceptable alternative. Clinicians should discuss with the patient the advantages and disadvantages of both SWL and URS, including the respective anesthesia requirements, stone-free rates, need for additional procedures, and associated complications of each procedure. Stone-free rates are higher for URS than SWL at all locations of the ureter, and URS is more commonly successful in achieving successful fragmentation and stone-free status in a single session than SWL. Complication rates are comparable between the two procedures except for a higher rate of ureteral perforation with URS than SWL. It should be noted that lower urinary tract symptoms and flank pain are more common in patients undergoing URS than SWL because of the more

Table 2: Stone-free rates for SWL and URS in the overall population after all sessions performed

Distal Ureter	**Overall**			**Size < 10 mm**			**Size > 10 mm**		
SWL									
	G/P	Median	CI (95%)	G/P	Median	CI (95%)	G/P	Median	CI (95%)
All forms	81/16573	74.65%	(74-75)%	29/11420	73.96%	(73-75)%	22/3785	71.47%	(70-73)%
Bypass	-	-	-	-	-	-	-	-	-
In situ	7/826	76.3%	(73-79)%	16/259	86.5%	(82-90)%	11/994	73.84%	(71-77)%
Pushback	-	-	-	-	-	-	-	-	-
Other	8/486	71%	(57-82)%	3/35	90%	(75-98)%	1/1	84%	(15-100)%
URS									
All forms	119/15938	93.58%	(93-94)%	19/4008	94.21%	(93-95)%	14/1705	92.26%	(91-93)%
Flexible	4/159	96.8%	(92-99)%	-	-	-	-	-	-
Mixed Flexible	9/431	93%	(89-96)%	1/38	97%	(88-100)%	1/10	79%	(50-96)%
Rigid	63/4254	89.9%	(89-90)%	13/181	90.6%	(85-94)%	8/533	94.7%	(92-96)%
Semi-rigid	30/5169	97.25%	(97-98)%	3/231	98.70%	(96-100)%	3/132	95.4%	(90-98)%

Total Ureter	**Overall**			**Size < 10 mm**			**Size > 10 mm**		
SWL									
Shock-wave Lith-otripsy	G/P	Median	CI (95%)	G/P	Median	CI (95%)	G/P	Median	CI (95%)
All forms	36/36215	68.95%	(68-69)%	50/18879	63.96%	(63-65)%	38/7433	61.62%	(61-63)%
Bypass	1/67	92%	(84-97)%	1/23	87%	(59-91)%	-	-	-
In situ	6/904	52.21%	(49-55)%	27/598	86.79%	(84-89)%	19/1683	65.18%	(63-67)%
Pushback	-	-	-	1/59	83%	(72-91)%	-	-	-
Other	-	-	-	11/196	88%	(81-93)%	10/698	70%	(57-82)%
URS									
All forms	101/29875	89.42%	(89-90)%	38/11879	92.53%	(92-93)%	31/5619	83.25%	(82-84)%
Flexible	6/481	94.59%	(92-96)%	2/81	97.5%	(91-99)%	-	-	-
mixed flexible	-	-	-	7/209	87%	(81-92)%	5/94	81%	(67-92)%
Rigid	26/6430	84.99%	(83-85)%	20/1715	87.35%	(86-89)%	16/1641	71.48%	(69-74)%
Semi-rigid	45/9984	91.86%	(91-92)%	6/2329	69.35%	(95-97)%	7/1064	90.79%	(89-92)%

universal use of stents in conjunction with URS than SWL. Stent placement prior to SWL for patients with ≤10 mm ureteral calculi has not been shown to improve stone-free rates and is not recommended.[5] Although stent placement after uncomplicated URS has also been shown in randomized trials to be unnecessary,[58] routine stent placement after URS is still widely practiced. As such, patients should be informed about the possible need for stent placement after URS, and less commonly, after SWL, because this information may influence their decisions. If successful treatment in a single procedure is the most important deciding factor for a patient, URS is the superior treatment option. On the other hand, if non-invasiveness and lower risk of complications are paramount, then SWL may be the more appropriate treatment selection. For women of child-bearing age who harbor mid or distal ureteral calculi, URS is preferred, as the effects of shock wave energy on the ovary have not been completely elucidated.

Alternative treatment options, such as open or laparoscopic ureterolithotomy, or antegrade URS via a percutaneous approach, are not preferred over SWL because of greater invasiveness. While based on the Panel's analysis, stone-free rates with URS for proximal ureteral stones <10 mm were superior, those for such stones >10 mm were equivalent. Therefore, the Panel chose to not extend the recommendation to proximal ureteral stones.

12. **URS is recommended for patients with suspected cystine or uric acid ureteral stones who fail MET or desire intervention.** ***Expert Opinion***

For those patients with known or suspected cystinuria or uric acid stones, the choice of definitive intervention following failed conservative therapy for a ureteral stone can be complex. SWL may not be the best option for patients with either stone composition for a number of reasons. Cystine stones are often only faintly radio-opaque and pure uric acid stones are typically radiolucent. Therefore, stone targeting with fluoroscopy may be problematic for SWL. Furthermore, cystine stones are typically resistant to SWL fragmentation, making this stone type less effectively treated by this modality.

URS with intracorporeal lithotripsy is an effective strategy for treating the majority of patients with ureteral stones, regardless of stone type.[59]

13. **Routine stenting should not be performed in patients undergoing SWL. (Index Patients 1-6)** ***Strong Recommendation; Evidence Level Grade B***

Some patients with ureteral stones undergo ureteral stent placement to relieve pain and/or obstruction until definitive treatment can be performed. However, some urologists place ureteral stents prior to SWL with the intention of improving stone-free rates or preventing complications. Both the 1997 AUA Guideline and the 2007 EAU/AUA Guideline for the Management of Ureteral Calculi recommended *against* routine stenting with SWL based on comparable stone-free rates with or without stent placement.[5,60] A recent systematic review and meta-analysis comprising 8 RCTs and 876 patients compared stented versus *in situ* SWL for renal and ureteral stones and found no significant difference in stone-free rates between the 2 groups (RR 0.97, 95% CI 0.91-1.03, p=27).[61] Subgroup analysis of the 2 RCTs involving 113 patients treated for ureteral stones only also showed no benefit of stented over *in situ* SWL (RR 0.95, 95% CI 0.79-1.14, p=0.58). One trial in the systematic review for which the incidence of steinstrasse was reported also showed no difference between the two groups; however, the incidence of lower urinary tract symptoms was higher in the stented group.

In the Panel's analysis, no difference in stone-free rates was found for SWL of ureteral stones with or without a ureteral stent (82% versus 91%, respectively, p=NS). As such, the current Panel reiterates the recommendation of the previous Panels in recommending against the use of ureteral stents with the intention of improving stone-free rates.

14. **Following URS, clinicians may omit ureteral stenting in patients meeting all of the following criteria: those without suspected ureteric injury during URS, those without evidence of ureteral stricture or other anatomical impediments to stone fragment clearance, those with a normal contralateral kidney, those without renal functional**

impairment, and those in whom a secondary URS procedure is not planned. (Index Patients 1-6) ***Strong Recommendation; Evidence Level Grade A***

The insertion of a ureteral stent has long been considered routine practice after URS. A number of randomized prospective trials performed over the past 15 years, however, have called into question the dogma of stent placement for uncomplicated URS.[62-73]

Reported complications, such as UTIs, ureteral strictures, and unplanned emergency room visits, were not found to differ significantly between stented and unstented groups in two published meta-analyses.[74,75] Moreover, stone-free rates were not appreciably different between stented and unstented patients. Patients without stents also typically reported less flank pain and fewer lower urinary tract voiding symptoms.

Based on the best available evidence, a selective approach to stent placement seems a more prudent strategy. Among patients with ureteric injury during URS, those with evidence of ureteral stricture or other anatomical impediments to stone fragment clearance, such as ureteral wall edema, a large stone burden (>1.5 cm), those who have an anatomically or functionally solitary kidney or renal functional impairment, and in those in whom another ipsilateral URS is planned, stent placement should be strongly considered.

15. **Placement of a ureteral stent prior to URS should not be performed routinely. (Index Patient 1-6)** ***Strong Recommendation; Evidence Level Grade B***

Some patients undergoing URS for ureteral calculi have ureteral stents placed prior to the procedure to relieve pain and/or obstruction, particularly in the setting of acute infection. However, some investigators have recently advocated for stent placement prior to URS with the intention of dilating the ureter and improving outcomes of URS. Rubenstein and colleagues reported higher stone-free rates in 36 prestented renal units compared to 79 unstented renal units (67% versus 47%, respectively, p<0.02) in a group of 90 patients who underwent URS (69% for ureteral stones).[76] In an attempt to control for confounding factors, Chu and colleagues also compared 45 prestented patients with 59 matched, unstented patients who underwent URS for stones and found that prestenting was associated with shorter first operative time in the whole cohort and shorter cumulative operative time and reduced need for reoperation in patients with > 1 cm proximal ureteral stones but not in patients with stones < 1 cm or distal ureteral stones.[77] Netsch and colleagues likewise performed matched pair analysis to compare 143 unstented with 143 prestented patients undergoing URS.[78] In the subgroup of patients with ureteral stones, prestenting was associated with higher stone-free rates in those with ≥5 mm stones (98% versus 83%, respectively, p<0.0105) but not in those with <5 mm stones (100% versus 93%, respectively, p=NS). Nevertheless, despite an association between prestenting and higher stone-free rates or shorter operative time, in the absence of prospective data and high level evidence, the Panel recommends against routine stent placement prior to URS when the sole purpose is to enhance stone-free rates or reduce operative times. The rationale for this is that the improved stone-free rates with certain stones achieved with prestenting do not override the added care costs and negative impact on quality of life associated with stents.

16. **Clinicians may offer α-blockers and antimuscarinic therapy to reduce stent discomfort. (Index patients 1-6)** ***Moderate Recommendation; Evidence Level Grade B***

Clinicians should counsel patients about the possibility of post-operative stent discomfort and may prescribe α-blockers to reduce stent discomfort. Other medications that can be used to alleviate stent discomfort include anticholinergics/antimuscarinics, bladder analgesics for dysuria, non-steroidal anti-inflammatory agents (NSAIDs), and narcotic analgesics.

α-blockers have been shown in multiple RCTs to have benefit for stent related discomfort. Several meta-analyses and systematic reviews of the literature have demonstrated significant improvement in urinary symptoms, body pain index score of the Ureteral Stent Symptom Questionnaire, total International Prostate Symptom Score (IPSS), Visual Analogue Pain Scale (VAPS) score and QoL with use of α-blockers compared

to placebo or no treatment.[79-82]

A meta-analysis evaluating the benefit of postoperative antimuscarinics alone has shown significant improvement in total IPSS and QoL scores with such therapy. However, there are discordant results regarding the benefits of combination therapy (α-blocker and antimuscarinic agent) over α-blocker monotherapy; one study reporting that combination was superior in alleviating symptoms and another demonstrating no advantage.[79]

The duration of ureteral stenting post-operatively should be minimized in order to reduce stent-related morbidity. In general, the Panel recommends three to seven days of stenting following routine, uncomplicated ureteroscopic stone intervention.

17. **In patients who fail or are unlikely to have successful results with SWL and/or URS, clinicians may offer PCNL, laparoscopic, open, or robotic assisted stone removal. (Index patient 1-6)** ***Moderate Recommendation; Evidence Level Grade C***

In some patients with large or complex ureteral stone burdens, neither URS nor SWL are likely to accomplish stone clearance in a reasonable number of procedures. In such cases, alternative approaches may be considered. Percutaneous antegrade URS may allow for more expeditious stone clearance, as larger and more efficient instrumentation can be utilized.[83-90] Ureterolithotomy may also be considered as an alternative therapy in these rare clinical scenarios. Both laparoscopic and robotic-assisted ureterolithotomy provide results equivalent to open surgery, but with reduced morbidity.[83,85,91-94] Therefore, if ureterolithotomy is performed, a laparoscopic or robotic approach is preferred for most cases.

18. **Clinicians performing URS for proximal ureteral stones should have a flexible ureteroscope available. (Index Patients 1, 4)** ***Clinical Principle***

Performing semi-rigid URS in the proximal ureter may not be possible, and if undertaken may incur a higher risk of ureteral injury because the semi-rigid ureteroscope may be unable to accommodate the angulation of the ureter associated with a large prostate or the iliac vessels. Additionally, performing semi-rigid URS above the level of the iliac vessels can cause additional torque on the ureteroscope, placing the ureteroscope itself at risk for damage. These limitations are overcome by flexible URS. While either laser or pneumatic lithotripsy maybe used with semi-rigid ureteroscopes, laser lithotripsy is the preferred intracorporeal lithotrite for use with flexible ureteroscopes. Small laser fibers easily pass through the working channel of all currently available flexible ureteroscopes, allowing adequate deflection and irrigant flow. Either holmium or thulium lasers can be utilized with flexible ureteroscopes.

The limitations of semi-rigid URS are overcome by flexible URS. Flexible URS has been shown in both prospective and retrospective studies to have high overall success rates with low morbidity/complications for < 2 cm proximal ureteral stones.[95-97] Failure and retreatment rates were higher in the proximal ureter for semi-rigid URS compared to flexible URS.[97]

19. **Clinicians should not utilize EHL as the first-line modality for intra-ureteral lithotripsy. (Index patients 1-6,13,15)** ***Expert Opinion***

Electrohydraulic lithotripsy (EHL) is highly effective at fragmenting most stone compositions with a 90% overall fragmentation rate.[98] EHL works as an underwater spark plug by which spark generation produces a cavitation bubble in the surrounding fluid resulting in stone fragmentation. Since the energy is not focused, the EHL probe must be positioned near the stone. The major disadvantage of EHL is its propensity to damage the ureteral mucosa, resulting in ureteral perforation. It is speculated that the expanding cavitation bubble generated by the spark may produce injury to the mucosa even when the probe is not in direct contact with the urothelium, with reported rates of ureteral injury of 8.5%-17.6%.[98-100] A prospective randomized trial of EHL versus pneumatic lithotripsy during URS for ureteral stones demonstrated equivalent efficacy of stone fragmentation with both technologies (85.3% EHL and 89.5% pneumatic), but the ureteral perforation rates were significantly higher in the EHL group (17.6% versus 2.6%, respectively).[99] Holmium:YAG laser produces stone fragmentation rates of 100% and has comparable fiber flexibility to the EHL

probe, but with a higher safety profile.[101] The holmium laser can be activated 0.5 mm from the urothelial surface without risk of injury.[102] Thus, with safer and more efficient technology available for ureteroscopic stone extraction, the Panel recommends EHL *not* be used for stone fragmentation. Due to a larger working area, EHL can safely be used in the kidney during PCNL, but the risk of perforation using this technology is still higher than other modalities. Therefore care should be taken to avoid activation of the probe near the urothelial surface.

20. In patients with obstructing stones and suspected infection, clinicians must urgently drain the collecting system with a stent or nephrostomy tube and delay stone treatment. *Strong Recommendation; Evidence Level Grade C*

Stone manipulation in the setting of active, untreated infection with concomitant urinary tract obstruction can lead to life-threatening sepsis. In this situation, it is mandated that the collecting system be drained, either with a nephrostomy tube or a ureteral stent to allow drainage of infected urine and permit antibiotic penetration into the affected renal unit.[103] Using the Nationwide Inpatient Sample to study the outcome of obstructing ureteral calculi associated with sepsis, Borofsky et al. demonstrated that mortality was higher in those not treated with surgical decompression compared to those who underwent drainage (19.2% vs 8.82%, p<0.001). Lack of surgical decompression, which occurred in 22% of the overall study population was independently associated with an increased odds ratio of mortality, even when adjusting for patient demographics, co-morbidities, and geographic region of treatment (OR 2.6, 95% CI 1.9-3.7).[104]

The choice of drainage modality, stent or nephrostomy tube, is left to the discretion of the urologist, as both have been shown in an RCT to be equally effective.[103] Definitive management of the stone should not be undertaken until sepsis has resolved and the infection has been treated with an appropriate course of antibiotic therapy.

21. In symptomatic patients with a total non-lower pole renal stone burden ≤ 20 mm, clinicians may offer SWL or URS. (Index Patient 7) *Strong Recommendation; Evidence Level Grade B*

Treatment options for patients with a <20 mm non-lower pole renal stone burden include SWL, URS, and PNL. Of these treatment options, PCNL stone-free rates are the least affected by stone size, while stone-free rates of both SWL and URS decline with increasing stone burden.[105] However, for stone burdens <20mm, stone-free rates of both URS and SWL are acceptable and have less morbidity compared to PCNL. Of the two options, URS and SWL, URS is associated with a lower likelihood of repeat procedure; therefore, the patient will become stone-free quicker than with SWL.[106] While SWL and URS are acceptable modalities, treatment selection process must include a shared decision-making approach.

22. In symptomatic patients with a total renal stone burden >20 mm, clinicians should offer PCNL as first-line therapy. (Index Patient 8) *Strong Recommendation; Evidence Level Grade C*

PCNL should be offered as first-line therapy for patients with a total renal stone burden > 20 mm because it offers a higher stone-free rate than SWL or URS and is less invasive than open surgery or laparoscopic/robotic assisted procedures. Compared to SWL and URS, the success rate of PCNL is also less affected by stone composition, density and location. In a RCT comparing PCNL to URS for >2cm renal pelvic stones, the stone-free rate was higher for PCNL compared to URS (94% versus 75%), although predominantly semi-rigid URS was used in this study.[107] A more recent prospective randomized trial comparing standard PCNL to staged flexible URS for renal pelvic stones > 2 cm showed an advantage of PCNL over URS because of the need for multiple treatments and longer treatment time for URS.[108]

The benefit of a higher stone-free rate must be weighed against the increased invasiveness and risk of complications for PCNL compared to URS or SWL. A recent systematic review and meta-analysis of PCNL versus URS reported higher complication rates for PCNL (OR 1.61; 95% CI 1.11-2.35).[109] The CROES PCNL Global Study reported a 15% overall complication rate with the majority of complications categorized as

Clavien Grade I. Bleeding necessitating blood transfusion was the most common complication at 7%.[110,111]

As recommended in the 2005 AUA guideline on the Management of Staghorn Calculi, PCNL should also be the first treatment utilized for most patients with staghorn calculi.[4] While studies comparing PCNL to open surgery for staghorn calculi have shown comparable stone-free rates, PCNL is the preferred treatment modality as it offers lower morbidity evidenced by decreased intraoperative and postoperative complications, decreased length of hospital stay, earlier return to work, and much smaller surgical incision.[112] In an older randomized prospective trial comparing PCNL to SWL for the treatment of staghorn calculi, Meretyk found a three-fold higher stone-free rate with PCNL combination therapy (PCNL/SWL) than with SWL monotherapy. In addition, the rate of sepsis was significantly higher with SWL.[113] The Panel's analysis of two non-randomized comparative studies enrolling a total of 263 patients comparing PCNL to SWL for the treatment of staghorn stones found the stone-free rate for PCNL to be superior (19-57% SWL versus 69.5-76.9% PCNL).[114,115]

23. When residual fragments are present, clinicians should offer patients endoscopic procedures to render the patients stone-free, especially if infection stones are suspected. (Index Patient 11) ***Moderate Recommendation; Evidence Level Grade CII***

Recent studies have demonstrated that residual stone fragments following treatment with SWL, URS or PCNL are not clinically insignificant. In a retrospective analysis of the natural history of residual fragments following PCNL, 43% patients experienced a stone related event at a median of 32 months. Multivariate analysis found residual fragment size > 2mm and location within the renal pelvis or ureter to be independent predictors of a stone event.[116] Similarly, in a recent report by the EDGE Research Consortium evaluating patients with residual fragments following URS, 15% of patients developed a complication requiring no intervention and an additional 29% of patients required intervention for residual fragments. Residual fragment size > 4mm was associated with a significantly higher rate of stone growth, complications, and re-intervention.[117] In patients with known or suspected infection stones, residual stone fragments have even greater consequences.

A number of studies have demonstrated that untreated struvite stones have a high likelihood of stone growth and recurrent infections. These "infection stones" may grow to a large size, often filling a large portion or the entire renal collecting system (i.e., staghorn calculus). Such stones may cause persistent infection and chronic obstruction, ultimately leading to severe renal damage with the possibility of life threatening sepsis. The Panel believes that removal of suspected infection stones or infected stone fragments may significantly limit the possibility of further stone growth, recurrent UTI, or renal damage. The Panel acknowledges that an endoscopic approach, either URS or PNL, offers the best chance of complete removal of infection stones and that complete stone removal should be the ultimate goal, in order to eradicate any causative organisms, relieve obstruction, prevent further stone growth or infection, and ultimately preserve kidney function. Although some investigations indicate that it may be possible to sterilize small residual struvite stone fragments and limit subsequent stone activity,[118] the majority of studies suggest that residual fragments can grow and become a source of recurrent UTIs.[115,119-123]

Non-surgical treatment with antibiotics, urease inhibitors, and other supportive measures only is not considered a viable alternative except in patients otherwise too ill to tolerate stone removal or when the residual fragments cannot be safely retrieved.

24. Stone material should be sent for analysis. ***Clinical Principle***

An exception would be a patient who has had multiple recurrent stones that have been documented to be of similar stone composition and there is no clinical or radiographic evidence that stone composition has changed.

25. In patients with total renal stone burden >20 mm, clinicians should not offer SWL as first-line therapy. (Index Patient 8) ***Moderate Recommendation; Evidence Level Grade C***

SWL is often considered an attractive treatment option

by patients and clinicians due to its decreased invasiveness and morbidity compared to PCNL and URS. However, SWL should not be offered as first-line therapy for patients with a total renal stone burden > 20 mm because several studies have reported significantly reduced stone-free rates and increased need for multiple treatments for SWL compared to PCNL in this setting.[115,124] Non-randomized comparative studies have found the stone-free rate for SWL to be inferior to PCNL.[114,115] The success of SWL is dependent on several other factors, including obesity, skin-to-stone distance, collecting system anatomy, stone composition and stone density/attenuation, which could also contribute to lower stone-free rates.[28,125-129] Furthermore, when SWL is utilized for one or more >2cm stones, the risk of ureteral obstruction from stone fragments (steinstrasse) increases to 24.3% compared to 15.9% for stones 1-2 cm in size and 4.5% for stones less than 1 cm.[130-132]

26. **Open/ laparoscopic /robotic surgery should not be offered as first-line therapy to most patients with stones. Exceptions include rare cases of anatomic abnormalities, with large or complex stones, or those requiring concomitant reconstruction. (Index Patients 1 -15)** ***Strong Recommendation; Evidence Level Grade C***

Advances in URS and PCNL instrumentation and technique, as well as newer understanding of SWL stone fragmentation, now allow endoscopic or shock wave management of the vast majority of symptomatic renal and ureteral calculi. Yet, there continue to be a limited number of cases where an endoscopic or SWL approach may not provide a reasonable chance at complete stone removal with a practical number of procedures. In these rare cases, patients may be offered open, laparoscopic, or robotic nephrolithotomy/ pyelolithotomy/ureterolithotomy as a more efficient way to remove large or complex stones, especially in patients with anatomic abnormalities of the urinary tract. A small number of case series, prospective trials and one meta-analysis suggest that laparoscopic or robotic nephrolithotomy/pyelolithotomy/ ureterolithotomy offers a reasonable alternative to PCNL or URS in these complex patients.[133-138]

One area where open laparoscopic or robotic stone removal offers an advantage over standard PCNL or URS is in patients with stones and anatomic defects that require reconstruction, such as those with concomitant UPJ obstruction or ureteral stricture.

27. **Clinicians may perform nephrectomy when the involved kidney has negligible function in patients requiring treatment. (Index Patients 1-14)** ***Conditional Recommendation; Evidence Level Grade*** **C**

When considering nephrectomy for the poorly functioning kidney, overall renal function and the condition of the kidney on the contralateral side should be considered. This is best accomplished with a nuclear renal scan as well as laboratory testing of renal function with serum creatinine and an estimation of glomerular filtration rate. Another option may be estimation of differential creatinine clearance in patients with an obstructed kidney and a nephrostomy tube. If the involved kidney is obstructed, drainage of the kidney and reassessment of renal function is a consideration if there is a chance of recovering function. Observation may be appropriate for some asymptomatic patients. However, poorly functioning kidneys can often be a source of persistent infection, pain, and pyelonephritis. In these cases, nephrectomy may be the best treatment option to relieve symptoms and prevent systemic complications, such as sepsis and xanthogranulomatous pyelonephritis.[139] The risk of the procedure must be weighed against the benefit to the patient and will depend on multiple clinical factors (e.g., age, medical co-morbidities, body habitus).[140] The approach utilized (open, laparoscopic, robotic assisted, retroperitoneal, trans-peritoneal) is based on a number of factors, including the degree of inflammation/ infection, renal size, patient condition, patient anatomy, patient preference, and the surgeon's experience. Nephrectomy should be avoided, if possible, in pregnant patients until after they deliver.

28. **For patients with symptomatic (flank pain), non-obstructing, caliceal stones without another obvious etiology for pain, clinicians may offer stone treatment. (Index Patient 12)** ***Moderate Recommendation; Evidence Level Grade C***

Whether non-obstructing caliceal stones can be a source of pain is controversial. However, since there are published reports of eradication of flank pain with stone removal in this setting, the Panel feels that patients with pain and non-obstructing caliceal stones, without another obvious source of their pain, may be offered surgical intervention for stone treatment.[141-144] The patient must be informed of the possibility that the pain may not improve or resolve after the procedure.

29. For patients with asymptomatic, non-obstructing caliceal stones, clinicians may offer active surveillance. *Conditional Recommendation; Evidence Level grade C*

The detection of asymptomatic stones has increased mainly due to the increased utilization of CT imaging. Observation of asymptomatic, non-obstructing caliceal stones is appropriate as long as the patient is counseled about the risk of stone growth, passage, and pain. There is conflicting data on the natural history of asymptomatic renal stones. Several studies have evaluated the risk of progression, defined as a symptomatic stone event, stone growth on serial imaging, and/or need for intervention. In a retrospective cohort study of 107 patients with asymptomatic renal stones followed for 31.6 months, Glowacki et al. reported a 31.8% rate of developing a symptomatic stone event.[145] Further Kaplan Meier analysis estimated the risk of a symptomatic stone episode or need for intervention to be approximately 10% per year with a cumulative 5 year event probability of 48.5%. Two additional retrospective studies[146,147] and one prospective study[148] of patients with asymptomatic renal stones (mean size 5.7-10.8 mm) demonstrated the risk of a symptomatic stone event to be 13%, of stone growth to be 30-46%, and a need for intervention of 7-26%. Lower pole stone location and isolated stone ≥ 4 mm were associated with a higher likelihood of failing observation.[146] In a prospective RCT comparing SWL to observation for asymptomatic caliceal stones <15mm total diameter, Keeley at al. reported no advantage of SWL with regard to stone-free rate, QoL, renal function, symptoms, or hospital admission.[143] However, in a prospective randomized trial comparing PCNL, SWL, and observation for asymptomatic lower pole stones (mean stone size was similar among groups 153, 139, 137 mm^2, respectively), stone-related events were noted in more than 20% of patients in the observation arm.[149] Taken collectively, these studies suggest that, while approximately 50% of asymptomatic stones will progress, a much smaller percentage will require surgical intervention.

There are certain settings for which treatment of asymptomatic, non-obstructing caliceal stones may be more appropriate than observation. Treatment should be considered in cases of associated infection, vocational reasons (e.g. airline pilots, military), and poor access to contemporary medical care.

If observation is chosen for asymptomatic, non-obstructing caliceal stones, active surveillance with follow-up imaging studies to assess for stone growth or new stone formation is recommended. Dietary modifications and medical therapy may be considered, especially if the latter occur.[6]

30. Clinicians should offer SWL or URS to patients with symptomatic ≤ 10 mm lower pole renal stones. (Index Patient 9) *Strong Recommendation; Evidence Level Grade B*

This recommendation is supported by the results of a multi-centered, prospective randomized trial that demonstrated that there was no statistically significant difference between the stone-free rates achieved with URS and SWL. Intraoperative complications were somewhat higher with URS, and patient-derived QoL measures were somewhat better with SWL in this study.150 CT imaging parameters should be used for patient selection. Patients with a skin-to-stone distance greater than 9-10 cm or stone attenuation greater than 900-1,000 Hounsfield units have less successful results with SWL. Current CT software allows these indices to be easily measured.[30,125,126] Certain techniques employed during URS, including repositioning of stones into the upper pole before fragmentation, utilization of a ureteral access sheath, and extraction of the generated fragments, may improve results.[151,152]

31. Clinicians should not offer SWL as first-line therapy to patients with >10mm lower pole stones. (Index Patient 10) *Strong Recommendation; Evidence Level Grade B*

Endoscopic approaches to the large lower pole stone

offer substantial benefit over SWL with regard to stone-free rate with a moderate associated increase in risk.[8] Therefore, the use of an endoscopic approach rather than SWL for a >10mm lower pole stone is a strong recommendation.

Endoscopic procedures appear to be less affected by stone burden than SWL. For lower pole stones 10-20mm in size, the median success rate for SWL was 58% compared to a median success rate of 81% for URS and 87% for PCNL. When the stone burden exceeded 20mm, the median success rate of SWL declined to 10%. In contrast, success rates for URS and PCNL were 83% and 71%, respectively. It should be noted that the URS series likely represented select populations and treating surgeons with particular expertise. Albala et al. reported an RCT that demonstrated higher success rates for PCNL over SWL for >10mm lower pole stones (91% versus 21%, respectively).[153]

32. Clinicians should inform patients with lower pole stones >10 mm in size that PCNL has a higher stone-free rate but greater morbidity. (Index patient 10). ***Strong Recommendation; Evidence Level Grade B***

Treatment options for lower pole stones >10 mm in maximum diameter include PCNL, retrograde URS, and SWL. Randomized trials demonstrated that PCNL is associated with superior single-treatment stone-free rates, but with greater morbidity.[153] URS and SWL are options for the management of these stones, but clinicians should inform patients that re-treatment rates are higher, and stone-free rates are significantly lower, with a higher likelihood of clinical stone recurrence due to retained fragments.[150] When considering SWL for these stones, clinicians should consider collecting system anatomy, stone attenuation, and skin-to-stone distance as they can significantly impact treatment results. When considering URS for these stones, clinicians should inform patients that there is a risk that the stone may not be accessible ureteroscopically, particularly in patients with a narrow lower pole infundibulum, an acutely angled lower pole infundibulum, severe hydronephrosis, or renal anomalies, such as a horseshoe kidney. In addition, stones larger than 10mm may not be possible to grasp and relocate, necessitating laser treatment in the lower calyx, with the flexible ureteroscope maximally deflected, potentially increasing the risk of laser fiber failure and ureteroscope damage.

PCNL should be considered the primary treatment for most cases, but patients should be well-informed of the nature of the procedure, expected morbidity and potential complications. PCNL with smaller access sheaths (mini-PCNL or micro-PCNL) may allow similar outcomes with lower complication rates.[154]

33. In patients undergoing uncomplicated PCNL who are presumed stone-free, placement of a nephrostomy tube is optional. ***Conditional Recommendation; Evidence Level Grade C***

PCNL has traditionally been performed with an indwelling nephrostomy tube left in place at the conclusion of the procedure. The purpose of the nephrostomy tube is to aid in healing of the nephrostomy tract, promote hemostasis, drain urine to prevent extravasation, and to allow for re-entry into the collecting system should a secondary PCNL procedure for residual stone fragments be necessary. However, studies have demonstrated morbidity associated with indwelling nephrostomy tubes following PCNL, specifically increased postoperative pain with greater narcotic requirements and increased length of hospitalization.[155-158] Tubeless PCNL was introduced to limit the negative side effects associated with nephrostomy tube drainage. There are various types of "tubeless procedures." A common theme is that no nephrostomy tube is inserted at the end of the procedure. Renal drainage can be established with an indwelling or externalized stent, or the patient can be left without a stent. The tubeless approach should not be undertaken if there is active hemorrhage or it is likely that another PCNL will be needed to remove residual stones.

In the appropriately selected patient, tubeless PCNL can result in similar stone-free and complication rates as standard PCNL. The Panel's meta-analysis pooled data from 38 studies, including 7 RCTs with a total of 2,073 patients, and demonstrated similar overall stone-free and complication free outcomes between patients undergoing standard PCNL versus tubeless PCNL.[8] Both upper pole and lower percutaneous access sites were

included in the pooled studies. Furthermore, in the 23 studies that recorded analgesia requirements in the first 24 hours, all but three demonstrated less analgesia usage in the tubeless PCNL patients compared to standard PCNL.[8] It should be noted that the majority of the patients in the pooled tubeless PCNL group were selected for the procedure and demonstrated limited hemorrhage, no signs of infection, and no intraoperative evidence of residual fragments at the conclusion of the procedure. Patients undergoing tubeless PCNL with an indwelling stent should be counseled that cystoscopy and stent removal will be required sometime after the procedure.

34. Flexible nephroscopy should be a routine part of standard PCNL. *Strong recommendation; Evidence Level Grade B*

Stone fragmentation (intracorporeal lithotripsy) is commonly performed during PCNL. The resultant fragments may migrate to areas in the collecting system that cannot be safely accessed with a rigid nephroscopy. If not removed, these fragments may result in future stone events.[116,159,160] The utilization of flexible nephroscopy during PCNL has been demonstrated to improve stone-free rates. Gücük and colleagues performed a randomized prospective study in which patients underwent rigid nephroscopy during PCNL with or without concomitant flexible nephroscopy, and the stone-free rate was higher with concomitant flexible endoscopy, 92.5% versus 70%.[161] If migration of stone fragments down the ureter is suspected, antegrade flexible nephroscopy should be considered. Ureteral stones can be extracted when they are identified.

35. Clinicians must use normal saline irrigation for PCNL and URS. *Strong Recommendation; Evidence Level Grade B*

Normal saline is the standard irrigation solution as it is isotonic and iso-osmolar and does not lead to significant electrolyte abnormalities when absorbed.[162] Some studies have advocated the use of sterile distilled water in place of sterile saline, suggesting that visualization in a bloody field may be superior with water irrigation.[163,164] However, use of a non-isotonic solution increases the risk of hemolysis, hyponatremia, and heart failure if sufficient volume is absorbed.[165] Furthermore, modern endoscope optics are of such high quality that sterile water irrigation provides little advantage with regard to improved visibility. Consequently, sterile normal saline remains the preferred standard irrigant for endourologic stone removing procedures.

Significant absorption of irrigation fluid may occur during endoscopic stone surgery and cause hypothermia and fluid overload. Maintenance of a low intrarenal pressure may decrease the risks of these occurrences. This can be facilitated with larger working sheaths during PCNL and ureteral access sheaths with URS.[166]

36. A safety guide wire should be used for most endoscopic procedures. (Index Patients 1-15) *Expert Opinion*

In general, a safety guidewire is advisable when performing retrograde URS or PCNL for stones. It can facilitate rapid re-access to the collecting system if the primary working wire is lost or displaced and can provide access to the collecting system in cases of ureteric or collecting system injury, including perforation or avulsion. This will facilitate placement of an internalized stent or nephrostomy tube in such cases.

This is particularly valuable during URS when the ureter is at risk (i.e., when there is pathology within the ureter [stricture or stone disease] that renders proximal access to the renal collecting system difficult.) This is particularly true for semi-rigid and flexible ureteroscopy for ureteral stones.

There are situations where a safety guidewire cannot be placed, may not be necessary, or may even be harmful:

1. Severely impacted ureteral stones where even a hydrophilic guidewire cannot safely be negotiated proximal to the stone. In these cases, a guidewire should be left below the stone, and the stone then approached ureteroscopically and carefully fragmented until the proximal ureteral lumen can be identified and a safety wire placed. An alternative would be placing a nephrostomy tube or antegrade stent and performing stone removal at a different time.

2. When a ureteral access sheath is being used to facilitate treatment of intra-renal stones with the flexible ureteroscope. If the ureteral access sheath is placed within or just below the renal pelvis, then the sheath itself can act as a safety wire.

37. Antimicrobial prophylaxis should be administered prior to stone intervention and is based primarily on prior urine culture results, the local antibiogram, and in consultation with the current Best Practice Policy Statement on Antibiotic Prophylaxis. *Clinical Principle*

In the absence of a UTI, SWL does not require antimicrobial prophylaxis as no invasive procedure is performed. Perioperative antibiotic therapy, where required, is administered within 60 minutes of the procedure and redosed during the procedure if the case length necessitates. Antibiotic prophylaxis is recommended for ureteroscopic stone removal and PCNL. A single oral or IV dose of an antibiotic that covers gram positive and negative uropathogens is recommended.[167]

Patients undergoing PCNL with sterile urine may still develop infectious complications including UTI and sepsis.[168,169] This was the impetus for recommending the utilization of prophylactic antibiotics in patients subjected to this procedure.[167] The presence of unsuspected bacteria within stones may be one of the underlying causes for infectious complications after PCNL. It has been reported that many patients with negative voided urine cultures before PCNL have positive kidney stone cultures.[39,40] In addition, a positive stone culture has been reported to predict sepsis following PCNL.[41] Mariappan et al. showed that the administration of a one-week course of ciprofloxacin to patients with sterile urine prior to PCNL reduced the risk of urosepsis, although historical controls were used in this trial.[170] Bag et al. demonstrated in a prospective randomized trial that taking nitrofurantoin for one week prior to PCNL reduced the risk of urosepsis in patients with sterile urine.[171] A low rate of significant antibiotic-related complications has been reported with this approach.[172] However, the Panel did not feel that there was enough evidence to endorse the practice of administering this one-week course of antibiotic therapy for patients with negative urine cultures prior to PCNL.

38. Clinicians should abort stone removal procedures, establish appropriate drainage, continue antibiotic therapy, and obtain a urine culture if purulent urine is encountered during endoscopic intervention. (Index Patients1-15) *Strong Recommendation; Evidence Level Grade C*

An accepted principle is that operating in an infected field carries increased risk. For endoscopic urological procedures, the risk of urosepsis is well established and feared. The presence of purulence at the time of instrumentation mandates placement of a ureteral stent or nephrostomy tube and aborting the procedure. The purulent urine should be cultured, and broad spectrum antibiotics should be administered, pending cultures. The procedure can be undertaken once the infection is appropriately treated.

39. In patients not considered candidates for PCNL, clinicians may offer staged URS. *Moderate Recommendation; Evidence Level Grade* C

While PCNL is the optimal treatment for most patients with complex, high-volume, and branched renal stones, some anatomic abnormalities and/or patient factors may provide relative contraindications to PCNL, including use of anti-coagulation or anti-platelet therapy that cannot be discontinued or the presence of contractures, flexion deformities, or other anatomic derangements that may preclude positioning for PCNL.

In these clinical scenarios, URS is a viable option, although it may require staged or repeated procedures to treat large stone volumes and may not render patients completely stone free.[95,173-179] Patients should be informed of these limitations, particularly those with known struvite stones, where a stone-free state is crucial for remaining infection- and stone-free. URS can be safely performed in fully anticoagulated patients and in those on anti-platelet agents, although the risk of gross hematuria and clot retention/colic is higher.

When performing URS in this setting, clinicians should make every effort to maintain low intra-renal irrigation pressure with a ureteral access sheath as these procedures can be lengthy, and prolonged high intra-

renal pressures can increase the risk of hemorrhage, infection, sepsis, collecting system perforation, and fluid absorption.

40. Clinicians may prescribe α-blockers to facilitate passage of stone fragments following SWL. Moderate Recommendation; Evidence Level Grade B

The Panel performed a meta-analysis of 24 RCTs assessing the efficacy of adjunctive therapy to facilitate stone passage after SWL for renal or ureteral stones, including 19 trials using α-blockers, and 16 using tamsulosin.[8] The studies comprised 2,110 patients, including 984 patients who received α-blockers and 883 who did not. Adjunctive therapy resulted in a nearly 2-fold higher stone-free rate (OR 1.878, 95% CI, 1.508-2.339). In addition, the time to clear stones was approximately three days less with adjunctive therapy. Many of these studies had limitations (inadequate randomization and blinding), which downgraded the quality of evidence.

Patients should be informed that the utilization of α-blockers to facilitate fragment passage after SWL is considered an off label indication.

41. If initial SWL fails, clinicians should offer endoscopic therapy as the next treatment option. (Index Patient 1-14) *Moderate Recommendation; Evidence Level Grade C*

If initial SWL fails, it is important to re-evaluate the stone characteristics (e.g., size, location, density, composition) and patient characteristics (e.g., obesity, collecting system anatomy, obstructed system) that may have contributed to the initial failure. Similarly, success may be stratified such that those who have had partial fragmentation and clearance may be considered for repeat SWL while those with no fragmentation and/ or clearance may be selected specifically for endoscopic intervention.

Though European studies demonstrate incremental increases in stone-free rates with repeated sessions of SWL, other studies have demonstrated the higher efficacy of an endoscopic approach in such instances. Success rates for PCNL and URS as secondary procedures after failed SWL are reported as 86-100% and 62-100%, respectively.[180-189]

42. Clinicians should use URS as first-line therapy in most patients who require stone intervention in the setting of uncorrected bleeding diatheses or who require continuous anticoagulation/antiplatelet therapy. (Index Patients1-15) *Strong Recommendation; Evidence Level Grade C*

Unlike both SWL and PCNL, URS can usually be safely performed in patients with bleeding diatheses or in those who cannot interrupt anticoagulation or antiplatelet therapy. URS should be considered first-line therapy for these patients when stone treatment is mandatory. Clinicians should also consider deferred treatment to a time when antiplatelet or anticoagulation therapy can be safely interrupted or observation alone for non-obstructing, non-infected, and asymptomatic stones that do not require urgent treatment.

When performing URS in this setting, anticoagulation should be modified to keep the INR near the lower acceptable range to minimize the risk of hematuria, hemorrhage, and clot retention/colic. Clinicians should also strongly consider implementing measures to minimize intra-renal pressure during these procedures to further reduce the risk of hemorrhage and hematuria by utilizing a ureteral access sheath, using non-pressurized irrigation and keeping the bladder decompressed with a small catheter if an access sheath is not used.'[190,191]

43. SWL should not be used in the patient with anatomic or functional obstruction of the collecting system or ureter distal to the stone. *Strong Recommendation; Evidence Level Grade C*

The presence of anatomic abnormalities or functional abnormalities of the collecting system or ureter that create obstruction distal to the targeted stone is associated with lower stone-free rates when SWL is utilized to treat urinary stones. Although studies looking directly at distal obstruction and SWL are lacking, experience with SWL in patients with anatomic abnormalities associated with urinary obstruction suggests that the ability to clear stone fragments is limited. Abnormalities, such as UPJ obstruction, urinary diversion with ureteral anastomotic narrowing, ureteral stricture, and caliceal diverticula are associated with

retained stone fragments after SWL resulting in low stone-free rates.[192-195] Although the overall risk of developing urosepsis is low with SWL, the risk is increased in the presence of obstruction distal to the treated calculi.[196] Based on these findings the Panel strongly recommends that any patient with obstruction distal to the targeted stone not undergo SWL treatment unless the obstruction can be treated.

44. In patients with symptomatic caliceal diverticular stones, endoscopic therapy (URS, PCNL, laparoscopic, robotic) should be preferentially utilized. *Strong Recommendation; Evidence Level Grade C*

The stone-free rates achieved with SWL for treating patients with caliceal diverticular stones are quite low, with the majority of series reporting 0-25%.[197] While some of these patients may experience a reduction or elimination of their symptoms, they are at risk for symptom recurrence, and new or residual stone growth.[198] The Panel's meta-analysis also demonstrated a low stone-free rate associated with SWL (13-21%). Substantially higher stone-free rates are attainable with URS, PCNL, laparoscopic and robotic surgery (18-90% with URS and 62.5-100% with PCNL).[8] In addition, the chance for eradication of symptoms is far greater.[197,198] An endoscopic approach also permits correction of the anatomic abnormality, with the chance for successful obliteration being highest with PCNL, laparoscopic, or robotic assisted surgery.[197] The choice of optimal endoscopic approach should be based on stone location and size, relation to surrounding structures, and patient preference.

45. Staghorn stones should be removed if attendant comorbidities do not preclude treatment. *Clinical Principle*

Numerous older retrospective studies have demonstrated that untreated patients harboring staghorn stones are at risk for deterioration of renal function, including loss of the involved kidney, end stage renal disease, infectious complications, and mortality.[115,119,120,123,199] While the majority of these older series involved patients with infection stones and more recent studies have demonstrated that patients with staghorn stones are more apt to have metabolic stones, the Panel still endorses stone removal in patients who are able to tolerate the rigors of long and perhaps multiple procedures and their attendant risks, including sepsis and hemorrhage.[200] Medical therapy and supportive care are considerations for those not thought to be operative candidates.

46. In pediatric patients with uncomplicated ureteral stones ≤10 mm, clinicians should offer observation with or without MET using α-blockers. (Index Patient 13) *Moderate Recommendation; Evidence Level Grade B*

An initial trial of observation with or without MET is appropriate in children with ureteral stones because a significant proportion of children will pass their stones spontaneously, thus avoiding the need for surgical intervention. In trials of MET in children, stone-free rates in the observation (non-treatment) arm averaged 62% for stones under 5 mm diameter in the distal ureter, and 35% for stones >5 mm.[201-203] Two of these trials demonstrated that α-blockers facilitated stone passage. Observation can be carried out under carefully controlled conditions, assuming no evidence of infection, the patient is able to hydrate orally, and pain can be adequately controlled. Families should be aware that the probability of spontaneous passage is lower for children with stone approaching 1 cm in size.

Limited evidence does suggest that MET is effective in increasing passage of distal ureteral stones in children, and MET appears to be safe in this population. Three modest randomized trials of α-blocker therapy in children with distal ureteral stones[201-203] showed significant benefit, with an overall odds ratio of being stone free of 4.0 (95% CI: 1.1-14.8). However, bias is a concern as these trials were not blinded.

The role of MET with α-blockers in pediatric patients with middle and proximal ureteral stones, similar to adults, is not well-defined. However, due to limited reports of side effects in children with distal ureteral stones, the Panel feels that such agents may be prescribed to children harboring stones in these locations. As in adults, the maximum time duration for a trial of MET is undefined, but it seems prudent to limit the interval of conservative therapy to a maximum of six weeks from initial clinical presentation (as in adults) in order to avoid irreversible kidney injury.

Parents and when appropriate the patient should be informed that the utilization of α-blockers to facilitate fragment passage after SWL is considered an off label indication.

47. Clinicians should offer URS or SWL for pediatric patients with ureteral stones who are unlikely to pass the stones or who failed observation and/or MET, based on patient-specific anatomy and body habitus. (Index Patient 13) ***Strong Recommendation; Evidence Level Grade B***

In children who are unlikely to pass a ureteral stone spontaneously for any reason or who have already failed a trial of medical or observational therapy, surgical intervention to eliminate the stone is appropriate. The benefits of treating the stone include alleviating symptoms, minimizing risk of infection, and preserving renal function by eliminating obstruction.

The Panel's meta-analysis demonstrates that stone-free rates in pediatric patients with ureteral stones <10 mm are high for both SWL (87%) and URS (95%); lower for larger ureteral stones (>10mm), stone-free rates are 73% for SWL and 78% for URS.[8]

While SWL is an acceptable option for ureteral stones, the poor visualization of the ureter (particularly the mid -ureter) with US-based lithotriptors may limit use of SWL in this setting. SWL may be preferable in certain pediatric populations, such as very small children, or other patients in whom ureteroscopic access may be challenging due to their anatomy (e.g., severe scoliosis, history of ureteral reimplantation).

48. Clinicians should obtain a non-contrast, low-dose CT scan on pediatric patients prior to performing PCNL. (Index Patient 13) ***Strong Recommendation; Evidence Level Grade C***

The rationale for obtaining a CT scan in this setting is similar to that as described for adults undergoing this procedure. Increased awareness of the potential adverse effects of ionizing radiation in children has led to efforts to reduce radiation exposure in this population. Children may be more susceptible to radiation-induced injury due to their rapidly developing tissues, and they have a longer potential lifespan during which radiation-induced illness may manifest. The substantial contribution of medical imaging (and particularly CT) to radiation exposure and subsequent cancer risk in the pediatric population has become a focus in the past 15 years.[204-207]

Modified protocols and equipment permit CT imaging in children that adheres to "ALARA" principles (radiation exposure kept "as low as reasonably achievable").[208] Several studies have shown that in adults, low dose CT is comparable to standard CT with respect to stone diagnosis and measurement.[22,209,210] Although comparative studies of low-dose CT in the pediatric population specifically are lacking, generalization of the findings in adults to the pediatric population seems reasonable, particularly given the smaller size and lower rate of obesity in children, which is thought to limit the sensitivity of low dose CT in adults.

49. In pediatric patients with ureteral stones, clinicians should not routinely place a stent prior to URS. (Index Patient 13) ***Expert Opinion***

In pediatric patients who require endourologic intervention for a ureteral stone, access is sometimes difficult or impossible due to a narrow ureterovesical junction and/or ureter. In such cases, placement of a ureteral stent typically results in passive dilation of the ureter, thus permitting access at the time of the next attempted URS.[211] However, "pre-stenting" should not be considered a routine aspect of a URS procedure in pediatric patients, since access to the upper tract is possible on the initial attempt in a majority of children undergoing attempted URS.[212]

50. In pediatric patients with a total renal stone burden ≤20mm, clinicians may offer SWL or URS as first-line therapy. (Index Patient 14) ***Moderate Recommendation; Evidence Level Grade C***

SWL has a long track record of success in treatment of renal stones in children. Stone-free rates are reported to be relatively high in children at 80-85% overall,[213,214] and at 80% for lower pole stones. Complication rates after pediatric SWL appear to be low with little evidence of long-term sequelae. URS also appears to have a high success rate for pediatric renal stones, with stone-free rates of around 85%.[215] Complication rates may be

somewhat higher with URS, estimated at 12.4%-20.5% in reviews.[216] While complication rates may be somewhat lower with SWL at 8%-10%, with serious complications being rare,[213] there are, unfortunately, very few high-quality comparative studies for SWL and URS or other modalities for treatment of renal stones in the pediatric population.

51. In pediatric patients with a total renal stone burden >20mm, both PCNL and SWL are acceptable treatment options. (Index Patient 14) ***Moderate Recommendation; Evidence Level Grade C***

High stone-free rates have been reported with both PCNL and SWL in children with larger stones. SWL has been reported to have stone-free rates of 73-83% in pediatric patients,[218-220] while PCNL results vary by site, but recent large series have approached 90% success rates.[221] If SWL is performed, placement of a ureteral stent or nephrostomy tube is recommended to prevent postoperative renal obstruction. Several factors must be taken into consideration when selecting which of these procedures to pursue, including stone composition and attenuation, stone location, body habitus, collecting system anatomy, relation of the kidney to surrounding viscera, medical co-morbidity, and the parental preference. The utilization of smaller instruments for PCNL (mini-PCNL, micro-PCNL) may limit the risk of hemorrhage in this population.[182,222-225]

52. In pediatric patients, except in cases of coexisting anatomic abnormalities, clinicians should not routinely perform open/ laparoscopic/robotic surgery for upper tract stones. (Index Patients 13, 14) ***Expert Opinion***

There is very little evidence directly comparing the use of laparoscopic surgery or robotic-assisted laparoscopic surgery with more conventional treatments for stone disease in children. Series in adults have suggested that laparoscopic approaches may compare favorably to percutaneous techniques for large or staghorn renal stones,[133,137,138,226] but in children, these approaches should be considered secondary or tertiary options for treatment of renal or ureteral stones since more conventional procedures, including SWL, URS, and PCNL, have high rates of success and lower risks of serious complications.

The primary exception to this statement is in the pediatric patient with one or more renal or ureteral stones and a co-existing anatomic anomaly, such as UPJ obstruction.[227] In such cases, open, laparoscopic, or robotic-assisted laparoscopic surgery is indicated to remove the stone(s) and repair the primary anatomic defect. Other anomalies that may be associated with stones that may be treated at the time of reconstructive surgery include ureterovesical junction obstruction and duplication anomalies with an obstructed ectopic ureter.

53. In pediatric patients with asymptomatic and non-obstructing renal stones, clinicians may utilize active surveillance with periodic ultrasonography. (Index Patient 14) ***Expert Opinion***

While observation of an asymptomatic, non-obstructing renal stone is an option for children, such patients should be seen regularly with routine surveillance US to monitor for increase in size or number of stones, or silent obstruction. Families should be counseled about the need for regular follow-up, as the wellness of the child may lead some to defer further assessment for long periods of time, after which some children may re-present with large or obstructing stones that present significant management challenges, with increased morbidity associated with the stone itself as well as surgical treatment.

Even if immediate surgical treatment is not pursued, evaluation of the pediatric patient for underlying abnormalities that may predispose to further stone formation is indicated. Metabolic evaluation for stone risk factors is appropriate in pediatric patients as the incidence of metabolic abnormalities is high in pediatric stone formers.[228,229] Twenty-four hour urine collections are appropriate in toilet-trained children and adolescents to assess urinary stone risk parameters. In infants and non-toilet trained children, "spot" urine samples can still be used to screen for hypercalciuria, although this approach has diagnostic limitations. Infants and young children with hyperoxaluria should be screened for primary hyperoxaluria.

54. In pregnant patients, clinicians should coordinate pharmacological and surgical intervention with the obstetrician. (Index

Patient 15) ***Clinical Principal***

Stone disease during pregnancy can be a challenging condition to diagnose and treat as standard imaging and treatment algorithms for urolithiasis can pose undo risk to the developing fetus. Investigations are complicated by the normal changes during pregnancy that can resemble obstructing calculi. The risks to the fetus of ionizing radiation, analgesics, antibiotics, and anesthesia must also be considered. All these factors can lead to a delay in diagnosis, inappropriate diagnosis, and difficult treatment decisions.

Evaluation and management of the pregnant patient with suspected urolithiasis must be multidisciplinary. The obstetrician or maternal fetal medicine physician, anesthesiologist, and urologist must work together to develop a safe and effective plan for the patient. By enlisting the assistance of other treatment professionals, the urologist can appropriately counsel the pregnant patient on the potential risks to the fetus before proceeding with any diagnostic or therapeutic treatment options. Due to the rarity of the condition and the unique vulnerability of the patient population, few prospective studies on pregnant patients with renal or ureteral stones are available and thus, most outcome data is based on animal studies or small case series. The obstetrician or maternal fetal medicine physician along with the pharmacist can insure that medications prescribed for control of stone-related symptoms are safe to the developing fetus based on gestational age at time of presentation. If ionizing radiation is necessary for diagnostic or treatment purposes, the radiation physicist along with the obstetrician can estimate radiation exposure so the total pregnancy exposure does not exceed the American College of Obstetrics and Gynecology (ACOG) recommended maximum of 50 mGy.[230] Should surgical intervention be warranted, the multidisciplinary team is imperative, utilizing an anesthesiologist who specializes in obstetrics to perform fetal monitoring, if indicated, and to keep drug exposure to the minimum. Although obstetric complications at time of surgical intervention are rare (<5%),[231] the procedure should be performed at a facility capable of managing obstetric emergencies should complications ensue intra or post operatively.

55. In pregnant patients with ureteral stone(s) and well controlled symptoms, clinicians should offer observation as first-line therapy. (Index Patient 15) ***Strong recommendation; Evidence Level Grade B***

The spontaneous passage rates for pregnant women with ureteral stones have not been demonstrated to be different than those of non-pregnant patients. Therefore, in a patient whose symptoms are controlled, a period of observation should be the initial therapy. The clinician should be aware that a stone event in pregnancy does carry with it an increased risk of maternal and fetal morbidity, so patients should be followed closely for recurrent or persistent symptoms.[232,233] Should MET be considered for the pregnant patient, the patient should be counseled that MET has not been investigated in the pregnant population, and the pharmacologic agents are being used for an "off-label" purpose.[234] NSAIDs (e.g., ketorolac) are contraindicated in pregnancy.

56. In pregnant patients with ureteral stones, clinicians may offer URS to patients who fail observation. Ureteral stent and nephrostomy tube are alternative options with frequent stent or tube changes usually being necessary. (Index Patient 15) ***Strong Recommendation; Evidence Level Grade C***

Should a trial of observation fail for the pregnant patient with a ureteral stone, an intervention is indicated. Ureteral stent and percutaneous nephrostomy will both effectively decompress the obstructed collecting system, and thereby bring symptom relief. However, the introduction of such foreign objects into the collecting system of a pregnant woman can be a point of concern, as they tend to encrust rapidly. Therefore, should such an approach be taken, frequent stent or tube exchanges are required. As an alternative, URS provides a definitive treatment for the pregnant patient, as it accomplishes stone clearance, obviating the need for prolonged drainage with stent or nephrostomy.[235] URS in the pregnant patient should only be undertaken by clinicians facile with the treatment approach and at an institution that has both the equipment required for URS and obstetric support for maternal and fetal considerations.[231]

FUTURE RESEARCH

It is unfortunate that the surgical treatment of kidney stones, a disease with such a great prevalence, has not been studied with greater rigor in previous years. One of the most disappointing aspects of the systematic review performed herein is the small number of high quality research studies identified. There is an extreme paucity of high quality RCTs comparing competitive surgical interventions for stone disease. However, this is not surprising, given that other urologic fields are also underpopulated with such studies.

Going forward, it will be beneficial to standardize the reporting of stone treatment studies. At present, there is great heterogeneity in the definitions of such important metrics as stone size, stone location, stone-free status, complications and economic outcomes. This terminology should be standardized as this will allow more reliable comparisons among studies, and make systematic reviews and meta-analyses more powerful.

Clinicians' ability to utilize imaging studies to predict treatment outcomes for differing stone interventions is limited at present. As a result, we cannot completely counsel patients on their likely course following a stone removal intervention. This is particularly true for SWL, where our pre-treatment understanding of stone fragility is lacking. It would be most welcome for the clinician to be better able to predict treatment outcomes from presently available imaging modalities. Furthermore, efforts should also be focused on identifying and advancing the utility of imaging modalities that do not rely on ionizing radiation such as MRI and ultrasonography.

Many patients with a symptomatic ureteral stone will pass their stones spontaneously. From a patient-centered standpoint, time course to passage, as well as maneuvers to increase the probability of spontaneous passage are exceedingly important. Clinicians' ability to counsel patients on how long it will take for a stone to pass is limited due in great part to a lack of research focused on answering this question. With regards to augmenting stone passage utilizing pharmacotherapy, our understanding is unclear as the literature is conflicted. Future studies better defining the ability of MET to promote stone passage will be important to improving the patient experience. In addition, the development of agents with better efficacy and tolerability to facilitate stone passage is warranted.

The mechanical action of stone fragmentation and removal is the primary driver of intra-operative time allocation during a stone removal procedure. For URS and PCNL, the technologies accomplish the same end, but via different mechanisms. For patients undergoing URS, in particular flexible URS, the Holmium laser is currently the lithotrite of choice. In some cases the laser may be used to fragment the stone into small pieces that can be individually retrieved; in other cases the laser may be used to fragment the stone into fine powder, which will spontaneously drain from the kidney. At present, it is not known which of these approaches yields superior outcomes, but such information would be immediately useful to the practicing urologist.

There is also a need to improve the devices that are used in the stone fragmentation and evacuation process during endoscopic surgery. With respect to URS, there is a need for mechanical devices that more efficiently and safely fragment and evacuate stone material; at present, this process is cumbersome and potentially dangerous as ureteral injury may occur during stone extraction. With respect to PCNL, advances in stone removal technology will enable a more rapid and efficient evacuation of larger burdens of stone.

Ureteral stent placement is commonly performed following stone interventions. In some cases, stent placement may not be necessary, such as in the case of an uncomplicated ureteroscopic procedure. However, in many of those cases, stents are still placed. It is well recognized that ureteral stents are the source of significant morbidity. Future efforts should be devoted to better identifying which patients may safely avoid stent placement. In addition, advances in stent technology, with a particular focus on identifying the nature and source of stent morbidity, as well as design advances to minimize these bothersome symptoms will also improve surgical care.

Stone disease in the pediatric population has been reported to be increasing. At present, our understanding of stone management among children is somewhat rudimentary, as the published literature is sparse. Future efforts to better define the effects of surgical stone treatment in this population will also be important.

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ABBREVIATIONS

ACOG	American College of Obstetrics and Gynecology
ASA	American Society of Anesthesiologists
AUA	American Urological Association
CBC	Complete blood count
CCT	Controlled clinical trial
COI	Conflict of interest
CT	Computed tomography
EHL	Electrohydraulic lithotripsy
GOC	Guidelines Oversight Committee
INR	International normalized ration
IPSS	International Prostate Symptom Score
IVP	Intravenous pyelogram
IVU	Intravenous urogram
J&E	Judicial & Ethics Committee
NSAID	Non-steroidal anti-inflammatory agent
MET	Medical expulsive therapy
MR	Magnetic resonance
PCNL	Percutaneous nephrolithotomy
PGC	Practice Guidelines Committee
PT	Prothrombin time
PTT	Partial thromboplastin time
QoL	Quality of life
RCT	Randomized controlled trial
SIR	Society of Interventional Radiology
SWL	Shock-wave lithotripsy
ULR	Update literature review
UPJ	Ureteropelvic junction
URS	Ureteroscopy
US	Ultrasound
UTI	Urinary tract infection
VAPS	Visual Analogue Pain Scale

American Urological Association (AUA) Endourological Society Guideline

Surgical Management of Stones

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DISCLAIMER

This document was written by the Surgical Management of Stones Guideline Panel of the American Urological Association Education and Research, Inc., which was created in 2014. The Practice Guidelines Committee (PGC) of the AUA selected the committee chair. Panel members were selected by the chair. Membership of the panel included specialists in urology with specific expertise on this disorder. The mission of the panel was to develop recommendations that are analysis-based or consensus-based, depending on panel processes and available data, for optimal clinical practices in the treatment of stones.

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While these guidelines do 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 guidelines will change. Today these evidence-based guidelines statements represent not absolute mandates but provisional proposals for treatment under the specific conditions described in each document. For all these reasons, the guidelines do 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 guideline does not guarantee a successful outcome. The guideline text may include information or recommendations about certain drug uses (‘off label‘) that are not approved by the Food and Drug Administration (FDA), or about medications or substances not subject to the FDA approval process. AUA urges strict compliance with all government regulations and protocols for prescription and use of these substances. The physician is encouraged to carefully follow all available prescribing information about indications, contraindications, precautions and warnings. These guidelines and best practice statements are not in-tended to provide legal advice about use and misuse of these substances.

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