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Management of Asymptomatic Renal Calculi and Residual Fragments*

Learning Objective: At the conclusion of this continuing medical education activity, the participant will be able to describe the prevalence of asymptomatic de novo and post-procedural urinary calculi, and identify the risk factors associated with stone/fragment progression and outcomes of observation versus treatment.

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***This AUA Update addresses the Core Curriculum topic of Urolithiasis and the American Board of Urology Module on Calculus, Laparoscopy-Robotics and Upper Tract Obstruction.**

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INTRODUCTION

The prevalence of nephrolithiasis has recently been estimated at 8.8% among U.S. adults.[1] A rise in prevalence over the preceding decades has been observed globally.[2] The annual cost of urolithiasis in the United States in 2000 was approximately $2.81 billion.[3] With anticipated population growth as well as increases in the prevalence of obesity and diabetes this cost is projected to rise to $4.05 billion by 2030. A large proportion of the increasing prevalence is due to greater use of high resolution imaging and detection of asymptomatic renal calculi in the general population.[4] Increased use of high resolution imaging has also spurred reappraisals of stone-free rate and likelihood of residual fragments following interventions. Many residual fragments previously thought to be clinically insignificant may indeed become a source of stone related morbidity in some patients. Asymptomatic renal calculi and residual fragments clearly pose a unique challenge for shared decision making between the urologist and patient.

De novo asymptomatic renal calculi. **In a cohort of 5047 asymptomatic patients undergoing computerized tomographic colonography the estimated screening prevalence of asymptomatic renal calculi was 7.8%.**[5] Mean age was 56.9 years, mean detected stone size was 3 mm and 38.5% of affected patients had more than 1 stone on imaging. In addition, 20.5% of those with incidental stones went on to experience symptoms over the 10-year observation horizon. Kang et al retrospectively analyzed the records of 347 men and women with a mean age 47.9 years and average follow-up of 31 months.[6] Mean stone size at presentation was 4.4 mm and distribution of location was the upper calyx in 12.4% of patients, mid calyx in 18.4%, lower calyx in 42.1% and multiple calyces in 27.1%. **The majority of patients (53.6%) experienced a stone related event (spontaneous passage, flank pain, stone growth or need for intervention) during follow-up.**

More recently Li et al performed a retrospective review of 297 patients with asymptomatic solitary renal calyceal stones identified during routine health screening who subsequently underwent imaging between 2007 and 2017.[7] The majority of patients in the initial cohort identified with renal stones (613) were excluded if there was any relative indication for intervention, which sheds light on the morbidity of this disease process. It is noteworthy that at the initial screening more than half of the patients (320) were excluded due to symptoms (18), history of intervention (210), bilateral stones (92), ureteral stones (24), multiple stones (75), solitary kidney (17), renal insufficiency (21), hydronephrosis (40) or congenital genitourinary anomalies (15). Patients were assessed with yearly renal ultrasound for a mean follow-up of 4.2 years. Symptoms developed in 47.2% of patients, spontaneous passage occurred in 53.4%, stone growth was detected in 49.3% and intervention was performed in 12.3%. Cumulative probability of any stone related event was 31.4% at 3 years and 51.2% at 5 years. Patients with lower pole stones were less likely to experience symptoms or spontaneous passage, and patients with stones >5 mm or with diabetes, hyperuricemia or non-lower pole stones were more likely to have stone growth.

Residual fragments after stone treatment. Data regarding the incidence of residual fragments following stone treatment are confounded by heterogeneous definitions of "residual fragment" as well as by differences in practice patterns with regard to post-intervention imaging timing and modality. The necessity of frequent follow-up imaging in patients with nephrolithiasis provides an impetus to minimize radiation exposure, and plain radiography and ultrasonography therefore tend to be favored. **However, stone fragments less than 5 mm or those with CT radiodensity less than 500 HU are not reliably detected by plain radiograph.**[8, 9] Despite concerns over cumulative radiation exposure, greater use of postoperative CT has led to increased detection of residual stone fragments.

Shock wave lithotripsy is widely considered a first line therapy for renal and proximal ureteral stones smaller than 1 cm, and an option for some non-lower pole stones smaller than 2 cm.[10] Predictors of residual fragments after SWL include higher body mass index, greater skin-to-stone distance, increased stone size and density (>1000 HU), and lower pole location (see Appendix).[11, 12] However, many studies evaluating efficacy allow multiple sessions and do not routinely assess for the presence of small residual fragments that remain after an appropriate posttreatment interval. Candau et al retrospectively reviewed the records of 154 of 1216 patients (12.6%) with residual fragments 4 mm or less identified on renal CT at least 3 months after SWL and invited patients for follow-up testing.[13] Of the 83 patients who underwent follow-up CT the residual fragments had increased in size in 32%, were stable in 29% and were eliminated in 38%. Sahin et al assessed quality of life in 71 patients with residual fragments after SWL.[14] Of patients with residual fragments >4 mm only 31% had spontaneous passage, 52% presented to the emergency department and 69% required an additional intervention. Lower health related quality of life scores were observed in patients with residual fragments >4 mm vs <4 mm, and this trend was observed across most quality of life domains.

Ureteroscopy and retrograde intrarenal surgery are first line treatment for ureteral stones of any size as well as renal stones that are 1–2 cm, and may be offered for larger stones in patients in whom a percutaneous approach is not favored.[10] Stone-free rates up to 90% have historically been noted following URS, although assessment with CT has revealed residual fragments >2 mm in up to 38% of cases.[12] Increasing stone size is associated with greater risk of residual fragments. As with SWL, some residual fragments may be significant. In 46 patients undergoing URS who had residual fragments on follow-up CT Rebuck et al observed a 19.6% risk of a stone event (emergency department visit, renal colic, unplanned procedure, hospitalization) over an average of 1.6 years.[15] In a multicenter retrospective analysis Chew et al observed a stone event rate of 44% in 232 patients with residual fragments following ureteroscopy.[16] When stratified by stone size, they observed an intervention rate of 18% for fragments <4 mm vs 38% for fragments ≥4 mm (p=0.001). The risk of experiencing a complication (renal colic, emergency

ABBREVIATIONS: AUA (American Urological Association), CT (computerized tomography), PCNL (percutaneous nephrolithotomy), SWL (shock wave lithotripsy), URS (ureteroscopy) department visit, renal insufficiency, unplanned admission) also doubled with stones 4 mm or larger (59% vs 27%, p=0.03). **They therefore concluded that removal of fragments 4 mm or larger should strongly be considered.**

Percutaneous nephrolithotomy remains the treatment of choice for patients with large and complex renal stone burden (>2 cm). Stone-free rates depend greatly on surgeon experience, stone burden complexity and other patient related factors.[17,18] A combination of fluoroscopy and flexible nephroscopy is recommended to ensure the greatest degree of stone clearance.[19] An earlier study by Raman et al of 42 patients undergoing PCNL demonstrated 43% had a stone related event at a median of 32 months, while a subanalysis showed that larger residual fragments (>2 mm) posed a much higher risk of a stone related event.[20] Similarly a retrospective study by Emmott et al involving 263 patients undergoing PCNL indicated that residual fragment size >4 mm was associated with both a higher risk of stone related events and a shorter interval between index surgery and a stone event.[21]

MANAGEMENT OF ASYMPTOMATIC URINARY CALCULI

The decision to treat or observe asymptomatic urinary calculi is nuanced and depends on several factors, including stone size and location, likelihood of passage and patient preference. While traditionally limited to underpowered retrospective series, there are emerging prospective data on outcomes associated with various treatment options for incidentally discovered and postoperative/residual urinary calculi. This Update reviews the literature and aims to better inform the management of de novo and postoperative asymptomatic urinary calculi.

Observation of asymptomatic renal calculi. **According to the United Kingdom based NICE (National Institute for Health and Care Excellence) guidelines, watchful waiting is recommended for asymptomatic renal calculi measuring up to 5 mm or for stones >5 mm after an informed discussion with the patient regarding the risks and benefits of watchful waiting.**[22] Similarly the European Association of Urology and American Urological Association guidelines regarding management of urinary calculi state that conservative management is acceptable in instances where indications for acute intervention are absent (eg infection, obstruction, acute kidney injury) and the patient is asymptomatic, or where intervention is declined after an informed/shared decision making process has taken place between the patient and provider (European Association of Urology/AUA grade C recommendation).[10,23] **These patients should be followed with periodic surveillance imaging to monitor for stone growth and silent hydroureteronephrosis, although no formal/validated surveillance protocols currently exist.**

The aforementioned guidelines are based on retrospective data supporting the use of observation for asymptomatic renal calculi. A retrospective case series of 301 renal units in 238 adults with incidentally diagnosed renal calculi between 2005 and 2016 showed that 58.8% of renal units remained on surveillance at a median follow-up of 63 months.[24] Stones passed spontaneously in 14.6% of the cases and surgical intervention was ultimately required in 26.6%. Of note, mean cumulative stone size in this cohort was 10.8 mm. Predictors of adverse events during surveillance (eg unremitting pain and/or need for surgical intervention) included male gender (p=0.019), younger age (p=0.012) and annual stone growth >1 mm (p=0.006). Interestingly stone location did not appear to be a predictor of intervention (p=0.07) or progression (p=0.8).

Conversely Dropkin et al retrospectively analyzed 110 patients with non-obstructing renal calculi and found that stone location was the only significant predictor of future intervention, with non-lower pole stones more likely than lower pole stones to become symptomatic (40.6% vs 24.3%, p=0.047) or pass spontaneously (14.5% vs 2.9%, p=0.016).[25] At a mean follow-up of 41 months only 20% of patients required surgical intervention for symptomatic progression, while 7% reported spontaneous stone passage. Koh et al performed a similar analysis assessing rates of spontaneous stone passage, stone progression and intervention in 50 patients with a mean stone size of 5.7 mm.[26] They observed overall incidences of spontaneous passage, progression and intervention of 20%, 45.9% and 7.1%, respectively, clearly demonstrating the important role of stone size on long-term outcomes.

There is emerging literature supporting observation of large (>2 cm) asymptomatic renal calculi in patients for whom surgical intervention represents a significant health risk (eg American Society of Anesthesiologists® score >2). In a single center case series following 22 individuals with either unilateral or bilateral staghorn calculi being managed conservatively the rates of progressive renal failure (14%), disease specific mortality (9%), progression to dialysis dependence (9%) and stone related hospital presentation (27%) were surprisingly low, suggesting that observation may be acceptable in patients with significant comorbidities and for whom surgery represents a considerable risk.[27]

Conversely in a retrospective series monitoring patients maintained on observation for asymptomatic renal calculi Burgher et al noted a 100% progression rate (defined as symptomatic stone pain, size increase or intervention) for patients with stone burden >1.5 cm.[28] Furthermore, a 2016 ecological study by Penniston et al assessing stone specific health related quality of life scores in recurrent stone formers suggests that asymptomatic patients may have worse health related quality of life compared to those without underlying stone burden in the form of greater lower urinary tract symptoms and/or anxiety or nervousness about the future (p <0.027).[29] In effect, they argue that intervention should be strongly considered for all patients with urinary stones regardless of symptomatology. **Consequently it may be reasonable to consider observation of asymptomatic renal stones measuring up to 1.5 cm, recognizing that previously noted factors such as stone location within the renal pelvis may raise the threshold for initiating observation given higher rates of symptomatic progression**.[25]

Determining Appropriateness for Observation: Several clinical *and* non-clinical factors should inform the decision to treat or observe asymptomatic renal calculi (see figure).[30] While there is emerging literature suggesting the important role of stone characteristics such as size and location (with observation being favored for lower pole location and smaller size—eg less than 5 mm—amenable to spontaneous passage), there is a paucity of literature evaluating other patient specific factors such as age, gender and/or comorbidity burden.[28,31] Intuitively, observation should be considered in patients for whom surgery poses a significant risk—such as those with underlying renal insufficiency, unusual anatomy or solitary kidney—whereas intervention should be considered in patients with recurrent urinary tract infections and/or an immunocompromised

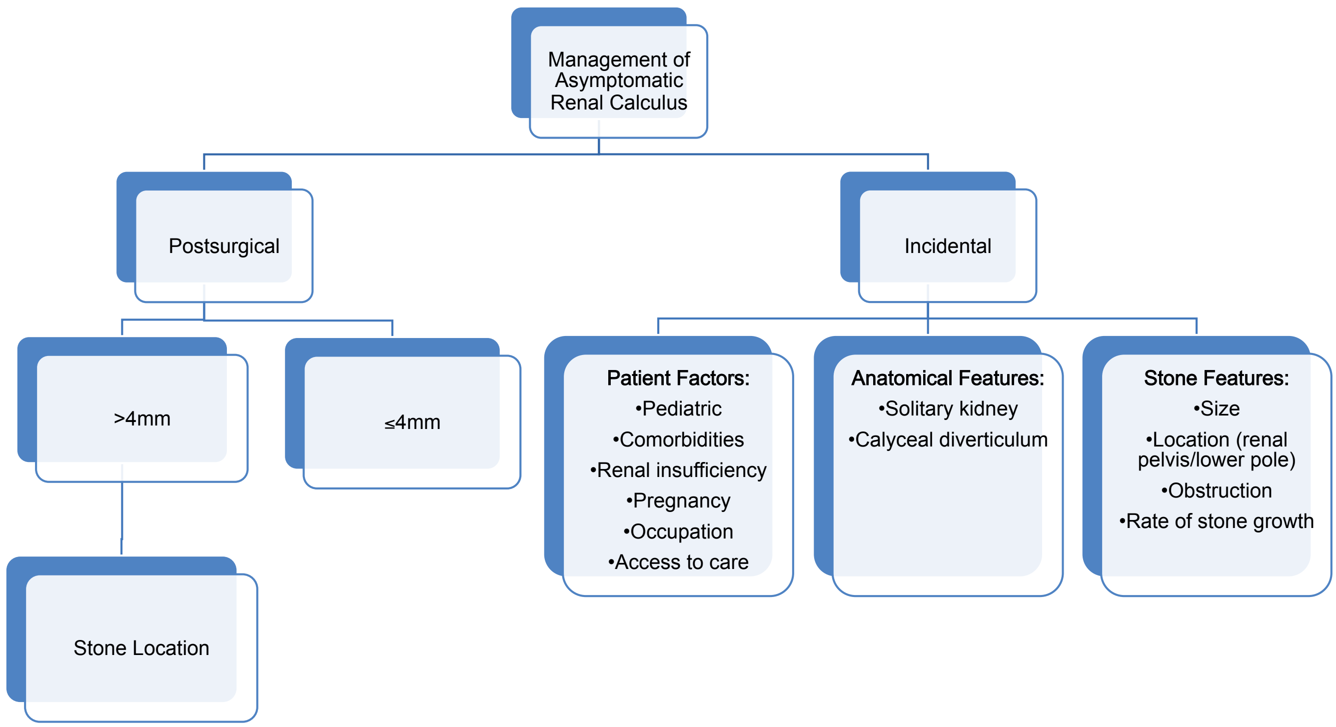

Figure. Algorithm for treating or observing asymptomatic renal calculi.[30]

state.[32,33] Socioeconomic factors such as high risk occupation (eg airline pilots) and convenient access to health/follow-up care should also be considered.[30,31]

Special Circumstances (Children and Pregnant Women): **As with adults, the AUA considers observation of asymptomatic non-obstructing renal calculi ≤10 mm an acceptable management option in children.[10] However, these individuals should be closely followed with serial imaging (eg renal ultrasound) to rule out silent obstruction and to monitor for increasing stone burden given the high prevalence of underlying metabolic disorders in this group (grade B recommendation).[34]** In a retrospective case series evaluating the natural history of incidentally discovered lower pole calculi in 224 children at a median age of 8 years Dos Santos et al observed a spontaneous passage rate of 53.6%, whereas 21.4% of stones ultimately required intervention.[35] Predictors of intervention were baseline stone size >7 mm (p <0.001) and stone growth over the study period (p=0.01). More recently, Telli et al evaluated long-term outcomes in 242 children with purely lower pole stones <1 cm and found that 61.2% of patients ultimately required surgery.[36] Of those who remained on surveillance only 9.1% had spontaneous stone passage by the end of the study period, demonstrating the important role of stone location with regard to long-term outcomes. Similar to the study by Dos Santos et al,[35] stone size >7 mm was predictive of undergoing a stone intervention.[36]

In pregnant women the AUA encourages an informed decision making process that weighs the risks and benefits associated with intervention and the accompanying ionizing radiation, analgesics, antibiotics and anesthesia inherent to endoscopic surgery.[10] As pregnancy represents a riskier clinical scenario for not 1 but 2 lives, a conservative approach is more logical. Hence, observation is the preferred option for pregnant women who are asymptomatic or have well controlled symptoms related to either a renal or ureteral stone.

Observation Protocols for Asymptomatic Urinary Calculi: There are currently no standardized/validated surveillance protocols for the management of asymptomatic urinary calculi and, as such, a variety of imaging modalities and intervals have been proposed. Growing awareness of the adverse effects associated with repeated exposure to ionizing radiation in the form of plain film radiography and/or CT has led to the emergence of kidney, ureter and bladder x-ray and ultrasound as commonly used, albeit less sensitive, surveillance modalities.[37] However, the advent of low and ultralow dose CT protocols suggests that the superior sensitivity of CT may be attainable without significant radiation exposure.[38, 39] For example the literature suggests that the effective radiation dose of ultralow dose CT ranges from 0.5–1.9 mSv, compared to 10 mSv for traditional non-contrast CT of the abdomen and pelvis.[40] In addition to imaging, metabolic evaluation should be offered to these patients to identify causative dietary constituents and, by proxy, potentially modifiable risk factors for stone formation and/or growth.[41] Regarding surveillance intervals, proposed protocols range from imaging and basic metabolic profile every 3 months to merely imaging every 2-3 years.[42, 43] **Consequently clinical judgement must be used to balance the patient's probability of stone/symptom progression against the risk posed by surgical intervention.**

Treatment of asymptomatic urinary calculi. Contemporary retrospective literature is somewhat conflicting regarding outcomes of asymptomatic urinary calculi. However, an estimated 10%-25% of patients with asymptomatic renal calculi will proceed to surgical intervention within a year of diagnosis, with the 2 most common indications for intervention being poorly controlled pain and migration of the calculus into the ureter.[6, 15, 24, 25, 30, 44] Stone size is an important determinant of the treatment approach to asymptomatic urinary calculi. **A survey**

of 167 practicing urologists indicated that stone size was the primary factor determining management approach, with size >5 mm serving as the threshold for treatment, consistent with AUA guidelines regarding surgical management of urinary calculi.[10, 45]

A limited number of prospective studies have evaluated management strategies for asymptomatic urinary calculi, with most focusing on lower pole calculi since this is the most common location for asymptomatic stones.[28] Inci et al prospectively followed 24 patients with asymptomatic lower pole calculi with a mean cumulative diameter of 8.8 mm for a mean of 52.3 months.[46] Of the patients 29.6% experienced an increase in stone size at the end of the study period (mean increase 0.05 mm), with 11% requiring surgical intervention. Sener et al went a step further by randomizing patients with asymptomatic lower pole stones (mean size approximately 8 mm) to URS, SWL or observation.[47] They found that intervention was associated with high stone-free rates and relatively low complication rates. At a median follow-up of approximately 21 months treatment via URS and SWL was associated with 92% and 100% stone-free rates, respectively. Complication (Clavien I to IV) rates in the URS and SWL cohorts were 14% and 6%, respectively. Of note, patients undergoing SWL required a median of 1.48 procedures. In the observation group 88% of patients remained asymptomatic at the end of the study period.

Compared to the findings of Sener et al,[47] a randomized study of 78 patients with asymptomatic lower pole calculi <10 mm showed equivocal, albeit significantly lower, stone-free rates among the URS (50%) and SWL (35%) cohorts (p=0.92).[48] In another study Yuruk et al randomized patients with asymptomatic lower pole renal stones <2 cm in diameter to either PCNL, SWL or observation.[43] They observed a 97% stone-free rate for PCNL compared to 55% for SWL (p <0.05), with 10% of patients undergoing SWL requiring repeat surgical intervention. Also noteworthy is their finding that 16.1% of patients undergoing SWL and 3.2% of those undergoing PCNL had postoperative renal scarring on dimercaptosuccinic acid scintigraphy. Of patients being observed 22% required surgical intervention at a mean follow-up of 19.3 months. Stone-free rates following PCNL for asymptomatic lower pole stones appear to be independent of stone size, whereas increasing stone burden is associated with lower stone-free rates following SWL.[49] **As such, PCNL should be considered for larger stone burdens, particularly those located within the lower pole. Taken collectively, these studies suggest that URS, SWL and PCNL are all acceptable treatment options for asymptomatic renal calculi.** Ultimately an informed patient-provider conversation weighing the risks and benefits of each procedure must be undertaken to guide treatment.

Management of residual stone fragments following index surgery. **The AUA currently recommends offering treatment for residual stone fragments following index percutaneous or endoscopic stone surgery so as to render the patient stone-free, particularly in instances where infectious stones are implicated (grade C recommendation).**[10] This recommendation is based largely on retrospective analyses demonstrating that stone-related events occur in 20%-43% of patients with residual stone fragments following PCNL or an endoscopic procedure.[16, 20] However, these same studies suggest that up to half of patients experiencing a postoperative stone event will spontaneously pass the implicated fragment(s). Of note, residual stone fragment size >4 mm in these series was an independent predictor of a postoperative stone event, while stones >3 mm predicted stone fragment growth, suggesting that patients with smaller fragments could be followed by surveillance. However, approximately 17% of patients with residual fragments <4 mm still require reintervention, with the most common indications for reintervention including pain (43%) and growth of residual fragment (37%).[21, 50] In addition to size, composition should influence the decision to intervene in residual stone fragments, with struvite and apatite stone composition being predictive of repeat surgical intervention.[17]

There are limited guidelines regarding treatment modality of residual fragments due largely to the paucity of literature evaluating this clinical question. **However, AUA guidelines stipulate that patients in whom initial SWL fails should be offered endoscopic treatment of residual stones/fragments (grade C recommendation) as success rates following secondary PCNL and URS may be as high as 86%-100% and 62%-100%, respectively.**[10] Alternatively patients who have experienced partial fragmentation may be considered for repeat SWL.

SHARED DECISION MAKING

Value based purchasing efforts have emerged as both a prominent and polarizing issue within the greater U.S. health care reform debate.[51, 52] Given the high prevalence and cost associated with the treatment of urinary stone disease,[53, 54] it is conceivable that management of urinary stones will someday be targeted by the aforementioned value based reform efforts. **Stone management guidelines from both the European Association of Urology and AUA make reference to the importance of employing a shared decision making process that respects patient preference/autonomy.** A 2013 survey study conducted by Sarkissian et al reaffirms the importance of shared decision making given the heterogeneity of patient preferences surrounding the management of asymptomatic renal stones.[55] The authors evaluated the treatment preferences of 101 patients receiving care within a single institution's stone clinic by asking about their preferred treatment modality for a hypothetical asymptomatic 8 mm lower pole renal stone. Of the patients 22.8%, 47.5% and 29.7% elected observation, SWL and URS, respectively. A history of larger urinary calculi influenced patient preference for intervention over observation (p=0.029). Consequently it is incumbent on providers to be well versed in the stone literature, particularly as it pertains to outcomes associated with observation versus intervention for urinary stones of various sizes and locations.

CONCLUSIONS

Owing to increasing use of diagnostic imaging, the incidence of asymptomatic urinary calculi has risen in recent years. Similarly advances in endoscopic equipment/technology have allowed endoscopic treatment of increasingly larger stone burdens, thereby raising the likelihood of residual stone fragments following endoscopic surgery. **Observation is a reasonable management option for most patients presenting with asymptomatic urinary calculi.** While approximately 50% of these patients will eventually experience symptoms, the majority will not require surgical intervention. **Risk stratification using both clinical and non-clinical factors is paramount in determining which patients are appropriate candidates for observation.**

There are currently no validated surveillance algorithms for patients with asymptomatic urinary calculi, although some combination of intermittent imaging and/or metabolic evaluation is generally accepted as reasonable. If definitive treatment of asymptomatic calculi is selected, SWL and URS offer similar overall stone-free rates, although repeat intervention is more frequently required following index SWL. **With regard to asymptomatic residual stone fragments following URS, SWL or PCNL, fragment size is an important, if not the most important, predictor of disease progression.** Additional variables that should guide management include socioeconomic factors such as access to care and clinical predictors such as stone composition or the presence of comorbidities. As value based purchasing reforms gain momentum, treatment of urinary calculi is likely to emerge as a tantalizing target given the burden and cost of disease. As such, shared decision making should also serve as a guiding principle in the management of asymptomatic urinary calculi.

DID YOU KNOW?

- The screening prevalence of asymptomatic renal calculi has been estimated at 7.8%, with 20%-50% of these individuals experiencing a stone related event within 10 years.
- The rate of residual fragments following stone surgery varies by approach but may be as high as 40%. Factors such as size, location and composition all influence whether these fragments will eventually become symptomatic/require intervention.
- Intervention should be considered for asymptomatic de novo stones and residual fragments >4 mm, although stone location, patient comorbidities and stone composition should also be considered before proceeding with intervention.
- Observation is reasonable for patients refusing intervention or in those for whom surgery represents a significant risk. Periodic surveillance imaging should be performed in this cohort.

Appendix. Predictors of reintervention/failure to clear residual stone fragments

Fragment size >4 mm
Higher stone density (>1000 HU)
Lower pole location
Complex renal anatomy
Surgical approach (eg SWL vs URS)

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Study Questions Volume 39 Lesson 20

1. The imaging modality with the highest sensitivity for detection of residual stone fragments following intervention is
   a. ultrasound
   b. abdominal x-ray
   c. computerized tomography
   d. magnetic resonance imaging

2. The effective radiation dose to the patient during ultralow dose CT compared to conventional non-contrast CT of the abdomen and pelvis is reduced by a factor of
   a. 2
   b. 10
   c. 30
   d. 50

3. During percutaneous nephrolithotomy the greatest degree of stone clearance is seen with a combination of
   a. supine positioning and larger diameter access
   b. ultrasound guided access and use of ureteral occlusion balloon
   c. upper and lower pole access
   d. fluoroscopy and flexible nephroscopy

4. A 37-year-old woman undergoes percutaneous nephrolithotomy for a 1.8 cm partial staghorn calculus and is found to have a 3 mm residual fragment on routine postoperative imaging. The patient is asymptomatic and elects to proceed with an initial strategy of surveillance. The factor that best predicts repeat surgical intervention is
   a. stone size of 3 mm
   b. lower pole location
   c. calcium apatite stone composition
   d. body mass index greater than 30 kg/m^2

5. A 55-year-old man is incidentally found to have an 8 mm lower pole stone and is asymptomatic. He is contemplating intervention and inquiries about the reported efficacy of ureteroscopy and shock wave lithotripsy. Allowing for multiple SWL treatments, the stone-free rate and complication rate for URS compared to SWL are
   a. less and greater
   b. less and less
   c. equal and less
   d. greater and equal

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