

### Title: Radiological Imaging for Renal Calculi: Guidelines and a Clinical and Cost Effectiveness Review

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### Context and policy issues:

About 10% of the population will have an episode of renal calculi (kidney stones) at some point in their lives and about 50% of individuals will have recurrence of kidney stones within about 10 years of their first episode.<sup>1</sup> The risk of developing kidney stones is about two to four times higher in males than females.<sup>1</sup> Kidney stones are responsible for about 450,000 visits to acute care facilities in the United States each year.<sup>1</sup> Patients with kidney stones often report to emergency departments (EDs) with symptoms of renal colic (e.g. acute flank or loin pain) and hematuria.<sup>2</sup> Imaging may be performed when patients initially present with renal colic to aid in the differential diagnosis<sup>3</sup> and if a stone is present, to determine its size and location.<sup>1</sup>

A number of different imaging techniques can be used to identify kidney stones. Their utility depends in part on the composition and sometimes the location of the stone.<sup>4</sup> About 80% of kidney stones are composed of calcium, but kidney stones can also be composed of uric acid, struvite, cystine.or medications that can crystallize in the urine.<sup>2</sup> Standard abdominal x-rays can be used to image calcium-based kidney stones. This technique involves passing low doses of radiation through the body onto a photographic plate to obtain images of the kidneys, ureters and bladder (also termed KUB or KUB films).<sup>1,4,5</sup> Calcium containing kidney stones do not allow the radiation to pass through and will appear white on the x-ray film. While abdominal x-rays are inexpensive, readily available and relatively quick to perform, they do not detect all stones, specifically stones composed of uric acid or indinavir, a drug used to treat HIV.<sup>4</sup>

Intravenous pyelogram (IVP) (also referred to as intravenous urography or IVU) is a technique used for imaging the kidneys that has been available since the 1920's and was considered the gold standard for detecting kidney stones.<sup>1</sup> During this procedure, a dye is injected into a vein and x-rays are then taken of the abdomen. If a kidney stone is present, the dye builds up in the

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affected kidney and is excreted more slowly. This deficiency in filling will be evident on the x-rays.<sup>4</sup> IVP is also useful for detecting kidney stones in the ureter and in identifying the site and amount of obstruction present<sup>1</sup>, but the dye can cause allergic reactions and performing IVP can be time consuming, particularly when an obstruction exists.<sup>1,4</sup>

Ultrasound (US) is a radiation and contrast-free alternative for imaging the kidneys.<sup>4</sup> During this procedure, a probe that emits sound waves is passed over the kidneys, ureters and bladder. The sound waves are used to create an image on a monitor or screen. Ultrasound detects kidney stones that are composed of calcium, uric acid or indinavir, but can miss stones that are passing through the ureter towards the bladder. This may be a disadvantage since it is the passage of the stone through the ureter that most frequently causes significant pain that would prompt the patient to seek care at an emergency department (ED). On the other hand, US may be beneficial in detecting an obstruction caused by a renal calculus that has lodged in a ureter.<sup>4</sup>

Computerized tomography (CT scan) can also be used to image kidney stones. During this procedure, the patient is placed in an x-ray tube and multiple images of the kidneys, ureters and bladder are taken by an x-ray beam that moves around the body.<sup>4,5</sup> A CT scan is referred to as unenhanced or non-contrast if no contrast media is used.<sup>5</sup> A helical or spiral CT scan is a more technologically advanced scan during which both the patient and the x-ray beam move continuously, with the beam circling the patient.<sup>5</sup> A helical CT scan produces images more quickly than a standard CT scan and also has the advantage of providing more detailed information as the images produced have greater resolution compared to a standard CT scan.<sup>4,5</sup> CT scans can detect stones composed of calcium and other materials such as uric acid, but may not detect some stones composed of indinavir or crixivan.<sup>4,5</sup> CT scans are relatively quick, can identify urinary obstruction, other causes of flank pain, such as appendicitis or pyelonephritis, and may be more sensitive than some other techniques, but use more radiation than x-rays and are more costly.<sup>1,4</sup>

Over the past few years CT has become increasingly popular for imaging kidney stones, but is more costly than some other imaging techniques.<sup>2</sup> Guidelines for the assessment of kidney stones and studies of clinical and cost-effectiveness of different radiological imaging techniques can help in managing patients presenting to the ED with symptoms suggestive of kidney stones. This report will review the clinical and cost effectiveness of the different imaging techniques, which could potentially help in decision-making at the individual patient level and more broadly, at the level of the healthcare system.

### **Research questions:**

- 1. What are the guidelines for radiological imaging to assess patients presenting to the emergency department (ED) with suspected renal calculi?
- 2. What is the comparative clinical effectiveness of different radiological imaging techniques to assess patients presenting to the ED with suspected renal calculi?
- 3. What is the cost effectiveness of different radiological imaging techniques to assess patients presenting to the ED with suspected renal calculi?

#### Methods:

A limited literature search was conducted on key health technology assessment resources, including PubMed, The Cochrane Library (Issue 1, 2008), University of York Centre for Reviews

and Dissemination (CRD) databases, ECRI, EuroScan, international HTA agencies, and a focused Internet search. Results include articles published between 2003 and February 2008, and are limited to English language publications only. Filters were applied to limit the retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, economic evaluations and guidelines. Some observational studies were also identified and included.

#### Summary of findings:

#### Guidelines for radiological imaging for suspected renal calculi

The literature search did not identify any Canadian clinical practice guidelines that included recommendations about imaging techniques in patients presenting to the ED with suspected kidney stones. Several American<sup>6,7</sup>, European<sup>8,9</sup> and Australian<sup>3</sup> practice guidelines were identified and included the following recommendations:

### American College of Radiology (ACR) (2007)<sup>6</sup>

The ACR Committee on Appropriateness and its expert panel developed criteria for assessing the appropriateness of imaging techniques, with the purpose of guiding radiologists, radiation oncologists and physicians in making decisions about radiologic imaging. The ACR ranked CT of the abdomen and pelvis without contrast as the most appropriate technique for assessing patients with acute onset of flank pain, in whom there is suspicion of renal calculi. CT was given a score of 8 out of 9, with 1 being the least appropriate and 9 being the most appropriate. X-ray intravenous urography (7 out 9), US of the kidney with Doppler and KUB (6 out of 9), magnetic resonance imagine (MRI) of the abdomen and pelvis (4 out of 9) and X-ray of the abdomen (1 out of 9) ranked lower in terms of appropriateness. For patients with recurrent renal calculi, CT of the abdomen and pelvis without contrast and US of the kidney with Doppler and KUB ranked highest (7 out of 9), followed by X-ray of the abdomen (6 out of 9), X-ray intravenous urography (4 out of 9) and MRI of the abdomen and pelvis (2 out of 9).

### American Urological Association (2007)<sup>7</sup>

The American Urological Association guidelines on the management of ureteral calculi were developed by an expert panel and involved a systematic review of the literature, grading of the evidence, and formulation of statements based on the evidence and expert opinion. Statements are graded according to level of flexibility in application. A 'standard' is the most rigid treatment policy, followed by a 'recommendation' (less rigid) and an option (high degree of flexibility). Guidelines from the American Urological Association recommended that for ureteral stones <10 mm, "Patients should be followed with periodic imaging studies to monitor stone position and to assess for hydronephrosis",<sup>7</sup> but did not recommend a specific imaging modality.

### Caring for Australasians with Renal Impairment Guidelines (CARI) (2007)<sup>3</sup>

The CARI Guidelines were developed by the Council of the Australian and New Zealand Society of Nephrology and the Board of Kidney Health Australia and are strictly evidence-based. They were developed through a systematic review of the literature, feedback from external peer review and comment from the nephrology community. Guidelines are based upon level I evidence (obtained from a systematic review of all relevant randomized controlled trials) and level II evidence (obtained from at least one properly designed randomized controlled trial). Suggestions are based on level III evidence (obtained from well-designed non-experimental

studies) or level IV evidence (obtained from expert committee reports or opinions or clinical experience of respected authorities. According to the CARI Guidelines for the Radiological Diagnosis of Kidney Stones there was insufficient level I or level II evidence to make a guideline recommendation on diagnostic imaging for renal calculi. Instead, they made the following 'suggestion':

### **"SUGGESTIONS FOR CLINICAL CARE**

Imaging confirms the presence of renal calculus disease and for the urologist, assists in determining outcome and management. Studies confirm that when available, noncontrast helical computed tomography (CT) scanning (spiral) has superior sensitivity and specificity in the detection of stones."<sup>3</sup>

### European Association of Urology (EAU) (2006)<sup>8</sup>

The EAU guidelines do not clearly outline the manner in which they were developed, but involve categorizing recommendations based upon the level of evidence and grade of recommendation. The EAU considered IVP to be the gold standard in imaging in patients with suspected renal calculi, but considered the grade of evidence for unenhanced helical CT to be grade A (Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomized trial) and US kidney with Doppler and KUB to be grade B (Based on well-conducted clinical studies, but without randomized clinical trials). Specifically, they write:

"The diagnostic work-up of all patients with symptoms of urinary tract stones requires a reliable imaging technique. In case of an acute stone colic, excretory urography (intravenous pyelography, IVP) has been established as a gold standard. During recent years, unenhanced helical computed tomography (CT) examinations have been introduced as a quick and contrast-free alternative. In randomized prospective studies, the specificity and sensitivity of this method for patients with acute flank pain was found to be similar to that obtained with urography. In selected cases, additional information regarding renal function maybe obtained by combining CT with contrast infusion. One great advantage of CT is the demonstration of uric acid and xanthine stones, which are radiolucent on plain films. Another advantage is the ability of CT to detect alternative diagnoses. However, the advantage of a non-contrast imaging modality has to be balanced against the higher radiation dose given to the patient during CT investigation."<sup>8</sup>

### National Health Service (NHS) – United Kingdom (2005)<sup>9</sup>

The NHS develops clinical knowledge summaries on the management of 500 commonly encountered conditions in primary care. Each one is based upon detailed, current clinical knowledge. Similar to guidelines from the European Association of Urology, guidance from the NHS states:

"Intravenous urography (IVU) is the usual first-line investigation for suspected ureteric stones: it may suggest that there is renal obstruction and it is the best technique for defining pelvi-calyceal anatomy. However, it misses some ureteric and renal stones. It should be avoided if the creatinine is elevated.

**Non-contrast helical computerized tomography (NCHCT)** has the highest diagnostic accuracy, but until recently availability has been limited. Problems of access and interpretation 'out of hours' may be a problem.

**Plain abdominal X-ray** is a useful adjunct to aid in the early diagnosis of renal colic. Most renal stones contain calcium and should be visible on X-ray; however, in practice, bowel gas, extrarenal calcification, and obesity are limiting factors.

**Ultrasound** has the advantage of being non-invasive, but its usefulness is limited as small stones are difficult to diagnose and stones in the ureter are poorly visualized. It is appropriate to use ultrasound when renal colic occurs in pregnancy and in the febrile patient.

**Magnetic resonance urography (MRU)** is usually only considered if other investigations are contraindicated (e.g. during pregnancy). The main drawback is scanning time and competing imaging priorities.

**Retrograde ureterography/ureteroscopy** is very occasionally necessary if a person has persistent symptoms of renal colic but the IVU or NCHCT is difficult to interpret (e.g. if there are multiple phleboliths or poor contrast medium excretion). In practice this situation is unusual."<sup>9</sup>

#### Economic evaluations of radiological imaging for renal calculi

Several studies included cost estimates of renal imaging techniques, but did not look at relative cost effectiveness. In an Australian-based study, non-enhanced spiral CT cost about A\$15.46 more per exam than IVU.<sup>10</sup> In a study carried out in Switzerland, the cost of IVU and unenhanced helical CT differed by only one Euro.<sup>11</sup> In an international comparison of medical management strategies for kidney stones, in Canada the cost of an emergency room visit including a CT scan in patients suspected of having kidney stones was \$US230.<sup>12</sup>

#### Clinical effectiveness of radiological imaging for renal calculi

No meta-analyses, health technology assessment reports or systematic reviews of the clinical effectiveness of imaging techniques for kidney stones were identified. Several randomized trials and observational studies that included patients reporting to an ED suspected of having kidney stones were identified.

### Randomized trials

Mendelson et al. (2003) conducted a randomized trial comparing nonenhanced spiral CT (NECT) with IVP in an ED of an Australian hospital.<sup>10</sup> They included 207 patients who reported to the ED with symptoms suggesting acute renal colic and randomized them to either NECT or IVP. The authors did not state whether or not these were consecutive patients. Patients who presented during the day were investigated and randomized that day. Those who presented after hours were treated symptomatically then randomized the following day. While the authors did not explicitly state any exclusion criteria, seven people were excluded from the study after randomization, due to other imaging in the 24 hours prior to randomization (n=5), lost films (n=1) and recent stone removal (n=1). The 200 remaining patients (102 in the NECT group and 98 in the IVP group) had an average age of 45 years (range 17 to 86 years). It was not entirely clear what was considered to be the gold standard for diagnosing kidney stones in this study, but they reported that larger proportion of people in the NECT group were diagnosed with renal calculi (63.7%) than in the IVP group (42.8%, p=0.003). Further, the imaging diagnosis was more likely to be uncertain in the IVP group than in the NECT group (14% vs 3%, respectively, p=0.005). The proportion of patients whose examination was considered normal was not significantly different between groups. No patients in the IVP group reacted to the contrast media. Significantly more patients in the NECT group (n=29) underwent IVP at follow-up visits than in the IVP group (n=12, p=0.005). Radiation dosages were higher with NECT than with IVP. The

authors concluded that if the radiation dosages from IVP and NECT were similar, NECT would be the investigation of first choice in all individuals with suspected renal colic.

Pfister et al. (2003) conducted a randomized trial comparing unenhanced helical CT (UHCT) and intravenous urography (IVU) in the ED of a university hospital in Switzerland.<sup>11</sup> The study enrolled 122 consecutive patients who reported to the ED with acute flank pain suspicious of renal colic. Individuals with known kidney stone disease, impaired renal function (based on creatinine > 150 mmol/L), or signs of infection with fever or chills were excluded, as were individuals who were pregnant or under the age of 17. Patients were randomized to UHCT or IVU if renal colic was the most likely diagnosis following an initial evaluation. The gold standard used to confirm a diagnosis of ureterolithiasis was the spontaneous passage of a stone, retrieval of a stone via cystoscopy or ureteroscopy, or identification of a stone during retrograde pyelography. One hundred and thirteen patients (55 in the UHCT group and 58 in the IVP group) were available for follow-up, 82 males and 31 females who had an average age of 44.8 years (range: 17 to 86). The sensitivity (true positive rate) and specificity (true negative rate) of UHCT were 85% and 98%, respectively and 75% and 92%, respectively, for IVU. The differences in sensitivities and specificities of UHCT and IVU were not statistically significant. Three individuals (5%) in the IVU group had adverse reactions to the contrast media. Despite the differences in sensitivity and specificity not being significant, the authors concluded that if available, UHCT was a better alternative than IVU as it had a higher diagnostic accuracy and is faster, less expensive and less risky than IVU.

#### Observational studies

Eray et al. (2003) compared the diagnostic effectiveness of urinalysis, plain abdominal films (KUB) and nonenhanced spiral CT (NECT) in individuals with acute flank pain who presented to an ED during the day at a university hospital in Turkey.<sup>13</sup> Patients who were pregnant, under the age of 14 or did not consent to being in the study were excluded. All patients received the three tests. The gold standard for a diagnosis of urinary stones was a clearly visualized stone on the NECT or the passage of a stone. One hundred and thirty eight patients consented to be in the study, but only 99 completed diagnostic tests and only 65 were available for follow-up. Of these 65 patients, 28 were female and 37 were male, and the average age was 38.8 (S.D. = 13.5). For urinalysis, the sensitivity and specificity were 69% and 27%, respectively. For KUB the sensitivity and specificity were 69% and 82%, respectively. For NECT alone, the sensitivity and specificity were both 91%. The authors concluded that urinalysis and KUB were much less accurate than NECT in diagnosing acute urolithiasis. This study had a number of limitations in that there was significant loss to follow-up and it had a relatively high risk of bias as it was non-randomized and only included patients that presented to the ED during the day.

Gaspari et al. (2005) assessed the sensitivity and specificity of hydronephrosis on emergency ultrasound (US) in a convenience sample (i.e, those patients who were easiest to reach were chosen) of 104 patients with flank pain consistent with renal colic who reported to the ED of a teaching hospital in the United States.<sup>14</sup> Individuals with fever, trauma, known kidney stone disease, unstable vitals signs and those unable to consent were excluded from the study. In this study, the presence of a kidney stone or evidence of recently passing a stone on CT scan, the passage of a stone into a urine strainer, or retrieval of a stone via a surgical intervention was considered the gold standard for diagnosing kidney stones. It was not clear if the CT scan used in this study was spiral/helical. All patients received both imaging techniques. About 55% of patients were female and the average age was 40 years (S.D. = 1.36). The sensitivity and specificity of US for hydronephrosis were 87% and 82%, respectively. When results were stratified by hematuria, sensitivity and specificity of US for hydronephrosis were 88% and 85%,

respectively, in individuals with hematuria. The sensitivity and specificity of hematuria alone were 93% and 33%, respectively. It was not clear if this stratification was specified *a priori*. One limitation of this study included the non-randomized design and the use of a convenience sample which is a potential source of bias. As well, 31 patients were not available for follow-up, so outcome data was obtained from their family doctor, urologist or medical record. As well, after hours CT scans were read by a radiology resident. When the results were re-read by a radiology attending physician, the sensitivity was reduced to 83%, while the specificity increased to 92%. The authors concluded that emergency US of the kidneys showed good sensitivity and specificity for diagnosing renal colic in individuals presenting with flank pain.

Poletti et al. (2007) compared low-dose to standard-dose unenhanced CT in 125 consecutive patients with suspected renal colic who reported during the day to an ED at a university hospital in Switzerland.<sup>15</sup> Patients who were pregnant or admitted following lithotripsy were excluded. The standard-dose CT was considered to be the gold standard in identifying kidney stones. All patients received both scans. The study population consisted of 87 males and 38 females, who had an average age of 45 years. The sensitivity and specificity of low-dose CT were 97% and 96%, respectively, for detecting at least one direct or indirect sign of renal colic. When only indirect signs of renal colic were considered, sensitivity and specificity of low-dose CT were 98% and 100%, respectively. The authors concluded that low-dose CT could be used as a first-line imaging tool in patients with renal colic, provided that patients and providers were both aware if its limitations and advantages compared to standard-dose CT. Similar to the previous study, this study had a relatively high risk of bias. It was non-randomized and only included patients that presented to the ED during the day. As well, it was not clear if spiral/helical CT was used.

### Limitations

Overall, there were relatively few studies that compared the effectiveness of renal imaging techniques specifically in the ED. Three studies were potentially at risk of bias due to observational designs, use of convenience samples, large loss to follow-up and restriction of the sample to individuals who presented during the day. This could potentially limit generalizability of the results as it has been estimated that 50% of individuals with renal colic will present to an ED during the night.<sup>16</sup> As well, it was not clear from the reporting in two studies whether or not the criterion was a spiral/helical CT or a standard CT. The randomized studies also had limitations to their designs with lack of a reference standard and loss to follow-up.

### Conclusions and implications for decision or policy making:

Clinical practice guidelines have conflicting recommendations regarding the first-line investigation for kidney stones, with some favoring helical CT and others recommending IVP. The search period did not identify a large number of studies of clinical effectiveness of renal imaging techniques in the ED and did not locate any studies of cost effectiveness. Thus, it is not possible to conclude which technique should be considered the first-line test in patients presenting to the ED with suspected renal calculi based on these results. Two systematic reviews outside of the search period were identified from the articles in the search period. One meta-analysis published in 2002 found that CT scanning was more sensitive and specific than IVP.<sup>17</sup> An older systematic review from 1998 found that the sensitivities and specificities of KUB, US and IVP were lower than CT scanning.<sup>18</sup> These reviews did not appear to be limited to the ED.

Within the randomized and observational studies in the search period, it seemed that CT scanning was often considered to be the gold standard, perhaps based on earlier research.

Regardless, it appeared that many imaging techniques were useful in the ED to aid in the diagnosis of renal calculi and would be beneficial if CT scanning was not available (e.g. after hours when a radiologist may not be available) or in patients in which CT would not be recommended (e.g. pregnant women or children).

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### Appendices: Studies of Clinical Effectiveness Not Limited to the ED

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