American College of Radiology
ACR Appropriateness Criteria®

Clinical Condition: **Indeterminate Renal Masses**

Radiologic Procedure	Rating	Comments	RRL*
MRI kidney without and with contrast	9	Either CT or MR is appropriate. See comments regarding contrast in text under "Anticipated Expectations."	None
CT kidney without and with contrast	9	Either CT or MR is appropriate. Thin-section CT.	High
US kidney duplex Doppler	8	To clarify mass seen on IVP that is probably cystic or to clarify mass seen on CT that is probably a hyperdense cyst.	None
INV biopsy and aspiration kidney	5	Depends on clinical scenario–the appearance and size of mass.	IP
MRI kidney without contrast	3	Can be useful to characterize simple cysts.	None
NUC DMSA scan kidney	3	May be useful to rule out pseudomass of functioning renal tissue.	Low
INV angiography kidney	3	To rule out arterio-venous malformation, arterio-venous fistula, or renal artery aneurysm.	IP
X-ray intravenous urography	2	May be helpful to differentiate parenchymal from collecting system masses.	Low
CT kidney without contrast	1		Med
Rating Scale: 1=Least appropriate, 9=Most appropriate			***Relative Radiation Level**

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Summary of Literature Review

Introduction

An indeterminate renal mass is one that cannot be diagnosed confidently as benign or malignant at the time it was discovered. Lesions or masses whose character and type are clearly defined by the first imaging test will not be discussed in this review.

In years past, discovery of a renal mass by excretory urography led to angiography, needle aspiration, or even exploratory surgery to characterize it accurately. The advent of ultrasonography (US) helped resolve many masses found at urography by identifying them clearly as simple cysts. Contrast-enhanced computed tomography (CT) has eliminated, to a great degree, the need for angiographic evaluation of renal mass lesions. Magnetic resonance imaging (MRI) of renal masses with fast scan techniques and intravenous (IV) gadolinium now provides imaging comparable to CT scanning. Radionuclide scintigraphy has in the past been helpful in identifying lobulated functioning renal tissue resembling a more ominous mass, but has limited applications now. The use of needle aspiration has declined as imaging techniques have improved.

Urography

The plain abdominal film has very poor sensitivity and specificity for evaluating a renal mass. Intravenous pyelography (IVP) with nephrotomography has only 67% sensitivity in detecting renal masses 3 cm or less in diameter [1], and without tomography, the sensitivity is even less. In a small series by Curry et al [2] over half of small tumors were not visualized or were missed on the initial IVP. IVP also lacks specificity in separating benign from malignant cystic masses [3]. However, the IVP continues to be an effective single test for imaging renal function, renal anatomy, and collecting system integrity. It has value in imaging the upper urinary collecting tracts, particularly in the patient with lower-tract transitional neoplasm. CT urography is being used in many centers to evaluate patients with hematuria, as it provides a comprehensive evaluation of the urinary tract and not only can detect renal calculi and masses but also can evaluate the urothelial tract for causes of hematuria [4,5].

Ultrasonography

The most common renal mass is a cyst, and US provides the most cost-effective method of defining and confirming a benign cyst [3]. Factors limiting US include the patient's body habitus, lesion location, multiple lesions, and calcification in the wall of a cystic mass and hemorrhagic fluid in a cystic mass. Early studies have suggested that US may have a problem in detecting small (<3 cm) renal masses [2,3]. A more recent study of von Hippel-Lindau patients using grayscale US detected only 70% of renal masses <2 cm, in contrast to CT which showed 95% of the lesions [6]. However, more recent studies using color and power Doppler imaging have shown improved and promising results [7,8]. In one study of 114 patients, phase-inversion harmonic imaging when combined with B-mode sonography improved lesion conspicuity as well as accuracy in tissue characterization [9].

Contrast-enhanced Doppler US using intravenously administered contrast agents has also been shown to have the potential to improve the detection and characterization of renal cell carcinomas, but it is not widely available in the United States [10]. In a small series, US failed to find or accurately characterize 40% of small (<3 cm) renal cell carcinomas [2]. Conversely, in a report of a much larger series by Amendola et al [1] sonography had a sensitivity of 79% in detecting small renal carcinomas 3 cm or less in diameter. In the future, color Doppler flow imaging with an IV contrast agent may improve sensitivity in detecting tumor vessels and evaluating the renal vein [11].

Previously, sonographic findings of a small hyperechoic mass were considered diagnostic of angiomyolipoma; however, a large series by Yamashita et al [12] showed that 61% of small (3 cm or less) solid renal cell carcinomas were hyperechoic relative to normal renal echogenicity, and therefore US cannot be used to definitively make the diagnosis of angiomyolipoma. One finding suggestive of a small-renal-cell carcinoma was a hypoechoic rim about the solid tumor [12,13]. Doppler

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US has been suggested as a way to further characterize solid masses; in the absence of clinical evidence of infection, a Doppler frequency shift greater than 2.5 kHz is advocated by some as a reliable indicator of malignancy [14,15]. However, US can be falsely negative with avascular tumor masses and falsely positive with inflammatory masses.

Renal cysts are the most commonly discovered renal masses, and the criteria for US diagnosis of renal cysts are well defined. These criteria include that the mass is sonolucent, demonstrates good through-transmission of the sound waves with posterior enhancement, and has a thin, well-defined wall. Complex masses not fulfilling the criteria of cysts are considered indeterminate and require further evaluation, usually by CT.

Computed Tomography

The accepted criteria of a benign simple cyst are well-defined [16]. Bosniak has developed a CT classification system for cystic renal masses, encompassing the spectrum from simple renal cyst to obvious cystic malignancy [17,18]. A cyst that contains simple fluid, has a hairline-thin wall, does not contain septa or calcification, and does not enhance with IV contrast is category I, a benign cyst. Category II cysts have a hairline-thin wall and may contain a few hairline-thin septa. Hairline-thin calcification or a short segment of slightly thickened but smooth calcification may be seen in category II lesions. These lesions do not show measurable enhancement with IV contrast. High-attenuation cysts are also included in category II. Initial reports indicated that category II cysts are invariably benign [19-21]. The hyperdense cyst can also present a diagnostic problem in that its initial attenuation coefficients are high [50-90 Hounsfield units (HU)] which can theoretically obscure tiny papillary projections along its wall. US may be useful in characterizing some of these high-attenuation lesions as approximately, 50% of these will be anechoic and can be characterized as benign [22].

While US is superior to CT in depicting the internal features of cystic renal masses, the presence of calcium can obscure other features. In these instances, CT can be useful to characterize these lesions, as the presence of a small amount of calcium does not hinder characterization [20,21].

Category IIF cysts are those cystic renal masses that are felt to be benign but are too complex to be diagnosed with absolute certainty. They have one or more of the following abnormalities: increased number of hairline septa; minimal thickening of cyst wall or septa, which may demonstrate perceived (not measurable) enhancement of septa or cyst wall; calcification, which may be thick and nodular [23]; no enhancing soft-tissue components; and totally intrarenal high-attenuation lesions 3 cm or more in size. These lesions, in view of their complexity when compared to category II lesions, warrant follow-up (usually at 6-month intervals for the first year, and then annually for a minimum of 5 years), to assure stability [16]. Israel and Bosniak [24] reported a series of 42 category IIF lesions with a minimum of 2-year follow-up and showed that most of them were stable (greater than 5-year mean follow-up) and only in two cases did the lesion become more complex and subsequently prove to be renal cell carcinoma.

Category III lesions have grossly thickened walls or septa in which measurable enhancement can be demonstrated. Malignancy cannot be excluded in these cases, and surgery is generally suggested.

Initially, it was felt that about half of category III cystic lesions will be malignant, but reported percentages vary from 25%-100% [19,20]. However, with the introduction of category IIF, some lesions that were initially felt to be category III are now considered category IIF and are followed, in lieu of surgery. Therefore, the overall percentage of malignancy within category III is felt to have increased.

Identification of enhancement after IV contrast is a key determinant in characterizing a renal mass as potentially malignant. CT is the most important imaging technique for evaluating the indeterminate renal mass. Images acquired before and after contrast are critical to define the lesion; enhancement indicates a vascularized mass and, therefore, a possible malignancy. Initially, enhancement of more than 10 HU was considered by Bosniak and others [22,25,26] to be significant. However, with the introduction of helical CT scanners, others suggest an increase of 20 HU to be indicative of enhancement [27,28]. Sensitivity of CT in identifying small renal masses is greater than 90% [1]. Analysis of enhancement for neoplasm is best done in the nephrographic phase of helical CT imaging of the kidneys [25]. False negatives may occur in the corticomedullary phase.

Although the Bosniak classification scheme is very useful for the clinical management of cystic renal masses, interobserver variation in distinguishing between category II, IIF, and III lesions does exist and may present problems in recommending surgical versus conservative management in some cases. In the study by Siegel et al [29] 11 (16%) of 70 cystic lesions classified as category I or II by one reader were upgraded to category III or IV by another reader.

CT enables detection of small amounts of fat that identifies the lesion as a benign angiomyolipoma [30]. Fat related to other malignant neoplasms has been reported,

but these masses are generally large tumors that had engulfed perinephric or renal sinus fat, or renal carcinomas that had areas of osseous metaplasia and small amounts of fat. Macroscopic fat within a noncalcified mass remains specific for benign angiomyolipoma [20,31]. For angiomyolipomas that do not contain macroscopic fat, chemical shift MRI may suggest the diagnosis by demonstrating loss of signal on the opposed-phase images [32]. However, clear-cell renal cell carcinoma may also lose signal on opposed-phase MRI images, and therefore the diagnosis of an angiomyolipoma that does not contain macroscopic fat cannot be made with absolute certainty with CT or MRI.

Oncocytomas cannot be diagnosed based on their imaging appearance. The CT finding of a central scar, previously felt to be specific for oncocytoma, has been found with renal cell carcinomas, and the finding is not specific [33,34]. As reported by Davidson et al [33] CT findings of homogeneity or a central stellate "scar" are poor discriminators in predicting oncocytoma or renal cell carcinoma, regardless of size.

The small (1.5 cm or less in diameter) renal mass poses a more complex problem for CT imaging, in that volume-averaging effects occur, making it difficult to assess accurately the density on noncontrast images and to evaluate for enhancement after IV contrast administration [22,26,27]. Among the more difficult entities to differentiate from a small renal cell carcinoma are a small dense cyst containing blood or proteinaceous material [1] and a simple cyst that demonstrates pseudo enhancement. Multidetector CT using thin overlapping reconstructions may help improve characterization of small renal masses. In a recent multidetector CT study of 37 patients with 175 small (<3 cm) renal masses, thin overlapping reconstructions were performed and compared to routine 5 mm thick sections to determine if the thin overlapping reconstructions could improve detection and characterization of small renal masses. Lesion characterization for cysts improved from 29%-84% when thin overlapping reconstructions were used, and the overall percentage of indeterminate lesions was reduced from 69% to 53% [35].

Very small solid renal nodules are common; in one study more than 50% of patients had some type of very small renal nodule at necropsy, and about one-third of these were termed "adenomas" [36]. The small renal adenoma is currently considered to be a "renal adenocarcinoma of low metastatic potential" [37,38]. The low metastatic potential of small renal cell carcinomas (less than 3 cm in diameter) is supported by many series [1,26,37,39-42]. In the elderly or in a patient who is a poor surgical risk, Bosniak feels that a small (less than 1.5 cm diameter) indeterminate renal mass can be followed until it reaches 2 cm in diameter [26]. Although a solid lesion up to 3 cm in diameter has low metastatic potential, once it has been characterized as a solid, non-fat-containing mass it should be considered and potentially treated as a malignancy [31,43]. If the patient's clinical condition militates against surgery or if there is surgical risk of causing the patient to become dialysis-dependent, such lesions, because of their low metastatic potential when small, can be followed with CT or MRI. Surgery is reconsidered if the mass shows rapid growth [26,27].

The effect of early detection of a very small renal mass by current technology operates insidiously to alter our perception of how radiological tests affect patient care, especially the detection and management data affected by "length bias" and "lead bias" [44]. Therefore, a "wait and see" approach is especially appropriate for managing the very small, asymptomatic indeterminate renal mass in an elderly patient [44]. For a younger, healthy patient, the approach is somewhat different [18]: 1) US is used first to confirm if it is a simple, benign cyst; 2) if US is not confirmatory, CT or MRI is used before and after IV contrast to determine if it enhances; 3) if there is no enhancement, nothing further need be done; 4) if it enhances, a early surgical intervention or a follow-up approach may be performed; 5) if it grows to 2 cm in diameter, it should be removed by kidney-sparing surgery.

Magnetic Resonance Imaging

With the exception of angiomyolipomas and simple renal cysts, unenhanced MRI cannot characterize renal masses. However, MRI using IV gadolinium contrast agents now provides sensitivity and specificity similar to CT in detecting contrast enhancement and identifying a mass requiring surgery [45-49]. Previously it was felt that MRI with gadolinium was particularly applicable to patients with renal insufficiency for whom conventional contrast would be significantly nephrotoxic [47]. However, it has been suggested recently that the development of nephrogenic systemic fibrosis is associated with the administration of gadolinium in patients with renal failure, and further studies are necessary to determine this exact relationship [50]. Gadolinium is still felt to be safe in patients with a history of allergy to conventional contrast agents.

Ho et al [51] demonstrated that it is possible to calculate percentage of enhancement of renal masses at MRI and that this can be used to characterize renal masses. In another study, 73 patients with 93 renal masses underwent contrast-enhanced MRI, and quantitative enhancement with signal intensity measurement analysis (percentage enhancement) was compared to qualitative analysis of enhancement with image subtraction to determine which was superior for detecting malignancy. Sensitivity and

specificity for diagnosing malignancy based on enhancement were 95% and 53%, respectively, for quantitative analysis and 99% and 58%, respectively, for qualitative analysis. Three of four malignant lesions incorrectly assigned as benign by quantitative method were hyperintense on unenhanced MRI. All were accurately diagnosed as being malignant by qualitative method [52].

In a recent study, 69 cystic renal masses were evaluated using CT and MRI within one year of each other, with consensus analysis by two radiologists. Wall thickness, septal thickness, number of septa, enhancement, and lesions were classified using the Bosniak classification. There was CT and MRI agreement in 56 of 69 lesions (81%) and disagreement in 13 of 69 lesions (19%). In 8 (12%) more septa were seen, and in 7 (10%) increased wall and or septal thickness were seen on MRI. In two lesions (3%) CT and MRI enhancement features were different. Overall MRI upgraded seven lesions: from category II to IIF in two, from IIF to III in three, and III to IV in two. CT and MRI were felt to be similar in evaluation of most renal cystic mass lesions. However, MRI may depict additional findings such as an increase in number of septa, septal and/or wall thickness, and enhancement. Such findings would result in MRI upgrading cystic lesions and thus may alter patient management. The authors recommend caution in interpreting MRI of complex cystic renal masses, and more specifically those that are borderline between categories IIF and III without additional correlative imaging [53].

Nuclear Medicine

Radionuclide scintigraphy with a cortical imaging agent (eg, DMSA) has a limited role in evaluating of the indeterminate renal mass, being used primarily to identify the so-called column of Bertin or junctional zone, which may be causing a pseudotumor effect on IVP or US [20]. Fluorine-18-2-fluoro-2-deoxy-D-glucose positron emission tomography (FDG-PET) may prove to be useful in detecting renal tumors and characterizing indeterminate renal cysts. Although there were false negatives in both the tumor group and the indeterminate cyst group, there were no false positives [54]. Others have reported varying accuracies for detecting renal cell carcinoma, but in general the low sensitivity of FDG-PET for renal cell carcinoma detection and characterization has limited its use for this purpose [55,56].

Angiography

Although two-thirds of renal tumors have enough vascularity to allow identification of tumor neovascularity, one-third will be of such a hypovascular or "avascular" state that angiography will not help identify the lesion as benign or malignant [27]. This is even true of renal carcinomas presenting with acute perirenal hemorrhage. For some applications of nephron-sparing surgery for small renal neoplasms, the urologic surgeon uses aortography or selective angiography to provide a road map to assist in resection.

Aspiration and Biopsy

Biopsy of the indeterminate renal mass has a limited role in the current era of high-quality imaging. In a survey by the Society of Uroradiology [57] reporting on approximately 16,000 cases, 92% of uroradiologists accepted the US findings of a cyst as being sufficient for diagnosis and 100% accepted the CT criteria of a simple or category II cyst as being sufficiently diagnostic. If cyst aspiration is done, cytologic evaluation is considered the laboratory study of choice. Although aspiration of clear fluid usually indicates a benign cyst, clear fluid was found in 19 cystic renal cell carcinomas, only 11 of which had positive cytologic evaluation. Therefore, the gross and laboratory analysis of aspirated fluid is not conclusive, and CT is considered the "gold standard" in evaluating cystic masses [57]. However, aspiration or biopsy does have certain indications: confirmation of an infected cyst or abscess, and identification of lymphoma or a metastasis in a kidney where either diagnosis would affect clinical management.

In the last few years, in part due to the development of new techniques in histological and molecular analysis, the indications for renal mass biopsy have increased and now include the following: confirmation of renal cell carcinoma when the surgical risk is high, when disease is either locally advanced or metastatic; when masses have equivocal imaging features; when a solid mass is present in a solitary or transplant kidney; and prior to ablative therapies [58-61].

Initial laparoscopic evaluation of complex renal cysts may replace open surgery in some cases. Laparoscopic biopsy of cystic renal cell carcinoma followed by open surgery does not seem to increase incidence of seeding or metastases [62].

Summary

CT is the modality of choice for evaluating indeterminate renal lesions that are suspicious for malignancy. For those patients who cannot tolerate iodinated IV contrast material due to allergy, MRI with gadolinium contrast is advised. The newer techniques have shown that MRI is also capable of characterizing indeterminate renal masses. When CT and MRI are compared in the evaluation of cystic renal masses, MRI appears to be more sensitive and tends to upgrade cystic lesions. Thus caution is advised when using MRI findings to direct clinical management at this time. Radionuclide scintigraphy has a role limited to confirming normal renal tissue. Angiography is used

primarily to define vascular anatomy before nephron-sparing surgery. Renal aspiration or biopsy has few indications: confirming an infected cyst or identifying lymphoma or a metastasis as the cause of the indeterminate renal mass.

Anticipated Exceptions

Nephrogenic systemic fibrosis (NSF, also known as nephrogenic fibrosing dermopathy) was first identified in 1997 and has recently generated substantial concern among radiologists, referring doctors and lay people. Until the last few years, gadolinium-based MR contrast agents were widely believed to be almost universally well tolerated, extremely safe and non-nephrotoxic, even when used in patients with impaired renal function. All available experience suggests that these agents remain generally very safe, but recently some patients with renal failure who have been exposed to gadolinium contrast agents (the percentage is unclear) have developed NSF [63-65], a syndrome that can be fatal. Further studies are necessary to determine what the exact relationships are between gadolinium-containing contrast agents, their specific components and stoichiometry, patient renal function and NSF. Current theory links the development of NSF to the administration of relatively high doses (eg, >0.2mM/kg) and to agents in which the gadolinium is least strongly chelated. The FDA has recently issued a "black box" warning concerning these contrast agents (http://www.fda.gov/cder/drug/InfoSheets/HCP/gcca_200705HCP.pdf).

This warning recommends that, until further information is available, gadolinium contrast agents should not be administered to patients with either acute or significant chronic kidney disease (estimated GFR <30 mL/min/1.73m^2), recent liver or kidney transplant or hepato-renal syndrome, unless a risk-benefit assessment suggests that the benefit of administration in the particular patient clearly outweighs the potential risk(s)[64].

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