Indeterminate Renal Mass
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
1. O'Connor SD, Pickhardt PJ, Kim DH, Oliva MR, Silverman SG. Incidental finding of renal masses at unenhanced CT: prevalence and analysis of features for guiding management. *AJR Am J Roentgenol.*2011; 197(1):139-145.	Observational-Dx	3,001 patients	To investigate the frequency and clinical relevance of the incidental finding of renal masses at low-dose unenhanced CT and to analyze the results for features that can be used to guide evaluation.	At least one renal mass was identified in 433 (14.4%) patients. The mean size of the index masses was 25 +/- 16 mm; 376 (86.8%) masses were classified as benign and 57 (13.2%) as indeterminate. The 20- to 70-HU attenuation criterion alone was used for classification of 53 indeterminate lesions. Follow-up data (mean follow-up period, 4.4 years; range, 2-6.3 years) were available for 353 (81.5%) patients with masses (41 indeterminate, 312 benign). 4/41 indeterminate masses were diagnosed as RCC. The sensitivity and specificity for RCC on the basis of the indeterminate criteria were 100% and 89.4%. The PPV and NPV were 9.8% and 100%.	3
2. Pooler BD, Pickhardt PJ, O'Connor SD, Bruce RJ, Patel SR, Nakada SY. Renal cell carcinoma: attenuation values on unenhanced CT. *AJR Am J Roentgenol.* 2012;198(5):1115-1120.	Observational-Dx	189 consecutive patients with 193 pathologically proven RCCs	To analyze the attenuation values of pathologically proven RCCs on unenhanced CT and to determine the range of values wherein malignancy should be considered.	The 193 malignant tumors ranged in size from 1.1 to 20.1 cm (mean [+/- SD], 5.1 +/- 3.4 cm). 18 RCCs (9.3%) were homogeneous in appearance on unenhanced CT. The minimum and maximum region of intrest attenuation values obtained by sampling throughout each tumor were 27.5 +/- 10.4 HU (range, 4-67 HU) and 39.7 +/- 10.6 HU (range, 21-80 HU), respectively. Regional areas of minimum attenuation <20 HU and maximum attenuation >70 HU were seen in 24.9% (48/193) and 2.1% (4/193) of RCCs, respectively. However, all 193 RCCs (100%) were predominantly composed of noncalcific regions within 20-70 HU; 72.5% (140/193) fell entirely within this 20-70 HU "danger zone," including all 18 homogeneous lesions.	4
3. Israel GM, Bosniak MA. How I do it: evaluating renal masses. *Radiology.* 2005; 236(2):441-450.	Review/Other-Dx	N/A	To summarize current approach to the imaging evaluation of renal masses, to review imaging findings in these lesions, and to discuss the limitations of CT and MRI.	Accurate imaging diagnosis will be dependent on the radiologist to perform high quality imaging examinations, to correlate these imaging findings with clinical and pathologic results and to be aware of the potential pitfalls in renal mass diagnosis so that proper management options can be instituted.	4

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4. Abdulla C, Kalra MK, Saini S, et al. Pseudoenhancement of simulated renal cysts in a phantom using different multidetector CT scanners. *AJR Am J Roentgenol.* 2002; 179(6):1473-1476.	Observational-Dx	N/A	To determine whether pseudoenhancement of renal cysts occurs on scans obtained with MDCT scanners and whether the effect is influenced by scanning parameters.	Although pseudoenhancement was observed with MDCT scanners, the effect was statistically significant only for scans depicting the smaller cyst at a background renal density of 250 HU on the matrix array MDCT. Modulation of scanning parameters did not alter these findings. Pseudoenhancement was significantly higher with the matrix array MDCT scanner than with the adaptive array MDCT scanner ($P<0.05$).	2
5. Silverman SG, Israel GM, Herts BR, Richie JP. Management of the incidental renal mass. *Radiology.* 2008; 249(1):16-31.	Review/Other-Dx	N/A	Review literature on management of incidental renal mass and recommend a method for diagnosis.	Cystic masses are managed with the Bosniak classification with observation reserved for selected patients and the presumption of benignity recommended for simple-appearing cystic masses <1 cm. Additional imaging, and in some patients, percutaneous biopsy, is recommended to diagnose benign neoplasms.	4
6. Amendola MA, Bree RL, Pollack HM, et al. Small renal cell carcinomas: resolving a diagnostic dilemma. *Radiology.* 1988; 166(3):637-641.	Observational-Dx	39 patients	Retrospectively examine imaging findings of patients with pathologically proved RCC $\leq$3 cm in diameter to determine effectiveness of different imaging techniques.	Results of IVU (n=30) were true positive in 20 patients and false negative in 10 (sensitivity, 67%). Renal US (n=29) had true-positive results in 23 patients and false-negative results in 6 (sensitivity, 79%) CT (n=36) had true-positive results in 34 and false-negative results in 2 (sensitivity, 94%). For selective renal angiography (n=35), the results were true positive in 26 and false negative in 9 (sensitivity, 74%), with typical hypervascular RCC demonstrated in 17. Findings of percutaneous fine-needle aspiration biopsy were true positive in 1/5 patients when US guidance was used (sensitivity, 20%) and in 5/8 when CT guidance was used (sensitivity, 62%). Small RCC are best imaged by CT.	3

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7. Kim EY, Park BK, Kim CK, Lee HM. Clinico-radio-pathologic features of a solitary solid renal mass at MDCT examination. *Acta Radiol.* 2010; 51(10):1143-1148.	Observational-Dx	466 non-fatty solid renal masses in 466 patients	To evaluate the clinico-radio-pathologic features of a solitary solid renal mass at MDCT examination.	Of 466 tumors, 443 (95%) were malignant and 23 (5%) were benign. Of 443 malignant tumors, 437 (99%) were RCC and 6 (1%) were non-RCC. Of 437 RCCs, 324 (74%) were asymptomatic and 113 (26%) were symptomatic. Asymptomatic RCCs (n=183, 56%) were more frequently pT1a than symptomatic RCCs (n=28, 25%) (P<0.05). MDCT accuracy for detection of RCC was 94% (437/466). Of 220 RCCs </=4 cm, low grade RCC (53%) was more common than high grade RCC (47%).	3
8. Birnbaum BA, Jacobs JE, Ramchandani P. Multiphasic renal CT: comparison of renal mass enhancement during the corticomedullary and nephrographic phases. *Radiology.* 1996; 200(3):753-758.	Observational-Dx	30 consecutive patients; 31 renal masses	Prospective study to evaluate thin-section CT performed during the corticomedullary and nephrographic phases of contrast material enhancement in the characterization of renal masses.	Enhancement of renal neoplasms is time dependent and may not be evident in hypovascular tumors analyzed during the early corticomedullary phase. Reliance on absolute CT attenuation measurements, without use of internal standards as controls, may lead to misdiagnosis of neoplasms as cysts.	3
9. Bosniak MA. The current radiological approach to renal cysts. *Radiology.* 1986; 158(1):1-10.	Review/Other-Dx	N/A	Summarize radiological approach to renal cysts.	Classifies renal cysts into categories relative to likelihood of benignity. US and CT (or a combination of these when necessary) have become the main diagnostic techniques for evaluating renal masses.	4
10. Silverman SG, Lee BY, Seltzer SE, Bloom DA, Corless CL, Adams DF. Small (< or = 3 cm) renal masses: correlation of spiral CT features and pathologic findings. *AJR Am J Roentgenol.* 1994; 163(3):597-605.	Observational-Dx	35 total patients: 27 RCC, 2 transitional cell carcinomas, 1 leiomyoma, 1 AML, and 4 benign cysts	Retrospective study to evaluate ability of spiral CT to correctly identify small renal masses.	Spiral CT very good, but some lesions remain indeterminate and require surgery.	3

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
11. Heneghan JP, Spielmann AL, Sheafor DH, Kliewer MA, DeLong DM, Nelson RC. Pseudoenhancement of simple renal cysts: a comparison of single and multidetector helical CT. *J Comput Assist. Tomogr* 2002; 26(1):90-94.	Observational-Dx	1 phantom consisting of four water-filled spheres	To compare the extent of pseudoenhancement (artifactual increase in measured attenuation of a simple cyst after contrast medium administration) in a phantom model on single detector and multidetector helical CT scanners.	The degree of pseudoenhancement was more pronounced with increasing iodine concentration, decreasing cyst size, and wider collimation (all P=0.0001). Pseudoenhancement was also more marked on the multidetector than the single detector scanner (P=0.0001). At physiological levels of renal enhancement, the average pseudoenhancement was +18 HU for the single detector vs +23 HU for the multidetector scanner. Variation in pitch had no effect.	3
12. Alshumrani G, O'Malley M, Ghai S, et al. Small (< or = 4 cm) cortical renal tumors: characterization with multidetector CT. *Abdom Imaging.* 2010; 35(4):488-493.	Observational-Dx	46 patients	To determine if the pathology of small (≤4 cm) solid renal tumors can be predicted from findings on MDCT.	The 47 tumors (median diameter, 2.5 cm; range, 0.6-4.0 cm) included: 26 (55%) clear cell RCCs; 9 (19%) oncocytomas; 7 (15%) papillary RCCs; 2 (4%) chromophobe RCCs; 2 (4%) inflammatory pseudotumors; and 1 (2%) AML with minimal fat. Amongst the three commonest tumors, heterogeneity was seen in 23/26 (88%) clear cell RCCs, 6/9 (67%) oncocytomas, and 2/7 (29%) papillary renal cell cancer. Median (minimum-maximum) absolute nephrographic phase enhancement (nephrographic minus unenhanced phase) was: clear cell RCCs 65 HU (34-120), oncocytomas 80 HU (51-111), and papillary RCCs 16 HU (7-32).	3

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13. Weibl P, Klatte T, Kollarik B, et al. Interpersonal variability and present diagnostic dilemmas in Bosniak classification system. *Scand J Urol. Nephrol.* 2011; 45(4):239-244.	Observational-Dx	104 patients with 113 complex renal cystic masses	To evaluate the management and interpersonal variability of Bosniak classification and demonstrate the present diagnostic dilemmas.	Only 11 patients (10.6%) were symptomatic (one Bosniak IIF, six III and four IV). Only one had RCC on final histology, whereas the others (n=10) had benign lesions. An overall pathological result was obtained in 71 masses (62.8%) (two Bosniak II, three IIF, 27 III and 39 IV). The overall incidence of RCC in surgically treated patients was 0%, 20%, 55.6% and 76.9% for each category, respectively. The interpersonal variability was significant among the three groups (especially in Bosniak II, IIF), and the overall category was changed in 54%, 20% and 41%, respectively (P<0.001). After correlation with final histology and presumed benign character of Bosniak II/IIF lesions (all patients having reached 5-year follow-up) the differences were not significant.	3
14. Smith AD, Remer EM, Cox KL, et al. Bosniak category IIF and III cystic renal lesions: outcomes and associations. *Radiology.* 2012; 262(1):152-160.	Observational-Dx	62 patients with 69 Bosniak IIF lesions; 131 patients with 144 Bosniak III lesions	To evaluate clinical outcomes, pathologic subtypes, metastatic disease rate, and clinical features associated with malignancy in Bosniak category IIF and III cystic renal lesions.	The malignancy rate of resected Bosniak IIF lesions was 25% (4/16) and that for Bosniak III lesions was 54% (58/107) (P=.03). 13% (9/69) of Bosniak IIF lesions progressed at follow-up, and 50% (4/8) of these resected cysts were malignant. History of primary renal malignancy, coexisting Bosniak category IV lesion and/or solid renal mass, and multiplicity of Bosniak III lesions were each associated with an increased malignancy rate in Bosniak III lesions. No patients developed locally advanced or metastatic disease from a Bosniak IIF or III lesion.	3
15. Aronson S, Frazier HA, Baluch JD, Hartman DS, Christenson PJ. Cystic renal masses: usefulness of the Bosniak classification. *Urol Radiol.* 1991; 13(2):83-90.	Review/Other-Dx	16 cystic renal masses	Retrospectively review CT and US findings to determine the usefulness of the Bosniak classification of cystic renal masses.	Bosniak classification is extremely useful in the management of cystic renal masses.	4

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
16. Jonisch AI, Rubinowitz AN, Mutalik PG, Israel GM. Can high-attenuation renal cysts be differentiated from renal cell carcinoma at unenhanced CT? *Radiology*. 2007; 243(2):445-450.	Observational-Dx	54 pathologically proved RCCs in 54 patients; 56 high-attenuation renal cysts in 51 patients	To retrospectively determine if RCC can be differentiated from high-attenuation renal cysts at unenhanced CT based on HU measurements and heterogeneity.	The average attenuation of cysts for reader 1 was 53.4 HU (range, 23-113 HU) and for reader 2 was 53.8 HU (range, 21-108 HU). The average attenuation of neoplasms for reader 1 was 34.7 HU (range, 21-60 HU) and for reader 2 was 38.4 HU (range, 22-60 HU). For cyst heterogeneity, a score of 1 was given in 55/56 (98%) cysts for reader 1 and in 53/56 (95%) cysts for reader 2. For neoplasm heterogeneity, a score of 1 was given in 35/54 (65%) neoplasms for reader 1 and in 36/54 (67%) for reader 2. Given the distribution of cyst and tumor attenuation values and lesion heterogeneity, a homogeneous mass measuring 70 HU or greater at unenhanced CT has a greater than 99.9% chance of representing a high-attenuation renal cyst.	4
17. Israel GM, Bosniak MA. Calcification in cystic renal masses: is it important in diagnosis? *Radiology*. 2003; 226(1):47-52.	Review/Other-Dx	81 renal masses: CT (n=81), follow-up CT (n=28), and pathologic examination (n=40)	Retrospective study to evaluate the significance of calcification in cystic renal lesions.	Presence of calcifications in cystic renal masses is not as an important hallmark of malignancy as enhancing soft tissue.	4
18. Volpe A, Panzarella T, Rendon RA, Haider MA, Kondylis FI, Jewett MA. The natural history of incidentally detected small renal masses. *Cancer*. 2004; 100(4):738-745.	Review/Other-Dx	29 patients with 32 masses	To study the incidence of RCC.	Overall, the average growth rate did not differ statistically from zero growth (P=0.09; 95% CI, - 0.005-0.2 cm per year) and was not associated with either initial size (P=0.28) or mass type (P=0.41). 7 masses (22%) reached 4 cm in greatest dimension after 12-85 months of follow-up. 8 masses (25%) doubled their volumes within 12 months. Overall, 11 masses (34%) fulfilled 1 of these 2 criteria of rapid growth. 9 tumors were removed surgically after an average of 3.1 years of follow-up because it was believed that they were growing fast. No patient had disease progression.	4

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
19. Israel GM, Bosniak MA. Follow-up CT of moderately complex cystic lesions of the kidney (Bosniak category IIF). *AJR Am J Roentgenol.* 2003; 181(3):627-633.	Review/Other-Dx	42 renal masses	To show the usefulness of follow-up CT studies in the management of moderately complex lesions (Bosniak Classification IIF).	Follow-up exams showed that three lesions had developed more calcification, one lesion had increased in overall size but appeared less complex, and three lesions had decreased in size. In addition, two lesions had become more complex and developed thicker septa, and these lesions proved to be cystic neoplasms. Follow-up CT studies are an effective way of managing patients with moderately complex cystic lesions of the kidney (Bosniak category IIF) because the absence of change supports benignity and progression indicates neoplasm.	4
20. Limb J, Santiago L, Kaswick J, Bellman GC. Laparoscopic evaluation of indeterminate renal cysts: long-term follow-up. *J Endourol.* 2002; 16(2):79-82.	Review/Other-Tx	57 patients	To present long-term follow-up of patients who have undergone laparoscopic evaluation for their indeterminate renal cysts, specifically reporting those patients who were found to have cystic RCC and assessing the safety and efficacy of the procedure.	11 patients (19% of the total) were found to have cystic RCC. 3 of these patients had Bosniak category II cysts, and 8 had category III cysts. All tumors were low grade (I or II), and the stages were T1-2, Nx-0, M0. There has been no evidence of laparoscopic port site or renal fossa tumor recurrence, local recurrence, or metastatic disease to date in these patients. There is no cancer-specific mortality.	4
21. Spaliviero M, Herts BR, Magi-Galluzzi C, et al. Laparoscopic partial nephrectomy for cystic masses. *J Urol.* 2005; 174(2):614-619.	Observational-Tx	50 patients	To report laparoscopic partial nephrectomy in patients with a cystic renal lesion.	Median tumor size was 3 cm in group 1 and 2.6 cm in group 2 (P=0.07). Groups 1 and 2 were comparable in regard to perioperative parameters. In patients with Bosniak II (9), IIF (4), III (12) and IV (21) cysts final histopathology revealed RCC in 22%, 25%, 50% and 90%, respectively. All 100 patients had a negative surgical margin. No patient in group 1 had intraoperative puncture/spillage of the cystic tumor. In group 1 during a mean follow-up of 14 months (range 1 month to 3 years), 1 patient had retroperitoneal recurrence at 1-year despite negative surgical margins during initial laparoscopic partial nephrectomy.	1

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22. Frank I, Blute ML, Cheville JC, Lohse CM, Weaver AL, Zincke H. Solid renal tumors: an analysis of pathological features related to tumor size. *J Urol.* 2003; 170(6 Pt 1):2217-2220.	Observational-Tx	2,770 patients	To examine the relationship between tumor size and malignancy among solid renal tumors, and the relationship between tumor size and RCC subtype within tumors with RCC.	There were 376 benign (12.8%) and 2,559 (87.2%) malignant tumors. The percentage of benign tumors decreased from 46.3% for those <1 cm to 6.3% for those ≥7 cm. Among RCC tumors the percentage that were clear cell increased from 25.6% for those <1 cm to 83.0% for tumors ≥7 cm, while the percentage that were papillary decreased from 74.4% for those <1 cm to 10.0% for tumors ≥7 cm. No RCC tumors <1 cm were chromophobe compared to 7.0% of tumors ≥7 cm. The percentage of malignant tumors that were high grade RCC increased from 2.3% for those <1 cm to 57.7% for RCC tumors ≥7 cm. Only 1% of all tumors <1 cm and 9.2% of all tumors <2 cm were high grade malignancies.	2
23. Maturen KE, Nghiem HV, Caoili EM, Higgins EG, Wolf JS, Jr., Wood DP, Jr. Renal mass core biopsy: accuracy and impact on clinical management. *AJR Am J Roentgenol.* 2007; 188(2):563-570.	Observational-Dx	152 renal mass biopsies in 125 patients	Retrospective review to determine accuracy of imaging-guided percutaneous renal mass biopsy and its impact on clinical management.	Sensitivity for malignancy was 97.7%; specificity 100%; PPV 100%; and NPV 100%. Imaging-guided percutaneous core needle biopsy of renal masses is safe and highly accurate.	3
24. Murphy AM, Buck AM, Benson MC, McKiernan JM. Increasing detection rate of benign renal tumors: evaluation of factors predicting for benign tumor histologic features during past two decades. *Urology.* 2009; 73(6):1293-1297.	Review/Other-Tx	1,244 patients	To determine whether the detection of benign renal tumors is increasing and to identity the predictors of benign histologic features.	The proportion of renal surgery for benign tumors of <or.0 cm in diameter has increased annually. When patients were stratified by the year of surgery, the proportion of benign tumors was 5.0% before 1998, 15.2% from 1998 to 2003, and 21.2% from 2004 to 2007. The mean diameter of benign and malignant tumors was 3.0 and 3.5 cm, respectively, and the mean tumor diameter significantly decreased during the study period (P=.006). Using multivariate analysis, the year of surgery, tumor diameter, and female sex were independent predictors of benign histologic features (P<.05). Age, incidental diagnosis, body mass index, and race were not significant predictors (P>.05).	4

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25. Kim JK, Park SY, Shon JH, Cho KS. Angiomyolipoma with minimal fat: differentiation from renal cell carcinoma at biphasic helical CT. *Radiology.* 2004; 230(3):677-684.	Observational-Dx	81 patients (19 with AML with minimal fat and 62 with RCC); 2 blinded reviewers	To compare various CT features of AML with minimal fat with those of size-matched RCC in a retrospective study.	When both CT findings were used as a criterion for differentiating AML from RCC, PPV and NPV were 91% (10/11 tumors) and 87% (61/70 tumors), respectively. 53% of AML vs 13% of RCC showed high tumor attenuation on unenhanced scans (P=.04), whereas, RCC showed greater mean enhancement than AML (114 HU +/- 44 [SD] vs 73 HU +/- 30 in corticomedullary phase and 66 HU +/- 24 vs 49 HU +/- 20 in early excretory phase) and a male predominance (male-to-female ratio, 50:12 vs 8:11; P=.001). Biphasic helical CT may be useful in differentiating AML with minimal fat from RCC, with homogeneous tumor enhancement and prolonged enhancement pattern being the most valuable CT findings.	3
26. Bird VG, Kanagarajah P, Morillo G, et al. Differentiation of oncocytoma and renal cell carcinoma in small renal masses (<4 cm): the role of 4-phase computerized tomography. *World J Urol.* 2011; 29(6):787-792.	Observational-Dx	69 patients	To investigate the use of 4-phase CT with intravenous contrast to help distinguish oncocytoma from RCC in tumors <4 cm.	Our cohort involved 69 patients (46 men, 23 women; mean age 66) who presented with 79 renal masses. Histopathologically 40 were clear cell, 22 papillary, 5 chromophobe RCC and 12 oncocytoma. On the arterial, venous and delayed phase images, oncocytoma showed the highest mean enhancement change, i.e., 546%, 396% and 239% followed by clear cell RCC 261%, 261% and 174%, chromophobe RCC 147%, 127% and 66% and papillary RCC 137%, 184% and 118%, respectively. The enhancement pattern differed significantly on comparing oncocytoma with RCC (P<0.007). The mean percentage contrast excreted at the end of the delayed phase was 33.3%, 13.8%, 32% and 53% for clear cell, papillary, chromophobe and oncocytoma, respectively.	3

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27. Choudhary S, Rajesh A, Mayer NJ, Mulcahy KA, Haroon A. Renal oncocytoma: CT features cannot reliably distinguish oncocytoma from other renal neoplasms. *Clin Radiol.* 2009; 64(5):517-522.	Review/Other-Dx	21 patients with 28 renal masses	To retrospectively review the CT imaging features of a series of histologically confirmed renal oncocytomas and to determine whether imaging features are predictive of this subtype of benign renal epithelial tumor.	There were 11 female and 10 male patients and the age at presentation ranged from 40-80 years (mean age 65.9 years). The size of the masses ranged from 1.2-12 cm in diameter (mean diameter 4.9 cm). All masses showed contrast enhancement. In 18 (64.3%) lesions the enhancement of the tumor was isodense to renal cortex. 10 (35.7%) lesions were hypodense to renal cortex. In 3 (10.7%) lesions, a well-defined stellate central scar was seen at CT and confirmed pathologically. In 2 (7.1%) lesions, a central scar was identified pathologically, but not seen on CT. The size of the central scars ranged from 10-29 mm diameter on CT. 22 (78.6%) lesions did not demonstrate a scar on CT or pathologically. None of the patients had regional lymphadenopathy or distant metastasis.	4
28. McGahan JP, Lamba R, Fisher J, et al. Is segmental enhancement inversion on enhanced biphasic MDCT a reliable sign for the noninvasive diagnosis of renal oncocytomas? *AJR Am J Roentgenol.* 2011; 197(4):W674-679.	Observational-Dx	29 patients with 32 oncocytomas	To retrospectively determine whether segmental enhancement inversion or other CT patterns seen at enhanced biphasic MDCT are predictive for the diagnosis of renal oncocytoma.	Of the 32 renal oncocytomas, 16 oncocytomas were eliminated from analysis. These masses were eliminated because they were <4 cm (n=4), the CT examinations were inadequate (n=10), or the pathology results were questionable (n=2). The remaining 16 tumors (mean size, 2.6 cm; range, 1.8-3.9 cm) were included in our study. Only 2 tumors showed distinct segments of variable degrees of enhancement, with one of those tumors having segmental enhancement inversion. Three masses had a central region of low density. The most common feature, identified in 8 of the 16 oncocytomas, was a slightly heterogeneous mass that became homogeneous on the later phase of CT. Three oncocytomas had a homogeneous appearance on both phases.	3

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29. Patel NS, Poder L, Wang ZJ, et al. The characterization of small hypoattenuating renal masses on contrast-enhanced CT. *Clin Imaging*. 2009; 33(4):295-300.	Observational-Dx	20 renal masses	To determine if small hypoattenuating renal masses can be characterized as simple cysts or RCCs on contrast-enhanced CT.	The overall area under the ROC curves for subjective visual impression, CT attenuation, border, and shape were 0.97, 0.82, 0.59, and 0.55, respectively. Using dichotomized ratings (1-2=cyst and 3-5=carcinoma), subjective impression had a sensitivity and specificity of 100% and 79%-100%, respectively, for the diagnosis of RCC. Using a threshold of 50 HU or more, CT attenuation had a sensitivity and specificity of 100% and 43%-64%, respectively.	3
30. Jinzaki M, McTavish JD, Zou KH, Judy PF, Silverman SG. Evaluation of small (</= 3 cm) renal masses with MDCT: benefits of thin overlapping reconstructions. *AJR Am J Roentgenol*. 2004; 183(1):223-228.	Review/Other-Dx	37 patients with 175 renal lesions; 2 independent reviewers	To determine if thin overlapping reconstructions using MDCT improve detection and characterization of small renal masses.	Lesion characterization for cysts improved from 29% to 84% when thin overlapping reconstructions were used and the overall number of indeterminate lesions was reduced from 69% to 53%. Using MDCT and thin overlapping reconstructions, renal cysts as small as 5 mm can be diagnosed with more confidence than is possible with standard reconstructions, and the overall number of indeterminate renal masses is reduced.	4
31. Graser A, Becker CR, Staehler M, et al. Single-phase dual-energy CT allows for characterization of renal masses as benign or malignant. *Invest Radiol.* 2010; 45(7):399-405.	Observational-Dx	202 patients	To evaluate the diagnostic accuracy of dual-energy CT in renal mass characterization using a single-phase acquisition.	Of the 202 patients, 115 (56.9%) underwent surgical resection of renal masses. Histopathology showed malignancy in 99 and benign tumors in 18 patients, in 48 patients (23.7%), follow-up imaging showed size stability of lesions diagnosed as benign and 37 patients (18.3%) had no mass. Based on dual-energy CT only, 95/99 (96.0%) patients with malignancy and 96/103 (93.2%) patients without malignancy were correctly identified, for an overall accuracy of 94.6%. The dual-phase approach identified 96/99 (97.0%) and 98/103 (95.1%), accuracy 96.0%, P>0.05 for both. Mean interpretation time was 2.2 +/- 0.8 minutes for dual-energy CT, and 3.5 +/- 1.0 minutes for the dual-phase protocol, P<0.001. Mean virtual nonenhanced/true nonenhanced image quality was 1.68 +/- 0.65/1.30 +/- 0.59, noise was 2.03 +/- 0.57/1.18 +/- 0.29, P<0.001 for both. Omission of the true unenhanced phase lead to a 48.9 +/- 7.0% dose reduction.	3

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32. Kaza RK, Caoili EM, Cohan RH, Platt JF. Distinguishing enhancing from nonenhancing renal lesions with fast kilovoltage-switching dual-energy CT. *AJR Am J Roentgenol.* 2011; 197(6):1375-1381.	Observational-Dx	39 patients	To evaluate the accuracy of dual-energy CT in distinguishing enhancing from nonenhancing or equivocally enhancing renal lesions.	83 renal lesions were evaluated. On the basis of attenuation measurements, there were 20 enhancing and 63 nonenhancing lesions. The sensitivity, specificity, and accuracy for the detection of enhancement according to the lesion appearance were 70%, 98.4%, and 91.6%, respectively, on iodine density images and were 85%, 90.5%, and 89.2%, respectively, on iodine overlay images generated from contrast-enhanced dual-energy CT scans. Of the various thresholds of measured lesion iodine density (1-3 mg/cm(3)), a threshold of 2 mg/cm(3) showed the highest accuracy for the detection of enhancement, with sensitivity, specificity, and accuracy of 90%, 93.7%, and 92.8%, respectively.	3
33. Neville AM, Gupta RT, Miller CM, Merkle EM, Paulson EK, Boll DT. Detection of renal lesion enhancement with dual-energy multidetector CT. *Radiology.* 2011; 259(1):173-183.	Observational-Dx	139 patients	To determine whether dual-energy MDCT enables detection of renal lesion enhancement by using calculated nonenhanced images with spectral-based extraction in a non-body weight-restricted patient population.	Hypoattenuating (n=66) and hyperattenuating (n=28) cysts, AMLs (n=18), and solid enhancing lesions (n=27) were detected. Mean attenuation values for hypoattenuating cysts on the acquired and calculated nonenhanced CT images were 6.5 HU +/- 5.8 (SD) and 8.1 HU +/- 3.1 (P=.13), respectively, with corresponding enhancement values of 1.1 HU +/- 5.2 and -0.5 HU +/- 6.2 (P=.12), respectively. Mean values for hyperattenuating cysts were 29.4 HU +/- 5.6 on acquired images and 31.7 HU +/- 5.1 on calculated images (P=.39) (corresponding enhancement, 4.7 HU +/- 3.3 and 2.3 HU +/- 4.1, respectively; P=.09). Mean values for fat-containing enhancing lesions were -90.6 HU +/- 24.7 on acquired images and -85.9 HU +/- 23.7 on calculated images (P=.57) (corresponding enhancement, 18.2 HU +/- 10.1 and 13.6 HU +/- 10.7, respectively; P=.19). Mean attenuation values for solid enhancing lesions were 26.0 HU +/- 15.0 on acquired images and 27.7 HU +/- 14.9 on calculated images (P=.45) (corresponding enhancement, 60.3 HU +/- 13.1 and 58.3 HU +/- 15.5, respectively; P=.38).	3

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34. Sahni VA, Shinagare AB, Silverman SG. Virtual unenhanced CT images acquired from dual-energy CT urography: accuracy of attenuation values and variation with contrast material phase. *Clin Radiol.* 2013;68(3):264-271.	Observational-Dx	100 consecutive patients	To determine how representative virtual unenhanced images are of true unenhanced images when performing CT urography on a dual-energy CT system, and whether the images are affected by the contrast material phase.	Virtual unenhanced attenuation values of liver, renal parenchyma, and aorta were significantly different to true unenhanced values (P<0.05); spleen and fat attenuation values showed no significant difference. No significant difference was found between virtual unenhanced nephrographic and virtual unenhanced excretory images. Image noise was significantly greater in true unenhanced images (P<0.0001) and correlated with patient thickness. Virtual unenhanced nephrographic and virtual unenhanced excretory images had sensitivities of 76.6 and 65.6% for detection of stones, identifying all stones greater than 3 and 4 mm, respectively. Both virtual unenhanced images received significantly lower image quality scores than true unenhanced images (P<0.0001); however, the majority of images were deemed acceptable. The mean theoretical dose saving by removing the true unenhanced phase was 35%.	3
35. Hecht EM, Israel GM, Krinsky GA, et al. Renal masses: quantitative analysis of enhancement with signal intensity measurements versus qualitative analysis of enhancement with image subtraction for diagnosing malignancy at MR imaging. *Radiology.* 2004; 232(2):373-378.	Observational-Dx	71 patients with 93 renal lesions: Quantitative 1 investigator; Qualitative 2 independent investigators	To retrospectively compare the accuracy of quantitative and qualitative contrast enhancement of renal mass lesions on MRI, using contrast enhancement as the basis for malignancy.	For diagnosing malignancy based on enhancement alone, sensitivity and specificity, respectively, were 95% (70/74 lesions) and 53% (10/19 lesions) at quantitative analysis and 99% (73/74 lesions) and 58% (11/19 lesions) at qualitative analysis. When the oncocytomas were excluded, specificities increased to 83% (10/12 lesions) and 92% (11/12 lesions) for the quantitative and qualitative evaluations, respectively. 3 of 4 malignant lesions incorrectly characterized as benign at quantitative assessment were hyperintense on unenhanced MRIs; all were diagnosed correctly at qualitative evaluation. Both techniques have high sensitivity, but qualitative enhancement analysis is superior for diagnosing malignancy in renal lesions that are hyperintense prior to contrast enhancement.	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
36. Ho VB, Allen SF, Hood MN, Choyke PL. Renal masses: quantitative assessment of enhancement with dynamic MR imaging. *Radiology.* 2002; 224(3):695-700.	Observational-Dx	74 patients	Retrospective study to establish a quantitative MRI contrast enhancement criterion for distinguishing cysts from solid renal lesions.	The optimal percentage of enhancement threshold for distinguishing cysts from malignancies with the imaging technique prescribed was 15%, and the optimal timing for measurement was 2-4 minutes after administration of contrast material.	3
37. Israel GM, Hindman N, Bosniak MA. Evaluation of cystic renal masses: comparison of CT and MR imaging by using the Bosniak classification system. *Radiology.* 2004; 231(2):365-371.	Review/Other-Dx	59 patients with 69 renal masses/ 2 reviewers	To retrospectively compare CT and MRI in the evaluation of cystic renal masses by using the Bosniak classification system.	CT and MRI demonstrate similar findings in most cystic renal lesions, but in some cases MRI may depict more septa, thickening of the wall or septa and enhancement which may upgrade a lesion. Renal cystic lesions that are on the borderline between category IIF and III need to be interpreted with caution and perhaps compared with CT prior to recommending treatment strategies.	4
38. Grobner T. Gadolinium--a specific trigger for the development of nephrogenic fibrosing dermopathy and nephrogenic systemic fibrosis? *Nephrol Dial Transplant.* 2006; 21(4):1104-1108.	Review/Other-Dx	9 patients	To describe a possible relationship between gadolinium and nephrogenic systematic fibrosis.	5/9 end-stage renal disease patients developed nephrogenic systematic fibrosis after receiving gadolinium.	4
39. Kim JK, Kim SH, Jang YJ, et al. Renal angiomyolipoma with minimal fat: differentiation from other neoplasms at double-echo chemical shift FLASH MR imaging. *Radiology.* 2006; 239(1):174-180.	Observational-Dx	55 patients with 55 renal tumors; 2 independent observers	To prospectively evaluate the diagnostic performance of double-echo gradient-echo chemical shift MRI in the differentiation of AML with minimal fat from other renal neoplasms, with pathologic examination or follow-up data serving as the reference standard.	The SI index and tumor-to-spleen ratio were different between AML (42% +/- 11 and –43% +/- 17, respectively) and non-AML (5% +/- 14 and –4% +/- 16, respectively) (P<.001). The area under the ROC curve was 0.975 for the SI index and 0.952 for the tumor-to-spleen ratio. For differentiation of AML from non-AML, sensitivity and specificity were (a) 96% and 93%, respectively, with a SI index of 25% and (b) 88% and 97%, respectively, with a tumor-to-spleen ratio of –32%. Double-echo gradient-echo chemical shift MRI can be used to differentiate AML with minimal fat from other renal neoplasms.	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
40. Hindman N, Ngo L, Genega EM, et al. Angiomyolipoma with Minimal Fat: Can It Be Differentiated from Clear Cell Renal Cell Carcinoma by Using Standard MR Techniques? *Radiology.* 2012; 265(2):468-477.	Observational-Dx	108 pathologically proved renal masses from 64 men and 44 women	To retrospectively assess whether MRI with opposed-phase and in-phase gradient-echo sequences and MR feature analysis can differentiate AMLs that contain minimal fat from clear cell RCCs, with particular emphasis on small (<3 cm) masses.	There were no differences between minimal fat AMLs and clear cell RCCs for the SI index (8.05% +/- 14.46 vs 14.99% +/- 19.9; P=.146) or tumor-to-spleen ratio (-8.96% +/- 16.6 and -15.8% +/- 22.4; P=.227) when all masses or small masses were analyzed. Diagnostic accuracy (area under ROC curve) for the SI index and tumor-to-spleen ratio was 0.59. Intratumoral necrosis and larger size were predictive of clear cell RCC (P<.001) for all lesions, whereas low SI (relative to renal parenchyma SI) on T2-weighted images, smaller size, and female sex correlated with minimal fat AML (P<.001) for all lesions.	2
41. Sasiwimonphan K, Takahashi N, Leibovich BC, Carter RE, Atwell TD, Kawashima A. Small (<4 cm) renal mass: differentiation of angiomyolipoma without visible fat from renal cell carcinoma utilizing MR imaging. *Radiology.* 2012; 263(1):160-168.	Observational-Dx	69 men and 42 women	To determine whether a combination of MR parameters can help differentiate small AMLs without visible fat from RCCs.	AML had significantly higher T1 SI ratio (P=.04), lower T2 SI ratio (P=.001), higher SII (P=.02), and higher arterial-to-delayed enhancement ratio (P<.001) than RCC. Sensitivity, specificity, and accuracy for combination of T2 SI ratio <0.9 and ([SII <20% and T1 SI ratio <1.2] or arterial-to-delayed enhancement ratio <1.5) were 73% (11/15), 99% (103/104), and 96% (114/119), respectively, for differentiating AML from RCC.	3
42. Helenon O, Correas JM, Balleyguier C, Ghouadni M, Cornud F. Ultrasound of renal tumors. *Eur Radiol.* 2001; 11(10):1890-1901.	Review/Other-Dx	N/A	Review diagnosis of renal tumors with US.	US increases the early detection of RCC. Gray-scale and color Doppler US findings may strongly suggest the histopathologic nature. US also may provide additional diagnostic information over CT in selected cases of RCC with venous invasion.	4

Indeterminate Renal Mass
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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
43. Schmidt T, Hohl C, Haage P, et al. Diagnostic accuracy of phase-inversion tissue harmonic imaging versus fundamental B-mode sonography in the evaluation of focal lesions of the kidney. *AJR Am J Roentgenol.* 2003; 180(6):1639-1647.	Observational-Dx	114 patients 3 reviewers	Prospective study to compare phase-inversion tissue harmonic imaging with fundamental B-mode US in the evaluation of focal lesions of the kidney. All US diagnoses were compared with a diagnostic reference modality: contrast-enhanced CT, contrast-enhanced MRI, or histopathology.	70 patients, fundamental B-mode US as the first technique depicted 73/111 lesions 10 mm or larger and enabled 71 lesions to be correctly characterized (sensitivity, 65.8%; accuracy, 64.0%). As the first mode, phase-inversion tissue harmonic imaging depicted 57/65 focal lesions and enabled 54 lesions to be accurately classified in 44 patients (sensitivity, 87.7%; accuracy, 83.1%). The differences in sensitivity and accuracy were statistically significant (95% CI). For overall image quality, lesion conspicuity, and fluid-solid differentiation phase-inversion harmonic imaging was superior to fundamental B-mode sonography (P<0.0001). Phase inversion tissue harmonic imaging is superior to B-mode US imaging for renal mass detection and characterization.	2
44. Jinzaki M, Ohkuma K, Tanimoto A, et al. Small solid renal lesions: usefulness of power Doppler US. *Radiology.* 1998; 209(2):543-550.	Observational-Dx	64 consecutive small (1.5-3.0 cm in diameter) solid renal lesions (26 RCC/34 AML, 2 oncocytomas 2 pseudotumors); 2 reviewers	Prospective study to evaluate whether the vascular pattern at power Doppler US improves diagnostic accuracy in small solid renal lesions over that at gray-scale US.	Findings at gray-scale US included an anechoic rim or intratumoral cysts in 20/26 RCCs (77%) and the 2 oncocytomas. Shadowing was seen in 7/34 AMLs (21%). Echogenicity, homogeneity, and a central scar were not pathognomonic. At power Doppler US, pattern 3 (peripheral) or 4 (mixed penetrating and peripheral) was seen in all RCCs, 7/34 AMLs, and the two oncocytomas. Pattern 1 (intratumoral focal) or 2 (penetrating) was seen in 27 AMLs. Pattern 1 or 2 was characteristic of AML. The rate of correct diagnosis was significantly increased with combined US (78%) as compared to that with gray-scale (42%) or power Doppler (45%) US alone.	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
45. Reichelt O, Wunderlich H, Weirich T, Schlichter A, Schubert J. Computerized contrast angiosonography: a new diagnostic tool for the urologist? *BJU Int.* 2001; 88(1):9-14.	Review/Other-Dx	60 patients	To evaluate the diagnostic potential of echo-enhanced US for depicting the vascularization pattern of RCC, and calculating the first-pass effect using harmonic imaging, against that obtained by triphasic helical CT.	Using B-mode US, the extent of all tumors was delineated (mean tumor size 3.8 cm, SD 0.6). After applying the microbubble agent all tumors were enhanced, whereas the perfusion was decreased (in 48%), increased (in 16%) or similar (in 36%) compared with the cortical reference area./ Using the HU classification, these results correlated well with the hypo/hypervascularity shown on CT./ US has considerable potential in diagnosing RCC, if combined with echo-enhancing methods, harmonic imaging and computer-based calculation of tumor vascularization. Dynamic US studies should provide a diagnostic yield similar to that of CT.	4
46. Quaia E, Bertolotto M, Cioffi V, et al. Comparison of contrast-enhanced sonography with unenhanced sonography and contrast-enhanced CT in the diagnosis of malignancy in complex cystic renal masses. *AJR Am J Roentgenol.* 2008; 191(4):1239-1249.	Observational-Dx	40 patients	To evaluate contrast-enhanced sonography in the diagnosis of malignancy in complex cystic renal masses.	Final diagnoses comprised two multilocular cystic nephromas, two inflammatory and seven hemorrhagic cysts, and eight uncomplicated benign cysts and 21 cystic RCCs. The overall diagnostic accuracy of contrast-enhanced sonography was better than unenhanced sonography and CT (contrast-enhanced sonography vs unenhanced sonography vs CT: reader 1, 83% vs 30% vs 75%; reader 2, 83% vs 30% vs 63%; reader 3, 80% vs 30% vs 70%; P<0.05, McNemar test).	2
47. Ignee A, Straub B, Brix D, Schuessler G, Ott M, Dietrich CF. The value of contrast enhanced ultrasound (CEUS) in the characterisation of patients with renal masses. *Clin Hemorheol Microcirc.* 2010; 46(4):275-290.	Observational-Dx	143 patients	To assess the value of contrast-enhanced US in its use in renal masses.	Baseline US and contrast-enhanced US with BR1, histology obtained by surgery (89%) or biopsy (11%). 88% of the patients had renal lesions which were malignant and 12% benign lesions. 80% had RCC. 7% of the lesions were cystic. Two patients were upgraded by contrast-enhanced US from contrast-enhanced CT Bosniak II into contrast-enhanced US Bosniak III-IV. Contrast-enhanced US could predict malignancy with a sensitivity, specificity, PPV, NPV and accuracy in 97%, 45%, 91%, 75%, and 90%. The correct staging was diagnosed by contrast-enhanced US (CECT) in 83% (69%). Contrast-enhanced US was superior to contrast-enhanced CT in the staging and characterization of RCC, also in the subgroup of patients with cystic lesions.	2

Indeterminate Renal Mass
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
48. Lechevallier E, Andre M, Barriol D, et al. Fine-needle percutaneous biopsy of renal masses with helical CT guidance. *Radiology.* 2000; 216(2):506-510.	Observational-Dx	63 consecutive patients; 73 biopsies performed	To evaluate the feasibility, accuracy, and clinical role of fine-needle percutaneous biopsy of renal masses, with helical CT guidance.	The accuracies of biopsy for histopathologic and Fuhrman nuclear grade evaluation were 89% and 78%, respectively. For tumors of 3.0 cm or smaller or larger than 3.0 cm, 37% (11/30) or 9% (4 /43) had failure of biopsy, respectively (P=.006). Fine-needle biopsy with helical CT guidance is accurate for the histopathologic evaluation of renal masses without morbidity.	3
49. Rybicki FJ, Shu KM, Cibas ES, Fielding JR, vanSonnenberg E, Silverman SG. Percutaneous biopsy of renal masses: sensitivity and negative predictive value stratified by clinical setting and size of masses. *AJR Am J Roentgenol.* 2003; 180(5):1281-1287.	Observational-Dx	115 consecutive percutaneous biopsies of renal masses in 113 patients: CT (n=76), US (n=28), both CT and US (n=5), or MRI (n=6)	Retrospective study to evaluate the sensitivity and NPV of percutaneous biopsy of renal masses stratified by clinical setting and the size of the mass.	For all procedures (n=115), the sensitivity and NPV were 90% (95% CI, 81%-95%) and 64% (95% CI, 44%-81%), respectively. For patients with a known malignancy who presented with a renal mass (n=55), the sensitivity and NPV were 90% (95% CI, 78%-96%) and 38% (95% CI, 10%-74%), respectively. For patients with no known malignancy and suspected unresectable tumor (n=36), the sensitivity and NPV were 92% (95% CI, 76%-98%) and 0%, respectively. For patients with no known malignancy who presented with a cystic mass (n=16), the sensitivity and NPV were 33% (95% CI, 2%-87%) and 87% (95% CI, 58%-98%), respectively. For patients who were not surgical candidates with a RCC (n=8) that was thought to be resectable, both the sensitivity and NPV were 100%. For masses ≤3 cm (n=31), the sensitivity and NPV were 84% (95% CI, 63%-95%) and 60% (95% CI, 27%-86%), respectively. For masses between 4 and 6 cm (n=42), the sensitivity and NPV were 97% (95% CI, 83%-100%) and 89% (95% CI, 51%-99%), respectively. For masses >6 cm (n=42), the sensitivity and NPV were 87% (95% CI, 71%-95%) and 44% (95% CI, 15%-77%), respectively.	3
50. Silverman SG, Gan YU, Mortele KJ, Tuncali K, Cibas ES. Renal masses in the adult patient: the role of percutaneous biopsy. *Radiology.* 2006; 240(1):6-22.	Review/Other-Dx	N/A	Review role of percutaneous biopsy in the diagnosis of renal masses.	Biopsy after a full imaging workup can help prevent unnecessary and potentially morbid surgical and ablation procedures in a substantial number of patients.	4

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
51. Heilbrun ME, Yu J, Smith KJ, Dechet CB, Zagoria RJ, Roberts MS. The cost-effectiveness of immediate treatment, percutaneous biopsy and active surveillance for the diagnosis of the small solid renal mass: evidence from a Markov model. *J Urol.* 2012; 187(1):39-43.	Review/Other-Tx	N/A	To assess the cost-effectiveness of adding percutaneous biopsy or active surveillance to the diagnosis of a 2 cm or less solid renal mass.	Immediate treatment was the highest cost, most effective diagnostic strategy, providing the longest overall survival of 18.53 life-years. Active surveillance was the lowest cost, least effective diagnostic strategy. On cost-effectiveness analysis using a societal willingness to pay threshold of $50,000 active surveillance was the preferred choice at a $75,000 willingness to pay threshold while biopsy and treatment were acceptable ($56,644 and $70,149 per life-year, respectively). When analysis was adjusted for quality of life, biopsy dominated immediate treatment as the most cost-effective diagnostic strategy at $33,840 per quality adjusted life-year gained.	4
52. Pandharipande PV, Gervais DA, Hartman RI, et al. Renal mass biopsy to guide treatment decisions for small incidental renal tumors: a cost-effectiveness analysis. *Radiology.* 2010; 256(3):836-846.	Review/Other-Dx	N/A	To evaluate the effectiveness, cost, and cost-effectiveness of using renal mass biopsy to guide treatment decisions for small incidentally detected renal tumors.	Under base-case assumptions, the biopsy strategy yielded a minimally greater quality-adjusted life expectancy (4 days) than did empiric surgery at a lower lifetime cost ($3466), dominating surgery from a cost-effectiveness perspective. Over the majority of parameter ranges tested in one-way sensitivity analysis, the biopsy strategy dominated surgery or was cost-effective relative to surgery based on a $75,000-per-quality adjusted life-year willingness-to-pay threshold. In two-way sensitivity analysis, surgery yielded greater life expectancy when the prevalence of malignancy and propensity for biopsy-negative cancers to metastasize were both higher than expected or when the sensitivity and specificity of biopsy were both lower than expected.	4

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
53. Beland MD, Mayo-Smith WW, Dupuy DE, Cronan JJ, DeLellis RA. Diagnostic yield of 58 consecutive imaging-guided biopsies of solid renal masses: should we biopsy all that are indeterminate? *AJR Am J Roentgenol.* 2007;188(3):792-797.	Observational-Dx	48 patients	To report the diagnostic yield of 58 consecutive imaging-guided biopsies of solid renal masses.	An adequate sample size was obtained in 55 (95%) of 58 renal masses and led to a definitive diagnosis in 52 (90%) of the 58. Renal cell carcinoma accounted for 36 (69%) of 52 diagnostic biopsies. The diagnosis of a benign lesion was made in 14 (27%) of 52 biopsies. Lymphoma (1/58) and metastatic disease (1/58) accounted for the remaining two diagnostic biopsies. Three biopsy samples obtained inadequate sample volumes, and an additional three samples were thought to have adequate sample volume but were not diagnostic. A single false-negative biopsy result was identified after growth was seen on follow-up imaging and subsequent nephrectomy revealed renal cell carcinoma.	3
54. Tan HJ, Jacobs BL, Hafez KS, et al. Understanding the role of percutaneous biopsy in the management of patients with a small renal mass. *Urology.* 2012; 79(2):372-377.	Observational-Dx	204 consecutive patients	To evaluate patient and tumor characteristics associated with percutaneous renal mass biopsy among patients with small renal masses and assessed the impact on clinical decision-making.	Among 204 patients, 78 (38%) received renal mass biopsy. Of the demographic and physiological parameters, only non-Caucasian race and family history of RCC were associated with biopsy (P<.05). In contrast, renal mass biopsy was significantly associated with several anatomic factors, including larger tumor size, solitary kidney, juxta-hilar tumor location, greater body mass index, and high-complexity nephrometry score (P<.05). On multivariable analysis, only body mass index >25 kg/m2, juxta-hilar location, and high-complexity nephrometry score remained significantly associated with renal mass biopsy (P<.05). Biopsy was performed in a greater proportion of patients who ultimately underwent radical nephrectomy vs nephron-sparing surgery (P=.04). Furthermore, renal mass biopsy results directly impacted treatment, with active surveillance more frequent among patients with benign or favorable histology and surgical management more common among patients with more aggressive disease (P<.001).	3

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
55. Leveridge MJ, Finelli A, Kachura JR, et al. Outcomes of small renal mass needle core biopsy, nondiagnostic percutaneous biopsy, and the role of repeat biopsy. *Eur Urol.* 2011; 60(3):578-584.	Review/Other-Dx	345 biopsies	To determine the results of small renal mass biopsy and the outcomes of nondiagnostic biopsy and repeat biopsy.	345 biopsies were performed (mean diameter: 2.5 cm). Biopsy was diagnostic in 278 cases (80.6%) and nondiagnostic in 67 cases (19.4%). Among diagnostic biopsies, 221 (79.4%) were malignant, 94.1% of which were RCC. Histologic subtyping and grading of RCC was possible in 88.0% and 63.5% of cases, respectively. Repeat biopsy was performed in 12 of the 67 nondiagnostic cases, and a diagnosis was possible in 10 (83.3%). Eight lesions were malignant and two were oncocytic neoplasms. Pathology was available for 15 masses after initial nondiagnostic biopsy; 11 (73%) were malignant. Larger tumor size and a solid nature on imaging predicted a successful biopsy on multivariate analysis. Grade 1 complications were experienced in 10.1% of cases, with no major bleeding and no seeding of the biopsy tract. There was one grade 3a complication (0.3%). This is a retrospective study and some data are unavailable on factors that may affect biopsy success rates. Repeat biopsy was not standard practice prior to this analysis.	4
56. Aide N, Cappele O, Bottet P, et al. Efficiency of [(18)F]FDG PET in characterising renal cancer and detecting distant metastases: a comparison with CT. *Eur J Nucl Med Mol Imaging.* 2003; 30(9):1236-1245.	Observational-Dx	53 FDG-PET studies (35 - characterization and staging of a suspicious mass, 18 - staging early after surgical removal of a renal cancer)	To assess the efficiency of FDG-PET in the characterization and primary staging of suspicious renal masses, in comparison with CT, the current standard imaging modality. Studies were performed within the framework of a prospective study.	In the characterization of renal masses, a high rate of false negative results was observed, leading to a sensitivity, specificity and accuracy of 47%, 80% and 51%, respectively, vs 97%, 0/5 and 83%, respectively for CT. FDG-PET detected all the sites of distant metastasis revealed by CT, as well as 8 additional metastatic sites, leading to an accuracy of 94% vs 89% for CT. However, 36/53 patients (68%) did not have any distant metastasis on either CT or on PET. All but one of these patients had a low Fuhrman histological grade and a limited local stage (≤pT2). FDG-PET does not offer any advantage over CT for the characterization of renal masses but that it appears to be an efficient tool for the detection of distant metastasis in renal cancer.	3

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
57. Kang DE, White RL, Jr., Zuger JH, Sasser HC, Teigland CM. Clinical use of fluorodeoxyglucose F 18 positron emission tomography for detection of renal cell carcinoma. *J Urol.* 2004; 171(5):1806-1809.	Observational-Dx	66 patients	Retrospective review to evaluate role of FDG-PET in patients with RCC. Accuracies of PET, chest CT, abdominal/pelvic CT and bone scan were compared.	For primary tumors, PET had sensitivity of 60% and specificity of 100%, CT had sensitivity of 91.7% and specificity of 100%. For lymph node metastases, PET had sensitivity of 75% and specificity of 100%. CT had sensitivity of 92.6% and specificity of 98.1%. For metastases to the lung parenchyma, PET had sensitivity of 75% and specificity of 97% compared to 91.1% and 73.1%, respectively, for chest CT. For bone metastases, PET had sensitivity of 77.3% and specificity of 100.0%, compared to 93.8% and 87.2% for combined CT and bone scan. PET may have a complementary role as a problem solving tool in cases that are equivocal.	3
58. Curry NS. Small renal masses (lesions smaller than 3 cm): imaging evaluation and management. *AJR Am J Roentgenol.* 1995; 164(2):355-362.	Review/Other-Dx	N/A	Summarize the literature regarding evaluation and management of small renal masses (≤3 cm diameter).	CT before and after intravenous contrast to determine enhancement is the most important evaluation.	4
59. Caoili EM, Cohan RH, Korobkin M, et al. Urinary tract abnormalities: initial experience with multi-detector row CT urography. *Radiology.* 2002; 222(2):353-360.	Review/Other-Dx	65 patients	Comparative study on findings from CT urography, urinalysis, cystoscopy and/or ureteroscopy, and/or surgery to determine the usefulness of MDCT urography in detecting urinary tract abnormalities.	MDCT urography is a useful method for detecting urinary tract abnormalities.	4
60. Hollingsworth JM, Miller DC, Daignault S, Hollenbeck BK. Rising incidence of small renal masses: a need to reassess treatment effect. *J Natl Cancer Inst.* 2006; 98(18):1331-1334.	Review/Other-Tx	34,503 patients	To assess incidence, treatment, and mortality trends for kidney cancer, overall and as a function of tumor size.	From 1983 to 2002, the overall age-adjusted incidence rate for kidney cancer rose from 7.1 to 10.8 cases per 100,000 US population; tumors ≤4 cm in size accounted for most of the increase. Adjusted rates of renal surgery increased concurrently, most notably for tumors ≤4 cm (0.9-3.6 surgeries per 100,000 US population). However, among kidney cancer patients, all-cause mortality per 100,000 US population increased from 1.5 deaths in 1983 to 6.5 deaths in 2002, with the greatest absolute increase noted for patients with lesions >7 cm.	4

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
61. Klatte T, Patard JJ, de Martino M, et al. Tumor size does not predict risk of metastatic disease or prognosis of small renal cell carcinomas. *J Urol.* 2008; 179(5):1719-1726.	Observational-Tx	1,208 patients	To characterize the clinicopathological features and the prognosis of small solid renal tumors defined as tumors 4 cm or smaller.	Of the tumors 88% were RCC and 12% were benign. Of those with RCC 995 (93%) were localized (N0M0) and 72 (7%) presented with metastatic disease. Tumor size did not predict synchronous metastatic disease. The incidence of metastatic disease in the tumor size ranges 0.1 to 1.0, 1.1 to 2.0, 2.1 to 3.0 and 3.1 to 4.0 cm was 7%, 6%, 5% and 8%, respectively (P=0.322). Survival rates were excellent. The majority of patients who died of RCC (54%) presented with synchronous metastatic disease, but 3% of patients with localized disease also died of RCC. In patients with localized disease there was a 7% chance of recurrence post nephrectomy at 5 years. Progression-free survival (28 months) was better than for patients with metastatic disease having a primary tumor greater than 4 cm (8 months). Tumor size was not retained as an independent prognostic factor of survival in multivariate analyses. The University of California Integrated Staging System and the Karakiewicz nomogram were the best predictors of cancer specific survival for all RCC stages (c-index 0.87).	2
62. Kunkle DA, Egleston BL, Uzzo RG. Excise, ablate or observe: the small renal mass dilemma--a meta-analysis and review. *J Urol.* 2008; 179(4):1227-1233; discussion 1233-1224.	Review/Other-Tx	99 studies representing 6,471 lesions	A MEDLINE search was performed for clinically localized sporadic renal masses to look at the incidence of RCC.	Significant differences in mean patient age (P<0.001), tumor size (P<0.001) and follow-up duration (P<0.001) were detected among treatment modalities. The incidence of unknown/indeterminate pathological findings was significantly different among cryoablation, radio frequency ablation and observation (P=0.003), and a significant difference in the rates of malignancy among lesions with known pathological results was detected (P=0.001). Compared to nephron sparing surgery significantly increased local progression rates were calculated for cryoablation (RR = 7.45) and radio frequency ablation (RR = 18.23). However, no statistical differences were detected in the incidence of metastatic progression regardless of whether lesions were excised, ablated or observed.	4

Indeterminate Renal Mass
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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
63. Hollingsworth JM, Miller DC, Daignault S, Hollenbeck BK. Five-year survival after surgical treatment for kidney cancer: a population-based competing risk analysis. *Cancer.* 2007; 109(9):1763-1768.	Review/Other-Tx	26,618 patients	To estimate patient survival after surgery for kidney cancer, as a function of patient age and tumor size at diagnosis.	Age-specific kidney cancer mortality was stable across all size strata but varied inversely with tumor size. Patients with the smallest tumors enjoyed the lowest cancer-specific mortality (5% for masses ≤4 cm). Competing-cause mortality rose with increasing patient age. The estimated 5-year competing-cause mortality for elderly subjects (70 years) was 28.2% (95% CI: 25.9%-30.8%), irrespective of tumor size.	4
64. Abou Youssif T, Kassouf W, Steinberg J, Aprikian AG, Laplante MP, Tanguay S. Active surveillance for selected patients with renal masses: updated results with long-term follow-up. *Cancer.* 2007; 110(5):1010-1014.	Review/Other-Tx	35 patients	To evaluate the outcome of a surveillance strategy in patients with renal masses.	A total of 35 patients (21 men and 14 women) with 44 renal masses were observed for a mean follow-up of 47.6 months. The mean age of these patients was 71.8 years. The majority of the patients (89%) were asymptomatic at the time of diagnosis. The mean and median initial tumor dimension was 2.2 cm and 2.2 cm, respectively (range, 0.5-4 cm). Of the 35 patients, 2 (5.7%) were lost to follow-up, 8 (22.9%) underwent surgical resection, and 9 (25.7%) died of other causes. The mean dimension growth rate was 0.21 cm/year (range, 0.03-1.9 cm/year). The mean and median volume growth rate was 2.7 cc/year and 1.4 cc/year, respectively. Progression to metastatic disease was identified in 2 patients (5.7%).	4
65. Zini L, Perrotte P, Jeldres C, et al. A population-based comparison of survival after nephrectomy vs nonsurgical management for small renal masses. *BJU Int.* 2009; 103(7):899-904; discussion 904.	Observational-Tx	10,291 patients	To examine population-based rates of cancer-specific and other-cause mortality after either non-surgical management or nephrectomy, in patients with small renal masses.	Cumulative incidence plots based on unmatched data, where the effect of other-cause mortality was controlled for, showed a 5.2%, 6.5% and 9.4% survival benefit for nephrectomy vs non-surgical management at 1, 2 and 5 years after nephrectomy or diagnosis, respectively. The same magnitude of the benefit (4.5%, 5.6% and 8.0%) persisted in analyses matched for age, tumor size and year of diagnosis or of nephrectomy. Finally, in multivariable analyses, treatment type, age, tumor size and year of diagnosis or of nephrectomy were independent predictors.	2

Indeterminate Renal Mass
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
66. Crispen PL, Viterbo R, Boorjian SA, Greenberg RE, Chen DY, Uzzo RG. Natural history, growth kinetics, and outcomes of untreated clinically localized renal tumors under active surveillance. *Cancer.* 2009; 115(13):2844-2852.	Review/Other-Dx	172 renal tumors in 154 patients	To report the largest series investigating the growth kinetics of any solid organ human neoplasm undergoing a period of radiographic active surveillance and to summarize pathologic features of tumors undergoing definitive treatment and the clinical outcomes of renal tumors subject to continuing active surveillance.	The authors identified 172 renal tumors in 154 patients under active surveillance. Median tumor diameter and volume on presentation were 2.0 cm (mean, 2.5; range, 0.4-12.0) and 4.18 cm(3) (mean, 20.0; range, 0.033-904). Median duration of follow-up was 24 months (mean, 31; range, 12-156). A significant association between presenting tumor size and proportional growth was noted, with smaller tumors growing faster than larger tumors. 39% (68/173) of tumors underwent delayed intervention, and 84% (57/68) were pathologically malignant. Progression to metastatic disease was noted in 1.3% (2/154) of patients.	4
67. Gabr AH, Gdor Y, Roberts WW, Wolf JS, Jr. Radiographic surveillance of minimally and moderately complex renal cysts. *BJU Int.* 2009; 103(8):1116-1119.	Review/Other-Dx	43 patients	To assess the effectiveness of radiographic surveillance for managing minimally and moderately complex renal cysts.	The complexity of the renal cysts was in the form of high attenuation before contrast-enhanced imaging ('hyperdense') in 29 patients, thin septations in 9, borderline enhancement in 6, thin calcifications in 5, and a thick wall in 1. The mean initial largest dimension was 2.9 cm and the mean final dimension was 3.0 cm, with the size increased in 29 cysts, decreased in 14 and with no change in 7. The cyst character worsened in 7 patients, improved in 4 and did not change in 39. Eventually 7 patients had surgery (laparoscopic partial nephrectomy in 5 and laparoscopic radical nephrectomy in 2), which revealed renal cancer in 5. Surgical intervention was prompted by growth alone in 2 patients, growth and worsening of cyst characteristics in 2, new onset of flank pain in 1, and appearance of an enhancing nodule in the wall or septa in 2.	4
68. American College of *Radiology.. Manual on Contrast Media*. Available at: http://www.acr.org/~/link.aspx?_id=29C40D1FE0EC4E5EAB6861BD213793E5&_z=z.	Review/Other-Dx	N/A	Guidance document on contrast media to assist radiologists in recognizing and managing risks associated with the use of contrast media.	N/A	4

Indeterminate Renal Mass
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
69. Taouli B, Thakur RK, Mannelli L, et al. Renal lesions: characterization with diffusion-weighted imaging versus contrast-enhanced MR imaging. *Radiology.* 2009; 251(2):398-407.	Observational-Dx	109 renal lesions in 64 patients	To compare the diagnostic performance of DWI MRI with that of contrast material-enhanced MRI and to assess the performance of these examinations combined for the characterization of renal lesions, with MRI follow-up and histopathologic analysis as the reference standards.	The 109 renal lesions; 81 benign lesions and 28 RCCs, had a mean diameter of 4.2 cm +/- 2.5 (SD). The mean ADC for RCCs (1.41 x 10(-3) mm(2)/sec +/- 0.61) was significantly lower (P<.0001) than that for benign lesions (2.23 x 10(-3) mm(2)/sec +/- 0.87) at DWI performed with b values of 0, 400, and 800 sec/mm(2). At a cutoff ADC of ≤1.92 x 10(-3) mm(2)/sec, the area under the ROC curve, sensitivity, and specificity of DWI for the diagnosis of RCCs (excluding AMLs) were 0.856, 86%, and 80%, respectively. The corresponding area under the ROC curve, sensitivity, and specificity of contrast-enhanced MRI were 0.944, 100%, and 89%, respectively. Combined DWI and contrast-enhanced MRI had 96% specificity. The area under the ROC curve for the DWI-based diagnosis of solid RCC vs oncocytoma was 0.854. Papillary RCCs had lower ADCs than nonpapillary RCCs.	3
70. Pedrosa I, Rafatzand K, Robson P, et al. Arterial spin labeling MR imaging for characterisation of renal masses in patients with impaired renal function: initial experience. *Eur Radiol.* 2012; 22(2):484-492.	Observational-Dx	11 patients	To retrospectively evaluate the feasibility of arterial spin labeling MRI for the assessment of vascularity of renal masses in patients with impaired renal function.	17 renal lesions were evaluated in 11 patients (8 male; mean age = 70 years) (range 57-86). The median eGFR was 24 mL/min/1.73 m(2) (range 7-39). The average blood flow of 11 renal masses interpreted as arterial spin labeling-positive (134 +/- 85.7 mL/100 g/min) was higher than that of 6 renal masses interpreted as arterial spin labeling-negative (20.5 +/- 8.1 mL/100 g/min)(P=0.015). Arterial spin labeling-positivity correlated with malignancy (n=3) or epithelial atypia (n=1) at histopathology or progression at follow-up (n=7).	3
71. Choi HJ, Kim JK, Ahn H, Kim CS, Kim MH, Cho KS. Value of T2-weighted MR imaging in differentiating low-fat renal angiomyolipomas from other renal tumors. *Acta Radiol.* 2011; 52(3):349-353.	Observational-Dx	71 patients	To retrospectively assess the usefulness of T2-weighted MRI for differentiating low-fat AMLs from other renal tumors.	The SI ratio values (77 +/- 24% vs 162 +/- 79%, P=0.002) were significantly lower in the AML than in the non-AML group. The area under the ROC curve was 0.926 for SI ratio. The sensitivity and specificity in the diagnosis of AMLs were 90% and 90.2%, using SI ratio cut-off of 92.5%.	3

Indeterminate Renal Mass
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
72. Verma SK, Mitchell DG, Yang R, et al. Exophytic renal masses: angular interface with renal parenchyma for distinguishing benign from malignant lesions at MR imaging. *Radiology.* 2010; 255(2):501-507.	Observational-Dx	162 exophytic (2 cm or greater) renal masses in 152 patients	To retrospectively determine whether benign exophytic renal masses can be distinguished from RCC on the basis of angular interface at single-shot fast spin-echo T2-weighted MRI.	Of 162 masses, 65 were benign, and 97 were RCCs. The sensitivity, specificity, PPV, NPV, and A(z) of angular interface for diagnosing benign masses were 78%, 100%, 100%, 87%, and 0.813, respectively. Angular interface (P<.001) was a significant predictor of benign renal mass but mass size (P=.66) was not. There was almost perfect interobserver agreement for mass size (ICC=0.96) and angular interface (kappa = 0.91).	2

Evidence Table Key

Study Quality Category Definitions

- *Category 1* The study is well-designed and accounts for common biases.
- *Category 2* The study is moderately well-designed and accounts for most common biases.
- *Category 3* There are important study design limitations.
- *Category 4* The study is not useful as primary evidence. The article may not be a clinical study or the study design is invalid, or conclusions are based on expert consensus. For example:
  a) the study does not meet the criteria for or is not a hypothesis-based clinical study (e.g., a book chapter or case report or case series description);
  b) the study may synthesize and draw conclusions about several studies such as a literature review article or book chapter but is not primary evidence;
  c) the study is an expert opinion or consensus document.

Dx = Diagnostic

Tx = Treatment

Abbreviations Key

AML = Angiomyolipoma

CI = Confidence interval

CT = Computed tomography

DWI = Diffusion-weighted imaging

FDG-PET = Fluorine-18-2-fluoro-2-deoxy-D-glucose-positron emission tomography

HU = Hounsfield units

IVU = Intravenous urography

MDCT = Multidetector computed tomography

MRI = Magnetic resonance imaging

NPV = Negative predictive value

PET = Positron emission tomography

PPV = Positive predictive value

RCC = Renal cell carcinoma

ROC = Receiver-operator characteristic

SD = Standard deviation

SI = Signal intensity

US = Ultrasound