Diagnostic Accuracy and Risks of Biopsy in the Diagnosis of a Renal Mass Suspicious for Localized Renal Cell Carcinoma: Systematic Review of the Literature

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Abbreviations and Acronyms

AHRQ = Agency for Healthcare Research and Quality

CT = computerized tomography

EPC = Evidence-Based Practice Center

FNA = fine needle aspiration

NPV = negative predictive value

PPV = positive predictive value

RCC = renal cell carcinoma

Purpose: Clinical practice varies widely on the diagnostic role of biopsy for clinically localized renal masses suspicious for renal cell carcinoma. Therefore, we performed a systematic review of the available literature to quantify the accuracy and rate of adverse events of renal mass biopsy.

Materials and Methods: MEDLINE®, Embase® and the Cochrane databases were searched (January 1997 to May 2015) for relevant studies. The systematic review process established by the Agency for Healthcare Research and Quality was followed. Nondiagnostic biopsies were excluded from diagnostic accuracy calculations.

Results: A total of 20 studies with 2,979 patients and 3,113 biopsies were included in the study. The overall nondiagnostic rate was 14.1% with 90.4% of those undergoing surgery found to have malignancy. Repeat biopsy led to diagnosis in 80% of patients. The false-positive rate was low (4.0%), histological and renal cell carcinoma subtype concordance was substantial, and Fuhrman upgrading notable (16%) from low grade (1 to 2) to high grade (3 to 4). Core biopsy was highly sensitive (97.5%, CI 96.5–98.5) and specific (96.2%, CI 90.7–100) when a diagnostic result was obtained, but most patients (~80%) did not undergo surgery after a benign biopsy. Among patients undergoing extirpation 36.7% with a negative biopsy had malignant disease on surgical pathology (negative predictive value 63.3%, CI 52.4–74.2). Direct complications included hematoma (4.9%), clinically significant pain (1.2%), gross hematuria (1.0%), pneumothorax (0.6%) and hemorrhage (0.4%).

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Conclusions: Diagnostic accuracy was generally high for biopsy of localized renal masses with a low complication rate, but the nondiagnostic rate and negative predictive value were concerning. Renal mass sampling should be used judiciously as further research will determine its true clinical utility.

Key Words: carcinoma, renal cell; biopsy; diagnosis; data accuracy; complications

KIDNEY cancer affects 65,000 new patients with more than 13,000 deaths annually.[1] Increasing incidental detection has led to the diagnosis of more asymptomatic, small and clinically localized renal masses, approximately 20% of which are benign at surgical resection.[2–6] It is estimated that 6,000 benign renal masses are removed each year.[7] Renal mass biopsy provides a potential route for tissue sampling to aid in histological and subtype diagnosis for risk stratification and management. However, clinical practice has varied widely due to uncertainty about diagnostic accuracy and potential harms of renal mass biopsy.

In 2009 the American Urological Association published the guideline used most widely by the United States urological community for the management of clinical stage 1 renal masses based on systematic review of observational studies available at the time and expert opinion.[8] According to the guideline renal mass biopsy was generally not indicated for healthy patients unwilling to accept uncertainty or older patients only considering conservative management options regardless of results. Data on renal mass biopsy were limited and numerous large institutional experiences have been reported in the last decade. Therefore, we performed a systematic review of the literature to quantify the diagnostic accuracy and rate of adverse events of biopsy for clinically localized renal masses suspicious for RCC.

MATERIALS AND METHODS

The methods of this systematic review follow the AHRQ Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[9] In an open process representatives of various stakeholder groups developed Key Questions, which are posted on the AHRQ web site for public comments (www.effectivehealthcare.ahrq.gov). The final review protocol was registered on PROSPERO (CRD42015015878, fig. 1). MEDLINE, Embase and the Cochrane Central Register of Controlled Trials were searched from January 1, 1997 through May 1, 2015.

The systematic review focused on 3 major topics, of which 1 topic included 2 questions on renal mass sampling for masses suspicious for stage I or II RCC. 1) What is the accuracy (eg sensitivity, specificity, positive and negative predictive value) of percutaneous renal mass sampling (using FNA with cytopathology or core biopsy with surgical pathology) in establishing a diagnosis (eg malignancy, histology, and grade)? 2) What are the adverse effects including direct complications (eg pain, infection, hemorrhage and radiation exposure) and harms related to false-positives, false-negatives or nondiagnostic results? Complete details are available in the full version of the EPC Report.[10]

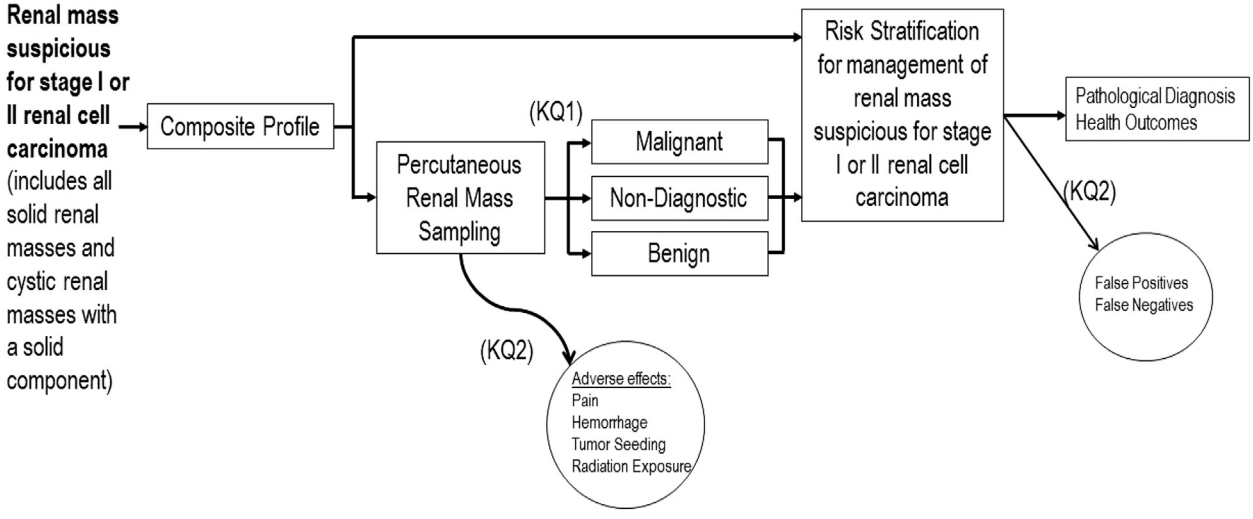

Figure 1. Analytic framework for systematic review of role of renal mass biopsy in diagnosis of renal masses suspicious for localized kidney cancer. *KQ,* key question.