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PERCUTANEOUS BIOPSY OF PRIMARY TUMOR IN METASTATIC RENAL CELL CARCINOMA TO PREDICT HIGH RISK PATHOLOGIC FEATURES: COMPARISON WITH NEPHRECTOMY ASSESSMENT

E. Jason Abel, MD^a, Stephen H. Culp, MD, PhD^a, Surena Matin, MD^a, Pheroze Tamboli, MD^c, Michael J. Wallace, MD^d, Eric Jonasch, MD^b, Nizar M. Tannir, MD^b, and Christopher G. Wood, MD^a

^aDepartment of Urology, The University of Texas M.D. Anderson Cancer Center, Houston, Texas

^bDepartment of Genitourinary Medical Oncology, The University of Texas M.D. Anderson Cancer Center, Houston, Texas

^cDepartment of Pathology, The University of Texas M.D. Anderson Cancer Center, Houston, Texas

^dDepartment of Radiology, The University of Texas M.D. Anderson Cancer Center, Houston, Texas

Abstract

PURPOSE—As treatment options evolve in metastatic renal cell carcinoma (mRCC), there is need for predictive information to help guide therapy. The purpose of this study was to assess accuracy of percutaneous primary tumor biopsy in mRCC by comparing biopsy findings to final nephrectomy pathology in patients undergoing cytoreductive nephrectomy (CN).

MATERIALS AND METHODS—Using an institutional database, we reviewed records of patients who underwent percutaneous primary tumor biopsy prior to CN. For patients who underwent biopsy at an outside institution, pathology was re-reviewed at our institution. Differences in accuracy based on biopsy technique, imaging modality, and biopsy time period were determined using chi-square analysis.

RESULTS—We identified 166 patients who underwent percutaneous biopsy of the primary tumor prior to CN between 1991 and 2007 and had data available for review. Median pathologic tumor size was 9.1 cm (range 3–32). Median time from biopsy to surgery was 46 days (range 6–717). Of 104 patients whose biopsy was assigned a Fuhrman nuclear grade, 33 (31.7%) had the same grade in the nephrectomy specimen or 74 of 109 (67.9%) when only high or low grade was

Corresponding author for proof and reprints: Christopher G. Wood, M.D., F.A.C.S., Associate Professor and Deputy Chairman, Department of Urology - Unit 1373, The University of Texas M. D. Anderson Cancer Center, 1515 Holcombe Boulevard, Houston, Texas 77030, Phone: 713-563-7463, Fax: 713-792-3474, cgwood@mdanderson.org.

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considered. Grade change by more than 2 points was seen in 18 of 104 (17.3%) patients. Sarcomatoid features were present in 34 of 166 (20.5%) nephrectomy specimens, however only 4 (11.8%) were identified pre-operatively.

CONCLUSIONS—In patients with mRCC, percutaneous renal biopsy has poor accuracy for assessment of Fuhrman nuclear grade or sarcomatoid features. Physicians should use caution when using biopsy data to guide therapy.

Keywords

renal cell carcinoma; metastasis; percutaneous biopsy

INTRODUCTION

Renal cell carcinoma (RCC) accounts for 3 percent of all solid cancers in the United States, and up to one-third of patients present with metastatic disease. Although recent advances in molecular targeted systemic therapy have resulted in increased response rates and progression-free survival (PFS) compared to cytokine therapy, the prognosis of patients with metastatic renal cell carcinoma (mRCC) remains poor.

In patients presenting with a renal tumor and clinical evidence of metastatic disease, percutaneous biopsy of the primary tumor and/ or metastatic lesion can be performed to obtain a tissue diagnosis. Indications for biopsy of primary tumor may include the inability to obtain a tissue diagnosis from a metastatic site, atypical appearance of primary tumor on preoperative imaging, the suspicion of multiple primary neoplasms, and/or to obtain histologic diagnosis to guide treatment. High Fuhrman nuclear grade and presence of sarcomatoid de-differentiation are known poor prognostic factors in mRCC, which may also be evaluated from biopsy specimens. This information may then be used to assess disease aggressiveness, estimate prognosis, and guide treatment decisions including whether or not to proceed with cytoreductive nephrectomy (CN).

The accuracy of percutaneous biopsy has been evaluated in patients with indeterminate renal masses in order to confirm a diagnosis of RCC. However, the accuracy of percutaneous biopsy of a primary lesion in patients with mRCC is less studied, especially for evaluating high risk pathologic features like sarcomatoid de-differentiation. The objective of this study was to evaluate the accuracy of percutaneous biopsy of the primary tumor in patients with mRCC by comparing pathologic findings from the biopsy with that of the nephrectomy specimens.

MATERIALS AND METHODS

Upon institutional review board approval, records were reviewed for all patients who had undergone percutaneous primary tumor biopsy prior to CN at The University of Texas M.D. Anderson Cancer Center (MDACC). The decision for biopsy of the primary tumor was made by the physician who performed the initial evaluation and, as such, the specific indication was not routinely recorded. Eligible patients included those who underwent percutaneous biopsy at MDACC or at an outside institution, the latter only if the specimen

was independently reviewed by a genitourinary pathologist at MDACC. Specimens were collected using fine needle aspiration (FNA), core needle biopsy, or a combination of these two techniques. In addition, biopsy specimens were obtained using ultrasound (US), fluoroscopic, or computed tomography (CT)-directed guidance.

In our analyses, Fuhrman nuclear grades 1 or 2 and grades 3 or 4 were considered low and high grade lesions, respectively. When two grades were assigned, the higher grade was used. We defined histologic subtypes based on the 2004 World Health Organization classification. Immunohistochemical staining and advanced diagnostic techniques were used at the discretion of the attending pathologist. Tumors with multiple histologic subtypes or unknown subtype were defined as unclassified. Tumors reported as RCC with no specified subtype were labeled RCC not otherwise specified (NOS).

We analyzed differences in accuracy of percutaneous biopsy based on technique, imaging modality, as well as the time period (1991–96, 1997–2001, and 2002–07) during which it was performed using chi-square analysis. All data were analyzed using Stata 10.1 (Stata Corp., College Station, Texas). A two-sided p-value ≤ 0.05 was considered significant.

RESULTS

We identified 686 patients undergoing CN from 1991 to 2007 at MDACC. Of these, 166 (24.2%) patients underwent percutaneous biopsy of the primary tumor prior to CN and had data available for analysis. Although the 166 patients who underwent primary tumor biopsy were more likely ($p=.002$) to have radiographically enlarged lymph nodes (≥ 1 cm,) there was no statistically significant difference in age, gender, ECOG performance status, tumor size, clinical T stage, symptoms at presentation, or body mass index when compared to CN patients who did not have primary tumor biopsy. Patient characteristics are listed in Table 1. Median time from biopsy to surgery was 46 days (range 6–717.)

Histologic subtypes are shown in Table 2. Overall, a histologic RCC subtype was assigned to 79 patients for both pathologic specimens. Out of 66 patients with clear cell RCC diagnosed on biopsy, 3 tumors were designated as RCC unclassified on nephrectomy pathology. Of the 13 patients with non-clear cell histology diagnosed on biopsy, 10 had the same RCC histologic subtype in the nephrectomy specimen. Two patients with papillary subtype and 1 patient with unclassified RCC in the biopsy specimen were reported as unclassified RCC and clear cell RCC, respectively, in the nephrectomy specimen.

In 16 patients, biopsy specimens were non-diagnostic for RCC. Of 9 patients with fibrosis or normal renal histology in the biopsy specimens, final pathology demonstrated clear cell RCC in 6 patients and unclassified RCC in 3 patients (5 FNA, 1 core, 2 FNA/core, and 1 unknown). Four non-diagnostic biopsies were performed at our facility and five biopsies were obtained at outside institutions. Seven patients had unspecified carcinoma reported in the biopsy specimen. In the corresponding nephrectomy specimen of these patients, histologic subtypes were clear cell RCC (2), collecting duct carcinoma (2), RCC NOS (2), and unclassified RCC (1).

Sarcomatoid de-differentiation was identified on final pathology in 34/166 (20.5%) patients. Of these, only 4 (11.8%) patients had sarcomatoid de-differentiation identified on pre-operative biopsy (2 FNA, 2 FNA/core). One patient had sarcomatoid features identified on pre-operative core biopsy but not in the corresponding nephrectomy specimen. For determining sarcomatoid features the sensitivity of biopsy was 0.118 (95% CI: .056, .142) and specificity was 0.992 (95% CI: 0.975, 0.999.) In 18/34 (52.9%) nephrectomy specimens, the percentage of sarcomatoid de-differentiation was reported, with a median percentage of 22.5% (range: 5–90). Of the 4 patients who had sarcomatoid features reported on pre-operative biopsy, percentage sarcomatoid was reported in 3 corresponding nephrectomy specimens: 5%, 40%, and 90%.

Fuhrman nuclear grade was reported on the biopsy specimen for 109 patients (Table 3). Of 104 patients who had an assigned numerical grade on biopsy, 33 (31.7%) had an identical grade assigned to the nephrectomy specimen. Of 65 patients who were assigned a Fuhrman grade of 4 from the nephrectomy specimen, 16 (24.6%) patients had a Fuhrman grade of 4 on pre-operative biopsy. When Fuhrman grade was categorized as low or high-grade, accuracy improved to 67.9% (74 of 109 patients). A Fuhrman grade change by more than 2 numerical points was seen in 18 of 104 (17.3%) patients. The sensitivity of biopsy for determining histologic grade (high vs. low) was 0.687 (95% CI: 0.659, 0.710) and specificity was 0.600 (95% CI: 0.323, 0.827.)

When determining histologic grade (high vs. low,) there was no statistically significant difference in concordance between biopsy and nephrectomy specimens based on biopsy technique ($p=0.44$), imaging modality ($p=0.26$), or the time period when biopsy was obtained ($p=0.61$).

DISCUSSION

With recent improvements in the understanding of molecular pathways involved in the pathogenesis of RCC, several targeted agents (sunitinib, sorafenib, temsirolimus, everolimus, bevacizumab, pazopanib) have been developed and approved for use in mRCC with unprecedented response rates and improved PFS as compared to cytokine therapy. As a result of expanded therapeutic options, there is an increasing need for predictive information to help guide treatment planning.

Biopsy of the primary tumor in mRCC serves many functions. It is useful to distinguish RCC from other rare tumors arising in the kidney. Urothelial carcinoma of the renal pelvis, primitive neuroectodermal tumors, lymphoma, sarcoma, and metastatic lesions may mimic the appearance of mRCC and need to be accurately identified since treatment options differ. In addition, percutaneous primary tumor biopsy may be valuable for assessment of clear cell RCC subtype prior to enrollment into pre-surgical clinical trials.¹

For renal masses, percutaneous biopsy is commonly performed with FNA or core biopsy techniques. In experienced centers, both methods have been reported to have high sensitivity and specificity for small renal masses^{2, 3} but these appear to be complimentary techniques as core samples seem to be superior in cystic lesions and FNA may be superior in high grade

tumors.⁴ Both US and CT guidance have advantages, but no high quality study has compared the two modalities head to head.⁴ In our study, choice of biopsy technique and imaging was at the discretion of the physician performing the procedure.

Multiple case series have been published regarding the improved accuracy of percutaneous renal biopsy for diagnosing RCC (92–100%) or to predict histologic subtype (92–100%) in those patients presenting with small indeterminate renal masses.^{4–6} However, reported accuracy is less when determining grade (46–83%)^{5, 7} and very little data exist with regard to determining the presence of sarcomatoid de-differentiation. In patients with metastatic disease, biopsy may be performed not only to establish the diagnosis of RCC, but also more recently, to help guide therapy. However, unlike most incidental renal masses which are small, the primary tumor in a patient with mRCC is often large, heterogeneous, and frequently necrotic, which may affect the accuracy of biopsy in this setting.

To diagnose mRCC, a biopsy may be taken of a metastatic site or from the primary tumor. In the present study, biopsy findings were non-diagnostic in 5.4 percent of patients and the neoplasm could not be identified as RCC in 4.2 percent of patients. In a review of 318 percutaneous renal mass biopsies since 2001, Lane *et al.* found similar results with rates of biopsy failure and indeterminate pathology rates of 5.2 and 3.8 percent, respectively.⁸ Improved accuracy for tumor detection may be seen in patients with combined FNA/core biopsy technique, obtaining more or larger samples, by immediate assessment of sample adequacy by a pathologist, and advanced tissue staining techniques with molecular analysis. The current standard practice at our institution is to use US, CT or MRI to target less necrotic areas of the lesion. To obtain tissue, a coaxial system is used with an outer 18 gauge needle, a 22 gauge chiba needle to obtain a FNA and a 20 gauge spring loaded system to obtain core samples.

The majority of patients with mRCC exhibit clear cell histology, with less than 10 percent of patients in large series having non-clear cell subtypes.⁹ Accurate identification of non-clear cell histology is important to guide treatment because these patients are more likely to be younger,¹⁰ have decreased survival,^{9, 10} and have less objective responses to targeted therapy.¹¹ In our series, percutaneous biopsy was able to accurately identify 75/79 (94.9%) patients as clear cell or non-clear cell RCC, which is comparable to data examining biopsy of indeterminate renal masses (94–100% for histologic subtype).⁸ Given that there is not a proven benefit for upfront CN in patients with non-clear cell mRCC, it is valuable to identify these patients using percutaneous biopsy preoperatively, so that they can be considered for upfront systemic therapy or enrolled in clinical trials of newer therapies.

Sarcomatoid de-differentiation is a pathologic pattern of spindle-shaped cells that can be associated with any recognized histologic RCC subtype¹² and has a reported incidence between 1.2 and 23.6 percent.¹³ The presence of sarcomatoid features in pathology specimens portends a poor prognosis with early metastasis to bone and lung,¹⁴ limited response to systemic treatment,^{15, 16} and apparent lack of benefit from CN.¹⁰ At our institution, the presence of sarcomatoid features is currently considered a relative, if not absolute, contraindication to proceeding with CN as very few patients benefit from surgery based on our experience. Responses with immunotherapy treatment were disappointing¹³

but some encouraging results have been reported with chemotherapeutic regimens.^{13, 17, 18} Minimal data exist on targeted therapy response to tumors with sarcomatoid features with the exception of a recent report by Golshayan *et al.*¹⁶ who demonstrated a partial response to targeted therapy in 8 of 43 patients with sarcomatoid elements in nephrectomy specimens.

Accuracy of percutaneous biopsy in determining sarcomatoid de-differentiation is especially important in patients with mRCC given their poor prognosis and lack of benefit with CN. If correctly identified before surgery, these patients may be spared unnecessary morbidity. Unfortunately, sarcomatoid de-differentiation was identified pre-operatively in only 11.8% of those who had sarcomatoid de-differentiation on final pathology. The inability to identify sarcomatoid features from biopsy may be largely due to sampling error given the low (22.5%) median percentage of sarcomatoid features present in nephrectomy specimens from our series.

The presence of a high Fuhrman nuclear grade in pathologic specimens is also recognized as a poor prognostic factor in patients with mRCC. In patients with a final Fuhrman grade of 4, only 24.6 percent of these patients were accurately identified from preoperative biopsy. In addition, 17.3 percent of patients had an increase in grade of two or more from biopsy to nephrectomy pathology. The ability to correctly identify Fuhrman grade from biopsy in mRCC patients is substantially worse when compared to the small series of renal masses where biopsy grade was compared to nephrectomy specimens (46–92%)^{7, 19, 20} for determination of grade, or 74–100%^{7, 19} when only high or low grade was considered. The poor accuracy seen in the mRCC population may be the result of sampling error due to grade heterogeneity within the tumor⁵ or inter-observer variability. From our data, we did not find a significant difference in accuracy of predicting grade based on biopsy method, type of imaging modality, or time period during which the biopsy was performed.

To our knowledge, this is the first large series evaluating findings of percutaneous renal mass biopsies with nephrectomy specimens in patients with mRCC. However, there are several limitations to our study. First, there were no standardized indications for biopsy and therefore, accuracy of percutaneous biopsy may have changed if every patient undergoing CN also underwent percutaneous biopsy. Patients who had primary tumor biopsy did have an increased incidence of radiographically enlarged lymph nodes, which may have led clinical uncertainty and increased sampling of the primary tumor. However there was no significant difference in tumor size, stage or symptoms when compared to the entire cohort undergoing CN. In addition, although pathology was reviewed initially by a genitourinary pathologist, it was not independently re-reviewed for the present analysis. We chose to use the data from the original pathology review (as opposed to central review), as the decision to perform a CN was made based on the biopsy diagnosis rendered at the time. Also, this data more accurately reflects clinical situations, where the biopsy and nephrectomy may be evaluated by different pathologists, with the potential for inter-observer bias. Therefore, we maintain that the data collected reflect an accurate appraisal of the utility of biopsy information collected in a standard manner from a center of excellence.

In conclusion, percutaneous biopsy of the primary tumor in patients with mRCC may provide useful information in the diagnosis of mRCC. However, biopsy has poor sensitivity

and specificity when assigning Fuhrman nuclear grade and biopsy rarely accurately identifies the presence of sarcomatoid de-differentiation. Future development of better imaging techniques, new molecular markers and/or improved immunohistochemical techniques may help to improve the predictive accuracy of percutaneous biopsy of large heterogeneous primary tumors in patients with mRCC. Physicians should regard with caution biopsy data assigning grade or the presence of sarcomatoid elements, especially when enrolling patients with mRCC in neoadjuvant clinical trials or making complicated treatment decisions.

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Key of Definitions for Abbreviations

RCC	renal cell carcinoma
mRCC	metastatic renal cell carcinoma
CN	cytoreductive nephrectomy
PFS	progression-free survival
CT	computed tomography
US	ultrasound
FNA	fine needle aspiration
MDACC	The University of Texas M.D. Anderson Cancer Center

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Table 1

Characteristics of patients (n=166) undergoing percutaneous biopsy of primary tumor prior to cytoreductive nephrectomy (MDACC, 1991–2007)

Median age at surgery (range)	57.4 (18.1–81.4)
Median primary tumor size (cm) (range)	9.2 (3–32)
Median body mass index (kg/m²) (range)	27.4 (18.0–48.1)
Male gender (%)	108 (65.1)
Laterality of primary tumor (%)	
Right	72 (43.4)
Left	94 (56.6)
Race (%)	
Caucasian	139 (83.7)
Black	7 (4.2)
Hispanic	18 (10.8)
Other	2 (1.2)
Biopsy type (%)	
FNA	110 (66.3)
Core	13 (7.8)
Both	31 (18.7)
Missing	12 (7.2)
Place where biopsy performed	
MDACC	88 (53.0)
Other institution	78 (47.0)
Imaging modality used in biopsy	
Ultrasound	42 (25.3)
CT	56 (33.7)
Fluoroscopy	6 (3.6)
Missing data *	62 (37.4)
Year of Biopsy	
1991–1996	37 (22.3)
1997–2001	51 (30.7)
2002–2007	78 (47.0)

* Biopsy obtained outside institution, type of imaging guidance unknown

Table 2

Comparison of histological findings in patients undergoing percutaneous biopsy of primary tumor prior to cytoreductive nephrectomy (MDACC, 1991–2007).

Histology	Percutaneous biopsy	Nephrectomy
Clear Cell (%)	68 (41.0)	118 (71.1)
Papillary	9 (5.4)	10 (6.0)
Chromophobe	0	1 (0.6)
Collecting duct	2 (1.2)	3 (1.8)
RCC, unclassified	3 (1.8)	23 (13.9)
RCC, subtype unspecified	68 (41.0)	11 (6.6)
Neoplasm, unclassified	7 (1.8)	0
No tumor identified	9 (4.2)	0

Table 3

Fuhrman nuclear grade based on percutaneous biopsy of primary tumor and final nephrectomy pathology (MDACC, 1991–2007)

Fuhrman Nuclear Grade	Percutaneous biopsy N (%)	Nephrectomy N (%)
1	4 (3.8)	1 (1.0)
2	33 (31.7)	9 (8.2)
3	51 (49.0)	34 (31.2)
4	16 (15.4)	65 (59.6)
High grade	5 (4.6)	0