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PATIENT AND TUMOR CHARACTERISTICS CAN PREDICT NON-DIAGNOSTIC RENAL MASS BIOPSY FINDINGS

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INTRODUCTION

The incidence and detection of renal cell carcinoma (RCC) has increased significantly over the past 50 years.¹ Increased use of cross-sectional imaging techniques have enabled detection of small renal masses (SRM) when they are asymptomatic, causing a stage migration in RCC,² with masses <4cm constituting 48–66% of new diagnoses.³

Recently, concerns have been raised about overtreatment of SRM because as many as 33% of SRM are found to be benign tumors,⁴ and many tumors have minimal metastatic potential.⁵ However, it is difficult to evaluate the risk associated with SRM using imaging alone and many urologists use renal mass biopsy (RMB) to provide a better assessment of specific patients' cancer risk.⁶ Improved techniques for biopsy allow for safer and more accurate diagnosis in many patients⁷ and may reduce total costs of treatment by identifying patients with benign renal masses.⁸ However, the optimal use of RMB continues to be debated and biopsy is performed in the minority of patients who are treated for RCC.⁹

To improve the utilization of RMB, experts have developed algorithms to guide treatment decisions based on pathologic findings.¹⁰ One consistent limitation of these algorithms, however, is an approximately 15–22% rate of non-diagnostic or indeterminate findings,^{6, 11–13} regardless of significant experience and the use of imaging guidance. Many factors may contribute to non-diagnostic biopsy findings, including sampling of tissue outside the target lesion (“miss”), failure to adequately sample the mass or obtaining tissue

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that is inadequate to pathologically diagnose a renal neoplasm. Identification of patient and tumor characteristics associated with a non-diagnostic biopsy is necessary to improve pre-biopsy counseling and patient selection. Avoiding RMB in patients with a high likelihood of non-diagnostic results could improve biopsy success rates, but predictors of non-diagnostic RMB findings have not been studied. Therefore, the objective of this study is to evaluate patient characteristics and tumor features that are predictive of non-diagnostic findings after percutaneous RMB.

MATERIALS AND METHODS

After receiving approval by the institutional review board, the clinical and radiologic records for 613 percutaneous RMB ≤ 7 cm from January 2000 to April 2014 at our institution were reviewed. Excluded from this study were 24 biopsies where pre-biopsy imaging within 3 months prior to RMB was not available and 24 repeat biopsies with initial non-diagnostic findings. Pre-biopsy and intra-biopsy imaging were analyzed using our institutional picture archiving and communication system (PACS, McKesson, San Francisco). Non-diagnostic biopsy was defined as the presence of normal renal parenchyma, or fibrotic/ necrotic material insufficient for pathological diagnosis. Pathologic specimens were reviewed by expert genitourinary pathologists, and immunohistochemistry was used to facilitate diagnosis when indicated.

Putative prognostic factors for non-diagnostic biopsy included: type of imaging modality used prior to biopsy [MRI vs. US vs. CT], laterality [left vs. right], biopsy guidance imaging modality [CT vs. US], biopsy type [fine needle aspiration vs. core vs. both], exophytic vs. endophytic appearance on imaging [defined by percentage of the tumor that extended beyond the renal capsule], presence of cystic features, proximity to liver or spleen, proximity to other organs, renal mass enhancement [≤ 20 HU vs. >20 HU], fat content [present vs. absent], calcifications [present vs. absent], necrosis/hemorrhage [present vs. absent], anterior or posterior positioning of mass, polarity of mass [inferior pole vs. interpolar vs. superior pole], mean axial mass diameter, patient BMI, skin-to-tumor distance, and number of biopsy cores obtained.

Differences in patient/tumor characteristics for diagnostic and non-diagnostic groups were assessed using a t-test (two-sided with unequal variances), Chi-squared test, or Fischer's exact test for each characteristic as appropriate. Univariate and multivariate logistic regression models were constructed to examine the association between biopsy outcome and clinical/radiographic features. All analyses were performed using SAS 9.2 (SAS Institute Inc., Cary, NC, USA). Two sided p-values ≤ 0.05 were considered significant.

RESULTS

A total of 565 biopsies from 525 patients were included in the study. Patient characteristics are shown in Table 1. There were no significant differences in age, BMI, Charlson comorbidity score, or gender between diagnostic and non-diagnostic biopsy patient cohorts. In 83/565 (14.7%) overall and 72/413 (17.4%) with mass ≤ 4 cm, the biopsy findings were non-diagnostic. Overall, 14.7% of the masses were cystic and 85.3% were solid with a

median tumor size was 2.75 cm (IQR 2.05 – 4.25). Renal mass enhancement (>20 HU) after IV contrast was seen in 84.8% of masses, while 4.4% were pseudo-enhancing (10–20 HU), 2.3% were non-enhancing, and 8.5% could not be evaluated as pre-contrast CT scans were not available. A skin-to-tumor distance of ≥ 13 cm was present for 9.2% of the masses.

In 482 (85.3%) RMB, pathologic evaluation of tissue resulted in diagnosis of a neoplasm, including: 346 (71.8%) renal cell carcinoma [75.1% clear cell, 13.9% papillary, 1.4% chromophobe, and 9.5% RCC unspecified], 77 (16.0%) oncocytoma, 11 (2.3%) angiomyolipoma, and 47 (9.8%) other malignant neoplasms (including urothelial cancer, collecting duct carcinomas, lymphoma or leukemia). For 83 biopsies with indeterminate findings, final pathologic diagnosis from RMB included: 43 (51.8%) benign renal parenchyma; 28 (33.7%) necrotic, fibrotic, or sclerotic tissue; and 12 (14.4%) inadequate tissue sample from biopsy.

Tables 2 and 3 show associations of non-diagnostic findings with common patient and tumor characteristics. Independent predictors of non-diagnostic biopsy overall included: laterality, cystic features, radiologic enhancement <20HU, tumor diameter, and skin-to-tumor distance. Similarly, when only SRM ≤ 4 cm were considered, cystic features, radiologic enhancement <20HU, tumor diameter, and skin-to-tumor distance were independent predictors of non-diagnostic RMB.

Cystic masses

A total of 83 masses were classified as cystic, including 4/1/10/18 Bosniak category 2/2f/3/4 lesions,¹⁴ respectively. The method for obtaining biopsy was core sampling in 88%, FNA in 3% and a combination of core/FNA in 9% of RMB. The non-diagnostic rate for RMB of cystic masses was 39.8%. For the 50 cystic masses where a diagnosis was obtained from biopsy, 45 (90%) were malignant including 35 ccRCC, 2 papillary RCC, 5 unspecified RCC, 1 SCC, and 1 oncocytic neoplasm, while 5 (10%) were oncocytoma.

Radiographic enhancement

Of 38 tumors with ≥ 20 HU enhancement, 25 (65.8%) were pseudo-enhancing and 13 (34.2%) were non-enhancing. Non-diagnostic findings were noted in 16 (42.1%) of these lesions overall (9 pseudo-enhancing and 7 non-enhancing). For the 22 tumors with diagnostic RMB, 17 (77.3%) were malignant and 5 (22.7%) were benign, including: 9 ccRCC, 5 papillary RCC, 2 unspecified RCC, 1 collecting duct carcinoma, 1 oncocytoma, 1 metanephric adenoma, 1 fibrotic specimen, 1 unspecified neoplasm, and 1 unspecified benign neoplasm.

Skin to tumor distance

Median skin-to-tumor distance was 10 cm (IQR 8.5 cm – 11 cm). When skin to tumor distance is analyzed as a continuous variable, each centimeter of distance is associated with increased risk of non-diagnostic biopsy (OR 1.20, 95% CI 1.08–1.34, $p = 0.001$). Among 52 tumors with a skin-to-tumor distance ≥ 13 cm, 14 (26.9%) of biopsies were non-diagnostic.

Patients with initial non-diagnostic biopsy

For 83 biopsies that were initially non-diagnostic, a repeat RMB was obtained in 24 (28.9%), 7 (8.4%) were treated with surgery, 10 (12.1%) were treated with thermal ablation, and 42 (50.6%) were followed with surveillance imaging. In 5/24 (20.8%) patients, non-diagnostic findings were present in the second biopsy, which was not statistically different from the non-diagnostic rate at the initial RMB attempt, 14.7%, ($p=0.38$). In 16/24 (66.7%) patients, a malignancy was identified after initially non-diagnostic biopsy (12 ccRCC, 2 unspecified carcinoma, and 2 papillary RCC). A benign tumor was eventually diagnosed in 3/24 (12.5%) patients (1 oncocytoma and 2 angiomyolipoma).

Interoperator variability

To evaluate whether experience with RMB contributed to indeterminate findings, the individual non-diagnostic rates of radiologists who performed biopsy was evaluated (figure 1A). Among 11 attending radiologists who performed at least 20 RMB, there was no association between experience and non-diagnostic rate, $p=0.76$. In 462 procedures where a trainee (resident or fellow) was involved, there was no difference in non-diagnostic rate compared to procedures without a trainee 14.7% vs. 15.7%, $p=0.80$. In addition, there was also no association found between pathologist experience who evaluated RMB specimens and non-diagnostic rate, $p=0.67$ (figure 1B).

Biopsy complications

In 7/565 (1.2%) patients, hospital admission was required after RMB. In 4 patients, no additional intervention was required including 2 patients with symptomatic perinephric hematoma, one patient with dehydration/ hematuria that resolved, and one patient with hypotension thought to be medication-related. In 3 patients, intervention was required, including 3 patients who require transfusion for bleeding. One major complication (Clavien-Dindo classification grade 3a¹⁵) occurred in a patient who required selective renal arterial embolization to manage post-procedure hemorrhage and hemodynamic instability.

DISCUSSION

Despite improved biopsy techniques and the use of imaging guidance, a significant percentage of patients undergoing RMB will have non-diagnostic pathologic findings. In this study, approximately 15% of patients had non-diagnostic RMB, consistent with prior large series.^{6, 11} Four patient or tumor characteristics were identified as being independently predictive of a non-diagnostic result from RMB including: absence of radiologic enhancement, small tumor size, presence of cystic features and increased skin to tumor distance. Urologic surgeons should consider these factors when counseling patients in order to optimize selection of patients who may benefit from RMB.

The decision to treat incidental small renal masses is often not straightforward, and multiple factors must be considered for each patient. Biopsy is not routinely recommended for young and healthy patients because the information obtained may not alter treatment planning. However, in older patients, patients with significant co-morbidities or patients that are borderline surgical candidates, biopsy can provide meaningful information to help guide

treatment. Typically, pathologic information is used to estimate risk of cancer mortality compared to risk of mortality from competing comorbidities¹⁶ or to guide decision-making when deciding among surveillance, surgery or ablation for treatment of a SRM.¹⁷ While low rates of biopsy-related morbidity were observed in this and other studies,⁶ one persistent criticism of RMB is that patients do not benefit when pathologic findings are non-diagnostic. Although there is likely a selection bias related to which patients were chosen to undergo a repeat biopsy, our investigation found repeat biopsy to be successful in 79% of attempts, which may be helpful when counseling patients who initially receive a non-diagnostic result.

Similar or higher non-diagnostic biopsy rates are reported in other large series, depending on each study's definition of non-diagnostic findings.^{3, 7, 11} In more than half of the non-diagnostic biopsies, normal renal parenchyma was identified, indicating a "miss" during percutaneous sampling. Another potential technical cause of nondiagnostic biopsy includes an inability to accurately target the lesion in obese patients. Tumor characteristics that likely impacted biopsy outcomes include cystic morphology (tumors may contain only small islands of malignant cells, leading to targeting challenges), lack of radiologic enhancement, tumor size and skin-to-tumor distance. Interestingly, increasing experience of physicians performing RMB or evaluating RMB tissue pathology was not associated with lower non-diagnostic rates. This observation may reflect the practice of triaging more challenging cases to more experienced radiologists or pathologists, leading to selection bias.

Cystic masses have the highest rate of non-diagnostic RMB at 40%. This is likely because cystic masses lack large areas of solid tumor, making adequate sampling less likely. Sampling the small soft tissue components is likely to be technically challenging and aspirating fluid for cytology is known to be relatively insensitive. Given the 60% rate of diagnostic findings with cystic masses, physicians may choose to defer biopsy in renal masses with cystic features. Interestingly, 90% of diagnostic RMB from cystic lesions, demonstrated malignancy despite the fact that cystic renal neoplasms generally are thought to behave more indolently than solid tumors.¹⁸ Not surprisingly and similar to cystic features, the absence of contrast enhancement in tumors is associated with higher risk of non-diagnostic biopsy (42%). Given the high rates of non-diagnostic biopsy in both cystic and non-enhancing renal masses, the limitations of RMB should be discussed prior to biopsy and RMB should be used judiciously in these patients.

This study is the first to describe skin-to-tumor distance as an independent risk factor for non-diagnostic biopsy. In patients with tumors greater than or equal to 13cm distance from the body surface, the rate of non-diagnostic biopsy was 27%, likely reflecting increased technical difficulty of maneuvering the biopsy needle in deep tissues and the decreased visualization of both the needle and tumor when using US-guidance for these biopsies. Interestingly, BMI was not predictive of non-diagnostic RMB. One possible explanation is that it is the distribution of adipose tissue that is more critical than the amount of adipose tissue. Specifically, superficial adipose tissue may impact tumor targeting/imaging less than peri-nephric adipose tissue. As a result, the skin to tumor distance is more accurate as a predictor than BMI, which doesn't necessarily reflect fat distribution. Small tumor size likewise is predictive of non-diagnostic findings after multivariate analysis. Patients with

masses less than 4cm were 2.7 times more likely to have a non-diagnostic biopsy compared to patients with masses greater than 4cm, which is likely due to the technical difficulty of hitting a smaller target with the biopsy needle. In patients with masses less than 2cm, the risk of metastasis is low and many of these patients may be candidates for active surveillance protocols in the setting of a non-diagnostic result.

Exclusion of patients with factors predictive of non-diagnostic findings may improve success rates (table 4); however, some number of indeterminate biopsy results is likely unavoidable because RMB is often recommended to gain information in atypical renal lesions. Given the low morbidity, RMB may still be a preferred option for management of some atypical masses, even if the yield is comparatively lower. Use of RMB has previously been shown to be cost effective,⁸ and improving patient selection may increase diagnostic rates and reduce the costs associated with additional biopsies. As noted above, patients with an initial non-diagnostic biopsy have a similar probability of non-diagnostic findings after a second RMB ($p=0.50$, 20.8% vs. 14.7%). It is also important to note that 77.4% of patients with non-diagnostic biopsy who had a second biopsy or surgery, were diagnosed with malignancy, which is similar to the 68.1% malignancy rate for patients undergoing initial RMB ($p=0.33$).

A limitation of the current study includes its retrospective nature. Patients selected for RMB at our tertiary care center may be more likely to have an atypical appearance, since not all patients with renal masses are treated with biopsy. This may negatively bias the rate of diagnostic biopsy, as patients with findings highly suggestive of malignancy may have not received biopsy. However, this investigation is representative of contemporary practice at a tertiary care center and non-diagnostic rates are similar to other large studies. Second, the use of RMB increased in the last few years, which may skew results as indications for RMB evolve. Interestingly, non-diagnostic rates have not changed significantly over the different time periods analyzed. Finally, since this was not a randomized study, the choice of technique and the type of imaging guidance was at the discretion of the radiologist performing the biopsy, so direct comparison of results based on the technique of the biopsy is not possible.

CONCLUSIONS

Non-diagnostic findings are present in 15% of RMB, and are more common in masses that are cystic, non-enhancing, small (<4 cm), or have a skin to tumor distance of ≥ 13 cm.

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List of Abbreviations

RMB	renal mass biopsy
SRM	small renal mass
RCC	renal cell carcinoma
CT	computed tomography
MRI	magnetic resonance imaging
US	ultrasound

FNA fine needle aspiration
CI confidence interval

Figure 1.

A. Among 11 attending radiologists who performed at least 20 RMB, there was no association between number of RMB performed and non-diagnostic rate, $p=0.76$

B. Among 7 attending pathologists who evaluated at least 20 RMB, there was no association between experience and non-diagnostic rate, $p=0.67$

Table 1

Patient and tumor characteristics of renal mass biopsies

Characteristic	All Renal Masses (n=565)		Small Renal Masses (< 4cm) (n=413)		p-value
	Diagnostic	Nondiagnostic	Diagnostic	Nondiagnostic	
No. of patients	482 (85.3)	83 (14.7)	341 (82.6)	72 (17.4)	
Age at biopsy, years	65 (56–72)	64 (55–70)	65 (56–73)	62 (54–69.3)	0.05
BMI, kg/m ³	29.1 (25.7–34.3)	30.0 (25.8–34.8)	29.6 (26.0–34.5)	29.8 (25.7–33.4)	0.22
Charlson Score	3 (2–5)	3 (2–5)	3 (2–5)	3 (2–5)	0.1
Number of cores obtained	2 (2–3)	2 (1.5–3)	2 (2–3)	2 (1.75–3)	0.16
Gender					0.81
Male	320 (66.4)	54 (65.1)	223 (65.4)	46 (63.9)	
Female	162 (33.6)	29 (34.9)	118 (34.6)	26 (36.1)	
Biopsy yr					0.04
2000–2009	123 (25.5)	15 (18.3)	100 (29.3)	14 (19.4)	
2010–2011	135 (28.0)	38 (45.8)	106 (31.1)	33 (45.8)	
2012–2014	224 (46.5)	29 (34.9)	135 (39.6)	25 (34.7)	
Biopsy imaging guidance					
US	441 (91.5)	76 (91.6)	307 (90.0)	65 (90.3)	1.00
CT	41 (8.5)	7 (8.4)	34 (10.0)	7 (9.7)	
Biopsy technique					
Core	448 (92.9)	75 (90.4)	315 (92.4)	66 (91.7)	0.87
FNA	19 (3.9)	4 (4.8)	14 (4.1)	3 (4.2)	
Both	15 (3.1)	4 (4.8)	12 (3.5)	3 (4.2)	
Mean diameter of primary tumor, cm	2.9 (2.1–4.7)	2.2 (1.9–3.2)	2.5 (1.9–3.0)	2.1 (1.8–2.7)	0.04
Skin-to-tumor distance, cm	10 (8.5–11)	10.5 (9.25–12)	10 (8.5–11.5)	10.5 (9–12)	<0.0001
Consistency					
Solid	432 (89.6)	50 (60.2)	305 (89.4)	44 (61.1)	<0.0001
Cystic	50 (10.4)	33 (39.8)	36 (10.6)	28 (38.9)	
Radiographic Enhancement					<0.0001

Characteristic	All Renal Masses (n=565)		Small Renal Masses (< 4cm) (n=413)		p-value
	Diagnostic	Nondiagnostic	Diagnostic	Nondiagnostic	
Enhancing (>20 HU)	420 (87.1)	59 (71.1)	297 (87.1)	50 (69.4)	
Pseudo-Enhancing (10–20 HU)	18 (3.7)	7 (8.4)	15 (4.4)	7 (9.7)	
Non-Enhancing (<10 HU)	4 (0.8)	9 (10.8)	0 (0.0)	8 (11.1)	
Not Assessible	40 (8.3)	8 (9.6)	29 (8.5)	7 (9.7)	

* n (%) or median (IQR) (unless otherwise noted)

Table 2

Univariate logistic regression variables associated with indeterminate findings in RMB 2000–2014 (n=565)

Feature		OR (95% CI)	p-value
Imaging modality prior to biopsy	MRI	1.06 (0.61–1.84)	0.94
	US	1.19 (0.39–3.59)	
	CT	ref	
Laterality	Left	1.76 (1.10–2.83)	0.02
	Right	ref	
Biopsy guidance imaging modality	CT	0.99 (0.43–2.29)	0.98
	US	ref	
Biopsy type	FNA	1.67 (0.60–4.62)	0.46
	Core	ref	
Exophytic shape	Exophytic	0.71 (0.43–1.16)	0.17
	Endophytic	ref	
Cystic features	Cystic	5.70 (3.36–9.67)	<0.0001
	Solid	ref	
Proximity to liver or spleen	<2cm	0.87 (0.55–1.39)	0.57
	2cm	ref	
Proximity to other organs	<2cm	0.98 (0.61–1.56)	0.93
	2cm	ref	
Renal mass enhancement	20HU	5.18 (2.57–10.42)	<0.0001
	>20HU	ref	
Fat content	Present	1.46 (0.16–13.21)	0.74
	Absent	ref	
Calcifications	Present	0.82 (0.28–2.40)	0.72
	Absent	ref	
Necrosis or hemorrhage	Present	0.86 (0.52–1.43)	0.56
	Absent	ref	
Anteroposterior positioning of mass	Posterior	1.21 (0.76–1.92)	0.43
	Anterior	ref	
Polarity of mass	Inferior pole	0.93 (0.53–1.62)	0.62
	Interpolar	1.23 (0.69–2.19)	
	Superior pole	ref	
Mean axial diameter	4cm	2.71 (1.39–5.26)	0.003
	>4cm	ref	

Feature		OR (95% CI)	p-value
Patient BMI		1.00 (0.97–1.03)	0.90
Skin-to-tumor distance	13cm	2.37 (1.22–4.60)	0.01
	<13cm	ref	
Number of cores obtained		1.06 (0.88–1.27)	0.55

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Table 3

a. Multivariable logistic regression analysis of all renal mass biopsies 7cm (n=565)			
Feature		OR (95% CI)	p-value
Laterality	Left	1.75 (1.02–2.98)	0.04
	Right	ref	
Cystic features	Cystic	4.42 (2.38–8.21)	<0.0001
	Solid	ref	
Renal mass enhancement	20HU	2.84 (1.26–6.41)	0.01
	>20HU	ref	
Mean axial diameter	4cm	2.66 (1.27–5.55)	0.01
	>4cm	ref	
Skin-to-tumor distance	13cm	2.40 (1.15–5.01)	0.02
	<13cm	ref	

3b. Multivariable logistic regression analysis of renal masses 4cm (n=413)			
Feature		OR (95% CI)	p-value
Cystic features	Cystic	4.85 (2.42–9.72)	<0.0001
	Solid	ref	
Renal mass enhancement	20HU	3.57 (1.49–8.52)	0.004
	>20HU	ref	
Mean axial diameter		0.59 (0.39–0.90)	0.01
Skin-to-tumor distance	13cm	2.62 (1.17–5.85)	0.02
	<13cm	ref	

Table 4

Hypothetical improvement in non-diagnostic rate after exclusion of patients with specific features

Criteria	Nondiagnostic Rate (%)
All masses	14.7
Exclude masses with skin-to-tumor distance $\geq 13\text{cm}$	13.5
Exclude masses with enhancement $\geq 20\text{HU}$	12.3
Exclude cystic masses	10.4
Exclude masses with above criteria	8.5