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ARTICLE

Does renal mass biopsy influence multidisciplinary treatment recommendations?

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ABSTRACT

Purpose: To examine how a multidisciplinary team approach incorporating renal mass biopsy (RMB) into decision making changes the management strategy.

Methods: A multidisciplinary team comprised of a radiology proceduralist, a pathologist and urologists convened monthly for renal mass conference with a structured presentation of patient demographics, co-mborbidities, tumor pathology, laboratory and radiographic features. Biopsy protocol was standardized to an 18-gauge core needle biopsy using a sheathed apparatus under renal ultrasound guidance. Biopsy diagnostic rate, and concordance with nephrectomy specimens were summarized. Descriptive statistics were used to evaluate influence of RMB on management decisions.

Results: A total of 83 patients with a $\leq$4 cm mass were discussed, and 66% of patients underwent RMB. Of those, 87% were diagnostic with 9% of core biopsies showing benign pathology. Active surveillance (AS) was recommended for 34% of patients with biopsy data as compared to 64% of those without biopsy. Ablation was recommended for 38% of the biopsy cohort compared to 7% without biopsy. Partial nephrectomy rates were similar for both cohorts, approximately 17% and 22%, respectively. Our complication rate was 1.5%, with only 1 Clavien-Dindo Grade 2 complication. Histology was concordant in 93% of patients that ultimately underwent partial nephrectomy after biopsy.

Conclusions: Over half of our SRM patients underwent a RMB that provided a diagnosis in 85% of cases. RMB aided in shared decision making by providing insight into the biology of renal masses, which helps to guide multidisciplinary management and consideration of nephron sparing options.

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Introduction

Frequent use of cross-sectional imaging has led to increased incidental diagnosis of small renal masses (SRMs). Although the incidence of these SRMs has increased, death rates from metastatic renal cell carcinoma (RCC) have modestly changed, suggesting we are detecting low-risk disease [1–3].

Over the last decade there have been significant changes in the management of SRMs [4]. Ablation therapies are now available at many centers and robotic-assisted partial nephrectomy (PN), available as the da Vinci Surgical System, has provided a minimally-invasive option for patients [5,6]. However, the penetration into worldwide communities of these technologies is variable [7]. Many patients meet criteria for active surveillance (AS), avoiding the morbidity of even these minimally invasive options [8,9].

Treatment decisions involve both provider and patient while incorporating co-morbid conditions, glomerular filtration rate (GFR), life expectancy and tumor factors [10]. However, these are relatively crude variables and decision-making is often steered by physician or patient preference [11]. There is currently no high-level evidence or algorithm to guide physicians.

Further, SRMs are comprised of varying histopathological diagnosis ranging from oncocytoma (benign), chromophobe and papillary type 1 (indolent), clear cell, and papillary type 2 (aggressive). The cancer biology is very different with papillary type 2 and sarcomatoid cancers clearly being more aggressive. For renal cortical tumors less than 3 cm, 24% are benign tumors based on both historic nephrectomy data and more recent RMB studies [12–14]. Having a diagnosis in advance of treatment would allow us to optimize nephron-sparing options. Knowledge of histologic subtype could change management given the different potential for metastasis, yet RMB is not traditionally a prerequisite for treatment, as opposed to breast, pancreas, colon, thyroid or virtually most other cancers. In fact, studies suggest that the current rate of SRM biopsy is that only 7% of SRM despite very high specificity for histologic subtype (97%) [15–18].

As a group, we felt that RMB could provide insight into how best manage these small cortical neoplasms that were not even known to be cancer. In order to address these concerns, we implemented broad inclusion criteria for RMB and standardized our process. We created a multi-disciplinary team to review each SRM that came to urologic attention in

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order to provide diverse opinions related to patient comorbidities and cancer biology. This work presents our findings after initiating a SRM conference informed by increased biopsy rates. Our hypothesis was that RMB would be associated with increased use of AS.

Methods

SRM conference

We assembled a group of physicians from the departments of radiology, pathology and urology to discuss biopsy information and appropriateness for radical nephrectomy, nephron-sparing techniques or AS.

The provider who initially met the patient screened the patient considering size of SRM, patient age and proximity to critical structures. There is no blinding or randomization in this registry study. For masses less than 4 cm, the provider explained the rationale for biopsy explaining the following: 20% of SRM may be benign, the complication rate is less than 2% and we prefer a biopsy prior to ablation to not obscure imaging during the ablation procedure. The patient was allowed to decline. Each monthly conference had time to discuss approximately 15 patients. Accounting for factors including GFR, nephrometry score, location of SRM and its proximity to adjacent structures, pathologic features, age, comorbidities and patient preference, the team debated the merits of each therapy and provided a consensus recommendation. A summary of the discussion and the consensus recommendation was summarized in the electronic medical record by the resident. The provider of record then discussed the recommendation with the patient for shared decision making.

SRM database

We prospectively added consecutive patients identified with SRMs to the database. Thirty-nine variables related to patient demographics, co-morbidities, tumor pathology, laboratory, radiographic features and recommendations were collected into a MySQL database (Supplementary Table 1). GFR was estimated using the Cockcroft–Gault formula [19]. If the following terms were employed by the pathologist, we considered the tumor benign: oncocytic cells, oncocytoma, oncocytic neoplasm or angiomyolipoma. Terms diagnostic of carcinoma included renal cell carcinoma, clear cell carcinoma (ccRCC) or papillary carcinoma. Terms such as suspicious, inflammation/fibrosis or atypia were considered non-diagnostic. While normal kidney tissue could also be non-diagnostic, we did not have any such cases.

Biopsy procedure

The three departments involved convened and standardized the biopsy process based on the consensus statement issued in 2014 [20]. We employed a Biopince 18 Gauge sheathed needle (coaxial) used to obtain 2 or 3 cores. Our intent was to have the biopsies were performed by a core group of three interventional abdominal imaging radiologists; however, staffing constraints did not guarantee adherence to the protocol. All biopsies were reviewed by a specialized genitourinary pathologist. The SRM conference served as a built-in quality control mechanism to refine the process.

Statistics

Characteristics of those who underwent a biopsy compared to those not electing biopsy prior to the conference are presented. Biopsy outcomes including technique, histology, grade and whether a biopsy was considered diagnostic are described. We compared differences in recommendation from the SRM conference and the management a patient received based on whether or not biopsy data were available, using the Fisher's exact test. We considered a patient to be managed with AS if there was a documented note in the EMR that the patient chose AS, or if the SRM conference recommended AS and no intervention was performed within 6 months. Analyses were performed using the R® programming language, version 3.4.3 (Vienna, Austria) and p-values (two-sided) <0.05 considered statistically significant.

Results

RMB

Analysis of patients enrolled from April 2015 and January 2017 revealed a total of 83 unique patients were presented at SRM conference. Table 1 shows the baseline characteristics of patients stratified into biopsy or no biopsy. Thirty-four percent of patients did not have a biopsy. There were no significant differences in demographic information or R.E.N.A.L nephrometry score between the biopsy and non-biopsy groups on univariate comparison. The data depicted in Table 2 represents the patients who underwent a biopsy. We had a total of 67 biopsies; patients who had more than one mass biopsied and those who had the same mass biopsied on separate occasions are included. Fifty percent of core biopsies were ccRCC, and 26% were papillary ($n = 15$) or chromophobe RCC ($n = 2$). Overall the diagnostic rate was 86.6%. We identified benign tumors (oncocytoma) in 9% of cases. Eight (11.9%) showed benign parenchyma, atypical cells or fibrosis and were considered non-diagnostic. Fuhrman Grade 1–4 was assigned in 65% of core biopsies showing ccRCC, and the 2-tier grading system (high or low) was assigned in an additional 12%, for a total of 77% that were able to be graded. All repeat biopsies were diagnostic. For patients who had a core biopsy and went on to PN or RN, the histology was concordant in 14/15 (93%). One patient had ccRCC on biopsy and had urothelial carcinoma on RN. Histologic grade was concordant in 8/11 (72%) cases that were graded on the surgical pathology specimen.

SRM recommendations

SRM consensus and the elected management strategy are classified by biopsy status in Table 3. SRM conference

Table 1. Demographics of Biopsy Population compared to the Non-Biopsy Population.

Baseline characteristics	No biopsy	Biopsy	*p* Value
n	28	55	
Age (%)			0.219
<65 years	16 (57.1)	20 (36.4)	
66–70 years	6 (21.4)	11 (20.0)	
70–75 years	3 (10.7)	13 (23.6)	
>75 years	3 (10.7)	11 (20.0)	
Male (%)	14 (50.0)	37 (67.3)	0.197
GFR, median (IQR)	71 (35, 97)	63 (44, 84)	0.378
Charlson Comorbidity Index (median (IQR))	3 (2, 4)	3 (3, 4)	0.640
BMI, median (IQR)[a]	34 (32, 35)	30 (26, 35)	0.021
>1 Mass (%)	3 (10.7)	7 (12.7)	1.000
Largest mass diameter (%)[b]			0.644
≤3 cm	16 (57.1)	27 (49.1)	
3–4 cm	12 (42.9)	28 (50.9)	
Nephrometry score (%)[b]			0.924
4–6	17 (60.7)	32 (57.1)	
7–9	10 (35.7)	21 (37.5)	
≥10 or hilar	1 (3.6)	3 (5.4)	
Married (%)	19 (67.9)	34 (61.8)	0.764
Smoking status (%)[c]			0.750
Current	4 (14.3)	9 (17.0)	
Former	13 (46.4)	20 (37.7)	
Never user	11 (39.3)	24 (45.3)	
Race (%)			0.109
Caucasian	21 (75.0)	50 (90.9)	
African American	5 (17.9)	4 (7.3)	
Other	2 (7.1)	1 (1.8)	
Insurance (%)[d]			0.544
Private	11 (39.3)	20 (36.4)	
Public	15 (53.6)	33 (60.0)	

[a]30 with missing BMI.
[b]1 with missing pre-operative imaging.
[c]2 with missing smoking status.
[d]1 self-pay in the non-biopsy group, 3 with missing insurance information.

Table 2. Biopsy outcomes.

Biopsy outcomes	
n patients	83
n biopsies total[a]	67
n patients undergoing a biopsy (%)	57 (68.7)
Biopsy Type	
Core biopsy or Core + FNA	57 (100)
Histology (%)	
ccRCC	33 (50.0)
Other RCC subtype	17 (25.8)
Oncocytoma	6 (9.1)
Other neoplasm[b]	2 (3.0)
Atypical cells	2 (3.0)
Benign/fibrosis	7 (9.1)
Grade (%)	
Low	33 (100)
High	0 (0.0)
Diagnostic (%)[c,d]	57 (86.4)

[a]Includes repeat biopsies.
[b]Includes other epithelial neoplasms and urothelial carcinoma.
[c]Defined as any biopsy showing neoplasia (benign or malignant).
[d]Includes one case where FNA was diagnostic of bland oncocytic cells, but core biopsy showed normal renal elements. Therefore, if both FNA and/or core biopsy are used to determine a diagnostic biopsy, we report a 58/67 (87.9%) diagnostic rate.

recommended more varied treatment strategies for those patients who were biopsied, with significantly more ablations; 34%, 38% and 16% of patients who were biopsied were recommended AS, ablation or PN, respectively, compared to 64%, 7% and 18% in those who did not receive a biopsy. Final management strategies mirrored SRM conference recommendations with a few variances. The biopsy group had a decreased actual PN rate compared to the non-biopsy group (22% versus 17%) and more radical nephrectomies (1.9% versus 0%). Table 4 presents the patient demographics and histology findings for the AS patients (separated by biopsy status) compared to ablation and PN. In general, AS patients were older, had smaller masses and had a higher Charlson Comorbidity Index compared to the patients that underwent ablation and PN.

Table 3. SRM recommendations and management strategies by biopsy status.

Management based on renal mass biopsy	No biopsy	Biopsy	*p* Value
n patients	28	55	
SRM Recommendation			0.010
Active Surveillance	18 (64.3)	19 (34.5)	
Percutaneous Thermal Ablation	2 (7.1)	21 (38.2)	
Partial Nephrectomy	5 (17.9)	9 (16.4)	
Radical Nephrectomy	0 (0.0)	0 (0.0)	
No Consensus	3 (10.7)	6 (10.9)	
Management[a]			<0.001
Active Surveillance	19 (70.4)	19 (35.8)	
Percutaneous Thermal Ablation	2 (7.4)[b]	24 (45.3)	
Partial Nephrectomy	6 (22.2)	9 (17.0)	
Radical Nephrectomy	0 (0.0)	1 (1.9)	

[a]Excludes 3 patients with follow up <6 months or lost to follow up.
[b]Two patients had a previous partial nephrectomy specimen used for histology.

Complications

We had only one Clavien-Dindo Grade 2 complication, a subcapsular hematoma requiring overnight hospital observation. This was a rate of 1.5%. This complication rate is very similar to the 2.1% cited by Tolouee et al. [21].

Discussion

While numerous papers have looked at diagnostic rates with RMB, our work specifically attempts to investigate how biopsy may be incorporated into clinical management decisions. Our 68.7% biopsy rate supports our contention that we have been early adopters of RMB. The results from a Norwegian population-based study confirm this is a much higher rate than either their localized rate of 8.4% or their advanced cancer population which had 54.5% [22]. The evolution of our SRM conference has paralleled the change in practice toward early RMB and serves as a quality improvement mechanism including our clinician, pathology and radiology teams. The SRM conference was developed to minimize physician bias, address lack of reliable treatment algorithms, and standardize treatment recommendations to patients in a space with multiple options. Our initial hypothesis posited that concrete pathologic information such as well-differentiated clear cell or oncocytoma would assuage patient fears over prognosis enabling us to steer more patients toward AS. We found that RMB led to increased rates of ablation as opposed to AS supporting the idea that tumor biology did indeed change our clinical management. Upon reflection of these findings, our hypothesis seems naïve and the patient with standard health literacy would

Table 4. Demographics and biopsy-based histology of the AS population separated by biopsy status compared to the Ablation and PN populations.[a]

Management				
	AS no Biopsy	AS with Biopsy	Ablation	PN
n	19	19	26	15
Age (%)				
<65 years	7 (36.8)	4 (21.1)	9 (34.6)	14 (93.3)
66–70 years	6 (31.6)	5 (26.3)	4 (15.4)	1 (6.7)
70–75 years	3 (15.8)	3 (15.8)	9 (34.6)	0 (0.0)
>75 years	3 (15.8)	7 (36.8)	4 (15.4)	0 (0.0)
Male (%)	8 (42.1)	12 (63.2)	19 (73.1)	9 (60.0)
GFR, median (IQR)	60 (33, 95)	57 (45, 68)	72 (46, 84)	92 (45, 107)
Charlson Comorbidity Index, median (IQR)	4 (3, 6)	4 (3, 6)	3 (3, 4)	3 (2, 3)
>1 Mass (%)	3 (15.8)	3 (15.8)	3 (11.5)	0 (0.0)
Largest mass diameter (%)[b]				
≤3 cm	12 (63.2)	11 (57.9)	13 (50.0)	5 (33.3)
3–4 cm	7 (36.8)	8 (42.1)	13 (50.0)	10 (66.7)
Nephrometry score (%)				
4–6	12 (63.2)	15 (78.9)	12 (46.2)	8 (53.3)
7–9	6 (31.6)	4 (21.1)	13 (50.0)	6 (40.0)
≥10 or hilar	1 (5.3)	0 (0.0)	1 (3.8)	1 (6.7)
Histology[c]				
ccRCC	N/A	6 (31.6)	13 (50.0)	5 (33.3)
other RCC subtype		4 (21.1)	5 (19.2)	4 (26.7)
Oncocytoma		3 (15.8)	1 (3.8)	0 (0.0)
Other neoplasm		2 (10.5)	0 (0.0)	0 (0.0)
Atypical cells		2 (10.5)	0 (0.0)	0 (0.0)
Benign/fibrosis		2 (10.5)	1 (3.8)	0 (0.0)

[a]Four patients are not included in this table. Three patients were lost to follow up and the fourth patient underwent a radical nephrectomy.
[b]1 with missing pre-operative imaging.
[c]Remaining patients did not undergo biopsy in the ablation and partial nephrectomy subsets.

choose treatment if any cancer was confirmed. Nonetheless, the paradigm of confirmation of malignancy prior to any intervention is prudent.

The conclusions we can draw from these data are limited by its small sample size, single institution and non-randomized nature. Because our practice emphasizes patient education and shared decision making, we could not initiate a standardized practice mandating that every patient receive RMB. Patients were allowed to choose both whether to undertake a biopsy as well as what treatment they wished to pursue if any. In our cohort, AS was chosen in older patients with smaller masses and more comorbid conditions, in keeping with our multidisciplinary discussion. At the same time, we noted improving outcomes from microwave ablation procedures for SRM [23]. This commonly encountered threat to validity is the inherent difficulty of untangling the impact of the biopsy data on our management recommendation because neither exists in isolation. We believe that the knowledge of the tumor biology and high- or low-grade differentiator inclined us to recommend treatment with the modality least likely to harm kidney function, which in our hands was ablation. This work is not intended to suggest that any one treatment modality is superior to another but rather that knowledge is power. For the 10% who had a benign lesion, RMB changed treatment strategy and we think RMB provides insight into the cancer biology changing recommendations in another third of patients. Our being early adopters of microwave ablation may have confounded our RMB experience. For context, if one looks at the 5-year analysis of the DISSRM registry comprised of three academic centers, 45% of patients chose AS initially. Of the 55% who chose primary intervention, 75%, 13% and 11% chose partial nephrectomy radical nephrectomy and ablation respectively [9]. When this group presented their updated results for the 12% who opted for delayed intervention, again 70% chose a partial nephrectomy, 11% nephrectomy and 20% ablation [24]. Even these groups who felt kidney function was best preserved in their hands by partial nephrectomy may be adopting ablative therapies as the ablative data have matured.

At first glance, the data may suggest that RMB was associated with a higher rate of active treatment compared to AS. The truth is more nuanced: despite our emphasis on patient education and shared decision making many of the patients have strong opinions formed prior to presenting at our practice. Many of the providers have already given the patient a strong preference for treatment for all SRMs, instilling their own prejudices against RMB and AS. When a patient arrives with a pre-formed opinion based on personal biases and anecdotal experiences of providers, family and friends, it may be difficult to dissuade these patients of these beliefs, despite our education efforts using well researched clinical evidence. In addition, our biopsy rates are affected by our initial calculations of tumor biology. Older patients with multiple comorbidities often do not warrant biopsy, thus confounding our results showing the non-biopsy group chose AS more frequently. That said, 20% of our biopsy patients were over 75 years of age suggesting we did individualize our recommendations. We included insurance and race in the analysis in case of unconscious bias but did not find any clear socioeconomic determinants. Similarly, our practice of always obtaining tissue (performing biopsy or prior partial nephrectomy specimen) ahead of ablation may skew the number of biopsy patients opting for that modality. Once we had the definitive knowledge of tumor biology, we lacked the ability

to persuade the patient that surveillance was safe. We may gain experience with AS for SRM malignancies similar to our prostate cancer AS experience. In the future, we may be more equipped to counsel on risks of AS.

RMB is still not widely accepted among practicing urologists; recent reports claim that 32% of practicing urologists claiming they would *never* consider biopsy of a mass $\leq$4 cm [25]. Our work was designed to assuage concerns over low diagnostic rates, failure to differentiate histologic subtype and suggest that RMB influences decision making. We found an acceptable diagnostic rate of 86.6% which is very similar to the rates 81, 88 and 86% described by Faraj et al. [26] for office based, hospital ultrasound guided, and CT guided, respectively.

Although we were attempting to institute broad criteria for biopsy, including any mass that had a less than a 90% likelihood of malignancy on nomograms, we only had a 68.7% biopsy rate. This is still considerably higher than epidemiological findings of 8–10/100,000 reported by Perera et al. [27]. We did not capture information on why biopsy was not performed when recommended, but our suspicion is that patient preference was the most common reason. A smaller subset was due to a patient factor such as anticoagulation or frailty. For example, an octogenarian with a SRM and comorbid conditions would not have been mandated or recommended to get a biopsy.

Our work has several limitations. This was exploratory work after an institutional change, namely the establishment of a SRM conference. Moving forward, we need to employ formal qualitative metrics on patient and provider utilities. We need to standardize the script that providers employ describing the risk benefit profile of RMB. We need to more stringently assess provider recommendation and patient perception *prior* to the SRM conference to identify how the information shaped their thinking. Similarly, we need to specifically capture information on provider rationale for not offering biopsy or patient rationale for refusal. The actual histology information then needs to be incorporated into patient decision aids to ascertain how the pathology influenced the treatment decision. While we attempted to have genitourinary radiologists perform the biopsy, scheduling constraints (e.g. vacation) prohibited this. However, as all of our body radiologists are proficient in tissue biopsy, this is unlikely to have affected the results.

Our data did not support our hypothesis that RMB would lead to increased acceptance of AS, but this work highlights the many challenges facing urologists in treating SRM. In other malignancies, such as pancreas, lung, or liver, emphasis is place on cancer biology to dictate management decisions. Urologists need to undergo a frameshift in our perception of RMB and liken it to these other diseases. We need to change how these data are discussed with patients, similar to the shift towards discussion of AS for low-risk prostate cancer patients.

Conclusion

We found that RMB has a high diagnostic rate and is safe at our institution, and has provided an important clinical parameter regarding biology of renal masses which helps to guide multidisciplinary management of SRMs. RMB was not associated with increased rates of AS, but rather with higher rates of intervention. Further qualitative work may clarify the utility of RMB in shared decision making.

Compliance with ethical standards

The database used in this research was sanctioned by the University of Virginia Institutional Review Board.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study formal consent is not required.

Authors contribution

JM Lobo: protocol/project development, data analysis, manuscript writing/editing; MB Clements: data analysis, manuscript writing/editing, data collection or management; DP Bitner: data collection or management, manuscript writing/editing; SW Noona: data collection or management, manuscript writing/editing; MI Sultan: data collection or management; MD Mikula: data collection or management, manuscript writing/editing; HP Cathro: data collection or management, manuscript writing/editing; DL Lambert: data collection or management, manuscript writing/editing; NS Schenkman: protocol/project development, manuscript writing/editing; TL Krupski: protocol/project development, data analysis, manuscript writing/editing.

Disclosure statement

The authors declare they have no conflicts of interest to report.

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