

# Perspectives on the Role of Biopsy for Management of T1 Renal Masses: Survey Results From Two Regional Quality Improvement Collaboratives

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<b>OBJECTIVE</b>	To understand perspectives on renal mass biopsy, a survey was distributed to urologists in the Michigan Urological Surgery Improvement Collaborative and Pennsylvania Urologic Regional Collaborative. Renal mass biopsy (RMB) may reduce treatment of benign renal neoplasms; however, utilization varies widely.
<b>MATERIALS AND METHODS</b>	Michigan Urological Surgery Improvement Collaborative and Pennsylvania Urologic Regional Collaborative are two quality improvement collaboratives that include a “real-world” collection of urologists from academic- and community-based settings. A 12-item survey assessing current RMB utilization, patient- and tumor-specific factors, adverse events, impact on management, and simulated patient scenarios was distributed. Responses are reported using descriptive statistics.
<b>RESULTS</b>	Many responders (n = 54) indicated using RMB in less than 25% of cT1a (59%) and cT1b (85%) tumors. The most important patient-specific factors on the decision to recommend RMB were possible metastasis to the kidney (94%), patient comorbidity as a risk factor for active treatment (89%), and patient age (81%). The most important tumor-specific factors were the presence of bilateral tumors (81%), tumor size (70%) and perceived potential of performing nephron-sparing surgery (67%). Ten responders (19%) noted barriers to RMB in their practice, 23 (43%) recalled experiences with complications or poor outcomes, and 43 (80%) reported experiences where the results of RMB altered management. When presented with simulated patients, few urologists (9%-20%) recommended RMB in younger patients with any sized mass. Recommendations varied based on patient age, comorbidity, and tumor size.
<b>CONCLUSION</b>	Understanding perspectives on RMB usage is essential prior to implementing quality improvement efforts. Most urologists participating in two statewide collaboratives infrequently recommend RMB. Optimizing RMB utilization may help reduce unnecessary treatments. UROLOGY 00: 1–6, 2022. © 2022 Elsevier Inc.

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**K**idney cancer contributed >431,000 new cancer diagnoses worldwide in 2020 with nearly 200,000 deaths.<sup>1</sup> Determining the optimal strategy when counseling patients with a clinical T1 renal mass (cT1RM) is not straightforward, with many competing factors to consider.<sup>2</sup> Many patients and providers pursue surgical removal upon discovery of a suspicious cT1RM,<sup>3</sup> yet a non-insignificant number of these tumors are benign on final pathology.<sup>4,5</sup> These avoidable surgeries represent an overall risk to individual patient morbidity and mortality as well as inherent costs to the healthcare system.<sup>6</sup> Despite American Urological Association (AUA) guidelines,<sup>7</sup> surveillance is uncommonly offered to patients (6.4%-19.2%) with cT1aRM ( $\leq 4$  cm) based on reports from SEER and other national databases,<sup>3,8,9</sup> with two contemporary studies also including patients with

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1

cT1bRM (>4 to 7 cm) (surveillance rates 6.8%-11%).<sup>10,11</sup> Rates of partial nephrectomy, instead of radical nephrectomy, for cT1RM have been increasing in recent years,<sup>3</sup> which limits renal functional loss; but nephrectomy of any kind, instead of surveillance, still carries the risks of morbidity and mortality from surgery.<sup>6</sup> A goal of quality improvement collaboratives, such as the Michigan Urologic Surgery Improvement Collaborative (MUSIC) and the Pennsylvania Urologic Regional Collaborative (PURC), is to determine how to optimize care for each individual patient and distribute this learning to the urologic community.

Renal mass biopsy (RMB) has the potential to reduce unnecessary treatment for benign tumors and better inform patient selection for surveillance.<sup>12,13</sup> It is safe and can be performed in an ambulatory setting.<sup>14,15</sup> Despite noted benefits and promising safety profile, utilization of RMB remains limited and highly variable between providers.<sup>16</sup> Even the 2017 AUA guidelines give great latitude to the provider regarding which patients to biopsy, stating that “In the setting of a solid renal mass, RMB is not required for: (1) young or healthy patients who are unwilling to accept the uncertainties associated with RMB; or (2) older or frail patients who will be managed conservatively independent of RMB findings.”<sup>7</sup> It is unclear which factors prompt providers to recommend RMB. Consensus on which patients are most likely to benefit from RMB is also unclear, as it is likely not necessary in all, or even most, patients.<sup>17</sup> Further, although use of RMB is increasing,<sup>18</sup> current U.S. practice patterns likely underutilize this modality in the diagnostic algorithm.<sup>19</sup> Better understanding of perspectives on RMB could help determine optimal practice.

To address this knowledge gap, a survey was distributed to urologists at two statewide quality improvement collaboratives. These collaboratives are composed of urologists from diverse settings, both community- and academic-based, and capture a representative “real-world” sampling of urologic practice. Herein, we qualitatively describe the current perspectives on RMB including the patient- and tumor-specific factors that may be more likely to prompt RMB and provider perspectives on simulated patient scenarios.

## MATERIALS AND METHODS

### Survey Population - Quality Improvement Collaboratives

MUSIC was created with support by Blue Cross Blue Shield of Michigan to design quality improvement efforts aimed at improving urologic care in the state of Michigan. MUSIC includes over 200 Urologists from 50 practices.<sup>20</sup> In 2016, MUSIC established Kidney mass: (Identifying and Defining Necessary Evaluation and therapy (MUSIC-KIDNEY) as a quality improvement initiative for patients with renal masses  $\leq 7$  cm (cT1RM).<sup>21</sup> PURC was established in 2015 with funding in part from the Partnership for Patient Care/Health Care Improvement Foundation. PURC includes 140 Urologists from 11 practices in Pennsylvania and 2 practices in New Jersey.

### Survey Design Process

A 12-item survey was designed and distributed electronically from the MUSIC coordinating center to all active participants in MUSIC and PURC (see [Supplemental Data](#)). Questions were developed by members of the MUSIC-KIDNEY working group and the co-directors of MUSIC-KIDNEY gave final approval on survey design. Following approval, the MUSIC coordinating center distributed the online survey via email. We did not attempt to pretest the survey outside of the KIDNEY working group or attempt to account for non-response bias.

### Survey Content

The first two questions assessed urologist’s RMB utilization patterns for patients with cT1a and cT1b tumors. Respondents then reviewed four patient scenarios assuming all masses were solid, enhancing, and in an RMB amenable location. Simulated patients included a 45-year-old healthy patient, a 60-year-old at risk for CKD, a 60-year-old with CKD, and an 80-year-old sickly patient. Scenarios asked whether RMB would be recommended for tumors 1-, 2-, 4- and 6-cm for each simulation.

Urologists next identified levels of importance for six patient-specific factors and six tumor-specific factors in deciding to recommend RMB. Patient factors included: age, comorbidity, patient preference, anticoagulation use, previous treatments, and possible metastasis to kidney. Tumor factors included: size, location, complexity, cystic features, bilaterality, and nephron-sparing-surgery potential. Relative importance was gauged for each factor using 5-point Likert-styled questions, ranging from “not important” to “very important” and included the option to respond with “no opinion”. Responses of “important” and “very important” were combined when reporting results.

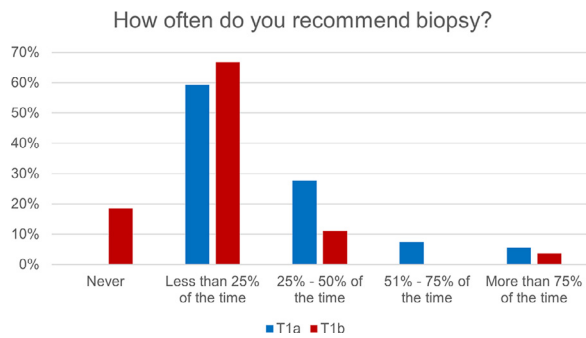
Next, the survey assessed potential barriers to RMB. Providers were asked what the likelihood of them performing RMB in clinic would be on a 5-point Likert scale ranging from “none” to “very likely”. Finally, providers were asked about their experience with adverse outcomes or altered management following RMB and to provide examples.

The aim of this study was to use descriptive statistics to qualitatively describe the responses to each survey question and thus capture a representative picture of provider beliefs across the two collaboratives. We collected the number and percentage of survey participants who responded to each question and report the results accordingly. We present this study in alignment with STROBE guidelines, as applicable, adapted for cross-sectional surveys.<sup>22</sup>

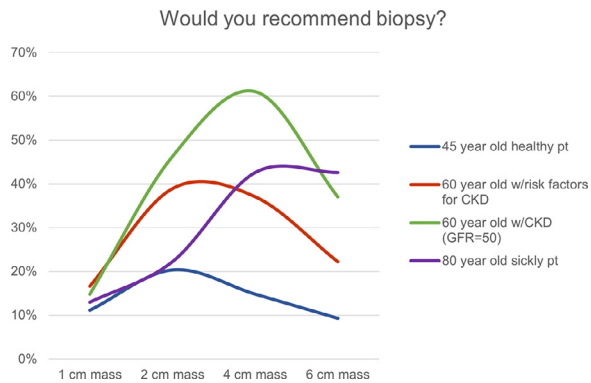
## RESULTS

In total, 54 urologists responded, representing a 15.9% response rate. For cT1a and cT1b tumors, respectively, 0% and 19% indicated they would never pursue RMB, 59% and 67% pursue RMB less than 25% of the time, 28% and 11% pursue RMB 25%-50% of the time, 7% and 0% pursue RMB 51%-75% of the time, and 6% and 4% pursue RMB >75% of the time ([Fig. 1](#)).

Recommendations for the simulated patient scenarios varied based on the select combination of tumor size and patient health ([Fig. 2](#)). Few recommended RMB for the 45-year-old patient (9%-20%). The only scenario with over 50% of urologists recommending RMB was the 60-year-old patient with CKD and a 4-cm tumor (61%). Recommendations for RMB for this hypothetical patient ranged from 15% for the 1-cm mass to 61%. For the 60-year-old at risk for CKD, recommendations ranged from



**Figure 1.** Frequency of recommendations for renal mass biopsy (RMB) for T1a and T1b masses. (Color version available online.)



**Figure 2.** Recommendations for renal mass biopsy (RMB) based on simulated patient scenarios. (Color version available online.)

17% for a 1-cm mass to 39% for a 2-cm mass. Finally, recommendations for the 80-year-old sick patient ranged from 13% for the 1-cm mass to 43% for both the 4- and 6-cm masses.

The most reported patient factor was the mass representing possible metastasis, which 94% of urologists described as “important” or “very important” in their decision to recommend RMB (Fig. 3). Patient comorbidity (89%), age (81%), and patient

preference (80%) were also commonly reported. Previous treatment history (54%) and anticoagulant use (44%) were less commonly reported.

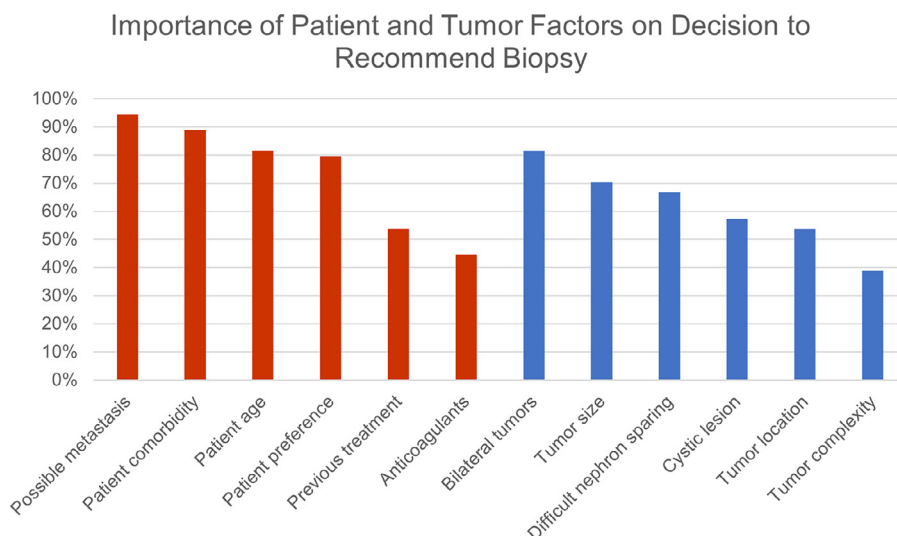
The most common tumor factor reported to impact the decision to perform RMB was the presence of bilateral masses (81%). This was followed by tumor size (81%), difficulty to perform nephron sparing surgery (67%), cystic features (57%), tumor location (54%), and tumor complexity (39%).

Ten (19%) urologists reported a perceived barrier to RMB: 8 reported concerns with collecting or interpreting the biopsy, 1 suggested the potential of definitive treatment being delayed, and 1 responded “Other” but did not expand further. Most (41, 75.9%) responded they were unlikely to consider performing RMB in clinic (“none” or “not likely”).

Regarding experience with post-RMB adverse effects and circumstances in which RMB impacted management; 23 (43%) reported experiencing an adverse outcome after RMB, most commonly excessive bleeding (n = 18). Also reported was pseudoaneurysm (n = 2), pneumothorax (n = 1), fistula (n = 1), and local recurrence (n = 1) after RMB. Most (n = 45, 83%) recalled an experience when RMB altered management, 32 recalled RMB leading them to avoid surgery altogether, including 17 who specifically mentioned RMB diagnosing oncocytoma. Other examples include 8 mentioned diagnosing metastasis from another primary cancer and 1 found an aggressive tumor in an elderly patient prompting radical nephrectomy.

**DISCUSSION**

The AUA guidelines avoid prescriptive statements regarding RMB for solid renal masses. The 2017 guidelines state that “RMB is not required for (1) young or healthy patients who are unwilling to accept the uncertainties associated with RMB; or (2) older or frail patients who will be managed conservatively independent of RMB findings.” The 2021 update adds the statement that, “In the setting of a solid renal mass, RMB should be obtained on a utility-based approach whenever it may influence management,” continuing to give great latitude to physicians



**Figure 3.** Importance of individual patient (Red) and tumor factors (Blue) on provider decision to recommend biopsy. (Color version available online.)

managing such patients.<sup>7</sup> By leveraging membership in two active U.S. urology collaboratives, this survey is uniquely able to capture a “real-world” sampling of perspectives on RMB, which should allow for the results to be generalizable to many practicing urologists (at least in the United States). In addition, subsequent analyses of actual use of RMB and QI activities within these collaboratives are ways to further engage these same practitioners. We established current practice patterns of RMB for cT1RM, captured how recommendations change based on patient and tumor status via simulated patient scenarios, and assessed factors that may prompt urologists to recommend RMB.

Most urologists in this survey study reported using RMB infrequently. For cT1aRM, 13% stated they use RMB over 50% of the time and only 4% answered the same for cT1bRM. MUSIC-KIDNEY collects data on RMB utilization, with 167 RMB in 965 patients (17.3%) recorded in our most recent analysis of registry data.<sup>23</sup> As the completed surveys were anonymous, we cannot compare survey responses to individual provider practice. Further work could be taken to analyze whether actual biopsy utilization reflects the factors suggested to be important in this study. Urologists in these two collaboratives may be more favorable toward RMB when compared to members of the AUA at large.<sup>24</sup> Patel et al reported that 31.8% of urologists would never consider RMB for cT1a tumors, while in our collaboratives no respondent indicated they would never consider RMB for tumors of that size. However, 59% would rarely (<25%) use RMB for cT1a masses which may reflect differences in survey design rather than practice.

Identifying factors that influence providers' decisions to recommend RMB is necessary to examine possible selection biases in current datasets evaluating RMB and surgery for cT1RM. Important factors for considering RMB share considerable overlap with those that impact treatment decisions.<sup>3</sup> Perhaps unsurprisingly, patient age (81%) and comorbidities (89%) were important, along with the possibility of the tumor being a metastasis (94%). Importantly, our simulated patient exercises demonstrate that these are not linear relationships (increasing age  $\neq$  higher likelihood to biopsy, more comorbidity  $\neq$  more likely to biopsy), and instead emphasizes the multifactorial decision-making as opposed to directionally directed by any individual factor. Younger patients were uncommonly recommended to undergo RMB (9%-20%). Presumably, these patients were felt to benefit from treatment regardless of biopsy results. Sicker, elderly patients with smaller masses were also unlikely to be recommended RMB (13%-22%), as they may be more suitable for imaging-based surveillance or watchful waiting independent of the results of RMB. These clinical practice patterns have been surmised in AUA guidelines,<sup>7</sup> but our survey captures this information directly using specific benchmark patient scenarios. Along with age and comorbidities, sex and race have been described as factors that impact RMB utilization,<sup>25</sup> which may reflect perceived differences in tumor

incidence and biology. Tumor size and complexity, as well as the potential for nephron sparing surgery, also influence RMB decisions. RMB utilization in the Clinical Research Office of the Endourological Society Small Renal Mass registry was 11.6% prior to extirpative surgery.<sup>26</sup> Biopsy was more commonly performed in patients with higher co-morbidities, multiple/bilateral tumors, or other malignancies. Shahait and colleagues found higher rates of pathological upstaging to pT3a in the RMB cohort and use of radical nephrectomy was higher than in patients undergoing surgery without prior RMB, as has been reported. Previously, in each of the prior studies, it is the minority of patients that are undergoing RMB,<sup>12,13,15,16,26</sup> consistent with the findings in this study.

Despite the results presented within, it remains unclear what potential combinations or cut-offs of these factors providers should use. For example, many providers view cystic masses as a contra-indication for RMB, while others offer it. Cystic features have been noted to be independent predictors of non-diagnostic RMB<sup>27</sup> and recommendations could more specifically state how to incorporate cystic findings into decision-making. Working groups for the European Association of Urology developed a model to help determine optimal candidates for RMB<sup>28</sup> but noted that it is incomplete regarding patient factors that may influence RMB recommendations. Efforts are underway within MUSIC to define patients that are likely to benefit from surveillance; a similar methodology could be applied to determine which patients may benefit from RMB. Together, these decision support tools can help determine how to incorporate RMB and subsequent results into a decision to pursue surveillance.

For seven of the twelve scenarios presented, between 37% and 61% of providers recommended RMB, suggesting differences of opinion that may be better elucidated by dialogue. Within our collaboratives, we have opportunities to do this at collaborative meetings, virtual meetings, and panel discussions. Following discussion, providers would likely benefit from updated, evidence-driven guidance on which groups of patients should undergo RMB. Utilizing the power of the collaborative to gather this evidence and generate consensus are future directions that the MUSIC-KIDNEY group has interest in studying.

Around one-fifth of respondents noted barriers to RMB and almost half recalled adverse outcomes following RMB. The largest barrier was concern with collecting and interpreting RMB. This may reflect the dual concerns of the noted rate of non-diagnostic procedures and the potential for procedural complications.<sup>29</sup> This represents an opportunity for multidisciplinary collaboration; multiple viable outcomes exist, including innovative machine learning technologies that could help pathologists interpret samples in the future. RMB workshops could be facilitated by the collaboratives to improve proficiency with the procedure. Alternatively, urologists could learn a technique for in-office biopsy that is gaining in popularity across the country.<sup>14</sup> Regarding potential adverse events, the data shows that RMB is safe, with serious

complications being rare,<sup>15,29</sup> although the recorded anecdotes indicate that adverse outcomes have the potential to delay or escalate care. Notably, many urologists reported an instance in which RMB influenced management, including 32 (59% of respondents) who recalled circumstances in which RMB led patients to avoid surgery. This supports the overarching goal to optimize care for each individual patient and reduce unnecessary treatments. Additionally, the use of initial observation (at least 120 days) within MUSIC is higher than observed in most other reports (53.5% for cT1a and 29.9% for cT1b),<sup>23</sup> which perhaps suggests our collaboratives' focus on decision-making for cT1RM may be impacting treatment selection for contemporary patients.

It is worth discussing this study's limitations, including the inherent limitations of surveys. Although we leveraged two large quality improvement collaboratives to capture "real-world" perspectives on RMB, not every provider completed the survey, and these results are subject to bias from response rate. The results are also subject to recall bias; providers' memory of their current RMB practice patterns may differ from their actual practice. We did not attempt to analyze provider demographics that may be associated with utilization of RMB (such as academic vs private practice), as this was an anonymous survey, but this is a concurrent area of study. The generalizability of the study may be limited by its inclusion of only U.S. urologists. It must also be mentioned that this survey was not designed to capture how often a RMB influences management. Instead, we note that RMB can influence management, but how often this occurs is a fair question to ask.

This study has important implications for future quality improvement efforts. Ultimately, within our collaboratives, the goal is to provide the optimal treatment for each individual patient. We were able to gain better understanding of current provider perspectives regarding RMB and identify areas for future study and intervention. The results were a focus of discussion at a MUSIC collaborative-wide meeting, and we have planned a consensus panel based on the Rand methodology<sup>30</sup> in follow-up to propose criteria in who to recommend biopsy. Additionally, identifying how providers would respond to a negative or inconclusive biopsy considering the known, limited negative predictive value could help guide preoperative planning. These steps to identify which patients are most likely to benefit from RMB and how to best incorporate RMB into clinical care pathways will likely shift the balance to maximize patient benefit while minimizing non-diagnostic examinations and adverse outcomes.

## CONCLUSION

We describe the results of a survey distributed to urologists participating in one of two large Quality Improvement Collaboratives designed to capture perspectives on RMB. Urologists currently practice limited use of RMB and

identified that age, comorbidity, and tumor size, among other factors, impact utilization. Efforts to better understand the optimal use of RMB and the barriers to greater implementation of RMB are future quality improvement initiatives.

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## SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.urology.2022.01.038>.

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