Development of a Novel Scoring System Quantifies Opportunities to Reduce Surgery for Benign Renal Neoplasms: A Retrospective Quality Improvement Analysis within the MUSIC-KIDNEY Collaborative

Henry Peabody IV, Amit Patel, Anna Johnson, Mahin Mirza, Sabrina L. Noyes, Edward Schervish, Sanjeev Kaul, Craig G. Rogers, Brian R. Lane and Alice Semerjian* for the Michigan Urological Surgery Improvement Collaborative

From Spectrum Health Hospital System (HP, SLN, BRL), Grand Rapids, Michigan, Henry Ford Health System (AP, CGR), Detroit, Michigan, Michigan Medicine (AJ, MM, MUSIC), Ann Arbor, Michigan, Michigan Institute of Urology (ES), St. Clair Shores, Michigan, Comprehensive Urology (SK), William Beaumont Hospital, Royal Oak, Michigan, Michigan State University College of Human Medicine (BRL), Grand Rapids, Michigan, and IHA Urology (AS), St. Joseph Mercy Hospital, Ann Arbor, Michigan

Abbreviations and Acronyms

AML = angiomyolipoma
AS = active surveillance
cT1RM = cT1 renal masses
MUSIC = Michigan Urological Surgery Improvement Collaborative
NMP = nonmalignant pathology
PN = partial nephrectomy
QI = quality improvement
RCC = renal cell carcinoma
RMB = renal mass biopsy
RN = radical nephrectomy
SRM = small renal mass

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* Correspondence: Saint Joseph Mercy Ann Arbor Hospital, Ann Arbor, Michigan (email: asemerjian@gmail.com).

Purpose: Nonmalignant pathology has been reported in 15% to 20% of surgeries for cT1 renal masses. We seek to identify opportunities for improvement in avoiding surgery for nonmalignant pathology.

Materials and Methods: MUSIC-KIDNEY started collecting data in 2017. All patients with cT1 renal masses who had partial or radical nephrectomy for nonmalignant pathology were identified. Category for improvement (none—0, minor—1, moderate—2 or major—3) was independently assigned to each case by 5 experienced kidney surgeons. Specific strategies to decrease nonmalignant pathology were identified.

Results: Of 1,392 patients with cT1 renal masses 653 underwent surgery and 74 had nonmalignant pathology (11%). Of these, 23 (31%) cases were cT1b. Radical nephrectomy was performed in 17 (22.9%) patients for 5 cT1a and 12 cT1b lesions. Only 6 patients had a biopsy prior to surgery (5 oncocytoma, 1 unclassified renal cell carcinoma). Review identified 25 cases with minor (34%), 26 with moderate (35%) and 10 with major (14%) quality improvement opportunities. Overall 17% of cases had no quality improvement opportunities identified (12 partial nephrectomy, 1 radical nephrectomy).

Conclusions: Review of patients with cT1 renal masses who underwent surgery for nonmalignant pathology revealed a significant number of cases in which this outcome may have been avoided. Approximately half of cases had moderate or major quality improvement opportunities, with radical nephrectomy for nonmalignant pathology being the most common reason. Our data indicate a lowest achievable and acceptable rate of nonmalignant pathology to be 1.9% and 5.4%, respectively. Avoiding interventions for nonmalignant pathology, particularly radical nephrectomy, is an important focus of quality improvement efforts. Strategies to decrease unnecessary interventions for nonmalignant pathology include greater use of repeat imaging, renal mass biopsy and surveillance.

Key Words: quality improvement, nephrectomy, kidney, biopsy

An estimated 73,750 new cases of kidney cancer and 14,830 deaths from kidney cancer will occur in 2020.[1] With the ubiquitous use of cross-sectional imaging has come the increased diagnosis of incidentally discovered small renal masses. However, despite this increased detection

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of SRMs, the mortality resulting from renal cell carcinoma remains unchanged.[2,3] As a result, significant overdiagnosis results in removal of SRMs that may not ever pose a threat to an individual patient. Unfortunately, radiological characteristics are commonly the only information guiding management and alone cannot identify malignant pathology. Previous studies have reported benign pathology rates between 15% and 20% in cT1a and 10% of cT1b masses after invasive surgical resection.[4–7] Furthermore, the rate of surgically resected benign masses has increased significantly in the United States in recent years, an almost 80% increase from 2000 to 2009.[4]

Resection of nonmalignant pathology is a potential unintended outcome of partial and radical nephrectomy for treatment of suspected RCC. Several consequences can result from unnecessary treatment, including overall morbidity reaching 15%, with complication rates (Clavien 3 or greater) of 5% or higher.[8] The risks of postoperative complications, loss of kidney function and even need for dialysis, and ongoing reductions in quality of life, can be substantial, especially in patients who have preexisting and other comorbid conditions. Additionally, Johnson et al estimated that a noteworthy 5,000 cases and associated costs burden the U.S. health care system yearly along with exposing patients to unnecessary costs, risks and harms that are associated with nephrectomy for NMP.[4]

Currently, no literature exists investigating quality improvement opportunities for minimizing intervention for NMP, which is a critical issue in the management of cT1RM. The objectives of this study are to 1) define a classification system for grading the appropriateness of surgical intervention, 2) define opportunities for QI using a defined scoring system and observe which elements in management most influenced scoring, and 3) quantify acceptable and unavoidable NMP rates.

MATERIALS AND METHODS

The Michigan Urological Surgery Improvement Collaborative is a physician led QI consortium established in 2011 and funded by Blue Cross Blue Shield of Michigan. MUSIC includes 45 practices across the state of Michigan, representing approximately 90% of the urologists in the state. In 2017 MUSIC began collecting data for cT1 renal masses for the Kidney mass: Identifying and Defining Necessary Evaluation and therapY (KIDNEY) initiative. To date, more than 13 practices within the MUSIC collaborative have contributed data to the MUSIC-KIDNEY database. Trained data abstractors review medical records of all patients with cT1 renal masses and enter new cases into a web based registry. Each MUSIC practice obtained approval or exemption for collaborative participation from a local institutional review board.

All patients with cT1RM in the MUSIC-KIDNEY registry who had undergone RN or PN for NMP were identified. Routinely available information included patient age, comorbidities, the urologist's plan, radiology reports, operative notes and pathology reports from biopsy (if done) and extirpation. These were reviewed for each individual case. Some notes contained RENAL (Radius, Exophytic/endophytic, Nearness of tumor to collecting system or sinus, Anterior/posterior, Location relative to polar lines) complexity scores and some others were retrospectively scored. All charts were de-identified and independently reviewed by 5 experienced, fellowship trained urological kidney surgeons and assigned to categories for improvement (none—0, minor—1, moderate—2 or major—3). No guidelines or examples were given to the surgeons prior to review. The cases were subjectively scored and comments were collected on each case. The pooled scores for each case were then calculated and opportunities for improvement were categorized by the average score, with a score of 0 (none), 0.1 to 1 (minor), 1.1 to 2 (moderate) and 2.1 to 3 (major). Comments from reviewers were pooled by category and common themes among cases in each group were identified. Acceptable rate of NMP includes cases that did not qualify as moderate or major QI opportunity scores divided by total surgical cases. This allows for some margin of error, understanding that in real practice case and patient specific factors do not always allow for ideal management. Tallying numbers of cases that had a score of 0 (no opportunity for improvement) demarcated cases in which NMP was inevitable.

RESULTS

Of 1,393 patients with cT1RMs 654 (47%) underwent surgical intervention. De-identified charts belonging to 74 patients who had surgery for NMP were reviewed individually. Of these, 17 resulted in RN and 57 in PN, overall comprising a NMP rate of 11.3% for all surgeries performed. Approximately half of the cases had moderate (1.1-2) or major (2.1-3) QI opportunities. Overall 17% (13) of cases had no room for improvement with a score of 0, 34% (25) had a score of minor (0.1-1), 35% (26) had a score of moderate (1.1-2) and 14% (10) had a score of major (2.1-3). Thus, the lowest achievable rate of NMP (QI score 0) was 1.9% as defined by these criteria. When expanding to include cases with a score indicating a minor QI opportunity (0.1-1), 5.4% is the acceptable rate of NMP at final pathology.

As expected, rates of NMP were higher for patients with smaller mass size and female sex. In masses 0 to 3 cm and 3.1 to 5 cm alike, 13% of masses were found to be benign. This decreased to 6% in 5.1 to 7 cm masses. When comparing cT1a and cT1b renal masses, the benign incidence was 12% and 11%. In women 16% of resected masses were benign, with the most common histologies being oncocytoma (34%) and angiomyolipoma (34%).

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Conversely, in men only 9% were benign, with 73% oncocytoma and 15% benign cyst.

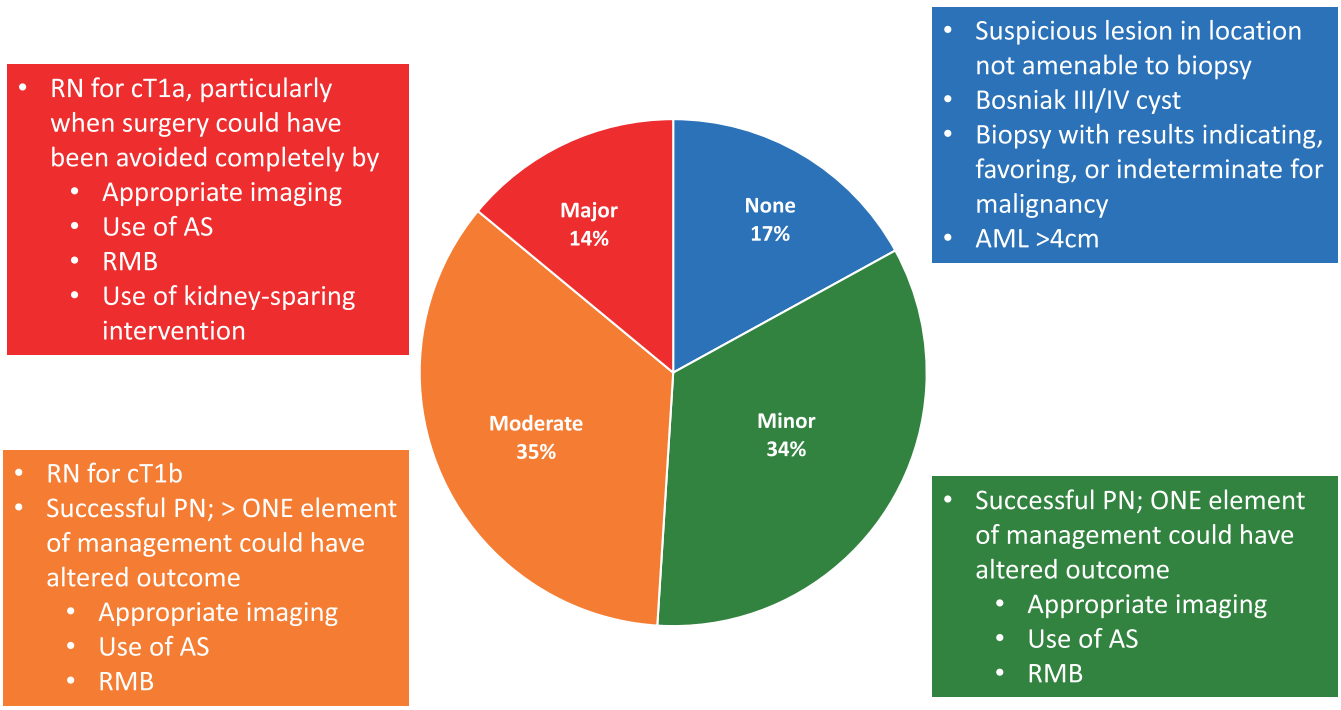
The most common reason that a case scored as having a moderate or major QI opportunity was RN for NMP (16). Additionally, this factor had the greatest agreement across reviewers. While 36% (21) of PN for NMP resulted in a moderate/major score, an overwhelming majority (94%, 16) of RN resulted in moderate/major QI opportunities. Evaluation of the factors associated with moderate/major (vs none/minor) QI opportunities found surgery type to be highly significant, with only minor differences in age (less than 70 and 70+ years), size (less than 2 cm, 2 to 4 cm, greater than 4 cm), clinical radiological impression (solid, complex cyst, indeterminate) and sex. Additional reasons for moderate or major QI category designation included patients with indeterminate imaging (no renal protocol reimaging); those who may have benefited from renal mass biopsy, active surveillance or both; intervention for small angiomyolipoma; or surgery resulting in RN for AML (see figure). The table further quantifies QI opportunity by category.

RMB was performed in 228 patients (16%) in the MUSIC-KIDNEY cohort overall. Of patients with RMB 45% (102) went on to have surgery, with a NMP rate of 5.0% (6), whereas 47% (552) of patients who did not undergo RMB went on to surgery, resulting in a NMP rate of 13% (70). When looking at moderate and major QI opportunities, the lack of RMB influenced outcome in 21 of 36 patients. Along the same lines, 19 patients who underwent surgery appeared to be appropriate candidates for AS based on age and comorbidity.

DISCUSSION

The MUSIC-KIDNEY collaborative allows for a unique platform to identify QI opportunities in the management of RMs statewide across various practice types and settings. Retrospective analysis of all patients with cT1RM with benign pathology after surgery in the MUSIC-KIDNEY registry identified the lowest achievable and acceptable rate for NMP. Furthermore, classification of management strategies as QI opportunities according to score were identified. To our knowledge, no such scoring system exists in the literature for kidney cancer or urology.

When scores were pooled as none, minor, moderate and major, certain themes appeared. In the "none" category, NMP at surgery occurred with resection of 1) appropriately characterized lesions in a location not amenable to biopsy, 2) young age and patient preference, 3) AML greater than 4 cm, and 4) masses that were biopsied with results favoring malignant or indeterminate pathology were common. NMP was considered unavoidable in these cases. Cases scoring as minor typically were those resulting in successful PN, but one element of management (performance of RMB, appropriately obtaining additional imaging, or use of AS) may



Breakdown of quality improvement opportunities by category

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QI category	QI Opportunity	No.
None: 0		
	Malignant or indeterminate RMB	3
	Known AML greater than 4 cm	3
	Young age/pt preference	3
	Same time as another abdominal surgery	2
	Not amenable to RMB	1
	Progression on AS	1
Minor: 0.1—1.0		
	No RMB	18
	Imaging indeterminate, PN performed	3
	Despite benign RMB pt preference, PN performed	2
	Indeterminate imaging, cystic mass (no RMB)	1
	AS candidate	1
Moderate: 1.1—2.0		
	No RMB + AS candidate	12
	No RMB + RN performed	6
	Indeterminate imaging + RN performed	3
	Known small AML less than 2 cm	2
	Indeterminate imaging + AS candidate	2
	Benign RMB + AS candidate	1
	Benign RMB + less than 2 cm size	1
Major: 2.1—3.0		
	No RMB + AS candidate + PN feasible, RN performed	2
	Known Bosniak 2F cyst	2
	AS candidate + RN performed	2
	Known AML + RN performed	1
	Indeterminate imaging + RN performed	1
	Known small AML less than 2 cm + increased perioperative risks	1
	Indeterminate imaging + cT1a + no RMB, RN performed	1

have resulted in a different outcome, eg imaging was not definitive for a solid, enhancing lesion or surgery was performed for a tumor less than 3 cm in a patient with life expectancy less than 5 years or with significant medical comorbidity.[9] Cases scoring as moderate tended to include those in which more than 1 management strategy could have been used (such as surveillance for a cT1a mass in an elderly patient with comorbidities to whom RMB was not offered), or those in whom RN was performed for cT1b masses. Major QI opportunity cases were characterized by patients with NMP who underwent RN for cT1a masses or when surgery was deemed to be avoidable completely. Multiple areas are identified as potential opportunities for improvement to drive a decrease in resected NMP.

AS has been identified as a safe and effective initial management strategy for select SRMs with comparable long-term cancer specific survival to surgical and ablative therapies, nearing 100%.[10] Moreover, kidney function remains unaffected. Although overall survival is worse in cohorts of patients who have undergone AS, this is generally attributed to appropriate selection based on age and comorbidities, rather than a treatment effect.[9] AS is used to safely treat incidentally found SRMs and spare patients unnecessary surgery, and has been advised in the most recent AUA (American Urological Association) guidelines.[11] Patients and providers alike can be reassured that the risk of synchronous metastasis in patients with SRMs less than 3 cm is exceedingly low, at less than 1% in most large series.[12] Furthermore, Umbreit et al noted 3-year metastasis-free survival and cancer specific survival rates after intervention to be 100%, 98.8%, 98.2% and 100%, 99.7% and 99.3%, for masses 0 to 2, 2 to 3 and 3 to 4 cm, respectively.[13] Despite these facts, AS remains underutilized. The percentage of patients managed with AS remains stable as more patients undergo surgical management each year for SRMs.[14,15] Even among patients initially electing for AS, about 50% of who later elect for delayed intervention cross over for reasons related to anxiety alone, without meeting clinical progression criteria. This further highlights the need for effective counseling to aid patient comfort with AS.[16]

The AUA guideline statement makes some recommendations on when RMB may be useful. However, no clear consensus exists, except that RMB should be used only when it will change management.[9] Our review makes the case for greater use of RMB, especially for patients in whom RN is planned or likely based on tumor complexity or size. Rates of RMB are variable, but approach 20% in patients with cT1a tumors.[17,18] Clinical utility of RMB is somewhat limited by the nondiagnostic rate (14%) and poor specificity for high grade versus low grade disease secondary to tumor heterogeneity (50%).[19,20] Nevertheless, RMB has excellent specificity, sensitivity and positive predictive value for detecting cancer (97.5%, 96.2% and 99.8%, respectively) with a low complication profile.[18] Given the high accuracy for differentiation between benign and malignant masses, RMB can be useful to decrease NMP. The National Cancer Database and other studies show an association between RMB and nonsurgical management (36.8% following RMB vs 11.4% in patients without RMB), although use remains relatively low.[15,21] Similarly, analysis of the MUSIC-KIDNEY registry revealed a decrease in NMP in patients undergoing RMB (5.0%) when compared to those receiving intervention without RMB (13%, $p=0.01$).[19]

Clinical and radiographic information remain the most widely available and useful tools for predicting malignant pathology. Certain radiographic features of renal lesions are diagnostic of NMP, like macroscopic fat in SRMs and hyperdense renal cysts. Existing models use data such as male sex, tumor complexity and tumor diameter.[4,18,22,23] The patterns of higher NMP in smaller masses and female sex were reproduced in our review. However, for lesions suspicious for RCC, no variables can universally or reliably predict malignancy, which

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contributes to the problem of NMP after surgical treatment. Novel imaging techniques such as ^{99m}Tc-sestamibi SPECT/CT have shown promise, but at present have yet to eliminate the need for RMB.[24]

The risk of chronic kidney disease as a result of surgery is substantial and augmented in patients who have preexisting chronic kidney disease. When patients undergo renal surgery, namely RN, and have a resultant new baseline glomerular filtration rate less than 45, nonRCC survival is significantly reduced.[25] Further, incremental decrease in glomerular filtration rate is very strongly associated with risk of death, cardiovascular events and hospitalization.[26] One important conclusion was the consensus by all reviewers that RN for NMP in nearly all cases represented a moderate or major QI opportunity. Focusing QI opportunities on the population of patients who are planned or likely to undergo RN will make the most significant impact. Although much attention has been paid to RMB for SRMs, our review suggests that increasing the use of RMB for larger and more complex tumors where RN is a possibility may be equally (or more) important. After all, it is known that up to 10% of cT1b lesions are benign at removal, which represents a significant number of patients.[4,5] In this cohort 16 of 17 patients with NMP at RN did not undergo RMB. In the single patient in whom RMB was performed, the biopsy and final pathology were not concordant, leading to an unavoidable outcome.

We identified patient groups that are at higher risk for NMP. Older and comorbid cases may benefit from surveillance for SRM when appropriate, as would those with smaller masses, given the high risk of NMP with size less than 3 cm.[4] Patients with SRMs and female patients might especially benefit from RMB given the increased finding of benign pathology in these groups.

Limitations include the retrospective nature of the study, in which we examined all of the prospectively collected data about cT1 renal mass patients in the MUSIC-KIDNEY registry. Additionally, the followup was relatively short, based on the duration that MUSIC-KIDNEY has been in existence. Complexity scores and management decision details were not documented or available in the medical records for some patients. However, this study is the first of its kind and may serve to lay the groundwork for future works of this type.

CONCLUSIONS

The treatment and management of renal masses are highly individualized processes, reliant on multiple patient, tumor and urologist specific factors. Within MUSIC-KIDNEY 11% of surgeries resulted in NMP, which is lower than in most published reports. However, moderate to major QI opportunities were identified in nearly half of these cases, notably related in most cases to the unintended outcome of RN for NMP. When allowing for minor QI opportunities, an acceptable rate for NMP was determined to be 5.4%. From individual chart reviews the absolute lowest rate of NMP appears to be approximately 2%. Understanding that ultimately the decision for management and intervention of a renal mass lies with the patient, these numbers represent an ideal situation in which the shared decision making discussion informs the patient of preferred management strategies and all alternatives, and the patient selects the most highly recommended option. Improvements in NMP rates can be achieved by ensuring that detailed imaging demonstrating a suspicious (vs indeterminate) mass has been performed prior to a decision for surgery, employing AS and other observational strategies when appropriate, and considering RMB for all cT1RM, particularly prior to RN or complex PN.

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EDITORIAL COMMENT

Management choice and underlying pathology are critical considerations for patients diagnosed with localized kidney tumors (reference 11 in article). In the present analysis the authors use data on cT1 renal masses from MUSIC-KIDNEY to identify 74 patients who had surgery and subsequent identification of nonmalignant pathology. Five experienced urological surgeons reviewed the cases to assess potential areas for quality improvement that could have impacted management decisions.

Several themes were elucidated with moderate (35%) and major (14%) QI opportunities identified including the potential to avoid surgery with active surveillance, roles for renal mass biopsy and need for improved assessment prior to performance of radical nephrectomy. The most common moderate QI opportunities were lack of renal mass biopsy among active surveillance candidates (12) and lack of renal mass biopsy for patients receiving radical nephrectomy (6). While renal mass biopsy is often not necessary, these are certainly situations in which it should at least be discussed.[1]

The inherent nature of a chart review makes it difficult to determine whether biopsy was simply not discussed by the urologist, the patient felt it would not change their management preference or if another factor was at play. Regardless, the QI opportunities identified should reinforce our approach to shared decision making for patients with cT1 renal masses to consider patient factors, adequacy of diagnostic imaging and whether biopsy could impact management decisions (reference 21 in article). Future studies should blind reviewers to surgical pathology and qualitatively evaluate patient-physician transcripts to better understand why these QI opportunities arose and help target specific interventions.

Hiten D. Patel and Gopal N. Gupta
Department of Urology
Loyola University Medical Center
Maywood, Illinois

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