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Kidney Cancer

Outcomes After Initial Noninterventional Management of Clinical Stage cT1b Renal Masses

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Abstract

Background and objective: Localized renal masses 4.1–7.0 cm in size (cT1bRMs) are typically treated with partial or radical nephrectomy. Utilization and results of initial nonsurgical approaches for cT1bRMs are unclear. Our primary objective was to evaluate overall (OS) and metastasis-free (MFS) survival after initiating surveillance for cT1bRMs.

Methods: We retrospectively examined initial management and subsequent follow-up of all patients diagnosed with cT1bRMs (from May 2017 to November 2024) in the Michigan Urological Surgery Improvement Collaborative (MUSIC). Patients were stratified by intervention versus surveillance at 90 d following initial consultation. Patients initiating surveillance were further stratified as those with continued surveillance versus delayed intervention (DI) at least 90 d after initiating surveillance. The 3-yr estimated rates of DI, OS, MFS, and cancer-specific survival (CSS) were reported.

Key findings and limitations: Of 1134 patients with cT1bRMs, 297 were initiated on surveillance (26%), including 207 (70%) with solid, 47 (16%) with Bosniak III/IV, and 43 (14%) with indeterminate lesions. In a multivariable analysis, the predictors of surveillance included Charlson Comorbidity Index $\geq$2 versus 0 (odds ratio [OR] 1.43, 95% confidence interval [CI] 0.97–2.13), nonsolid tumor type (Bosniak III/IV cyst: OR 8.03, 95% CI 4.58–14; indeterminate: OR 5.42, 95% CI 2.86–10.3), and benign findings on a renal mass biopsy (OR 24.0, 95% CI 9.07–63). For the 297 surveilled cT1bRM patients, the cumulative incidence of DI at 2 yr was 27%, and the rates of MFS, CSS, and OS were, respectively, 91%, 96%, and 84% at 3 yr after initiating surveillance. A subset analysis excluding cystic, indeterminate, and biopsy-proven benign tumors found the cumulative incidence of DI at 2 yr to be 35%, with MFS and OS rates to be 95% and 78%, respectively, at 3 yr. In a multivariable analysis, initial surveillance was not associated with OS (vs immediate treatment; hazard ratio [HR] 1.47, 95%

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CI 0.83–2.63), with age as the only significant factor (HR 1.31, 95% CI 1.16–1.48). Limitations include the study's observational and retrospective nature.
Conclusions and clinical implications: The MUSIC data support active surveillance for select patients with cT1bRMs.
Patient summary: In this report, we looked at the outcomes of surveilling larger (cT1b) renal masses in a large population in Michigan. We found that watching instead of treating cT1b renal masses immediately in older people with more medical conditions did not change survival or cause the cancer to spread compared with people who were treated immediately. We conclude that surveillance for cT1b cancer is an option that should be considered for all patients but implemented selectively.

1. Introduction

The use of active surveillance (AS) for renal masses is expanding for patients with clinically localized tumors ≤4 cm (cT1aRMs) [1,2] and is incorporated into recent guidelines [3–6]. The role of AS for renal masses >4 and ≤7 cm (cT1bRMs) is unclear [7–10], as cT1bRMs more commonly have potentially aggressive pathological features than cT1aRMs [11,12]. Prior literature suggests that surveillance for cT1bRMs is safe, albeit with small cohort sizes. We aim to further explore the use of surveillance for cT1bRMs in a much larger cohort than previously reported.

Prior studies have evaluated AS for cT1bRMs, with none focused specifically on this clinical group [4,7–9,13,14]. While surveillance for cT1bRMs may carry increased risks, we aim to identify outcomes of patients electing a noninterventional approach to management. We hypothesize that the use of initial noninterventional approaches is appropriate for patients with comorbidities, limited life expectancy, or surgical constraints, without compromising long-term outcomes and with appropriate counseling.

In this study, we assess the use of surveillance and delayed intervention (DI) for patients with cT1bRMs across practices participating in the Michigan Urologic Surgery Improvement Collaborative—KIDNEY (MUSIC-KIDNEY).

2. Patients and methods

2.1. MUSIC-KIDNEY

The inception, protocols, and methodology of MUSIC-KIDNEY have been reported previously [15]. Patient demographics, tumor characteristics, initial workup, plan, and treatment decision are collected for each patient at 20 academic, hybrid, and community/private-based MUSIC-KIDNEY practices. All participating sites either were exempted by or obtained approval from local institutional review boards for participation in MUSIC-KIDNEY quality improvement activities.

2.2. Study sample

All patients ≥18 yr of age and diagnosed with cT1bRMs (>4 to ≤7 cm) from May 2017 to June 2024 were identified. A CONSORT diagram outlines the study population and inclusion/exclusion criteria (Supplementary Fig. 1).

Patients were first stratified into two cohorts: immediate treatment and initial surveillance [16]. "Surveillance" includes patients undergoing AS with the intention of DI if indicated, as well as those who receive "less than active" surveillance and those being followed with no expectation of treatment unless symptoms develop ("watchful waiting"/"expectant management"). Renal mass biopsies (RMBs) varied across practices in MUSIC; patients undergoing an RMB were less likely to have benign histology at intervention [17]. Surveillance of individual patients was conducted according to the urologist's decisions; guidance for surveillance across MUSIC was provided in the "Roadmap for Management of Patients with T1 Renal Masses" [16]. For example, the first imaging study is to be performed at 3–6 mo and the second between 6 and 18 mo according to tumor and patient characteristics. The surveillance group was further stratified based on whether it continued surveillance or underwent DI, defined as treatment ≥90 d after diagnosis. The collected data included demographics, comorbidities, tumor characteristics, and treatment decisions, with follow-up recorded annually. We conducted a systematic literature review using the search terms "surveillance" and "renal mass" or "kidney cancer." For the identified articles, we recorded the number of patients with cT1bRMs and those undergoing surveillance in each dataset, sometimes estimating the rates of surveillance for cT1bRMs from available information. We also recorded follow-up time, outcomes, and conclusions, which were reported variably.

2.3. Objectives

Our primary objective was to assess overall survival (OS) with immediate treatment versus initial surveillance for cT1bRMs. Our secondary objectives were to examine the durability of surveillance, including rates of DI, metastasis-free survival (MFS), and cancer-specific survival (CSS). We also examined practice-level variability in the rates of immediate treatment versus Surveillance, and factors associated with DI in cT1bRM patients.

2.4. Statistical analysis

Patient, tumor, practice, and treatment factors were compared between immediate treatment and initial surveillance in a multivariable logistic model. The first encounter with the urologist for the kidney mass was used as time

zero for all survival outcomes in both cohorts. Patients without DI in the surveillance cohort were censored at their last clinical event date, with the date of death considered a competing risk. OS time was censored at the last clinical event date; CSS time was censored at the last clinical event date or the date of death due to other causes. MFS time was censored at the last imaging date. Survival outcomes were analyzed using Kaplan-Meier curves for DI, OS, MFS, and CSS. Cox modeling of OS accounted for age, Charlson Comorbidity Index (CCI), and tumor size, and Fine-Gray regression was used to assess factors linked to DI. All analyses were performed using SAS 9.4 (SAS Institute, Cary, NC, USA), and statistical significance was set at $p = 0.05$.

3. Results

3.1. Initial management (surveillance vs immediate treatment)

We included 1134 patients who were diagnosed with cT1bRMs from May 2017 to June 2024; 26% of patients underwent surveillance ($n = 297$) and 74% underwent immediate treatment ($n = 837$). Among those who did not die, the median follow-up time of the study was 10.4 mo (interquartile range: 3.9–37.4). The characteristics of these two cohorts are described in Supplementary Table 1. Of note, 70% of patients in the surveillance group had solid tumor type, 16% had complex cysts, and 14% were indeterminate on initial imaging study. Patients in the surveillance group were older (median: 73 vs 64 yr) and more likely to have an initial estimated glomerular filtration rate (GFR) of <60 ml/min/1.73 m^2 (38% vs 18%). Additionally, more patients underwent an RMB prior to a decision for surveillance (26%) than prior to immediate treatment (18%). The factors associated with surveillance versus immediate treatment are reported in Table 1. Increasing age, lower GFR, smaller tumor size, tumor type, and benign pathology at a biopsy were associated with surveillance. The risk of going on surveillance was greater for patients with complex cysts (odds ratio [OR] 8.03, 95% confidence interval [CI] 4.58, 14.1) and indeterminate lesions (OR 5.42, 95% CI 2.86, 10.3) versus solid tumors, and those with an RMB indicating benign/favor benign results (OR 24.0, 95% CI 9.07, 63.4) versus no RMB performed (each with $p < 0.001$). Practice-level variation in the initiation of surveillance was observed (Supplementary Fig. 2); the range in surveillance use across 14 practices with at least ten included patients was 6.7–47% ($p < 0.01$). Finally, our literature review found limited information on the use of surveillance in cT1bRM patients, with most articles being limited to case series with short follow-up periods and inconsistent outcomes, and in a total of less than half of the patients reported in our work (Table 2).

3.2. Follow-up in patients initiating surveillance (continued surveillance vs DI)

Of 297 patients in the surveillance group, 46 patients received DI (radical nephrectomy [RN], partial nephrectomy [PN], or thermal ablation), 14 had a competing event without DI and are no longer on surveillance, and the remaining 237 patients continued surveillance.

Table 1 – Multivariable mixed-effect logistic regression model analysis of factors associated with initial surveillance (vs immediate treatment) for cT1bRMs

	Odds ratio (95% confidence interval)	*p* value
Age (per 5-yr increase)	1.28 (1.18–1.40)	**<0.001**
CCI (Ref: CCI = 0)		0.18
1	1.28 (0.82–2.00)	
≥2	1.43 (0.97–2.13)	
Preoperative GFR (per unit)	0.94 (0.91–0.98)	**0.001**
Insurance type (Ref: private)		0.7
Public	1.16 (0.79–1.70)	
None/unknown	1.13 (0.23–5.62)	
Tumor size (per cm)	0.75 (0.61–0.93)	**0.008**
Tumor type (Ref: solid)		**<0.001**
Complex cystic	8.03 (4.58–14.1)	
Indeterminate/unknown	5.42 (2.86–10.3)	
Renal mass biopsy (Ref: not performed)		**<0.001**
RCC/favor RCC	0.96 (0.61–1.50)	
Indeterminate	3.67 (0.60–22.5)	
Benign/favor benign	24.0 (9.07–63.4)	

CCI = Charlson Comorbidity Index; GFR = glomerular filtration rate; RCC = renal cell carcinoma; Ref = reference.
Model includes a random intercept for the urologist nested within practice to account for clustering.
Significant *p* values are given in bold font.

The cumulative incidence of DI among patients initiating surveillance was 17% (95% CI 12–24) at 1 yr and 27% (95% CI 20–34) at 2 yr (Fig. 1A). In a competing-risk proportional hazard model, factors associated with DI included a higher preoperative GFR, private insurance, and solid tumor type (Table 3). Patients with complex cysts were less likely to undergo DI (OR 0.21, 95% CI 0.07, 0.65), as well as those with benign RMB results (OR 0.15, 95% CI 0.03, 0.79). Prior to DI, 39% of patients underwent an RMB. When additional imaging was available prior to DI, 38.1% showed a growth rate of >0.5 cm/yr.

3.3. Survival and oncological outcomes

Kaplan-Meier curves indicate that the surveillance cohort had lower OS than the immediate treatment cohort ($p < 0.001$; Fig. 1B). However, after adjusting for confounders in a multivariable analysis, OS difference between cohorts was not statistically significant (hazard ratio [HR] 1.47, 95% CI 0.83–2.63, $p = 0.18$; Table 3). At 3 yr, the probability of OS was 84% (95% CI 75–90) in the surveillance group and 93% (95% CI 89–95) in the immediate treatment group. Twenty-one patients died while under surveillance; of these patients, two died due to kidney cancer, while 19 died from other causes. Age was the only factor associated with OS, with older patients having decreased survival (HR 1.31; $p < 0.001$).

Adverse pathological features were more commonly identified in patients undergoing upfront RN/PN. Of 837 patients undergoing immediate RN/PN, 13.3% had upstaging to pT3/T4 and 7.9% had grade 4 disease. The rate of upstaging found in our study is similar to what is currently available in the literature [18,19]. MFS was higher in the surveillance cohort than in the immediate treatment cohort, although this difference was not statistically significant ($p = 0.13$; Fig. 1C). The probability of MFS in the surveillance group was 95% at 1 yr, and 91% at 2 and 3 yr. The 3-yr

Table 2 – Published cohorts of patients with cT1bRM managed with surveillance

Study	Database	Included RCC clinical stage (s)	cT1b patients on AS	Follow-up (mo), median (IQR)	Overall survival	Cumulative incidence of delayed intervention, *n* (%)	Estimated rate of metastasis	Cancer-specific death, *n* (%)
Lamb et al (2004) [8]	Single institution: Beatson Cancer Centre	cT1b-T3b N0M0 unsuitable for surgery	21 (of 36 AS pts)	24	64%	–	1 (4.8%)[a]	0 (0%)
Lane et al (2010) [4]	Single institution: Cleveland Clinic	cT1 N0M0	15 (of 159 cT1b pts; of 105 AS pts)	47 (32, 66)	58% at 5 yr[b,c]	–	6 of 105 (5.7%)[a,b]	6 of 105 (5.7%)[b]
Mues et al (2010) [9]	Single institution: Columbia University	cT1b-cT2 N0M0	<18 (of 36 AS pts)	36 mean (range: 6–96)	4 deaths	3	2[a,b]	0 (0%)
Mehrazin et al (2014) [7]	Single institution: Fox Chase Cancer Center	cT1b-T2b N0M0	43 (of 65 cT1b pts)	43	–	23 (43%)[a]	–	0 (0%)
McIntosh et al (2018) [13]	Single institution: Fox Chase Cancer Center	cT1-T2 N0M0	69 (of 457 AS pts)	67 (41, 94)	89% at 5 yr[c]	153 (34%)[a]	–	1.2%[c]
Whelan et al (2019) [14]	Two institutions: Dalhousie University and Queen Elizabeth II Health Sciences Centre	cT1 (<6 cm) N0M0	<15 (of 103 AS pts)	56 (34–84)	52% at 11 yr[c]	17; 17% at 3 yr[b]	1[a]	1
Current study	24 institutions: MUSIC	cT1b N0M0	297	6 (4, 37)	84% at 3 yr[b]	11 (16%) at 1 yr, 23 (27%) at 2 yr	8.7% at 3 yr	3.9% at 3 yr

AS = active surveillance; IQR = interquartile range; MUSIC = Michigan Urological Surgery Improvement Collaborative; pts = patients; RCC = renal cell carcinoma.
[a] Did not report cumulative incidence.
[b] For T1 patients.
[c] Survival estimate.

cancer-specific death rate was 3.9% in the surveillance cohort and 1.0% in the immediate treatment. However, upon further review of the 11 patients with suspected metastases in the surveillance cohort, three were ruled out as having a renal cell carcinoma (RCC) metastasis and three had indeterminate lung nodules, leaving only five with likely metastases from RCC. Similarly, a cursory review of the 60 patients with a suspicion for metastasis from RCC after initial intervention identified 18 patients in whom metastasis from RCC was unlikely. Of the five cT1bRM patients who developed RCC metastases while on surveillance, metastasis was to the lung in three and liver in one; two of these patients died from RCC.

3.4. Comparison of surveillance in confirmed solid versus cystic/indeterminate/benign masses

A subset analysis was performed focusing on patients with noncystic, nonindeterminate, and non–biopsy-proven benign masses. We excluded 101 patients, including 32 with cystic lesions, 36 of 43 with initially indeterminate lesions, and 33 biopsy-proven benign lesions out of a total of 196 patients with continued suspicion for solid tumors.

The cumulative incidence of DI among patients initiating surveillance and with confirmed solid masses was 35% at 24 mo (95% CI 26–45%), while patients with cystic/indeterminate/benign masses had a cumulative incidence of 9.2% (95% CI 3.0–20%; Supplementary Fig. 3A). The OS rate in the surveillance group for patients with solid tumors was 78% (95% CI 66–87%) at 36 mo and 95% (95% CI 83–99%) for cystic/indeterminate masses (Supplementary Fig. 3B). Finally, the MFS rate for patients with solid tumors at 36 mo was 87% (95% CI 77–93%), and it was 100% for patients with cystic/indeterminate/benign masses who were on surveillance (Supplementary Fig. 3C).

4. Discussion

In this study, we report the largest series of surveillance for patients with cT1bRMs to date. Surveillance is commonly utilized for cT1aRMs, with prior evidence indicating safety for extended periods of time without impacting oncological outcomes [20]. However, the outcomes of surveillance for cT1bRMs are not well defined, based on the data from case series, which used variable entry criteria and inconsistent reporting of outcomes [4,7–9,13,14]. Guidelines make limited reference to surveillance for this population of patients as well [5,21]. Surveillance can be initiated with the option of DI (AS) or when DI is unlikely unless significant local symptoms or metastatic disease develops (expectant management or watchful waiting) [22]. We observed surveillance to be used more commonly than expected within MUSIC, with a noninterventional approach being initiated in 26% of 297 patients presenting with cT1bRMs. Perhaps as expected, given the lack of guideline direction regarding surveillance for cT1bRMs, we observed significant practice-level variability. Nevertheless, several criteria for the selection of patients for a noninterventional approach emerged. In correlation with our hypothesis that surveillance for cT1bRMs may be performed in appropriate candidates, a multivariable analysis revealed independent predictors of surveillance to be higher age, a lower preoperative GFR, nonsolid lesions (complex cysts

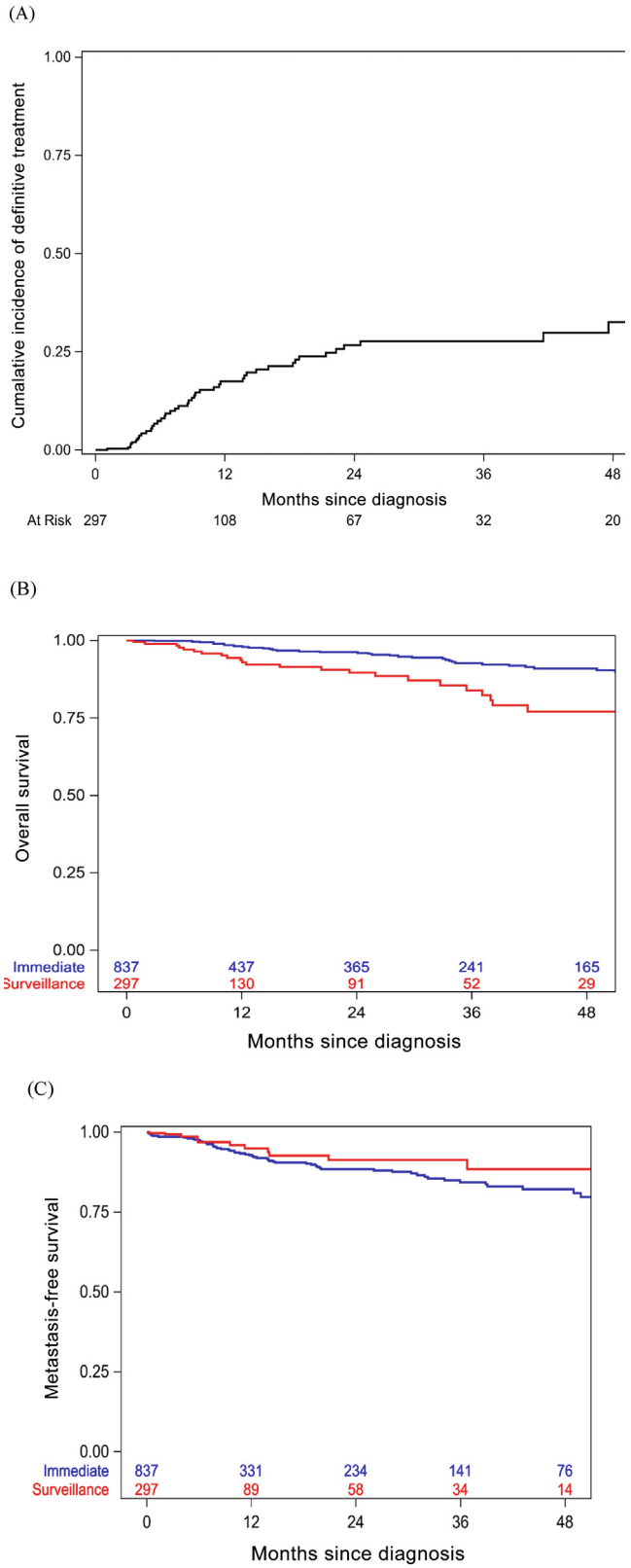

Fig. 1 – Kaplan-Meier curves of (A) the cumulative incidence of delayed intervention (46 events) for patients initiating surveillance, (B) overall survival of patients in the immediate treatment (38 events) and initial AS (25 events) cohorts (log-rank $p < 0.001$; adjusted HR = 1.47 [95% confidence interval: 0.83–2.63]), and (C) metastasis-free survival of patients in the immediate treatment (92 events) and initial AS (11 events) cohorts (log-rank $p = 0.13$). AS = active surveillance; HR = hazard ratio.

and indeterminate lesions), and benign pathology at RMBs (Table 1).

Initial surveillance for patients with cT1RMs has previously been reported to be associated with numerous factors, including higher age and CCI score, lower baseline GFR and tumor size, and nonsolid tumor type [23,24]. Importantly, prior reports have not demonstrated significant downsides, such as cancer-related mortality, metastasis, or kidney loss [4,13,23]. In addition, the number of cases with non-RCC death was significantly greater than that of RCC death in T1b patients, independent of tumor histology [10]. In fact, a systematic review found surveillance to be a safe intermediate- and long-term management option for patients with localized renal masses [25]. Prior literature has also found that surgery for patients with cT1bRMs may be delayed safely for up to 6 mo without impacting OS significantly [26]. Additionally, a larger tumor size has been associated with an increased risk of pre-existing chronic kidney disease [27]. These patients are at an increased risk of significant kidney function decline after surgery, highlighting the need for kidney-preserving options [28]. We observed an OS rate of 84% in the surveillance cohort versus 93% in the treatment cohort at 3 yr of follow-up. In the multivariable analysis, age was associated with OS, while treatment type and tumor size were not (Table 3). Similar rates of OS (52–89%) were seen in the six studies that investigated surveillance of large renal masses (Table 2) [4,7–9,13,14].

It might be expected that patients with larger tumors would be more likely to transition to treatment. The cumulative incidence of DI ranged from 17% to 43% in prior cohorts [4,7–9,13,14], with several having longer median follow-up than in our cohort. We found that most cases of DI occurred within 1–2 yr after diagnosis, with a plateau observed for years 3 and 4; the cumulative incidence rate at 2 yr was 27%. Our data are consistent with the prior reports and indicate that patients can transition to DI at an appropriate time when indicated. We would also like to highlight the importance of a thorough evaluation of renal masses under surveillance and that this can be obtained with a high-quality imaging study at a short interval after initiating surveillance (3–6 mo) [5].

We observed metastases in five patients and cancer-related mortality in two patients while under surveillance for cT1bRMs. One had an unconfirmed liver nodule and died from non-RCC causes. Another had both chromophobe RCC and invasive urothelial carcinoma, with the metastasis source being unclear but more likely related to the urothelial carcinoma. Three patients had metastasis to the lung, two of whom died from RCC. These findings support cautious surveillance for larger renal tumors, considering that many patients with cT1RMs are more likely to die from other conditions than from kidney cancer [4,29]. While metastasis and/or recurrence is a concern, it is important to consider the competing risks of initial surveillance compared with immediate treatment. The 3-yr cancer-specific mortality rates was 3.9% with surveillance, compared with 1.0% with immediate treatment. We do not feel that these oncological outcomes justify subjecting all cT1bRM patients

Table 3 – Multivariable Cox regression model analysis of factors associated with delayed intervention and overall survival for cT1bRM patients

	Delayed intervention		Overall survival	
	Hazard ratio (95% CI)	*p* value	Hazard ratio (95% CI)	*p* value
Surveillance (Ref: immediate treatment)	–	–	1.47 (0.83–2.63)	0.18
Age (yr)	–	–	1.31 (1.16–1.48)	**<0.001**
CCI (Ref: CCI = 0)		0.9		0.4
CCI = 1	0.92 (0.43–2.01)		1.14 (0.56–2.33)	
CCI ≥2	1.15 (0.54–2.47)		1.48 (0.84–2.61)	
Preoperative GFR (per 5 unit)	1.08 (1.02–1.15)	**0.01**	–	–
Public/none/unknown insurance (Ref: private)	0.44 (0.23–0.83)	**0.011**	–	–
Tumor size (per cm)	0.89 (0.61–1.31)	0.6	1.06 (0.78–1.43)	0.7
Tumor type (Ref: solid)		**0.018**	–	–
Complex cystic	0.21 (0.07–0.65)			
Indeterminate/unknown	0.59 (0.22–1.52)			
Renal mass biopsy (Ref: not performed)		0.053	–	–
RCC/favor RCC	1.17 (0.54–2.54)			
Benign/favor benign	0.15 (0.03–0.78)			

CCI = Charlson Comorbidity Index; CI = confidence interval; GFR = glomerular filtration rate; Ref = reference.
Significant *p* values are given in bold.

to immediate treatment. Additionally, consistent with prior studies, we demonstrate that surveillance for cT1bRMs is a more common choice in older patients with greater comorbidities and poorer renal function [30]. Our data showed that patients in the surveillance group were more likely to succumb to their comorbidities as opposed to their renal cancer, as the overall mortality rate was 16% at 3 yr. Our surveillance cohort included 70% of patients with solid tumor type on initial imaging, with 16% having a complex cystic renal mass. Indeterminate renal masses were classified on subsequent imaging studies. Evidence has consistently pointed to the more aggressive nature of solid renal masses; however, surveillance can be used appropriately for solid, complex cystic, and indeterminate lesions. We provide rates of DI, MFS, CSS, and OS for the subset of patients with solid tumors suspicious for RCC to further strengthen the claim that surveillance for cT1bRMs may be acceptable in older and highly comorbid patients.

In contrast, we recognize that while the risk of metastasis is low, it remains non-negligible [30]; thankfully, there are more advanced imaging modalities, such as [^{89}Zr]Zr-girentuximab positron emission tomography computed tomography imaging [31], which can assist in decision-making. Consequently, shared decision-making plays an important role in determining the best course of action for patients with cT1bRMs. Although there is a risk associated with undergoing surveillance, there is also an inherent risk associated with undergoing surgery. Patients with cT1bRMs are less likely to undergo kidney-sparing interventions (PN, thermal ablation, or stereotactic body radiation therapy) than those with cT1aRMs, and older patients with greater comorbidities are more likely to incur postoperative complications after renal mass resection [32]. The amount of renal functional decline after RN is higher than that after surveillance and has previously been observed in the literature [33]. Preservation of renal function is important when considering interventions for older patients with comorbidities, as chronic kidney disease is an independent risk factor for cardiovascular disease and premature death [28,34].

We also conducted a subset analysis to evaluate the potential bias associated with the inclusion of cystic, indeterminate, or biopsy-proven benign masses in our surveillance cohort. We evaluated the cumulative incidence of DI, OS, and MFS of the surveillance group including only solid tumors. The cumulative incidence of DI in the original cohort was 27% at 2 yr compared with 35% at 2 yr in patients with solid masses only. The OS rate was 84% at 3 yr for our original cohort compared with 78% at 3 yr for patients with solid tumors only. Finally, the MFS rate at 3 yr for our original cohort was found to be 91%, compared with 78% when considering solid tumors only. While we understand that the inclusion of complex cysts, indeterminate lesions, and biopsy-proven benign lesions in our surveillance group of 297 patients may seem suboptimal as these have lesser to no oncological risk, we would caution that the majority of patients undergoing surveillance in our cohort (and others) lack a definitive pathological diagnosis. Indeed, the rates of DI, OS, and MFS for the cohort with solid tumors only are comparable with the rates for the larger cohort. Select patients with cT1bRMs can be managed with surveillance, particularly when radiographic and/or pathological features suggest benign or indolent disease.

This study's limitations include the cohort's retrospective nature, which can introduce a bias and residual confounding. Although the MUSIC registry aims to reduce the selection bias, the data lack granular prospective information on patient and decision-making. As a statewide collaborative that receives data from various practices, variation in the way surveillance is practiced at each site is an inherent limitation (or strength) to our data. We acknowledge that a 10-mo follow-up period is short and future, long-term studies would be beneficial, but 25% of our patients have a follow-up of >3 yr. Loss of follow-up is also a concern, as in any long-term study. We were also unable to evaluate tumor growth rates due to the limited follow-up data and short median follow-up period. Additionally, the MFS and CSS rates that we report are an overestimate following individual chart reviews of patients initiating surveillance. A randomized trial would be needed to address these limitations. Finally, the current literature reports variable criteria for termination of surveillance (initiation of DI) [13,14,20,35,36]. A MUSIC Delphi consensus panel previously found that tumor growth rate and tumor

size were triggers for intervention, but consensus on cutoff points for each category was not achieved [16]. MUSIC aims to improve collection of follow-up imaging and RMB data to better define the criteria for DI. In future studies, we hope to provide a more comprehensive overview of the reasons for DI and type of DI performed.

5. Conclusions

Surveillance for cT1bRMs is a viable strategy for select patients after appropriate counseling and caution. Based on short-term follow-up, although OS for surveillance is lower than for immediate treatment, most patients who begin with initial surveillance have favorable outcomes, including high 3-yr MFS and CSS rates, supporting its use as a reasonable approach in appropriately selected individuals. DI for cT1bRMs was performed within 2 yr in 27% of patients. We provide a context for discussion and use of surveillance selectively for cT1bRM patients who would benefit less from immediate intervention due to older age, poor renal function, and/or high comorbidity.

Author contributions: Banna Hussain had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Patel, Hussain, Lane, Rogers, Semerjian.
Acquisition of data: Daignault-Newton, Van Til, Mirza.
Analysis and interpretation of data: Daignault-Newton, Van Til.
Drafting of the manuscript: Hussain, Wilder, Butaney, Osei, Wang.
Critical revision of the manuscript for important intellectual content: Patel, Hussain, Lane, Considine.
Statistical analysis: Daignault-Newton, Van Til.
Obtaining funding: Mirza.
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Supervision: Patel, Rogers, Lane, Semerjian.
Other: None.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.euros.2025.09.008.

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