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Incidence of Local Treatment and Metastasis During Active Surveillance for Patients With a Small Renal Mass in a National Multicenter Prospective Cohort

Luke T. Lavallée, Antonio Finelli, Simon Tanguay, et al.

Correspondence: Luke T. Lavallée (lulavallee@toh.ca).

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Study Need and Importance: An increasing number of patients diagnosed with a small renal mass are considering active surveillance, an approach supported by guideline recommendations. Accurate counseling regarding the incidence of treatment and metastasis is helpful for patients to make an informed management plan.

What We Found: This national study of 1393 patients on active surveillance for a solitary renal mass $\leq$ 4 cm reports a 2- and 5-year cumulative incidence of treatment of 8.4% (95% CI 6.9-10) and 21% (95% CI 19-24), respectively. The 2- and 5-year cumulative incidence of metastasis were 0.67% (95% CI 0.32-1.3) and 2.3% (95% CI 1.5-3.5), respectively. Notably, of the 29 patients who developed metastases, 23 had progressed using size or growth rate cutoffs, but only 7 of these patients received local treatment with curative intent before the identification of metastases (Figure).

Limitations: Limitations of this study include a lack of data indicating why patients opted to receive, or avoid, definitive treatment. It is possible that the incidence of metastases in the cohort may have been even lower if more patients had selected definitive treatment when they met size or growth rate thresholds.

Interpretation for Patient Care: These results support that active surveillance is safe for well-selected and appropriately monitored patients with a small renal mass.

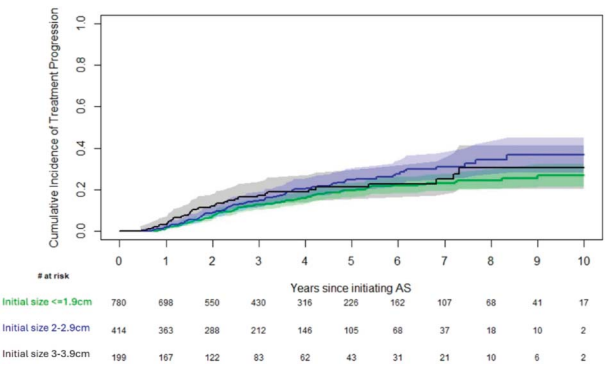

Figure. Cumulative incidence of treatment over time after adjusting for competing risk of death for patients initiating active surveillance (AS) for tumors $\leq$ 4 cm in the Canadian Kidney Cancer information system.

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Incidence of Local Treatment and Metastasis During Active Surveillance for Patients With a Small Renal Mass in a National Multicenter Prospective Cohort

Luke T. Lavallée,[1] Antonio Finelli,[2] Simon Tanguay,[3] Bimal Bhindi,[4] Lori A. Wood,[5] Ricardo Rendon,[6] Rahul Bansal,[7] Aly-Khan A. Lalani,[8] Daniel Y. C. Heng,[9] Naveen Basappa,[10] Jasmir G. Nayak,[11] Georg Bjarnason,[12] Frederic Pouliot,[13] Ryan McLarty,[14] Ammar Alam,[1] Ranjeeta Mallick,[1] and Rodney H. Breau[1]

[1]*Ottawa Hospital Research Institute, University of Ottawa, Ottawa, Ontario, Canada*
[2]*University Health Network, Toronto, Ontario, Canada*
[3]*McGill University Health Centre, Montreal, Quebec, Canada*
[4]*Alberta Health Services, Calgary, Alberta, Canada*
[5]*Capital Health Queen Elizabeth II Hospital, Halifax, Nova Scotia, Canada*
[6]*Division of Urology, Dalhousie University, Halifax, Nova Scotia, Canada*
[7]*Division of Urology, McMaster University, Hamilton, Ontario, Canada*
[8]*Juravinski Cancer Centre, McMaster University, Hamilton, Ontario, Canada*
[9]*University of Calgary Arthur JE Child Comprehensive Cancer Centre, Calgary, Alberta, Canada*
[10]*Cross Cancer Institute, University of Alberta, Edmonton, Alberta, Canada*
[11]*Section of Urology, University of Manitoba, Winnipeg, Manitoba, Canada*
[12]*Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada*
[13]*Centre Hospitalier Universitaire de Québec, Quebec City, Quebec, Canada*
[14]*Windsor Regional Hospital, Windsor, Ontario, Canada*

Purpose: The objective of this study was to determine the incidence of local treatment and incidence of metastasis for patients with a solitary small renal mass (SRM; ≤4 cm) initiating active surveillance (AS).

Materials and Methods: Patients enrolled in the Canadian Kidney Cancer information system between January 2011 and January 2023 with a solitary renal mass ≤ 4 cm opting for AS were included. The primary outcome was local treatment progression, achieved if the patient received definitive local treatment after initiating AS. The secondary outcomes were growth rate progression (>0.5

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Author Contributions:

Conception and design: Bjarnason, Lavallée, Rendon, Breau, McLarty, Tanguay.

Data analysis and interpretation: Lalani, Alam, Finelli, Bhindi, Heng, Pouliot, Wood, Lavallée, Mallick, Tanguay.

Data acquisition: Alam, Heng, Pouliot, Wood, Lavallée, Tanguay.

Critical revision of the manuscript for scientific and factual content: Lalani, Alam, Finelli, Bhindi, Heng, Pouliot, Bjarnason, Nayak, Wood, Lavallée, Basappa, Bansal, Mallick, Rendon, Breau, McLarty, Tanguay.

Drafting the manuscript: Lalani, Alam, Bjarnason, Lavallée.

Co-authorship as data analysis, interpretation, manuscript draft, and critical revision for final submission: Lalani.

Statistical analysis: Lavallée, Mallick, McLarty.

Supervision: Finelli, Bhindi, Heng, Lavallée, Bjarnason, Nayak, Wood, Bansal, Rendon, Breau, Tanguay.

Data collection, analysis, and drafting manuscript: Alam.

Corresponding Author: Luke T. Lavallée, MDCM, MSc, FRCSC, Urologic Oncology, Division of Urology, Ottawa Hospital Research Institute, The University of Ottawa, 501 Ch Smyth Rd, Ottawa, Ontario K1H 8L6, Canada (lulavallee@toh.ca).

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cm/y), size progression (>4 cm), composite progression (either size or growth rate progression), and development of metastases.

Results: The Canadian Kidney Cancer information system included 1393 patients who initiated AS for an SRM $\leq$ 4 cm during the study period. At a median follow-up of 4.0 years (95% CI 2.1-6.4), 238 patients received local treatment, and of these, 195 were nephron sparing. Two- and 5-year cumulative incidence of treatment was 8.4% (95% CI 6.9-10) and 21% (95% CI 19-24), respectively. Twenty-nine patients developed metastasis. Two- and 5-year cumulative incidence of metastasis was 0.67% (95% CI 0.32-1.3) and 2.3% (95% CI 1.5-3.5), respectively. Of the 29 patients who developed metastases, 23 had progressed using size or growth rate cutoffs, and 7 had received local treatment with curative intent before the identification of metastases.

Conclusions: Patients choosing surveillance for an SRM have low cumulative incidence of local treatment and metastasis at 5 years, demonstrating AS is a safe initial management approach.

Key Words: kidney cancer, active surveillance, metastasis, renal neoplasm

The incidence of small renal masses (SRMs) is increasing.[1] Definitive treatments (surgery or thermal ablation) for SRMs aim to cure by preventing metastases and local progression. Although most patients safely receive definitive treatments, some experience adverse events, making active surveillance (AS) an attractive management strategy for some patients.[2,3] AS aims to avoid the morbidity of invasive interventions, while maintaining the opportunity to treat patients if their mass demonstrates more aggressive clinical behavior (eg, growth on subsequent imaging).[4] Characterizing the risks of local treatment and metastasis for patients on AS for an SRM may help decision making.[5]

Although there is no consensus on the timing and frequency of AS imaging or indications for local treatment, most AS patients are monitored with serial imaging and choose treatment if the mass becomes large or grows quickly—because the benefits of treatment are perceived to outweigh the benefits of surveillance.[6,7] Patients may choose AS based on several factors, including mass size, growth rate, biopsy result, patient age, and competing health risks. American, European, and Canadian guidelines support AS as a management option for patients with an SRM.[3,8-10] The Canadian guideline recommends AS as the preferred initial approach for most patients with a mass $\leq$ 2 cm[3].

Our ability to confidently counsel patients with an SRM considering AS remains limited by inadequate data describing outcomes. Previous cohort studies have reported low metastatic risk and similar renal cell carcinoma (RCC)–specific outcomes for patients initiating AS or definitive therapy.[11-14] Studies have also attempted to characterize the association between growth kinetics and outcomes to facilitate decision making during AS.[15,16] Although these previous studies have improved our understanding, uncertainty remains as many studies are single-institution cohorts that may not be generalizable, and others are population-based reports that use administrative data lacking granularity and validated outcomes.[11-13,17-19]

The objective of this study was to describe the experience of a large nationally representative multi-institutional cohort of patients with a solitary SRM $\leq$ 4 cm initiating AS. The primary outcome was conversion from AS to local treatment. The secondary outcomes were size progression, growth rate progression, composite progression, and development of metastasis.

METHODS

Cohort

This study examined a cohort of patients from the Canadian Kidney Cancer information system (CKCis) diagnosed between January 1, 2011, and January 2, 2023. CKCis is a multicenter prospective database, and this study included data from 15 Canadian academic hospitals across 6 provinces.[2,20] CKCis includes data on patients with renal masses at all clinical stages. For each patient, renal mass characteristics, treatment characteristics, and outcomes are recorded and updated prospectively over time. Institutional ethics review board approval was obtained at each institution for inclusion in CKCis, and this study was approved by the Ottawa Hospital Research Ethics Board.

An SRM active surveillance cohort was created by identifying all patients in CKCis over 18 years of age with a solitary renal mass $\leq$ 4 cm whose primary management was AS. Patients needed to be on AS with at least 2 imaging tests 3 months apart to ensure patients choosing up-front local therapy were not labeled as AS while awaiting treatment. Patients were excluded if they had a personal or family history of kidney cancer, multifocal or bilateral tumors, or had metastases at diagnosis. These patients were excluded because their treatment decisions and clinical course could be influenced by a real, or perceived, differential risk compared with the average patient with a solitary SRM.

Patient and Renal Mass Characteristics

Baseline patient characteristics abstracted include age, sex, smoking history (never smoker, currently smoker, previous smoker), estimated glomerular filtration rate (eGFR) at diagnosis (<30, 30-59, 60-89, $\geq$90 mL/min/1.73 m^2), Charlson score, and diagnoses of diabetes, hypertension, or cardiovascular disease. Baseline renal mass characteristics

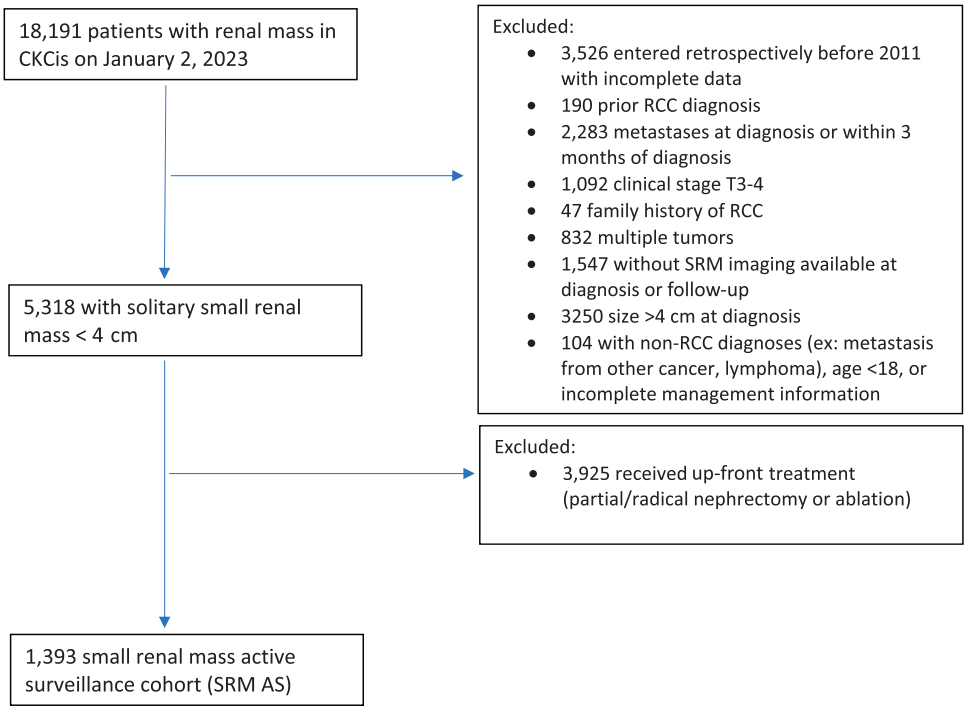

Figure 1. Flowchart of participant identification in the Canadian Kidney Cancer information system (CKCis) for small renal mass (SRM) active surveillance (AS) cohort. ex indicates for example; RCC, renal cell carcinoma.

were collected including mass size at diagnosis (cm), tumor consistency (solid or partially cystic), date of diagnosis, and biopsy status (yes vs no). If a renal mass biopsy was performed before or during AS, the biopsy histology was reported (benign or malignant), and all patients were included in the cohort regardless of biopsy timing or result.

Outcomes

The primary outcome was conversion from AS to definitive local treatment. The secondary outcomes were (1) size progression (if the renal mass size grew to over 4 cm), (2) growth rate progression (if the linear growth exceeded 0.5 cm per year), (3) composite progression (either size or growth rate progression), and (4) development of metastasis. Tumor size and growth rate were calculated based on imaging measurements at follow-up, and measurements from all imaging modalities were included. The timing and modality of follow-up imaging was at the discretion of the treating physician. Management characteristics included if definitive local treatment was initiated during AS and the treatment date and type (partial nephrectomy, radical nephrectomy, radiofrequency ablation, or cryoablation). For patients who developed metastasis, individual patient records in CKCis were audited by study investigators to confirm the presence of metastasis and document metastasis characteristics including location, number, size, and treatments.

Analyses

Descriptive statistics are reported. Median follow-up was calculated from the date of initiating AS using reverse Kaplan-Meier estimator. For the primary outcome, conversion from AS to definitive local treatment, patients were censored at last follow-up, metastasis, or death. For size progression, growth rate progression, and composite progression, patients were censored at the date of last imaging. For development of metastasis, patients were censored at last follow-up or death. Loss to follow-up was defined as patients within 5 years of diagnosis without follow-up for more than 18 months. Univariable and multivariable cox proportional hazard models were used to determine the association between baseline patient and renal mass characteristics with outcomes. For local treatment, size progression, and growth rate progression, baseline factors were evaluated in the multivariable model if they were statistically significantly associated with the outcome in univariable analysis. The relationship between growth rate and size progression was explored with a Cox proportional hazards model where rate progression was a time-dependent covariate. For metastases, only 3 variables that are available at the time of initial counseling were included in the model because of the limited number of metastatic events observed during follow-up. Cumulative incidence functions were used to determine the incidence of treatment, size progression, growth rate progression, composite progression, and metastatic progression adjusting for competing risk of death stratified by tumor size at initial diagnosis ($\leq$1.9 cm, 2.0-2.9 cm, 3.0-4.0 cm). Statistical significance was defined as $P < .05$. No correction was performed for multiple testing. All analyses were performed using SAS version 9.4.

RESULTS

During the study period, 18,191 patients were included in the CKCis cohort. Of them, 5318 had a solitary renal mass $\leq$ 4 cm of whom 3925 received up-front definitive treatment and 1393 received active surveillance. These 1393 patients formed the SRM AS cohort used for

Table 1. *Baseline Characteristic of Small Renal Mass Active Surveillance Cohort in the Canadian Kidney Cancer Information System Database*

Patient and renal mass characteristic	No. (%)
Age (y)	
<50	110 (8)
50-59	202 (15)
60-69	387 (28)
70-79	473 (34)
≥80	220 (16)
Missing	1
Sex	
Male	832 (60)
Female	561 (40)
Diabetes	
Yes	316 (23)
No	997 (72)
Missing	80 (6)
Hypertension	
Yes	712 (51)
No	601 (43)
Missing	80 (6)
Cardiovascular disease	
Yes	227 (16)
No	1086 (78)
Missing	80 (6)
Charlson score	
0	30 (2)
1	51 (4)
2	109 (8)
3	191 (15)
4	260 (20)
5	276 (21)
6	194 (15)
7	99 (8)
8	57 (4)
9	28 (2)
10	12 (1)
11	5 (0)
12	1 (0)
Smoking status	
Never smoker	477 (34)
Current smoker	154 (11)
Past smoker	427 (31)
Missing	335 (24)
Estimated glomerular filtration rate (mL/min)	
<30	28 (2)
30-59	110 (8)
60-89	815 (59)
≥90	439 (32)
Missing	1 (0)
Size of renal mass at initiation of active surveillance (cm)	
<1	168 (12)
1-1.9	612 (44)
2-2.9	414 (30)
3-3.9	199 (14)

analyses in this study (Figure 1). The median follow-up of the AS cohort was 4.0 years (95% CI 2.1-6.4).

Patient and Small Renal Mass Characteristics

The median patient age of the cohort at the time of initiating AS was 68 years (IQR 59 to 74) and 60% were male (Table 1). The median mass size at initiation of AS was 2.0 cm (IQR 1.5-2.8). Many patients had comorbid diseases, including 316 with diabetes, 712 with hypertension, and 227 with cardiovascular disease. eGFR exceeded 60 mL/min/m^2 in 1254 patients. One hundred and thirty-nine masses had a cystic component on imaging. Five hundred and fifty-six patients received a biopsy at some time during the study period, 307 of which were malignant, 172 of which were benign, and 77 of which had missing or nondiagnostic histology. One thousand three hundred and twenty-eight had baseline chest imaging within 6 months of starting AS.

Local Treatment Progression

Two- and 5-year cumulative incidence of treatment after adjusting for competing risk of death was 8.4% (95% CI 6.9-10.1) and 21% (95% CI 18%-24%), respectively (Figure 2). Progression to definitive treatment after initiating AS occurred in 238 patients, of whom 107 received partial nephrectomy, 42 radical nephrectomy, and 89 thermal ablation. At the time of treatment, the median patient age was 70 years (IQR 61-76), and the median renal mass size had grown to 2.8 cm (IQR 2.2-3.6). Before treatment, 43 patients had experienced size progression, 120 had experienced growth rate progression, and 132 had experienced composite progression. Factors independently associated with eventual receipt of local treatment included younger age, higher Charlson score, male sex, and larger tumor size at diagnosis ($P < .05$; Table 2).

Size and Growth Rate Progression

Size progression > 4.0 cm occurred in 214 patients. Two- and 5-year cumulative incidence of size progression was 9.1% (95% CI 7.5-10) and 22% (95% CI 19-26%), respectively. Growth rate progression (>0.5 cm/y growth) occurred in 520 patients. Two- and 5-year cumulative incidence of growth rate progression was 38% (95% CI 35-40) and 44% (95% CI 41%-47%), respectively. Fifty patients had size progression without growth rate progression, and 356 patients had growth rate progression without size progression. Composite progression occurred in 570 patients. Two- and 5-year cumulative incidence of composite progression was 39% (95% CI 36%-41%) and 49% (95% CI 45%-52%), respectively. The incidence of size progression was higher in patients who had experienced growth rate progression (HR 1.4 95% CI 1.0-1.8). The incidence of size and growth rate progression over time stratified by tumor size at initiation of AS is illustrated in Figure 3. Factors independently associated with size progression included older age, higher Charlson score, and larger tumor size at diagnosis ($P < .05$). Larger tumor size at diagnosis was independently associated with growth rate progression (Table 2).

Development of Metastasis

Twenty-nine patients in the AS cohort developed metastasis after a median time on AS of 5.0 years (IQR 2.9-7.1; Table 3). The median patient age at the time of developing metastasis was 80 years (IQR 70-85). Two- and 5-year cumulative incidence of metastasis were 0.67% (95% CI 0.32%-1.29%) and

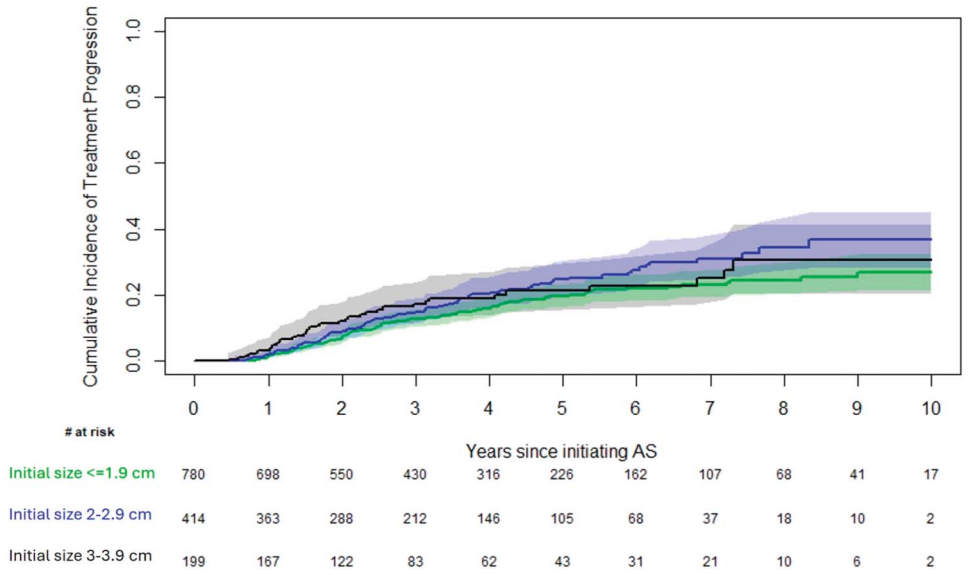

Figure 2. Cumulative incidence of treatment over time after adjusting for competing risk of death for patients initiating active surveillance (AS) for tumors $\leq$ 4 cm in the Canadian Kidney Cancer information system.

2.3% (95% CI 1.5%-3.5%), respectively. Among the patients who developed metastasis, 23 had experienced growth rate progression, 14 had experienced size progression, 23 had experienced composite progression, and 7 had received local treatment with curative intent before the identification of metastases. On multivariable analysis, baseline factors associated with development of metastases were older age (HR per year 1.07, 95% CI 1.04-1.09), male sex (HR 2.55 95% CI 1.32-4.94), and larger tumor size (HR per cm 2.28 95% CI 1.83-2.84; Table 4).

DISCUSSION

This prospective multicenter cohort study of 1393 patients with a solitary SRM initiating AS identified a low cumulative incidence of treatment (21%) and low incidence of metastasis (2.3%) at 5 years. Common thresholds for treatment (size >4 cm or growth rate >0.5 cm/y) occurred in 49% of the cohort by 5 years of follow-up. Notably, of the 29 patients who developed metastases, 23 had progressed using size or growth rate cutoffs, but only 7 of these patients received local treatment with curative intent before the identification of metastases. It is possible that the incidence of metastases in the cohort may have been lower if more patients had selected definitive treatment when they met size or growth rate thresholds. Together, these results support that active surveillance is safe for well selected and appropriately monitored patients with an SRM.

Results observed in CKCis are consistent with other reported cohort studies of AS for an SRM. A systematic review of 18 cohort studies, most including 50 to 250 patients identified with retrospective data collection, reported a range of definitive treatment rates during AS of 1% to 26% over various follow-up times, while an older review reported a 45% treatment rate by 30 months.[14,16,21] This CKCis study included 1393 patients managed at 15 centers by many physicians, and the cumulative incidence of treatment was 21% at 5 years. These results suggest good acceptance of AS by physicians and patients. Notably, of patients who received definitive treatment

Table 2. *Multivariable Associations Between Baseline Patient and Tumor Characteristics With Size Progression, Rate Progression, and Treatment Progression*

Patient and tumor characteristic	Size progression, HR 95% CI	Rate progression, HR 95% CI	Treatment progression, HR 95% CI
Increase in age by 1 y	1.01 (1.00-1.03)	1.01 (0.99-1.02)	0.97 (0.96-0.98)
Sex, female vs male	0.97 (0.73-1.30)	0.86 (0.71-1.03)	0.78 (0.65-0.93)
Increased Charlson score of 1	1.13 (1.04-1.22)	1.04 (0.99-1.09)	1.10 (1.04-1.17)
Estimated glomerular filtration rate, mL/min (referent ≥90)			
<30	1.12 (0.49-2.55)	1.32 (0.90-1.93)	0.18 (0.04-0.91)
30-59	1.07 (0.66-1.75)	1.13 (0.86-1.47)	0.98 (0.40-2.41)
60-89	0.97 (0.61-1.54)	1.14 (0.89-1.45)	1.20 (0.91-1.58)
Increase initial tumor size by 1 cm	4.37 (3.59-5.31)	1.09 (1.02-1.16)	1.29 (1.06-1.56)

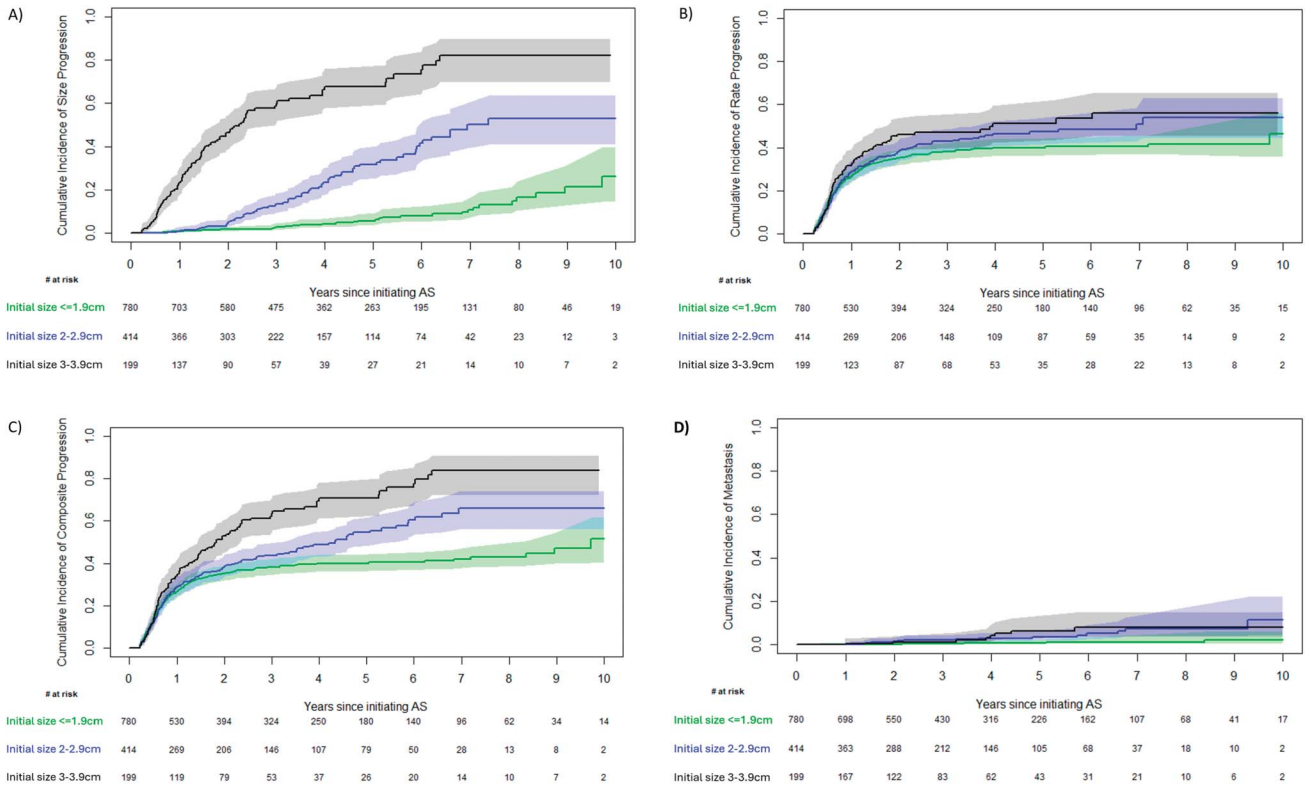

Figure 3. Cumulative incidence of progression over time after adjusting for competing risk of death for patients initiating active surveillance (AS) for tumors $\leq$ 4 cm in the Canadian Kidney Cancer information system. A, Size progression, defined as renal mass diameter $>$ 4 cm. B, Growth rate progression, defined as growth $>$ 0.5 cm/y. C, Composite progression, defined as either size progression (>4 cm) or rate progression (>0.5 cm/y). D, Metastatic progression.

after a period of AS, the majority received nephron-sparing treatments, indicating that preservation of functioning kidneys is technically feasible in most patients progressing on AS. This finding is in keeping with previous reports of patients who received surgery after a period of AS.[22,23]

One of the primary concerns of patients and clinicians is the risk of developing metastases while on AS. Previous studies have reported a risk of metastases between 1% and 6% for patients with tumors <4 cm.[16] The CKCis cohort identified 29 patients with metastases after a median time on AS of 5 years. Although a 2.3% cumulative incidence of metastases at 5 years is low, one could argue that any metastatic progression in a patient with an SRM is too high. However, it is important to note that even with up-front definitive therapy of an SRM $\leq$ 4 cm, a proportion of patients are expected to develop metastases during follow-up.[14,24] For example, 1 large single-center study of 1984 SRMs treated with surgery reported a 2% metastasis rate after 2.7 years of follow-up.[24] Furthermore, several features of the CKCis SRM group that developed metastases may influence interpretation. This was an older group of patients with a median age of 80 years at the time of metastasis identification. Furthermore, most (79%) of these patients did not receive definitive therapy during AS despite exceeding size and growth thresholds. For context, a previous single-center study of 128 patients, with similar progression thresholds for treatment as defined in this study, reported that no patients developed metastases while adhering to strict intervention criteria.[17]

This study provides important information to help counsel patients considering surveillance for an SRM. Given that numerous management options are available, clarifying the likelihood of receiving future treatment and incidence of metastasis is important.[5] Factors associated with treatment included younger patient age, male sex, increased Charlson score, and larger mass size. Interestingly, growth rate appeared to stratify patients early during the monitoring period of AS regardless of initial mass size (Figure 3, B). This suggests many patients with SRMs demonstrating rapid growth kinetics will be identified early in the surveillance period allowing consideration of biopsy or local treatment with curative intent, while patients with slow growth kinetics early in the AS period may be reassured their risks of rapid local growth in the future is lower. These results support guideline

Table 3. *Patient, Renal Mass, and Treatment Characteristics of Cohort With a Metastatic Diagnosis After a Period of Active Surveillance*

	AS			Progression outcomes before metastasis			Local treatment		Metastasis characteristics and treatment					
Patient No.	Mass size at AS initiation (cm)	Age at AS initiation (y)	Duration of AS before metastasis (mo)	Size progression (yes/no)	Growth rate progression (yes/no)	Composite progression (yes/no)	Renal mass treatment before metastases (yes/no)	Treatment type	Age at metastasis (y)	Mass size at identification of metastasis (cm)	Systemic treatment initiated (yes/no)	Metastasectomy (yes/no)	Metastasis location	Pathology from biopsy or surgery (local tumor or metastasis)
1	3.6	77	53	Y	Y	Y	Y	Radical nephrectomy	82	4.8	N	N	Lymph node	Papillary type 2
2	2.3	88	24	N	Y	Y	N		90	3.9	N	N	Lung	-
3	1.9	76	41	N	N	N	N		79	3.2	N	Y	Perirenal	-
4	3.2	81	69	Y	Y	Y	Y	Radical nephrectomy	86	4.2	N	N	Liver	Clear cell RCC
5	2.8	77	69	N	N	N	N		83	2.9	Y	N	Lung	RCC unclassified
6	3.7	84	47	Y	Y	Y	N		88	4.1	N	N	Liver, adrenal	-
7	2.3	84	13	Y	Y	Y	N		85	4.8	Y	N	Lymph node	-
8	2.9	76	25	Y	Y	Y	N		78	4.9	Y	Y	Bone	Clear cell RCC
9	3.2	76	49	Y	Y	Y	N		80	6.7	Y	N	Lung	Clear cell RCC
10	2.6	75	18		Y	Y	N		76	3.7	N	N	Bone	Carcinoma (not specified)
11	3	70	26	Y	Y	Y	Y	Radical nephrectomy	72	4.9	Y	N	Liver, lung, lymph node	Clear cell RCC
12	2.7	65	81	N	N	N	N		71	2.7	Y	N	Liver	Clear cell RCC
13	1.7	61	101	N	N	N	Y	Partial nephrectomy	70	3	Y	N	Peritoneum	Chromophobe
14	1.1	61	6	N	Y	Y	N		61	2.2	Y	N	Lymph node, bone	Collecting duct
15	3.3	64	12	N	N	N	N		65	3.3	Y	N	Bone	-
16	2.1	87	45	Y	Y	Y	N		91	7.6	N	N	Lung	-
17	1.8	67	26	N	Y	Y	Y	Cryotherapy	69	2.6	N	N	Liver	Carcinoma (not specified)
18	2.4	80	79	Y	Y	Y	N		87	5	N	N	Lung, lymph node	Clear cell RCC
19	2.3	61	111	Y	Y	Y	Y	Radical nephrectomy	70	4.1	N	N	Lymph node	Clear cell RCC
20	2.5	78	72	N	Y	Y	Y	Radical nephrectomy	84	3.4	N	N	Peritoneum	Clear cell RCC
21	2.4	65	58	N	Y	Y	N		70	3.1	N	N	Lung	RCC unclassified
22	3.1	77	39	N	N	N	N		80	1.6	N	N	-	Chromophobe
23	3	89	16	N	Y	Y	N		90	3.6	Y	N	-	RCC unclassified
24	3.5	80	24	Y	Y	Y	N		81	3.3	N	N	Brain	-
25	2.7	82	39	Y	Y	Y	N		85	4.8	N	N	Adrenal gland	-
26	2.5	81	17	N	Y	Y	N		83	2.3	N	N	Lung	-
27	3.1	84	48	Y	Y	Y	N		88	7.1	N	N	Lung	-
28	1.4	62	62	Y	Y	Y	N		67	6.3	N	N	Lymph node	Carcinoma (not specified)
29	2	65	26		Y	Y	N		68	4	Y	N	Lung	Clear cell RCC

Abbreviations: AS, active surveillance; RCC, renal cell carcinoma.

Table 4. *Multivariable Associations Between Baseline Patient and Tumor Characteristics With Development of Metastasis*

Patient and tumor characteristic	Development of metastasis HR 95% CI multivariable
Age, increase by 1 y	1.07 (1.04-1.09)
Sex, male vs female	2.55 (1.32-4.94)
Tumor size, increase at initial diagnosis by increments of 1 cm	2.28 (1.83-2.84)

recommendations to image SRMs every 3 to 6 months in the first year followed by every 6 to 12 months in subsequent years if the growth kinetics are reassuring[3,10]

This study has strengths. It is a large national multicenter prospective cohort that includes data from many providers in different geographic and practice settings. These characteristics make the results generalizable to a broad population of patients with an SRM.[20] Furthermore, CKCis is an observational cohort, so the outcomes presented are more consistent with real-world management instead of what might be obtained by prespecified trial protocols.

Limitations of this study are also noteworthy. First, the approach to surveillance was inconsistent as some patients received treatment before reaching progression "thresholds," whereas others did not receive treatment despite exceeding thresholds. Strictly defined, AS suggests the intent to provide definitive treatment should clinical parameters or patient preference change. Conversely, watchful waiting implies a choice to avoid treatment unless symptoms arise (even in the event of metastatic spread). It is likely a proportion of patients in the CKCis AS cohort transitioned over time to an approach more consistent with watchful waiting. Second, similar to most reports of AS for SRM, a proportion of patients in this cohort likely had benign masses because most were not biopsied at initial diagnosis or during follow-up. Patients with biopsy-proven RCC may have different natural histories, on average, than those reported here. Third, this study is not able to comment on outcomes of more specific subgroups of patients such as those with cystic tumors or specific RCC histologies. Finally, because this is not a randomized study, there was likely selection bias regarding which patients (masses) were surveilled compared with those who received definitive therapy. Therefore, although these results are reassuring, this cohort may not be similar to a cohort that chose up-front treatment with curative intent.

CONCLUSIONS

This large multicenter prospective study describes the incidence of treatment and metastases for patients undergoing AS for an SRM. This study demonstrates low cumulative incidence of treatment and metastasis at 5 years. Physicians and patients can use these data to improve counseling and follow-up schedules for patients with SRMs considering AS.

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EDITORIAL COMMENTS

Active surveillance (AS) has emerged as a well-established practice in the management of small renal masses (SRMs), grounded solely by retrospective data. Systematic review and meta-analysis of these studies have shown AS to be associated with a 2% rate of metastatic progression over a 3- to 5-year period, with significantly lower rates for tumors with indolent growth kinetics.[1,2] Rates of progression to definitive treatment are more variable, between 5% and 40%, reflecting wide practice variations of clinicians contributing to these series, most of which are smaller single-center studies, with a handful of larger collaborations—most notably, the Delayed Intervention and Surveillance for Small Renal Masses registry.[1,2]

Larger studies on this topic using national cancer registries are often fraught with major limitations. Primarily, inclusion in most cancer registries requires a histologic diagnosis of cancer, which is rarely present in patients starting AS for their SRM. In addition, practice patterns tend to display incredible variation, and follow-up periods are brief, especially in the United States where patients' care is often fragmented between several medical groups and hospital systems.

In this study, Lavallée et al describe the outcomes for 1393 patients on AS for an SRM from Canadian Kidney Cancer information system, a prospectively collected kidney cancer–specific dataset from 15 Canadian academic hospitals.[3] This dataset is ideally suited to study this topic, with a very large cohort, contemporary era, lengthy follow-up, an academic setting likely ensuring standard-of-care protocols, and not requiring a histologic cancer diagnosis for inclusion. Although the primary findings are not new or surprising—with 2% of patients progressing to metastasis and 21% progressing to definitive treatment at 5 years—this is the largest high-quality study on this topic by a significant margin and is a landmark addition to the AS literature.

Nicholas H. Chakiryan [1,2,3,4]

[1]*Department of Urology, Oregon Health & Science University Portland, Oregon*

[2]*Department of Urology, Portland VA Medical Center Portland, Oregon*

[3]*Knight Cancer Institute, Translational Oncology Program Portland, Oregon*

[4]*Review Board Member, The Journal of Urology®*

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REPLY BY AUTHORS

We thank Dr Chakiryan for his insights[1] on our study.[2] We agree that the Canadian Kidney Cancer information system is an ideal cohort to study active surveillance for patients with a small renal mass due to its generalizability. This study included data from 15 centers with numerous physicians at each site, and no formal protocol was applied to the surveillance strategy or indication for intervention. The results should therefore inform a broad number of patients of what they may expect should they initiate active surveillance.

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EDITORIAL COMMENTS

Active surveillance (AS) for small renal masses (SRMs; ≤4 cm) offers patients a chance to avoid or defer potentially burdensome interventions. Although it has been widely adopted internationally and incorporated into European, American, and Canadian guidelines, our ability to predict outcomes for patients opting for this approach is limited. Lavallée et al examine a large multicenter prospective cohort of patients undergoing AS for SRMs to better define the need for definitive therapy.[1]

After a median of 4 years, only 17% patients diagnosed with a solitary SRM went on to intervention, with the majority (82%) receiving nephron-sparing treatment. Reassuringly, they further showed a low rate of metastases (2.1%) at a median of 5 years. As we aim for more personalized treatment selection, this paper highlights several risk factors for progressing to intervention on AS including larger tumor size at diagnosis, younger age, male sex, and higher burden of comorbidities.

Driven by the pragmatic, real-world data acquisition (which lends generalizability), there are 2 notable features of the study which affect how we may apply the data in practice. First, there were inconsistent (and unreported) triggers for intervention. However, 55% patients experienced either size progression (>4 cm) or growth rate progression (>0.5 cm/y) before intervention. Better understanding the reasons for intervention in the remaining patients may offer opportunities to improve surveillance adherence. Certainly, others have shown that anxiety and uncertainty over management outcomes may lead patients to opt for intervention in the absence of overt signs of tumor progression.[2,3] Second, the minority of patients (39.9%) underwent renal mass biopsy during the study period, let alone at diagnosis. Higher uptake of biopsy may allow for improved shared decision-making between patients and providers and allow more patients to have confidence in a surveillance strategy.

Clare O'Connell[1] and Christopher J. D. Wallis[1,2,3,4]

[1]Division of Urology, Department of Surgery, University of Toronto Toronto, Ontario, Canada

[2]Division of Urology, Department of Surgery, Mount Sinai Hospital Toronto, Ontario, Canada

[3]Department of Surgical Oncology, University Health Network Toronto, Ontario, Canada

[4]Review Board Member, The Journal of Urology®

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REPLY BY AUTHORS

We appreciate the insightful comments Drs O'Connell and Wallis provided[1] to our study of patients receiving active surveillance for a small renal mass in the Canadian Kidney Cancer information system (CKCis).[2] We agree that striving for more personalized management is needed, and we hope that data from CKCis and other similar studies will help us achieve this goal. We are unable to report what prompted patients to transition from surveillance to treatment because these data are not available in CKCis. We agree that some patients may have opted for intervention because of anxiety; however, we also note that many patients who experienced size or growth rate progression did not immediately select definitive therapy, driving home the need to better understand patient perspectives.

Second, we acknowledge that many patients in the CKCis cohort did not receive a renal mass biopsy. We believe renal mass biopsy is an important diagnostic test for some patients; however, the CKCis cohort demonstrates that many patients are able to receive surveillance without a biopsy and achieve good outcomes. We believe biopsy should be reserved for patients in whom the test result will affect management.[3] Indeed, it is possible that if all patients received a biopsy, many more indolent cancers would have been diagnosed, which may have caused anxiety and prompted some patients to seek potentially unnecessary interventions.

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EDITORIAL COMMENT

The literature on the risks and benefits of active surveillance (AS) for managing small renal masses (SRMs) has largely been limited to single-institution cohorts and population-based reports, which lack clinical generalizability and validated outcomes. The report by Lavallée et al[1] includes a large cohort of patients with SRMs undergoing AS across 15 academic hospitals, offering more rigorous clinical insights into the use of AS.

It was demonstrated that definitive treatment incidence was low. Importantly, however, most patients who met size "thresholds" of $>$ 4 cm and/or growth rate of $>$ 0.5 cm/y did not receive definitive therapy during AS. Through shared decision-making, some patients likely transitioned to care more consistent with watchful waiting rather than AS, which may have artificially suppressed the incidence of definitive treatment as an outcome measure. Notably, 82% of definitive treatment patients received nephron-sparing techniques, demonstrating that delayed surgical management can still allow for treatments that preserve kidney function, as previously suggested.[2]

The authors allude to a possible selection bias within their dataset. More concerning SRMs at initial presentation could have undergone biopsy and definitive treatment selection over management with AS.[3] This removes potentially more aggressive renal masses from the AS group, lowering the rate of metastasis observed, which was reported below 3%. Alternatively, the dropout rate of concerning masses at presentation is reflective of real-world patient management, validating the rate of metastasis on AS seen in this review.

A limitation of this study is that a formal, prescriptive AS protocol was not followed, and the timing and modality of follow-up imaging were left to the discretion of the treating physician. There was also no discussion on the frequency and modality of chest imaging to assess for thoracic metastasis, classically recognized as a site of concern following

guideline-based care although more recently considered a less common risk in appropriately selected patients on AS.[4]

This review highlights that AS can be used safely for the management of SRMs, with true oncologic safety demonstrated by a low rate of metastasis and ability to offer nephron-sparing treatment in those pivoting to definitive treatment with curative intent.

Nicos Prokopiou[1], **Maxwell L. Sandberg**[1], and **Soroush Rais-Bahrami**[1,2,3]

[1]*Department of Urology*
Wake Forest University School of Medicine
Winston-Salem, North Carolina

[2]*Atrium Health Wake Forest Baptist Comprehensive Cancer Center*
Wake Forest University School of Medicine
Winston-Salem, North Carolina

[3]*Review Board Member, The Journal of Urology®*

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REPLY BY AUTHORS

We thank Dr Prokopiou et al[1] for their comments on our report[2] and for highlighting some strengths of the Canadian Kidney Cancer information system cohort, including most importantly the real-world generalizability of the data. On this point, it is noted that a formal prescriptive active surveillance (AS) protocol was not followed, and that this could be a weakness of the study. We acknowledge that the lack of a strict AS and intervention protocol is an important characteristic that may influence study interpretation. However, we actually believe the lack of a strict protocol is a strength of the study, and the main reason the data are generalizable. While it is likely each individual institution and physician adhered to some form of surveillance protocol, personalized medicine warrants that such protocols should be adaptable to individual patients' goals and competing risks. It is our hope that data from the Canadian Kidney Cancer information system, and other studies that do apply strict monitoring and intervention protocols, may together inform patients and physicians of what to expect when considering AS for a small renal mass.

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