Determinants of Active Surveillance in Patients With Small Renal Masses

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OBJECTIVE To evaluate trends in the utilization of active surveillance (AS) in a nationally representative cancer database. AS has been increasingly recognized as an effective strategy for patients with small renal masses but little is known about national usage patterns.

METHODS We identified patients with clinical T1a renal masses within the National Cancer Database in 2010 through 2014. Patients were classified according to initial management strategy received including AS, surgery, ablation, or other treatment. We characterized time trends in the use of AS vs definitive therapy and examined clinical and socio-demographic determinants of AS among patients with small renal masses using multivariable logistic regression models.

RESULTS We identified 59,189 patients who satisfied the inclusion criteria. Of the total cohort, 1733 (2.9%) individuals received initial management with AS, while 57,456 (97.1%) received definitive treatment. Surveillance rates remained below 5% in all years. On multivariate analysis, patient age (OR: 1.08, 95% CI 1.08-1.09), smaller tumor size of <2 cm vs ≥2 cm (OR: 2.43, 95% CI: 2.20-2.7, $P < .0001$), management at an academic center vs community center (OR: 2.05, 95% CI: 1.83-2.29), and African American vs Caucasian race (OR: 1.56, 95% CI:1.35-1.80) were independently associated with use of AS as initial management.

CONCLUSION In a representative national cohort of patients with small renal masses, we observed clinical and facility-level differences in the utilization of active surveillance in patients with T1a renal masses. Further investigation is warranted to better understand the forces underlying initial management decisions for patients with small renal masses. UROLOGY 123: 167–173, 2019. © 2018 Published by Elsevier Inc.

As a consequence of the expanding use of cross sectional abdominal imaging, there has been a significant increase in the incidence of small renal masses (SRM) in the past 2 decades.[1,2] Although early detection has resulted in a migration toward lower stage disease at diagnosis, meaningful declines in cancer specific mortality have not been observed.[3,4] On this basis it has been proposed that SRMs may possess distinct pathologic characteristics and metastatic potential compared with larger tumors.[5] Indeed, SRMs (≤ 4 cm) are more likely to display indolent biological characteristics, and approximately 20%-30% of SRMs have been shown to be histologically benign upon examination of pathology review after resection.[6,7]

Active surveillance (AS), a period of close disease observation, has been recognized as an appropriate initial management strategy for select patients with SRMs.[8] Historically, AS has been preferentially offered to patients with a high degree of comorbidity, limited life expectancy, or strong personal preference. Prospective observational cohorts indicate that AS avoids harms associated with treatment, including deterioration of renal function, while offering very low risks of metastatic progression (less than 2%).[9-16] These recent studies have been reflected in recent American Urological Association guidelines, which offers AS as an initial management option for all patients with SRMs, especially those with tumor sizes less than 2 cm.[16]

With expanding clinical evidence in support of the safety and viability of AS, there has been growing momentum to expand the eligibility and use of this approach as a means to reduce over-treatment. However, at present, there is little population level evidence to indicate whether utilization of AS has increased in recent years, or if management patterns are uniform across patient and provider-level factors. Therefore, we examined contemporary management patterns among patients

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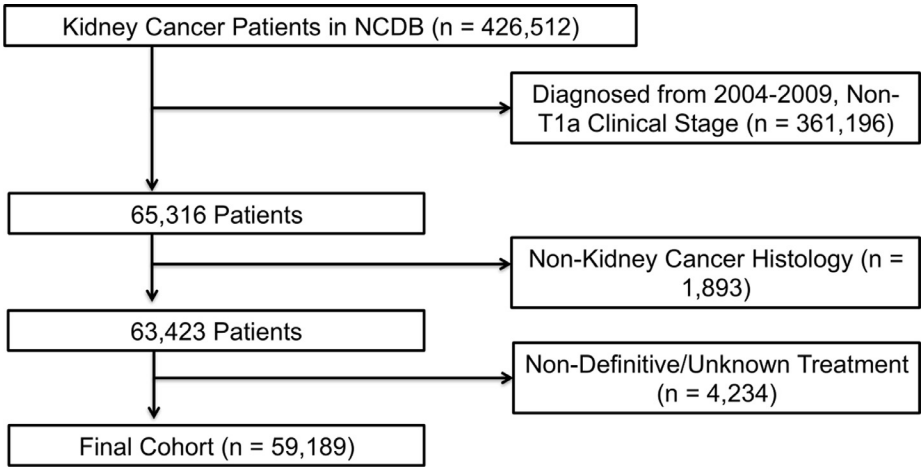

Figure 1. Flow diagram with inclusion and exclusion criteria.

with clinical stage T1a kidney tumors in the United States and evaluated factors associated with treatment selection.

MATERIALS AND METHODS

Patient Population

We used the National Cancer Data Base (NCDB), a shared project between the American College of Surgeons and American Cancer Society, to identify patients with clinical T1a renal masses (AJCC Cancer Staging Manual) diagnosed from 2010-2014. The NCDB provides deidentified data from hospitals affiliated with the Commission on Cancer program representing approximately 70% of new cancer diagnoses in the United States.[17] Demographic information, such as treatment center (Academic, Community, Unknown), age of diagnosis, sex, race, primary insurance payer (Government, Private Insurance, Uninsured, Unknown Status), median income quartile in county of residence (<$38,000, $38,000-$47,999, $48,000-$62,999, $63,000+), high school education levels in county of residence (>21%, 13%-20.9%, 7%-12.9%, <7%), levels of urbanization (urban vs rural), distance from treatment center (miles), and basic clinical information, such as Charlson-Deyo Comorbidity Score (0, 1, 2), treatment modality (active surveillance or definitive treatment (partial nephrectomy, radical nephrectomy, cryo-ablation, thermal ablation, etc), tumor size (≥2 cm, <2 cm, Unknown), and Clinical Stage were compiled and tabulated. We excluded patients based on the following criteria: unknown follow-up, metastatic or locally advanced disease (M1 or N1 disease), unknown management, nonkidney cancer histology subtype (ie transitional cell carcinoma), or those who were offered but refused treatment outside of surveillance (Fig. 1).

Statistical Analysis

Frequency tables, Chi square tests and ANOVA were used to evaluate demographic characteristics by management strategy. Multivariable logistic regression analysis was performed to assess to assess factors associated with initial management with AS. The models were constructed in a forward-step fashion; univariate analysis was first conducted, and statistically significant predictors were then pooled together into multivariate analysis. We also evaluated the utilization of AS among patients ≥75 years with tumor sizes less ≤2cm, a subset of individuals in whom surveillance has been increasingly advocated. Statistical significance was considered if $P \leq .05$. Statistical analysis was performed using JMP 11.2.1 (SAS Institute Inc., Cary, NC).

RESULTS

We identified 59,189 patients with clinical T1a kidney cancers from 2010-2014, of whom 54,989 (92.9%) received histologic confirmation of renal cell carcinoma (RCC) (Table 1). Of the total cohort, 1733 (2.9%) individuals received initial management with AS, while 57,456 (97.1%) received definitive treatment. Of the patients receiving definitive treatment, treatment received were: partial nephrectomy in 32,190 (56.0%), radical nephrectomy in 13,768 (24.0%), cryo-ablation in 6075 (10.6%), thermal ablation in 1950 (3.4%), and other definitive therapy in 3473 (6.0%).

On univariate analysis, when compared to those who received definitive treatment, patients receiving AS were older (70.7 vs 60.1 years, $P < .0001$), more likely treated at academic centers (69.3% vs 52.9%, $P < .0001$), had a higher proportion of Government insurance (73.6% vs 51.1%, $P < .0001$), had a greater degree of comorbidity scores of ≥2 (11.1% vs 8.4%, $P < .0001$), smaller tumor size of <2 cm vs ≥2 cm (36.8% vs 22.1%, $P < .0001$), and a higher proportion of African American race (16.4% vs 13.2%, $P < .0001$). During the study period there was a small increase in utilization of surveillance from 2010-2012 relative to 2013-2014 (2.6% vs 3.4%, $P < .0001$) (Fig. 2).

Among patients greater than 80 years of age, 12.9% received AS, while 87.1% received a definitive form of treatment (20.4% cryo-ablation, 20.3% partial nephrectomy, 21.1% radical nephrectomy, 7.5% thermal ablation, and 17.8% other form of definitive therapy). For patients with greater degrees of comorbidity (Charlson-Deyo scores ≥2), rates of definitive treatment were high including 11.7% cryo-ablation, 41.8% partial nephrectomy, 30.7% radical nephrectomy, 3.1% thermal ablation, 8.9% receiving another form of definitive therapy, and only 3.8% of patients managed with AS. Among patients ≥75 years with tumor sizes less ≤2cm, 13.1% received initial AS.

On multivariable analysis, increasing patient age (OR: 1.08, 95% CI: 1.08-1.09, $P < .0001$), treatment at an academic center vs community center (OR: 2.05, 95% CI: 1.83-2.29, $P < .0001$), smaller tumor size of <2 cm vs ≥2 cm (OR: 2.43, 95% CI: 2.20-2.7, $P < .0001$), and African American vs Caucasian race (OR:

Table 1. Clinical and demographic characteristics of patient cohort

Variable	Active Surveillance	Definitive Treatment	*P* Value
Number of patients	1,733 (2.9%)	57,456 (97.1%)	
Facility type			
Academic	1,201 (69.3%)	30,344 (52.9%)	<.0001
Community	498 (28.7%)	23,856 (41.5%)	
Unknown	34 (2.0%)	3,256 (5.7%)	
Age of onset			
Mean (SD)	70.7 (12.6)	60.1 (12.6)	<.0001
Median (IQR)	72 (63-80)	62 (53-70)	
Tumor size (mm)			
≥2 cm	1,090 (62.9%)	44,608 (77.6%)	<.0001
<2 cm	637 (36.8%)	12,713 (22.1%)	
Unknown	6 (0.35%)	135 (0.23%)	
Sex			
Male	1,024 (59.1%)	34,515 (60.1%)	.417
Female	709 (40.9%)	22,941 (39.9%)	
Insurance status			
Government	1,276 (73.6%)	39,254 (51.1%)	<.0001
Private insurance	387 (22.3%)	25,781 (44.9%)	
Uninsured	39 (2.3%)	1,574 (2.7%)	
Unknown status	31 (1.8%)	747 (1.3%)	
Median income quartiles			
<$38,000	322 (18.6%)	10,208 (17.8%)	.0208
$38,000-$47,999	528 (30.5%)	18,156 (31.6%)	
$48,000-$62,000	405 (23.4%)	13,525 (23.5%)	
$63,000+	478 (27.6%)	15,401 (26.8%)	
Unknown	0 (0%)	166 (0.29%)	
Charlson/Deyo score			
0	1,233 (71.2%)	39,114 (68.1%)	<.0001
1	307 (17.7%)	13,505 (23.5%)	
2	193 (11.1%)	4,837 (8.4%)	
Race			
African American	284 (16.4%)	7,566 (13.2%)	<.0001
Caucasian	1,384 (79.9%)	47,486 (82.7%)	
Other/Unknown	65 (3.8%)	2,404 (4.2%)	
Urbanization			
Rural	33 (1.9%)	1,027 (1.8%)	.267
Urban	1,668 (96.3%)	55,040 (95.8%)	
Unknown	32 (1.9%)	1,389 (2.4%)	
Distance to treatment center (Miles)			
≤25	1,184 (68.3%)	39,921 (69.5%)	.0012
<25≤50	232 (13.4%)	8,571 (14.9%)	
<50≤75	111 (6.4%)	3,495 (6.1%)	
>75	203 (11.7%)	5,226 (9.1%)	
Unknown	<10*	243 (0.4%)	
Facility location			
East North Central	342 (19.7%)	10,156 (17.7%)	<.0001
East South Central	95 (5.5%)	4,254 (7.4%)	
Middle Atlantic	328 (18.9%)	9,006 (15.7%)	
Mountain	42 (2.4%)	2,176 (3.8%)	
New England	110 (6.4%)	2,921 (5.1%)	
Pacific	160 (9.2%)	5,001 (8.7%)	
South Atlantic	305 (17.6%)	1,1660 (20.3%)	
West North Central	199 (11.5%)	4,186 (7.3%)	
West South Central	118 (6.8%)	4,840 (8.4%)	
Unknown	34 (2.0%)	3,256 (5.7%)	

* To prevent patient identifability, the National Cancer Database does not allow reporting of any cell sizes of <10 patients.

1.56, 95% CI:1.35-1.80, $P < .0001$) were significantly associated with increased likelihood of management with AS (Table 2). In addition, there were regional level differences along U.S. census tracts, with greatest utilization in New England, Middle Atlantic, West North Central, and Pacific regions when compared to the West South Central region.

DISCUSSION

The viability of AS in the management of SRMs has been increasingly recognized with an improved understanding of the biology and natural history of the disease. SRMs appear to be distinct from larger tumors, on the basis of

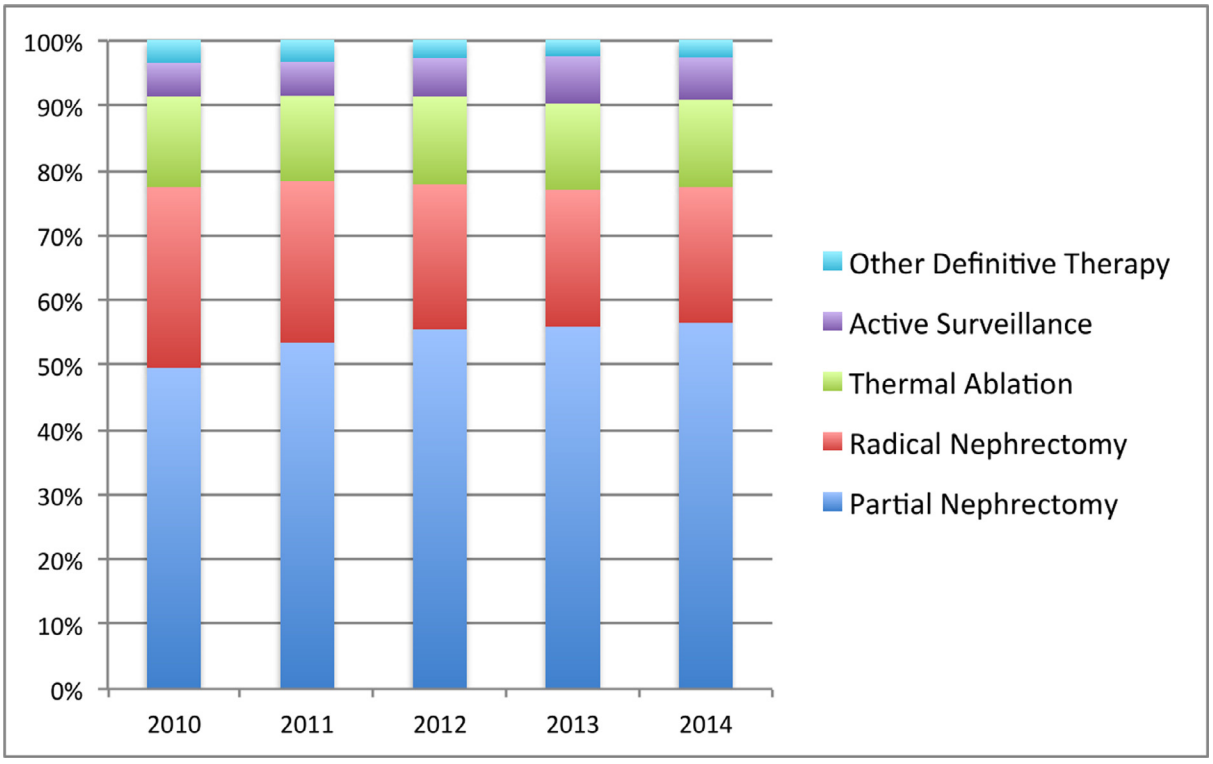

Figure 2. Comparison of treatment patterns between 2010 and 2014 for patients with clinical T1a small renal masses. (Color version available online.)

biologic characteristics, metastatic potential, and growth kinetics with observation.[4,6,8,18,19] Because of measurable risks associated with definitive treatment including procedural complications and long-term renal deterioration, there is growing interest in initial surveillance strategies for patients with SRMs.[20] Indeed, major guideline issuing bodies, including the American Urological Association, have highlighted surveillance as a strategy for all patients with SRMs as a potential initial management strategy, especially for those with a tumor size of less than 2 cm.[16] In light of growing clinical evidence to support the suitability of this strategy, we aimed to examine contemporary patterns in the management of of small renal masses and explore clinical and demographic factors that contribute to the utilization of AS.

Despite growing enthusiasm for surveillance of SRMs, we observed low utilization of this approach, indicating relatively little change in practice patterns over time. These findings are consistent with prior national studies of management strategies. An NCDB study of elderly patients (≥70) diagnosed with T1 localized RCC from 2002-2011 reported an expectant management rate of 12.6%, while our study had an overall low AS utilization rate of 2.9%.[21] The observed differences between these 2 studies may be attributed to changes in NCDB data consolidation over the years and due to differences in inclusion criteria. From 2010, the NCDB began to stringently define AS as surveillance, while in previous years in the prior study, patients who did not receive active treatment were defined as undergoing expectant management. Furthermore, the prior study specifically examined use of AS in patients ≥70, a subset in which expectant management is more common. In a separate study of Medicare-insured patients represented in the Surveillance, Epidemiology, and End-Results (SEER), 90.0% of patients with SRMs were treated with surgery, while 10% were managed nonoperatively.[22] Using a hospital-based cancer registry data, we observed a lower overall utilization of AS (2.9%). Differences in AS utilization may be attributed to the inclusion of older patients and those with a higher degree of medical comorbidity in SEER-Medicare. Furthermore, patients in SEER-Medicare were not distinguished by AS expectant management and nonoperative management. These findings are supported by surveys of urologists that indicate that older age, comorbidities, smaller tumor size, and perihilar tumor location are the characteristics which drive a preference for AS compared with extirpative therapy.[23]

There are several notable findings from this analysis regarding contemporary management trends for small renal masses. We demonstrate that there were significant facility-level differences in the utilization of surveillance. We observed that patients residing in New England, Middle Atlantic, West North Central, and Pacific regions were more likely to be managed with surveillance when compared to the West South Central region. Patients were more likely to be managed with AS in an academic center compared to a community center (OR: 2.05, 95% CI: 1.83-2.29, $P < .0001$), perhaps reflecting differing attitudes regarding the safety and feasibility of surveillance

Table 2. Determinants of active surveillance on multivariate analysis

Variable	OR (95% CI)	*P* Value
Facility type		<.0001
Community	1.00 (Ref)	
Academic	2.05 (1.83-2.29)	
Age of onset	1.08 (1.08-1.09)	<.0001
Tumor size		
≥2 cm	1.00 (Ref)	
<2 cm	2.43 (2.20-2.7)	<.0001
Unknown	1.58 (0.68-3.67)	.288
Insurance status		
Government	1.00 (Ref)	
Private Insurance	0.855 (0.748-0.978)	.0218
Uninsured	1.79 (1.27-2.51)	.0008
Median income quartiles		
<$38,000	1.00 (Ref)	
$38,000-$47,999	0.950 (0.813-1.11)	.521
$48,000-$62,000	0.986 (0.845-1.15)	.857
$63,000+	0.885 (0.756-1.04)	.129
Charlson/Deyo score		
0	1.00 (Ref)	
1	0.659 (0.580-0.750)	<.0001
2	1.03 (0.88-1.21)	.698
Race		
Caucasian	1.00 (Ref)	
African American	1.56 (1.35-1.80)	<.0001
Other/Unknown	0.979 (0.755-1.27)	.870
Distance to treatment center (Miles)		
≤25	1.00 (Ref)	
<25≤50	0.986 (0.851-1.14)	.851
<50≤75	1.02 (0.828-1.25)	.867
>75	1.20 (1.01-1.41)	.033
Facility location		
West South Central	1.00 (Ref)	
East South Central	0.991 (0.751-1.31)	.991
Middle Atlantic	1.33 (1.07-1.66)	.011
Mountain	0.80 (0.558-1.15)	.226
New England	1.49 (1.13-1.95)	.004
Pacific	1.31 (1.02-1.68)	.032
South Atlantic	0.970 (0.780-1.21)	.786
West North Central	1.88 (1.48-2.38)	<.0001
East North Central	1.20 (0.965-1.49)	.1012

strategies. These findings also appear consistent with national trends in the use of surveillance in low-risk prostate cancer with patients significantly more likely to receive AS in an academic center when compared to a community center.[24] This similarity across genitourinary malignancies may reflect a growing recognition of the overtreatment of certain cancers and greater recognition of the benefits of AS management, particularly in academic medical centers.[25]

We observed that uninsured patients were significantly more likely to receive AS than initial definitive treatment, while those with private insurance were more likely to be treated. Although insurance status was significantly associated with management strategy, no significant association was seen among income level. Taken together, these findings suggest that insurance disparities rather than intrinsic income-level differences might underlie differences in management.

We observed that African American patients were significantly more likely to receive management with surveillance for kidney tumors. While reasons underlying racial variation in management of SRMs are unclear and have not been widely studied, racial disparities in the receipt of guideline-concordant treatment for intermediate and high risk prostate cancer are well-reported.[26] Similarly, it is believed that African American patients are less likely to be treated as a result of receiving fewer options from physicians.[27] Additional study is warranted to better understand whether higher rates of surveillance among African-American patients are the consequence of differential preferences, counseling from physicians, access to care, or other unmeasured factors.[28]

The strengths of our study stem from the inclusion of a large, hospital-based cohort encompassing approximately 70% of cancer diagnoses in the United States, thereby offering a robust representation of conetmpoarary care patterns. Additionally, the NCDB specifically reports active surveillance as a management strategy, which is distinguished from from definiitions of nonoperative management used in other large population-based registries.

We acknowledge limitations in our study: first, by the nature of the NCDB cohort, our sample disproportionately weighs patients treated at CoC-accredited sites, which may skew our data towards practice patterns at higher volume centers. As a result, we are unable to characterize the nature of initial management at smaller volume centers. In addition, the majority patients with SRMs represented in the NCDB underwent histological confirmation. This may result in a disproportionate sampling of patients who underwent biopsy, thereby favoring patients who were more likely to receive treatment. As the NCDB only includes malignant disease, we are unable to evaluate treatment patterns on patients diagnosed with masses that are histologically found to be benign. Lastly, although we are able to evaluate intended initial treatment decisions, we are unable to evaluate the length of time on surveillance, oncologic, or functional outcomes. As information regarding the time interval between diagnosis and treatment initiation is unknown for those on active surveillance, we were unable to distinguish between patients who received AS and those in whom definitive treatment was never intended ("watchful-waiting"). As only first course treatment is recorded, we are unable to determine whether patients received subsequent treatment after being placed on active surveillance. Although there is growing enthusiasm for biopsy in the management of small renal masses, we acknowledge that biopsy is not routinely undertaken in all patients, which may lead to potential bias in treating biopsy-confirmed cancers as opposed to observing benign tumors. Here, prospective cohorts of closely monitored patients offer important insights into understanding the long-term clinical outcomes of AS utilization upon expectant management.

In light of national trends indicating highly variable adoption of surveillance, additional studies will serve to clarify barriers and facilitators of this practice, particularly in older invididuals and those with significant comorbidity who are less likely to derive benefit from immediate treatment.

CONCLUSION

Among patients with SRMs in a nationally-representative cancer registry, utilization of AS remains low even in those with high levels of comorbidities. Utilization of AS was variable across multiple determinants, including race, insurance status, treatment center, and geographic region. Further investigation is warranted to further understand the forces underlying initial management decisions for patients with SRMs.

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