Kidney Function Decline in cT1a Patients Treated With Microwave Ablation Versus Partial Nephrectomy

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ABSTRACT

BACKGROUND: Microwave ablation (MWA) is an emerging treatment modality for clinical T1a (cT1a) small renal masses (SRM) with studies showing it has comparable oncological outcomes to partial nephrectomy (PN). However, more research is needed on the impact of each treatment on kidney function decline.

OBJECTIVE: To compare the progression of kidney function decline in patients with cT1a SRM treated with MWA or PN.

METHODS: This study included prospective data on patients treated between 2015-2021 with kidney function data collected from 2015-2024 from a single institutional database. Three outcomes for kidney function decline were examined: 30% decline in estimated glomerular filtration rate (eGFR) compared to pre-treatment, chronic kidney disease (CKD) upstaging compared to pre-treatment and eGFR <60 mL/min/1.73m^2, and the composite endpoint of the previous two events. Cox proportional hazards models were used to compare outcomes between the two treatments.

RESULTS: Among 97 MWA and 49 PN included, MWA patients were older, had lower baseline eGFR, and higher rates of CKD prior to treatment. Univariate Cox proportional hazard model showed treatment modality was not significantly associated with reaching kidney decline endpoints. After adjusting for patient characteristics (age, race, baseline eGFR, Charlson Comorbidity Index), only baseline eGFR was associated with reaching kidney function endpoints.

CONCLUSION: There was no statistically significant difference in kidney function decline between PN and MWA treatments for cT1a SRM. After adjusting for patient factors, the higher hazard for MWA was attenuated.

INTRODUCTION

Renal cell carcinoma (RCC) incidence has steadily increased by over 50% in the last three decades making it one of the fastest growing cancer diagnoses in the United States. Increasing incidence may be attributed to frequent use of cross-sectional abdominal imaging as most RCC are diagnosed incidentally or to higher rates of known RCC risk factors, most often in older populations between 65-74 years.[1,2] Partial nephrectomy (PN) is the current standard of care for clinical T1a small renal masses (SRM), defined as ≤4 cm. PN has been demonstrated to have comparable oncological outcomes with a lower risk of chronic kidney disease (CKD) when compared to radical nephrectomy (RN).[4] Thermal ablation techniques, including microwave ablation (MWA), radiofrequency ablation, and cryoablation, are accepted as an alternative for select patient populations.[3] This is especially relevant as SRM patients are older, commonly between 65-74 years old, and often have more comorbidities.[1,2]

Amongst nephron sparing strategies such as PN and thermal ablation, there remains uncertainty regarding how kidney function is affected. CKD is associated with significant morbidity and mortality, but without specific preceding symptoms prior to kidney failure, it is

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difficult to define endpoints in trials that measure earlier CKD stages. The National Kidney Foundation (NKF) and US Food and Drug Administration (USFDA) put forth a recommended surrogate endpoint for clinical trials to measure eventual kidney failure. Using this, we sought to compare kidney function decline as well as association of demographics and baseline kidney function between MWA and PN for the treatment of cT1a small renal masses.[5]

METHODS

Patient selection

The institutional review board approved our SRM database which has collected data retrospectively from 2009-2015, and prospectively since 2015. The data is collected via REDCap, a secure web-based HIPAA-compliant database tool and stored securely on an institutional server. Patients receiving care for SRMs at UVA Urology are reviewed by a monthly SRM conference that consists of urologists, pathologists, and radiologists. Treatment recommendations include open PN, robot-assisted laparoscopic PN, RN, MWA, or active surveillance. Tumor characteristics, such as RENAL nephrometry score as well as patient demographics such as age, body habitus, comorbidities, and kidney function are considered. Recommendations were presented to patients by urologists and shared-decision making was used to finalize the treatment plan. In our study cohort, only patients treated between 2015-2021, with tumors ≤4 cm undergoing either MWA or PN, and with pre-treatment kidney function measurements were included (Figure 1). Kidney function data was collected from 2015-2024. We excluded patients with genetic predisposition to SRMs, SRM on transplanted kidney, metastatic disease at diagnosis, or no kidney function measurement during the follow-up period after 3 months of surgery.

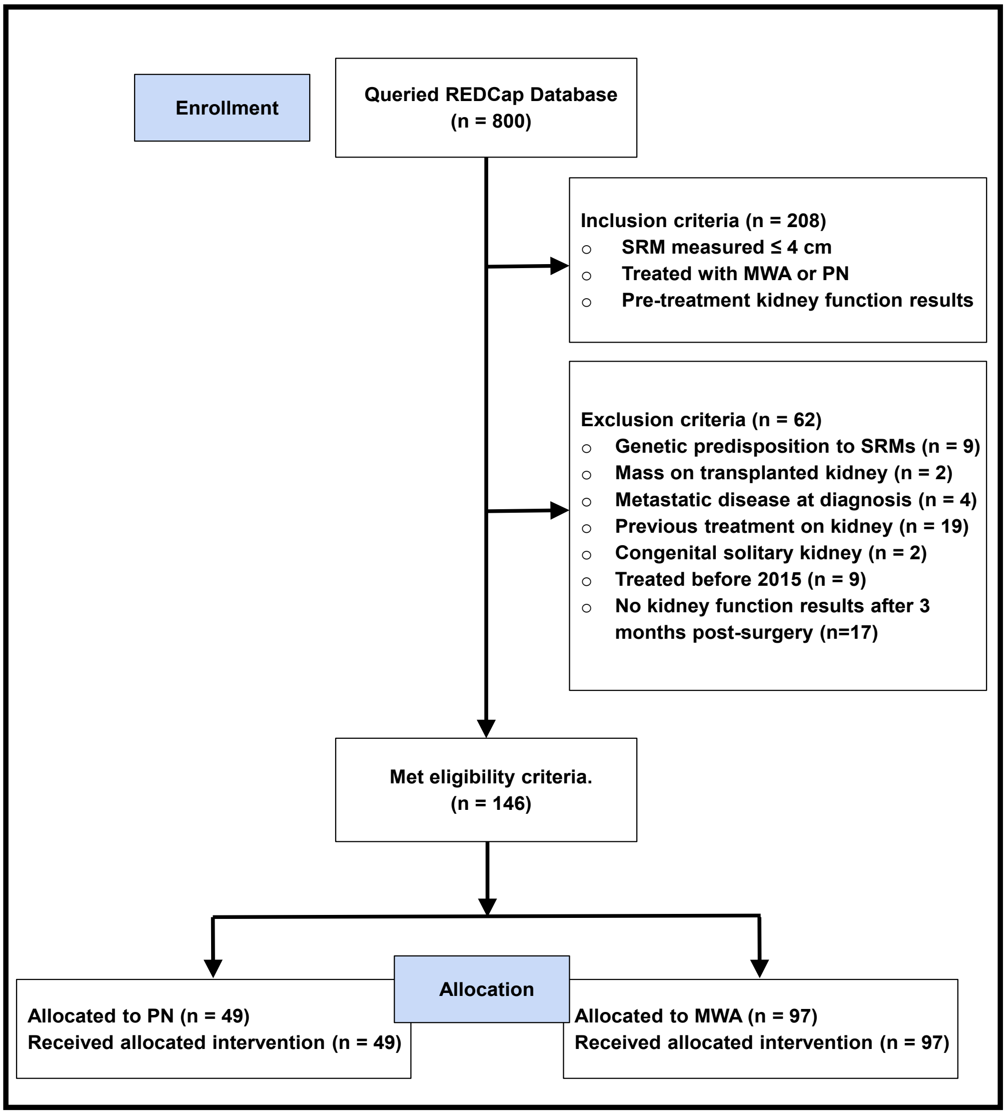

FIGURE 1. Patient flow chart with inclusion and exclusion criteria.

Partial nephrectomy

Robotic assisted PN were performed under general anesthesia with a transperitoneal approach. Standard clamping of the renal artery was utilized, and warm ischemia time was limited to 30 minutes. Open PN was performed as per surgeon preference. Generally, the renal artery and vein were clamped and then ice was applied with cold ischemia time limited to 60 minutes. Ureteral stenting was not standard practice. Afterwards, drains were left in place; patients remained hospitalized until they could tolerate solid food and ambulate without pain.

Microwave ablation

MWA (NeuwaveTMETHICON) was performed under general anesthesia with a percutaneous approach. Image guidance in the form of CT, US, or a combination, was used to place and confirm antenna position. Hydrodissection was used to protect adjacent organs if the expected ablation zone included non-target anatomy. Continuous cold saline irrigation via ureteral catheter was used to cool the renal collecting system if there was concern for injury. Patients were monitored afterwards for 4 hours and either discharged the same day or admitted for 23-hour observation. CT with contrast was typically performed to assess immediate treatment efficacy.

Data collection and outcomes

Kidney function was assessed based on estimated glomerular filtration rate (eGFR) calculated using the race-free 2021 CKD Epidemiology Collaboration (CKD-EPI) creatinine equation6 for outpatient serum creatinine measurements. To ensure no inpatient kidney function data was included, any measurements during an admission period were excluded as well as measurements collected on consecutive days. Baseline eGFR was determined using the average of all eGFRs within 3 months prior to surgery. Follow-up eGFRs after 3 months of surgery were used to evaluate kidney function decline. Measurements within 3 months after surgery were not used due to potential for reversible perioperative changes.

Three outcomes of interest were 1) >30% decline in eGFR from baseline that persisted for >3 months; 2) Increase in CKD stage and eGFR <60 mL/min/1.73m2 that persisted for >3 months; and 3) The composite endpoint of the previous two events, whichever occurred first. CKD upstaging was defined as any increase in CKD stage, including advance from stage 3a (eGFR 45-59 mL/min/1.73m2) to 3b (eGFR 30-44 mL/min/1.73m^2). Patient demographics, tumor characteristics including tumor diameter and biopsy results were collected. Charlson Comorbidity Index (CCI) was calculated for each patient at time of diagnosis.[7] Complications were scored by Clavien-Dindo classifications.

	MWA	PN	p value
Patient Characteristics			
Patients, n	97	49	
Median Age, years (IQR)	62 (56-69)	60 (48-67)	**0.037**
Male, no. (%)	60 (61.9)	31 (63.3)	0.87
Female, no. (%)	37 (38.1)	18 (36.7)	-
CCI, points (IQR)	5 (3-6)	5 (4-6)	0.86
Tumor Characteristics			
RCC, n (%)	91 (93.8)	46 (93.9)	0.364
Clear cell RCC, (% of RCC)	68 (73.9)	38 (82.6)	-
Papillary (% of RCC)	14 (15.2)	7 (15.2)	-
Clear cell RCC + Papillary (% of RCC)	5 (5.4)	0 (0)	-
Chromophobe, n (%)	2 (2.2)	1 (2.2)	
Oncocytoma, n (%)	2 (2.1)	0 (0)	-
Other, n (%)	4 (4.1)	3 (6.1)	-
Kidney Function			
Baseline eGFR, mL/min/1.73m^2 (IQR)	87 (64-98)	97 (82-106)	**<0.001**
Baseline CKD 3a+, %	21	0	-
Patient Complications			
Total complications, n (%)	10 (10.3)	6 (12.2)	0.73
High grade complications 3b+, n (%)	4 (4.1)	2 (4.1)	0.81

TABLE 1. Baseline demographic, clinical, and tumor characteristics for patients undergoing microwave ablation versus partial nephrectomy

Statistical analysis

The follow-up period for the outcome started 3 months after surgery and ended at the earliest date of the following events: first occurrence of the outcome event, new treatment, loss-to-follow-up, and the last eGFR (prior to end of study, 02-24-2024). New treatment occurred as a few patients required additional treatment either for recurrence or another SRM. Loss-to-follow-up was defined as >2 years passed without kidney function measurement and patients were censored at the last eGFR before the 2-year gap.

Effects of MWA compared to PN were assessed using Cox proportional hazards models, fitted for each outcome, with and without adjustment for covariates. The covariates, selected a priori as they are known to be associated with CKD outcomes, were demographics including age, sex, and race (non-black versus black), baseline eGFR, and CCI. We also calculated the event rate for each treatment arm, expressed as the number of outcome events per 100 patient-years.

Baseline characteristics are presented as median with interquartile ranges (IQR), or number (%), as appropriate with comparisons analyzed by student's t-test. A threshold of p = 0.05 was used for statistical significance. Analyses were performed with SPSS Statistics Version 29.0.0.

RESULTS

Baseline characteristics

Patient and tumor characteristics of 146 patients, treated with MWA or PN for tumors ≤4 cm, are presented in Table 1. Patients undergoing MWA were older compared to PN

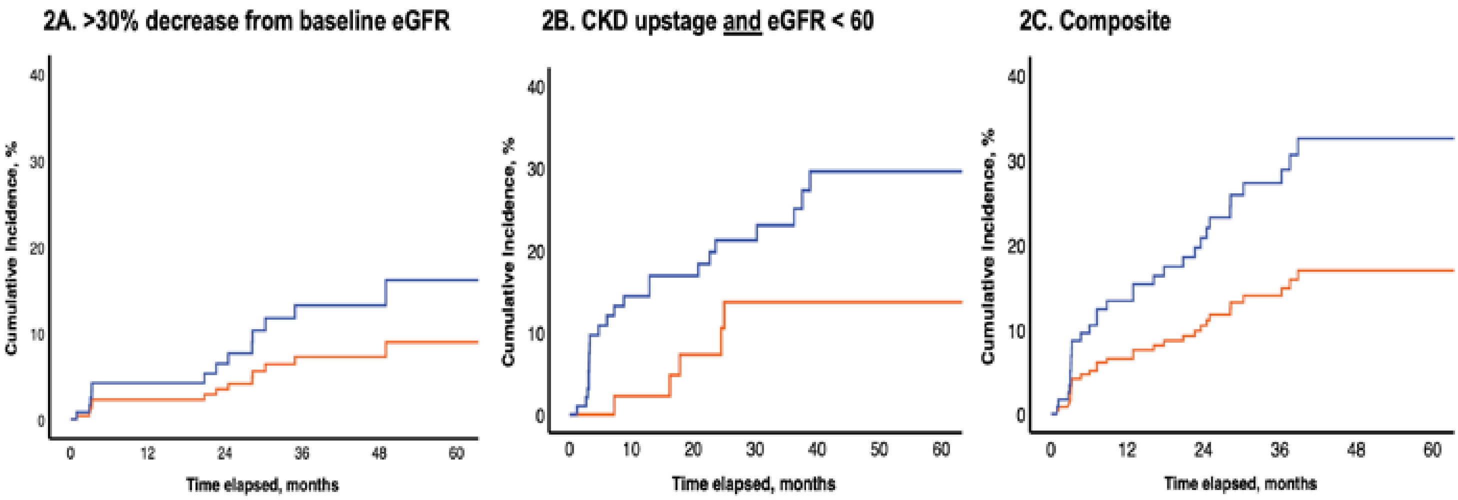

FIGURE 2. Cumulative incidence, unadjusted. Legend: blue represents microwave ablation; orange represents partial nephrectomy. eGFR = estimated glomerular filtration, CKD = chronic kidney disease

(median 62 versus 60 years, p = 0.037). Baseline eGFR for MWA was significantly lower at median 87 versus 97 mL/min/1.73m2 ($p<0.001$). Of MWA patients, 21% had stage 3 CKD, defined as eGFR <60 mL/min/1.73m^2, compared to 0% in PN.

Biopsy data demonstrated similar rates of malignancy between both groups. Within RCC, clear cell RCC was the predominant pathology across both groups. Rate of total and high-grade complications, defined as Clavien Dindo 3b+, were observed at similar rates between the two groups. Total complication rate was 12.2% and 10.3% in PN and MWA patients respectively. High-grade complications were less common at 4.1% in both groups.

Kidney function outcomes

The median months between eGFR measurements were 5.03 and 5.09 (p=0.75) for PN and MWA. Over a median follow-up of approximately 3 years (32.5 months in PN and 36.9 months in MWA), fewer patients in the PN group versus MWA reached the three kidney outcome events (outcome 1: 6.1 vs 11.3%; outcome 2: 12.2 vs 22.7%; outcome 3: 14.3 vs 25.8%; Table 2). This trend remained consistent for event rate, with PN having approximately half the event rate of MWA (Table 2).

As shown in Figure 2, cumulative incidence of outcome 1 for MWA versus PN at 2 years was 7.2% versus 2%, and at 4 years was 14.2 versus 5.1%. For outcome 2, MWA versus PN at 2 years was 21.2% versus 7.3%, and at 4 years,

	MWA	PN
Outcome 1: >30% decrease from baseline eGFR		
Events, no (%)	11 (11.3)	3 (6.1)
Event rate, per 100 PY for all patients	4.0	2.1
Event rate, per 100 PY for patients with baseline eGFR >60	3.6	2.3
Event rate, per 100 PY for patients with baseline eGFR <60	28.6	–
Outcome 2: CKD upstaging & eGFR <60 mL/min/1.73m^2		
Events, no (%)	22 (22.7)	6 (12.2)
Event rate, per 100 PY for all patients	9.1	4.3
Event rate, per 100 PY for patients with baseline eGFR >60	7.1	5.0
Event rate, per 100 PY for patients with baseline eGFR <60	14.2	–
Outcome 3: Composite		
Events, no (%)	25 (25.8)	7 (14.3)
Event rate, per 100 PY for all patients	10.7	5.1
Event rate, per 100 PY for patients with baseline eGFR >60	8.3	5.4
Event rate, per 100 PY for patients with baseline eGFR <60	**16.8**	**–**

TABLE 2. Kidney outcomes by treatment group

29.6% versus 13.7%. For outcome 3, MWA versus PN at 2 years was 21.2% versus 9.4%, and at 4 years was 33.1% versus 15.6%.

Table 3 presents the unadjusted and adjusted hazard ratios of each outcome for patients who underwent MWA compared to PN. Consistent with the higher cumulative incidence of each outcome observed for patients treated with MWA, the unadjusted hazard of kidney function decline was similarly higher for MWA compared to PN for each outcome, but the difference was not statistically significant. After adjustment for covariates (age, sex, race, baseline eGFR, CCI), the higher hazard for MWA was attenuated and remained nonsignificant. Among the covariates in the model, baseline eGFR was a significant risk factor for the development of outcome (Table 3). For example, a 10-unit increase in eGFR was associated with a 34% reduction in hazard of the composite outcome (95% CI: 19-47%; p <0.001).

A sensitivity analysis was performed for patients with baseline eGFR >60 mL/min/1.73m^2. Of these patients, 76 were treated with MWA and 49 with PN. Baseline eGFR for MWA patients versus PN was 93.5 (80-101.3) versus 97 (82-106). This is contrasted to the 21 patients with baseline eGFR <60 that were treated only by MWA with baseline eGFR of 44 (32-50). As shown in Table 2, in patients with baseline eGFR >60, treated with MWA or PN, the event rate per 100 patient-years was less for every outcome compared to the entire cohort, treated respectively with MWA or PN, as well as those with baseline eGFR >60 treated by MWA only. In the cohort of patients with baseline eGFR >60, Kaplan Meier analysis for each outcome did not show a difference kidney event -free survival (outcome 1, p=0.91; outcome 2, p=0.08; outcome 3, p=0.076).

For the 19 patients (Figure 1) excluded for previous treatments on kidney prior to treatment (treatment patterns described in Supplementary Table 1) with MWA or PN, we performed a subset analysis that is shown in Supplementary Table 2. The event rate per 100-patient years for all three outcomes was higher in patients with previous treatment compared to those in our main cohort without previous treatment.

	Hazard Ratio	95% Confidence Interval	p value
Event 1: >30% eGFR decrease from baseline eGFR			
Cox PH comparing treatment	1.88	0.53-6.75	0.33
Cox PH with covariates	0.28	0.04-2.25	0.28
Baseline eGFR as covariate	0.63	0.43-0.92	**0.017**
Event 2: CKD upstaging & eGFR <60 mL/min/1.73m^2			
Cox PH comparing treatment	2.22	0.89-5.54	0.088
Cox PH with covariates	0.58	0.15-2.27	0.44
Baseline eGFR as covariate	0.67	0.54-0.83	**<0.001**
Event 3: Composite			
Cox PH comparing treatment	2.12	0.91-4.95	0.083
Cox PH with covariates	0.48	0.13-1.78	0.27
Baseline eGFR as covariate	0.66	0.53-0.81	**<0.001**

TABLE 3. . Cox Proportional Hazard models for Kidney Event Free Survival.

DISCUSSION

Thermal ablative techniques are increasingly utilized as an alternative to PN for treating cT1a SRMs. As evidence accumulates to suggest cancer specific outcomes, such as survival free of local recurrence, metastatic recurrence, cancer-specific death, of ablative methods are comparable to PN, there is growing interest in preservation of kidney function.[8–12] With patients living longer after treatment and the growing rate of incidental SRM diagnoses in older patients, preventing kidney function decline and minimizing CKD-associated morbidity and mortality is critical. This study sought to compare changes in kidney function as well as association of demographics and baseline kidney function between patients with cT1a SRM undergoing MWA versus PN. Patients treated with MWA were significantly older with worse baseline kidney function. After adjusting for covariates, there was no significant difference in kidney function decline for patients treated with MWA compared to PN.

With the rising rates of SRM diagnosis as well as greater prevalence of CKD, the use of suitable end points to measure kidney failure is paramount.[5,13] The timing of measurement and follow-up is also important. Both MWA and PN will likely cause an acute effect on GFR that may not accurately represent long-term irreversible nephron loss. Follow-up should be long enough to thoroughly characterize benefits and harm. Levey et al. reported in a study cosponsored by the NKF and USFDA that GFR decline of 30% over 1-3 years could serve as a useful surrogate end point for progression to kidney failure as it is associated strongly and consistently with future ESRD.[4] Determining when kidney function reaches a steady state after intervention can address the challenge of measuring true nephron loss as opposed to acute perioperative insult. Lane et al. demonstrated with a larger study group of 1,169 patients that steady state was achieved for PN patients after 3 weeks.[14]

To our knowledge, few studies have utilized these rigorous parameters to study kidney function decline and progression of CKD in patients with RCC. By using three outcomes, 30% eGFR decline, CKD upstaging, and a composite end point, we hope to strengthen the clinical validity of our study. The second event included both CKD upstaging and eGFR <60 as our clinical concern was patients with transitioning to moderate-severe CKD or worse. Our median follow-up time for both treatment arms, 32.5 and 36.9 months for PN and MWA, were adequate to thoroughly evaluate a longitudinal decline. The median CKD for MWA was 2 (IQR 1-2) and for PN was 1 (IQR 1-2). Our follow-up falls within the recommended interval of measurement for patients in stages 1-2, which is 6-12 months.[15]

Before adjusting for covariates, we observed a higher, but not statistically significant, risk of kidney function decline for patients treated with MWA compared to patients treated with PN when covariates were not adjusted for. After adjusting for demographics, baseline eGFR, and CCI, the higher risk was attenuated and revealed statistical non-significance. This suggests that the unadjusted higher risk of kidney function decline observed for MWA compared to PN was largely explained by the patient factors in the model. Of these factors, baseline eGFR was statistically significant, which is consistent with a previous study reporting that patients with worse CKD are more likely to have faster decline of kidney function.16 This is further demonstrated in our subset analysis of patients with baseline eGFR >60 as the event rate per 100 patient-years was consistently less per treatment modality and outcome. These results suggest that systematic factors could be influencing the decision to select MWA vs PN for any given patient, and/or that those systematic factors could also be influencing the outcome. Indeed, we considered applying propensity-score matching to deal with the nonrandom treatment assignment and the baseline differences between treatment groups, but we were unable to sufficiently match the cohorts. Given that this is an observational study, these factors could influence our results. We may not have enough statistical power to detect the true effect size, and/or systematic factors may be confounding the true effect of treatment.

The mortality benefits of NSS have been shown in studies comparing PN to RN, with PN demonstrating decreased rates of de novo CKD, AKI, overall mortality, and cardiovascular events.[17–19] Within those PN patients, predictors of long-term kidney function include preoperative eGFR, older age, female gender, and acute loss of kidney function in the postoperative period.[14] Within NSS, investigators have found that kidney function decline in ablative strategies are comparable if not better than PN. A systematic review was published demonstrating that ablative techniques had smaller decreases in eGFR compared to PN.[10] Lucas *et al.* compared radiofrequency ablation to PN and found that patients treated with PN was 10.87 times more likely to lead to GFR decreasing below 60.18 Unfortunately, there is great variability in the studies comparing kidney function amongst NSS, with some measuring the acute period prior to discharge while others follow patients anywhere from 6 months - 3 years. Most studies also report either absolute or relative decreases in eGFR or progression to a certain CKD stage, which may not necessarily serve as an appropriate surrogate for future progression to kidney failure. Potentially, the use of warm ischemia in PN could lead to development of CKD compared to thermal ablative methods that do not require any ischemia period.[20,21]

Our study is limited by the small sample size. After applying exclusion criteria and required follow up parameters, there were only 49 PN and 97 MWA patients to be analyzed. Such a small number likely limited our statistical modeling and prevented us from applying propensity-score matching to our treatment arms. As our populations are significantly different in age and baseline eGFR, both factors which have been previously demonstrated to predict long-term kidney function, propensity matching in larger sample sizes may allow for a better comparison of the treatment modalities. We were also limited by the retrospective and non-randomized nature of the study. Finally, progression of CKD should be assessed with both eGFR and albuminuria. Unfortunately, as many of our SRM patients do not present with or develop moderate-severe CKD, we do not routinely measure albuminuria.

CONCLUSION

The impact of CKD on patient outcomes such as mortality and cardiovascular morbidity is well established. Therefore, treatment modalities for cT1a SRM must balance oncological efficacy and preservation of kidney function. While recommendations have been made by the NKF and the USFDA as to the best end points to measure potential for future kidney function decline, this is the first study we know of that utilizes these recommendations to measure kidney function for patients undergoing PN versus MWA. Our findings show that despite worse baseline kidney function and older patient age, MWA is noninferior to PN in preserving kidney function in those patients treated for cT1a SRMs. After adjustment for demographics, the association between treatment and kidney function decline outcomes remained nonsignificant, and the only factor significantly associated with risk of outcomes was baseline eGFR. In patients with CKD, microwave ablation should be further explored as an alternative therapeutic option that could offer at least equal renal preservation to PN.

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