# Surveillance post-radiofrequency ablation for small renal masses: Recurrence and followup

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## Abstract

**Introduction:** Small renal masses (SRMs), enhancing tumors <4 cm in diameter, are suspicious for renal cell carcinoma (RCC). The incidence of SRMs have risen with the increased quality and frequency of imaging. Partial nephrectomy is widely accepted as a nephron-sparing approach for the management of clinically localized RCC, with a greater than 90% disease-specific survival for stage T1a. Radiofrequency ablation (RFA) has been emerging as an alternative management strategy, with evidence suggesting RFA as a safe alternative for SRMs. We aimed to evaluate the time to recurrence and recurrence rates of SRMs treated with RFA at our institution.

**Methods:** A retrospective review between October 2011 and May 2019 identified 141 patients with a single SRM treated with RFA at Hamilton Health Sciences and St. Joseph's Healthcare Hamilton. Patients with familial syndromes and distant metastases were excluded. Repeat RFAs of the ipsilateral kidney for incomplete ablation were not considered a new procedure. The primary variable measured was time from initial ablation to recurrence. A Cox proportional hazard regression model was used to identify possible prognostic variables for tumor recurrence defined a priori, including age, gender, mass size, RENAL nephrometry, and PADUA scores.

**Results:** The overall average age of our patients was 69.0±11.1 years, with 71.6% being male. Average tumor size was 2.6±0.8 cm. There were 22/154 total recurrences (15.6%) post-RFA. Median followup time was 67 (18–161) months. Those with new recurrences had median time to recurrence of 15 months and no recurrence beyond 53 months. Thirteen of 141 patients had residual disease (9.2%) and were identified within the first eight months post-RFA. The only prognostic variable identified as a predictor of residual disease was tumor size (hazard ratio 2.265; p<0.001).

**Conclusions:** This study shows the risk of a new recurrence following RFA for SRMs is 6.4%. Most recurrences (9.2%) were a result of residual tumor at the ablation site identified within the first eight months post-RFA. No recurrences were identified beyond 53 months, with a total median followup time of 67 months. Tumor size alone, without need for complex scoring systems, may serve as a predictor of incomplete ablation following RFA and could be used to assist in shared decision-making on management strategies.

## Introduction

Small renal masses (SRMs) are defined clinically as solid enhancing tumors ≤4 cm consistent to stage T1a N0 M0 renal cell carcinoma (RCC).[1-3] The incidence of SRMs has increased in part due to the increased use of cross-sectional imaging; however, mortality rates have not followed similar patterns.[4-6] Currently, the standard treatment therapy for local RCC has been partial nephrectomy and radical nephrectomy, depending on the location and characteristics of the lesion.[2,3,6-8] Treatment for these SRMs has changed tremendously over the past decades, with radiofrequency ablation (RFA) emerging as a treatment option for soft tissue tumors in the 1990s.[9] Recently, RFA and active surveillance (AS) have been used as alternative management strategies dependant on patient preference and surgical risk factors.[2,8,10-13] Outcomes from surgical management with partial nephrectomy are excellent for T1a RCC, with over 90% disease-specific survival.[7,14] Long-term followup and outcomes have not been as well-studied for RFA therapy for SRMs, although there have been a few reported studies suggesting that RFA is a safe and effective treatment option for SRMs <3 cm in diameter.[12,15]

SRMs found in the elderly, frail, or patients with a solitary kidney may not be good candidates for surgical management and may be better managed under AS. Those patients unwilling to accept the inherent risks of AS or are poor surgical candidates may benefit from RFA. Risk of surgery should be weighed against life expectancy, malignant potential, and chance of recurrence. Approximately 20–25% of SRMs are benign and even when malignant, growth rates are only approximately 0.12 cm/year on average.[16,17]

With the increased use of RFA for SRMs and lack of long-term evaluation of oncological outcomes, consensus for followup, imaging surveillance, and chance of recurrence needs to be determined. In contemporary literature, local recurrence rates post-RFA have been reported from 0–19%.[10,12,13,18-28]

Here, we performed a retrospective review of SRMs treated with RFA between October 2011 and May 2019 at our academic center. The objective of this study was to assess and review the overall rate and time to recurrence of RFA-treated SRMs to better guide our management and followup strategies. Secondary objectives were to identify predicting factors selected a priori for recurrence and incomplete ablations based on expert opinion and a previous pilot study.

## Methods

### Patient selection and predicting factors

Institutional review board approval was obtained prior to retrospective chart review of electronic medical records of patients with a new diagnosis of a SRM who underwent RFA. A total of 174 recorded ablation procedures were reviewed between October 2011 and May 2019. Patients with familial syndromes at risk for multiple RCC lesions, distant metastases, biopsy-proven oncocytomas, and those with less than 12 months' followup were excluded from the dataset. Repeat RFAs of the ipsilateral kidney for incomplete ablation were not included as new ablation procedures in the context of predicting factors for tumor recurrence.

Tumors were imaged prior to RFA using either contrast-enhanced computed tomography (CT) or magnetic resonance imaging (MRI). Biopsies were available in 174 patients and done simultaneously at the time of RFA. Benign lesions were excluded from the analysis. The final cohort consisted of 141 patients. Prognostic variables were defined beforehand based on expert opinion and a previous pilot study that included patient age and gender, as well as tumor size, pathology, RENAL nephrometry score, and PADUA score. RENAL nephrometry score and PADUA score were determined by two separate non-radiologist observers based on most recent imaging prior to RFA, as previously defined.[29,30] In the pilot study, we looked at both total score and each individual component, but found no significance. Pilot study data is included in Supplementary Tables 1, 2, 3. Tumors were staged according to the American Joint Committee on Cancer TNM system.

### Radiofrequency ablation procedure

All patients were seen by a urologist and referred for outpatient consultation with an interventional radiologist prior to the ablation for assessment. The parameters for the RFA procedures, including probe size, energy, and roll off time, were as per radiology protocols based on original imaging and tumor size.

The LeVeen RF3000 RFA system (Boston Scientific) and accompanying electrodes were used in all cases. Probes were placed under CT, ultrasound, or cone-beam CT guidance. Cone beam CT was used instead of conventional CT due to limited availability of CT time. Ablation was carried out per the IFU for renal mass ablation. Choice of probe size and use of overlapping ablations was at the operator's discretion.

### Post-procedure followup

All patients were followed with contrast-enhanced CT, MRI, or ultrasound post-RFA at intervals of three, six, nine, and 12 months, then annually thereafter to evaluate evidence of recurrence locally and for any metastatic spread, unless poor renal function prohibited the use of contrast as determined by radiology. In general, abdominal MRI was done with or without gadolinium or CT was performed according to standard protocol with 5 mm sections both with and without contrast.

Recurrence was defined as any sign of new or residual tumor at any point during followup with imaging on either CT or MRI anywhere in the originally ablated kidney. We had also predetermined to analyze a subgroup for incomplete RFA procedures, which we defined as any evidence of residual disease at the ablation site on first imaging post-RFA done three months after the initial procedure with a CT scan, as this was likely incomplete ablation rather than true recurrence. Though we attempted to standardize intervals for followup imaging, due to patient factors the primary measure for duration to recurrence was measured in months rather than number of negative imaging studies. This subgroup selection was based on our pilot study, which showed that larger tumors tended to have a higher frequency of recurrence, but that they were all in the first 3–6 months and did not have a disease-free period before recurrence.

Though complications were not recorded in a standardized fashion at the time of procedure, each chart was reviewed for any significant complications post-procedure based on followup clinical visits.

### Statistical analysis

Categorical variables are reported here through descriptive statistics, including frequencies and proportions. Means and medians with standard deviation and interquartile ranges are presented for continuous variables.

Univariate and multivariate Cox proportional hazard analyses were completed to assess for predicting factors between patient factors (age, gender) and tumor characteristics (tumor size, location, biopsy pathology) with recurrence and incomplete ablations. Tumor size was analyzed in increments of 0.1 cm corresponding to the degree of specificity of the size reported on conventional imaging. The multivariate analysis included all significant variables and one variable to include with the smallest p-value in addition to tumor size to evaluate if the results remained significant

and independent in all groups and subgroup analyses. We initially included the RENAL and PADUA scores in our pilot study as predictive factors, but the data did not show any significant predictive value with respect to tumor recurrence (Supplementary Tables 1, 2, 3). Subgroup analysis was completed for patients with new tumor recurrences, as well as for those with residual tumor following first RFA procedure as described above.

All statistical analyses were performed using IBM® SPSS® Statistics software package (IBM Corp. Released 2015. IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp).

## Results

Baseline patient demographic and tumor characteristics are reported in Table 1. Most patients who had biopsy before the procedure had pathology in agreement with clear-cell RCC (51.1%). Of note, 44 patients either had biopsies that were non-diagnostic or not done before RFA and we chose to include these patients in the study. Although 22 patients were shown to have papillary RCC, their charts did not reflect whether these were specially type I or type II. Overall average tumor size was 2.57±0.84 cm. Subgroup analysis showed that although there was evidence that patients who had residual disease or incomplete ablation had higher average tumor size than those in the new recurrence group, this did not reach statistical significance when comparing the two groups (3.53±1.22 cm vs. 2.69±0.75 cm,; p=0.08). Table 2 shows the distribution of recurrences based on tumor size.

Thirty-three patients had benign lesions (32 oncocytomas and one angiomyolipoma) and were not included in the 141 patients reviewed. Median time to recurrence was 15 months (range 6–53), with no recurrences occurring beyond 53 months post-RFA.

Of the 141 patients, nine (6.4%) had new recurrences and 13 (9.2%) had evidence of residual disease or incomplete ablation during the followup period. In total, 126 patients (89.4%) were initially evaluated with CT scans and the remaining 15 (10.6%) were initially evaluated with MRI. Median length of followup for all patients was 67 months (range 18–161). Three of the nine new recurrences (33.3%) had successful repeat RFA procedures, four (44.4%) were kept on AS, one had a radical nephrectomy, and one patient progressed to metastatic disease after surveillance and chose to have no further treatment. Six of the 13 patients (46.1%) with residual disease had successful repeat RFA, while three (18.8%) went on to radical nephrectomy, two (15.4%) elected for AS, one (7.7%) was treated with sunitinib for metastatic disease likely due to pT3 disease in the contralateral kidney previously resected, and one patient was lost to followup. Median followup of all patients was 67 months (range 18–161).

On univariate and multivariate analysis (Table 3), tumor size was positively associated with recurrence disease (hazard ratio [HR] 2.158, 95% confidence interval [CI] 1.477–3.153, p<0.001). Subgroup analysis for either incomplete ablation or residual disease (Table 4) was also positively associated with tumor size (HR 2.256, 95% CI 1.461–3.512, p<0.001), but this was not shown for new recurrence (Table 5) (HR 1.395, 95% CI 0.629–3.095, p=0.436).

No clinically significant complications (≥ Clavian-Dindo III) requiring subsequent intervention were reported.

**Table 1. Patient demographics**

| Parameter | Variable |
|---|---|
| Cases | 141 |
| Mean age | 69.0±11.1 |
| New recurrences, n (%) | 9 (6.4%%) |
| Incomplete ablations, n (%) | 13 (9.2%) |
| Total recurrences, n (%) | 22 (15.6%) |
| Median followup (range) | 67.0 (18.0–161.0) months |
| Gender | 101 male (71.6%), 40 female (28.4%) |
| Mean tumor size | 2.57±0.84 cm |
| Pathology | 72 clear-cell RCC (51.1%), 44 non-diagnostic (31.2%), 22 papillary RCC (15.6%), 3 chromophobe (2.1%) |

RCC: renal cell carcinoma.

## Discussion

SRMs are increasing in incidence likely due to the increasing accessibility, and reduction in cost of axial imaging results in more incidental findings. The current gold standard treatment for RCC has been either partial or radical nephrectomy, but RFA has been used more frequently in the past 20 years for SRMs.[2,8,10-13] RFA is a less invasive procedure that can be beneficial for patients who are poor surgical candidates, have declined AS, or in which AS is inappropriate. No clinically significant complications were reported based on our data; however, we acknowledge that this is limited by the retrospective nature of the review. Shared decision-making should be undertaken with patients to discuss the potential benefits and risks of RFA vs. other modalities of treatment or surveillance. These include RFAs less invasive nature, but lack of long-term data and potential need for secondary intervention. While there are various guidelines on followup

**Table 2. Distribution of recurrence by tumor size**

| Tumour size | n | | |
|---|---|---|---|
| | True recurrence | Incomplete ablation | No recurrence |
| <1 cm | 0 | 0 | 0 |
| 1–2 cm | 2 | 0 | 37 |
| 2–3 cm | 4 | 8 | 62 |
| >3 cm | 3 | 5 | 20 |

**Table 3. Cox proportional hazard regression analysis for all recurrences and incomplete ablation**

| | Univariate analysis | | | Multivariate analysis | | |
|---|---|---|---|---|---|---|
| **Parameter** | **HR** | **95% CI** | **p** | **HR** | **95% CI** | **p** |
| Age | 1.017 | 0.977–1.058 | 0.408 | | | |
| Gender | 0.925 | 0.362–2.364 | 0.871 | | | |
| Tumor size | **2.158** | **1.477–3.153** | **<0.001** | **2.027** | **1.369–3.001** | **<0.001** |
| Tumor side | 1.917 | 0.781–4.703 | 0.155 | 1.005 | 0.971–1.041 | 0.771 |

CI: confidence interval; HR: hazard ratio.

and imaging post-partial or radical nephrectomy for RCC, there have been few on RFA-specific followup.

Our original pilot study was designed to gather information on recurrences rates in our patients who underwent RFA and determine if tumor characteristics could be used as predictors for patients who are at risk for recurrence. At first, we attempted to use more complex scoring systems, such as the RENAL nephrometry and PADUA scores, but they did not show any significant benefit for prediction of tumor recurrence or residual tumor post-RFA over maximum tumor size alone. Here, we completed a larger review of our patients with long-term followup after RFA and again showed that larger tumors appear to be a positive predictor of recurrence, with a HR of 2.256. Patients who had recurrences had statistically significantly larger tumors (3.53±1.22 cm vs. 2.47±0.72 cm). This is explained by subgroup analysis for patients who had incomplete ablation post-RFA, which showed significance of tumor size and is not seen in patients with true new recurrences during their followup. This suggests that although tumor size may be helpful in determining which patients may require a secondary procedure after RFA, it is still unclear whether this can be used to determine patients are at higher risk for recurrence following successful treatment.

The original design and purpose of this study was to identify patients who had recurrence of RCC post-RFA therapy to help guide followup strategies. Overall, our recurrence rates (15.6%) were within what is reported in contemporary literature for partial and radical nephrectomy. It is important to highlight from this data that most of these recurrences were a result of incomplete ablation (13/22 cases). Only one patient with residual disease went on to eventual progression of metastatic disease and the rest had secondary procedures with either a repeat RFA, nephrectomy, or continued with AS.

Of all recurrences, the median time to recurrence was 15 months, with no recurrences occurring after 53 months. This suggests that most recurrences are likely to occur within the first few years after RFA and that followup for RCC post-RFA can be similar to that of RCC post-surgical resection after 1–2 years. Post-RFA surveillance can possibly be discontinued after five years, but further research is needed for confirmation.

The authors acknowledge that there are limitations to this study. These include the retrospective nature, single-center patient population, lack of pathological confirmation of RCC in 44/141 (31%) of patients, and smaller sample size for regression analysis. As a result, we cannot comment on a cutoff tumor size that would significantly increase risk of incomplete ablation or future recurrence. This could be investigated in the future with larger studies and more data

## Conclusions

Overall, this study shows the risk of recurrence following RFA for SRMs is 15.6%. Most recurrences were a result of incomplete ablation at the original site identified within the first eight months post-RFA and that tumor size is predictive of this occurrence. Tumor size alone, without need for complex scoring systems, may serve as a predictor of incomplete ablation following RFA and could be used to assist in shared decision-making on management strategies. No recurrences were identified beyond 53 months, with a total median followup time of 67 months. A modified followup imaging schedule post-surgical resection for non-metastatic RCC can be used with more frequent imaging in the first year. This report suggests that post-RFA surveillance may be discontinued after five years, but further data is needed to confirm this.

**Table 4. Cox proportional hazard regression analysis for incomplete ablation following RFA**

| | Univariate analysis | | | Multivariate analysis | | |
|---|---|---|---|---|---|---|
| **Parameter** | **HR** | **95% CI** | **p** | **HR** | **95% CI** | **p** |
| Age | 1.029 | 0.976–1.086 | 0.286 | | | |
| Gender | 1.106 | 0.341–3.593 | 0.866 | | | |
| Tumor size | **2.506** | **1.640–3.827** | **<0.001** | **2.265** | **1.461–3.512** | **<0.001** |
| Tumor side | 1.950 | 0.600–6.332 | 0.267 | 1.451 | 0.429–4.910 | 0.550 |

CI: confidence interval; HR: hazard ratio; RFA: radiofrequency ablation.

**Table 5. Cox proportional hazard regression analysis for new tumor recurrences following RFA**

| | Univariate analysis | | |
|---|---|---|---|
| **Parameter** | **HR** | **95% CI** | **p** |
| Age | 1.000 | 0.942–1.062 | 0.998 |
| Gender | 0.695 | 0.144–3.348 | 0.650 |
| Tumor size | 1.395 | 0.629–3.095 | 0.413 |
| Tumor side | 1.872 | 0.468–7.489 | 0.375 |

CI: confidence interval; HR: hazard ratio; RFA: radiofrequency ablation.

**Competing interests:** Dr. Kapoor has been an advisory board member for and participated in clinical trials supported by Amgen, Astellas, Janssen, GSK, Novartis, Pfizer, and Sanofi. The remaining authors report no competing personal or financial interests related to this work.

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**Supplementary Table 1. Patient demographics**

| **Parameters** | **Variables** |
|---|---|
| Cases (n) | 84 |
| Mean age | 68.6±10.6 years |
| Gender | 59 male, 25 female |
| Tumor size | 2.42±0.81 cm |
| Pathology | 40 clear cell, 16 papillary RCC, 3 chromophobe, 25 not completed |
| RENAL nephrometry score | 6.81±1.58 |
| PADUA score | 8.13±1.39 |

RCC: renal cell carcinoma.

**Supplementary Table 2. Cox proportional hazard regression analysis for residual tumor following RFA**

| | Univariate analysis | | | Multivariate analysis | | |
|---|---|---|---|---|---|---|
| **Parameters** | **HR** | **95% CI** | **p** | **HR** | **95% CI** | **p** |
| Mean age | 1.03 | 0.94–1.13 | 0.582 | | | |
| Gender | 1.61 | 0.27–9.60 | 0.604 | | | |
| Mean tumor size | 2.40 | 1.01–5.71 | 0.047 | 2.13 | 0.81–5.63 | 0.127 |
| RENAL score | 2.95 | 0.53–16.41 | 0.217 | 1.05 | 0.08–13.45 | 0.973 |
| PADUA score | 2.62 | 0.64-10.78 | 0.183 | 1.98 | 0.26-15.33 | 0.512 |

CI: confidence interval; HR: hazard ratio; RFA: radiofrequency ablation.

**Supplementary Table 3. Cox proportional hazard regression analysis for new tumor recurrence following RFA**

| | Univariate analysis | | |
|---|---|---|---|
| **Parameters** | **HR** | **95% C** | **p** |
| Mean age | 1.01 | 0.92–1.10 | 0.900 |
| Gender | 0.03 | 0–354.34 | 0.464 |
| Mean tumor size | 1.27 | 0.41–3.93 | 0.684 |
| RENAL score | 1.21 | 0.21–6.95 | 0.830 |
| PADUA score | 1.56 | 0.38–6.43 | 0.541 |

CI: confidence interval; HR: hazard ratio; RFA: radiofrequency ablation.