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Radiofrequency Ablation of Renal Tumors in Patients with Metastatic Renal Cell Carcinoma

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Abstract

Purpose—The goal of this retrospective study was to evaluate the feasibility, safety, and outcomes of using radiofrequency ablation (RFA) of primary renal tumors as a means of controlling local disease while preserving renal parenchyma in a series of patients with metastatic renal cell carcinoma (RCC) in a single-institutional, multidisciplinary setting.

Materials and Methods—We evaluated the records of patients with metastatic RCC who had undergone percutaneous RFA of a primary renal tumor. Patients' demographic and disease characteristics, adjunctive medical and surgical therapies, recurrence, and clinical outcomes were studied.

Results—Fifteen patients treated between 2002 and 2008 met the inclusion criteria. There was no incomplete ablation or local recurrence. Ten patients had a biopsy-proven RCC in the ablated renal mass. Eight patients had a solitary metastasis, 3 patients had 2-site metastases, and 4 patients had 3 or more metastatic sites. Four patients experienced major complications. Median radiographic and clinical followup of patients at risk for an event was 25.5 and 33.0 months, respectively. Overall survival rates at 1, 3, and 5 years after RFA were 73.3%, 57.1%, and 38.1%, respectively. At last evaluation, 4 were alive and in complete remission, 4 were alive with no evidence of local recurrence but with evidence of distant disease, and 7 had died of their disease.

Conclusions—RFA is feasible and safe in highly selected patients with metastatic RCC, resulting in durable local control as part of multimodality management, and achieving renal preservation. Further investigation is required to define the role of RFA in this patient population.

Keywords

renal cell carcinoma; radiofrequency ablation; metastasis

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Metastases occur in up to a third of patients with newly diagnosed RCC.^{1, 2} In addition, up to 40% of patients with localized RCC eventually develop metastases during followup. In 2001, results from 2 studies established cytoreductive nephrectomy followed by immunotherapy as the standard of care for patients with metastatic RCC who had good performance status and favorable prognostic features.^{3, 4} In a meta-analysis of these 2 trials, a median survival of 13.6 months was observed for patients treated with nephrectomy plus interferon vs 7.8 months for those treated with interferon alone.⁵

Because of the potential morbidity associated with cytoreductive radical nephrectomy, however, partial nephrectomy has been explored as an alternative in patients with metastatic RCC and imperative indications for nephron preservation.^{6–8} In these small series, the CSS rates were not significantly different from those of patients who underwent cytoreductive radical nephrectomy. Even though the morbidity associated with partial nephrectomy has improved greatly over the years, its use in patients with metastatic RCC is not without complications and controversy.

Recent series have revealed intermediate-term outcomes of localized RCC treatment using RFA, with encouraging local control and very low rates of development of new metastases.^{9–11} To date, only 2 reports, including only 5 patients total, have described the use of RFA to control the primary renal tumor in patients with metastatic RCC.^{9, 12}

Therefore, we conducted this retrospective study to evaluate the feasibility, safety and outcomes of RFA as a means of controlling local disease while preserving renal parenchyma.

MATERIALS AND METHODS

All patients with metastatic RCC who were treated with RFA of the primary tumor in our urology and interventional radiology services at M.D. Anderson Cancer Center between February 2002 and January 2008 were included in this study. The study was approved by our Institutional Review Board, and the need for written informed consent was waived. Patients had undergone baseline laboratory evaluations, chest radiography, and CT or MRI scanning with multiphasic intravenous contrast to evaluate the renal lesion. Renal nuclear scans were not routinely done.

Patients were generally managed by the medical oncology service and were referred to urology for consideration of treating the renal mass as part of the multimodality management of the disease. The decision to proceed with therapy was performed as part of a multidisciplinary discussion and always with complete informed counseling of the patient. Imperative indications for nephron-sparing treatment were the presence of a solitary kidney or poor renal function. Imperative indications for RFA included multiple medical comorbidities, and/or the patient having been judged a poor surgical candidate or having refused to undergo observation or a surgical procedure involving tumor resection.

Pre-ablation diagnostic core needle biopsies were performed using a 20-gauge needle(Cook, Bloomington, IN), either immediately before RFA or separately before the RFA procedure. Percutaneous RFA was done as previously described.¹³ Briefly, the procedure was

performed using a 200-W, impedance-based device(Cool Tip®, Covidien, Valleylab, Boulder, CO). Under general anesthesia, patients were placed in the prone position in a CT gantry, and the tumor was localized. One or more electrodes were positioned in the tumor with CT-fluoroscopy guidance. Sequential overlapping ablations were performed as indicated by the tumor's size and anatomy and as needed to treat the tumor fully in a single session. Intravenous contrast was frequently given immediately after to assess the zone of ablation and ensure adequate treatment of the mass.

Patients were followed up routinely with medical histories, physical examinations, chest imaging, complete metabolic profiles, and other diagnostic tests as indicated for followup of metastatic sites. We typically obtain a contrast enhanced renal mass protocol CT or MRI within 6 weeks, and again at 6, 12, 18, and 24 months.¹⁴ Thereafter, semiannual or annual followup was performed. However, for this cohort of patients with metastatic disease, abdominal imaging was performed more frequently(typically every 3 months) using contrast-enhanced CT or MRI plus chest imaging and other diagnostic tests as indicated for followup of metastatic disease.

The eGFR was calculated by using the Modification of Diet in Renal Disease equation.¹⁵ Kaplan-Meier life tables were used to estimate overall survival times. Medians (with ranges) and means (with standard deviations) were used to summarize continuous variables. Paired samples with continuous variables were compared using the Wilcoxon's rank-sum test. P values less than 0.05 were considered statistically significant. SPSS version 17.0 was used for all analyses.

RESULTS

A total of 124 patients with RCC were treated with RFA at our center during the period of our study. Of these, 15 had RCC metastases before or at the time of their RFA, and these patients constitute our study cohort. Complete demographic information is summarized in Table 1. Ten of the 15 patients had a previous distant diagnosis of RCC, and 9 had previously undergone a nephrectomy (median size of renal tumor in these patients was 5cm, range 3.5–16). None of the patients in this study had a diagnosed familial RCC syndrome.

The clinical, pathological, and radiological information are detailed in Table 2. Before or at the time of RFA, metastases were present in the lung in 10 patients, bone in 5, adrenal gland in 4, and liver/perihepatic nodules in 3; metastases to the brain, pancreas, soft tissue, pleura, retroperitoneal nodes, and paraesophageal nodes were each present in 1 patient. Eight patients had a solitary metastasis (six solitary lesions were considered metastatic by pathologic evaluation and two solitary lesions were considered metastatic by CT scan), 3 had 2-site metastases, and 4 had 3 or more metastatic sites. No patients experienced incomplete ablation or local recurrence, as defined by absence of contrast enhancement of the tumor or enlargement of the ablated renal mass on imaging.

Median eGFR in all 15 patients before RFA and at last followup was 67.0 and 58.9 mL/min/1.73m², respectively(p=0.55). Median eGFR in the 9 patients with solitary kidneys before RFA and at last followup was 58.7 and 55.3 mL/min/1.73m², respectively(p=0.37).

Four patients experienced major complications (including two patients with a renal mass >6m), and 3 patients had minor complications (including one patient with renal mass >6m) during followup. Three patients with a solitary kidney developed hematuria with subsequent clot occlusion of the ureter; they underwent temporary ureteral stent placement until the hematuria and renal failure resolved, as previously described.¹³ Two patients experienced acute hypertension after the procedure, and were medically managed with no sequelae. One patient experienced a perinephric hematoma that was managed conservatively. None of these patients required selective renal angioembolization. No cardiopulmonary complications or deaths occurred within 30 days of the RFA. Minor complications included pain in 3 patients, transient obstructive uropathy in 2 patients (same as those with clot obstruction described above), and paresthesia in 1 patient. The overall survival rates (standard error) of the patients at 1, 3, and 5 years after RFA were 73.3%(11.4), 57.1%(13.7), and 38.1%(18.0), respectively.

At the time of last evaluation, 4 patients were alive and in complete remission with no evidence of disease at a median followup of 25.5 months(range 19–88). Three of these patients had a histologically proven RCC metastatic lesion before or at the time of RFA. The first patient was treated temporarily with sunitinib before RFA and is currently off therapy. The second patient underwent a metastasectomy(internal hemipelvectomy) with no systemic therapy for RCC prior to RFA. The third patient had not undergone any surgical or systemic therapy besides RFA, which resulted in resolution of hematuria and pain as well as spontaneous resolution of pulmonary metastases. This patient was the subject of a previous report.¹² The fourth patient had no cancer noted in his pre-RFA biopsy specimen; however, his perihepatic metastases resolved after RFA of the renal mass. This patient did not receive any systemic therapy, but had undergone cryoablation of a flank metastasis(located on the same side as his radical nephrectomy) and resection of local renal bed recurrence, both of which were done prior to RFA.

Another 4 of the 15 patients were alive with no evidence of local recurrence but with evidence of distant disease at a median followup of 45 months (range 16–66). One of these patients had RFA of a recurrence after laparoscopic cryoablation. Three of these 4 patients had metastases in 1 organ only(2 in 6 the lung and 1 in the bone), and 1 patient had metastases in 2 organs(lung and liver). Three of these patients received systemic therapy prior to RFA(2 sorafenib only and 1 sunitinib followed by sorafenib). Two of these 3 patients still had stable disease at the time of our evaluation and were no longer being treated with sorafenib; the third was treated with 1 course of erlotinib followed by pemetrexed and gemcitabine since undergoing RFA.

The remaining 7 of the 15 patients died of their disease at a median followup of 10 months (range 2–59). The median number of organs with metastatic involvement for this group was 3(range 1–4).

DISCUSSION

To our knowledge, we report the first series describing in detail the use of RFA of renal masses in patients with metastatic RCC. At the time of our analysis, 4 of the 15 patients

were alive in complete remission, 4 patients were alive with disease, and 7 had died of disease. Complications related to RFA occurred mainly in patients with a solitary kidney and central tumors. However, these complications were temporary and were easily treatable, and therefore had not resulted in the loss of any renal unit. While it may be difficult to say with certainty which patients needed cytoreductive treatment or not, we note that patients with multiple metastases did not benefit from RFA, but it is possible that they would not have benefited from cytoreductive nephrectomy either. In addition, patients who are still alive at last follow-up are ones with low-volume metastatic disease (1 or 2 metastatic sites).

RCC is highly lethal in the presence of metastases. Even with targeted therapy, the median overall survival of patients with metastatic RCC is 10 to 18 months.^{16, 17} Although cytoreductive nephrectomy followed by systemic therapy is the current standard of care in the treatment of metastatic RCC,^{3–5} critics of that approach argue that surgery could introduce unnecessary morbidity and mortality in this patient population and that it could potentially delay or even prevent these patients from receiving systemic therapy.¹⁸

Because of these concerns, several investigators evaluated the use of nephron-sparing surgery in patients with metastatic RCC.^{6–8} Krambeck et al⁶ were the first to report on the use of partial nephrectomy in 16 patients with metastatic RCC. CSS in these 16 patients was not inferior to that in a contemporary cohort of patients with metastatic RCC who underwent radical nephrectomy. However, 4 patients experienced early complications, and 6 patients experienced late complications. Subsequently, Hutterer et al,⁷ using a multi-institutional database of 45 patients, and Capitanio et al,⁸ using records of a population-based cohort of 46 patients, both concluded that in patients with metastatic disease who underwent partial nephrectomy, CSS was not inferior to that in matched cohorts of patients who underwent radical nephrectomy. Our RFA results compare favorably with the published partial nephrectomy outcomes. We found CSS rates of 73.3%, 57.1%, and 38.1% at 1, 3, and 5 years after RFA, respectively, whereas Krambeck et al⁶ reported CSS rates of 81.3%, 49.2%, and 49.2% at 1, 3, and 5 years after partial nephrectomy and Capitanio et al⁸ reported CSS rates of 79.4%, 61.1%, and 40.3% at 1, 2, and 5 years after partial nephrectomy.

The mechanisms by which surgical cytoreduction improves survival in patients with RCC metastases are not conclusively known. One explanation is that the primary tumor acts as an immunologic sink, and once this tumor is removed, immunotherapies can act more effectively on metastatic sites.^{19, 20} In addition, the primary tumor can produce growth and proangiogenic factors, such as VEGF, TGF- β 1, PDGF, and FGF,^{21–24} which could be important in maintaining metastatic sites and be relevant in disease progression.

The systemic effects of RFA in patients with RCC have not been investigated; however, they have been extensively evaluated in other malignancies. In a melanoma model, RFA resulted in an immune response, which was augmented by using an anti-CTLA-4 antibody at the time of RFA.²⁵ These results were consistent with findings indicating that RFA creates an antigen source that generates an antitumor effect.²⁵ RFA has been shown to induce antitumor immunity by augmenting T-cell responses to recall tumor-specific antigens in hepatocellular carcinoma²⁶ inducing antigen-presenting cell infiltration in urothelial carcinoma²⁷, trafficking CD62L+ T cells from circulation to tissues²⁸ and enhancing the

expression of costimulatory molecules and chemokine receptors, antigen presentation, and cytokine secretion.²⁹ In a murine model, cryoablation of RCC was noted to result in an inflammatory tumor infiltration consisting mainly of neutrophils, macrophages, and T cells (both CD4+ and CD8+).³⁰

RFA of renal masses is a relatively new technique, but many studies have reported on its use in patients with localized RCC.^{9–11} In addition to our previous report of 1 patient treated for metastatic RCC with RFA,¹² Gervais et al⁹ studied 4 similar patients as part of a larger study targeting mainly patients with localized RCC; however, detailed clinical information and outcomes were not provided for these 4 patients. Encouraged by our results in patients with nonmetastatic RCC, we began offering RFA to highly selected patients with metastatic disease who had a solitary kidney, baseline chronic renal insufficiency, a large metastatic burden, or marginal performance status for surgery or those who chose RFA over surgery.

Our study had several limitations. First, it is a retrospective study reporting on a single institution's small number of highly selected patients. Second, half of the treated tumors were smaller than 4cm, and it is possible that they were not the source of metastatic disease in patients with a history of contralateral treated RCC. On the other hand, this is the first series to evaluate in detail the use of 8 RFA of renal masses in patients with metastatic disease. Although we observed complete responses in 4 patients, all of whom were still free of disease at the time of our study, it is important to note that we are not advocating the routine use of RFA for the treatment of primary renal tumors in patients with metastatic disease. The effect of patient selection on our results was clearly evident: most of our patients had relatively small renal tumors, whereas many patients with metastatic RCC have large renal tumors in which ablative therapy is contraindicated. Within this carefully selected patient population, our findings indicate that RFA is safe and feasible to use as another therapeutic option for controlling the primary renal tumor.

CONCLUSIONS

RFA is feasible and safe to perform in selected patients with metastatic RCC; it resulted in durable local control and achieved renal parenchymal preservation. We believe that well-designed studies in both animal models and humans should be performed to investigate the local and systemic biologic and immunologic consequences of treating RCC with RFA. In addition, a prospective study could be initiated to use RFA for treating primary renal tumors in patients with metastatic disease who have poor performance status, a solitary kidney, or other contraindications to cytoreductive surgery, and in well-informed patients who choose not to undergo other treatment options.

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Abbreviations and Acronyms

CSS	cancer-specific survival
CT	computed tomography
CTLA-4	cytotoxic T-lymphocyte-associated protein 4
eGFR	estimated glomerular filtration rate
FGF	fibroblast growth factor [AU: Please verify the definitions for the growth factors.]
MRI	magnetic resonance imaging
PDGF	platelet-derived growth factor
RCC	renal cell carcinoma
RFA	radiofrequency ablation
TGF-β1	transforming growth factor beta 1
VEGF	vascular endothelial growth factor

Table 1

Summary of baseline characteristics of 15 patients with metastatic RCC who underwent percutaneous RFA

Characteristic	No.(%)
Age (years)	
Median (range)	64 (35–76)
Mean (standard deviation)	60.5 (12.2)
Sex	
Male	11 (73.3)
Female	4 (26.7)
Race	
White, non-Hispanic	13 (86.7)
Hispanic	2 (13.3)
Tumor location	
Right kidney	8 (53.3)
Left kidney	7 (46.7)
Tumor characteristic	
Exophytic	5 (33.4)
Nonexophytic	10 (66.6)
Tumor diameter before RFA (cm)	
Median (range)	3.6 (2–7)
Mean (standard deviation)	3.9 (1.6)
RFA Technique	
Percutaneous	15 (100.0)
Indication for RFA/nephron sparing	
Imperative	13 (86.7)
Elective	2 (13.3)
Solitary kidney	
Yes	9 (60.0)
No	6 (40.0)
Pre-RFA renal biopsy histology	
RCC, clear cell	9 (60.0)
RCC, papillary	1 (6.7)
No cancer	2 (13.3)
No biopsy done	3 (20.0)
Disease grade on pre-RFA renal specimen biopsy	
1	0
2	3 (20.0)
3	2 (13.3)
4	0
Not reported	10 (66.7)
Radiographic followup* (months)	
Median (range)	25.5 (1–76)

Characteristic	No.(%)
Mean (standard deviation)	33.5 (25.4)
Clinical followup [*] (months)	
Median (range)	33 (16–88)
Mean (standard deviation)	40.6 (26.4)

^{*}
In patients at risk for an event.

Table 2

Outcomes among 15 patients with RCC metastases whose primary renal tumor was treated with RFA

Age*	Sex	Race [†]	Tumor Size (cm)	Tumor Location [‡]	Tumor Characteristic [§]	Solitary Kidney	Histologic Diagnosis at Previous Nephrectomy	Pre-RFA Biopsy Results of Renal Mass	Time to last followup (months)	Status at Last Followup [¶]	Systemic or Surgical Therapy Prior to RFA	Metastatic Sites Prior to or at Time of RFA
56	M	W	6.5	R	NE	Y	Clear cell RCC	Not done	88	Alive, NED	None	Lung
58	M	W	N/A	L	E	Y	Clear cell RCC	Nondiagnostic	30	Alive, NED	Cryoablation of flank recurrence	Perihepatic nodules
75	M	W	2.1	L	E	Y	Clear cell RCC	Clear cell RCC	21	Alive, NED	Resection of bone metastasis	Bone
72	F	W	2.5	L	E	N	N/A	Clear cell RCC	19	Alive, NED	Sunitinib	Lung
67	M	W	2.3	R	NE	N	Clear cell RCC	Nondiagnostic	36	Alive, WD	Sorafenib	Lung
58	M	W	4.5	L	E	Y	Papillary RCC	Papillary RCC	54	Alive, WD	None	Liver, lung
66	M	W	2.7	L	NE	Y	Clear cell RCC	Clear cell RCC	66	Alive, WD	Sorafenib	Lung
46	M	H	3.5	R	NE	N	N/A	Clear cell RCC	16	Alive, WD	Sunitinib; sorafenib	Bone
64	F	W	5	L	NE	N	N/A	Clear cell RCC	10	DOD	None	Lung, brain, bone
42	M	H	2.6	L	E	Y	Clear cell RCC	Clear cell RCC	59	DOD	Adriamycin/ifosfamide/Interferon; 5-Fluorouracil/Gemcitabine; Interferon/Thalidomide/Taxotere	Lung, paroesophageal nodes
76	F	W	3.6	R	NE	Y	Clear cell RCC	Not done	5	DOD	Interferon	Lung, adrenal gland, pancreas, bone
56	M	W	4.5	R	NE	Y	Clear cell RCC	Clear cell RCC	9	DOD	None	Lung, pleura, adrenal gland
72	M	W	6.5	R	NE	N	N/A	Not done	14	DOD	None	Soft tissue, bone
35	F	W	6	R	NE	N	N/A	Clear cell RCC	2	DOD	Gemcitabine/Interferon/Capcitabine	Lung, liver, adrenal gland, retroperitoneal nodes
65	M	W	2.7	R	NE	Y	N/A	Clear cell RCC	29	DOD	Gemcitabine/interferon/capecitabine; thalidomide; bevacizumab	Adrenal gland

* Age at time of RFA.

[†]W indicates white, non-Hispanic; H indicates Hispanic.

[‡]R indicates right kidney; L indicates left kidney

[§]E indicates exophytic; NE indicates nonexophytic.

[¶]NED indicates no evidence of disease; WD indicates with distant disease; DOD indicates died of disease.