Review of Radiofrequency Ablation for Renal Cell Carcinoma

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ABSTRACT
This review will discuss how minimally invasive, image-guided radiofrequency (RF) tumor ablation [i.e., coagulating tumor using short-duration heating (<15 minutes) by directly applying temperatures >50°C via needle electrodes] is being incorporated as a clinical tool for the treatment of renal cell carcinoma. RF ablation has been used to treat focal liver tumors. Potential benefits of this thermal therapy include reduced morbidity and mortality compared with standard surgical resection and the ability to treat nonsurgical patients. More recently, this technique has been introduced to treat focal renal tumors, particularly incidental lesions smaller than 3 cm in elderly patients and those with comorbid conditions. Other uses have included treatment in patients with von Hippel-Lindau syndrome and other diseases that predispose patients to multiple renal carcinomas, where renal parenchymal preservation is desired. Techniques, complications, and results will be discussed. Additionally, strategies that we are currently studying to improve RF outcomes and enable the potential treatment of larger tumors will be addressed. Most notably, recent data on increased coagulation achieved by combining RF ablation with antivascular/antiangiogenic therapies, such as arsenic trioxide, that reduce blood flow and promote heat retention are provided.

INTRODUCTION
Image-guided percutaneous radiofrequency (RF) ablation continues to gain attention as a viable treatment option for the focal destruction of solid tumors because it provides many potential advantages over surgical resection, including reduced morbidity, outpatient therapy, and the ability to treat poor surgical candidates. Historically, the greatest attention has been given to the potential of RF ablation for the treatment of colorectal metastases to the liver and to primary liver tumors, fueled in part by the significant morbidity and mortality associated with hepatic resection. Indeed, more than 5,000 RF ablations of focal liver tumors have been performed during the last 5 years, with Food and Drug Administration (FDA) approval being granted for this indication (1–6). More recently, however, the clinical potential of RF ablation has greatly expanded under the blanket FDA approval for soft tissue including the treatment of kidney (7–13), breast (14), bone (15–17), lung (18), retroperitoneum (19), thyroid (20), adrenal gland (21), spleen (22), prostate (23, 24), and even pheochromocytoma (25). One site in particular, the kidney, is poised for significant growth as a target for RF ablation. A contributing factor includes the significant increase in the incidence of renal cell carcinoma (RCC), which, when coupled with improved understanding of RF techniques, has recently led many investigators to assess the feasibility and efficacy of RF ablation for renal tumors in select patient populations (7–13).

In 2003, there were more than 31,000 new cases of RCC diagnosed in the United States (26), an incidence that has more than doubled since 1950. The reason for such an increase is partially attributable to widespread high-resolution diagnostic imaging, which has led to the serendipitous detection of small tumors in asymptomatic patients (27–29). Many of these incidentally noted RCCs are found in elderly patients who were initially imaged for other comorbid conditions. Because many of these small, nonaggressive RCCs have a low incidence of eventual metastatic progression (30), a less invasive therapy than surgery has been sought for this high-risk population. RF ablation has been proposed to fill this role.

Other patients who can theoretically benefit from RF ablation include patients with genetic predisposition to multiple tumors or patients with only one kidney or bilateral RCCs (8, 31, 32). Genetically predisposed patients, such as patients with von Hippel-Lindau (VHL) syndrome, usually undergo multiple partial nephrectomies for recurrent RCCs and ultimately require hemodialysis when surgery depletes the number of functional nephrons. In addition to the decreased morbidity of multiple procedures, RF ablation minimizes destruction of normal renal tissue and thus minimizes removal of functional nephrons. Furthermore, RF ablation might be useful in the therapy of lung metastases, (33), in which there is some preliminary evidence of increased survival after resection in selected patients (34, 35), and painful bony metastases, in which there is evidence of improved pain control in patients refractory to radiation therapy (17). A less invasive approach would also be welcome as an alternative to surgical tumor debulking that is practiced in conjunction with immunotherapy in patients presenting with stage IV disease and small primary tumors (36).

Indeed, these multiple rationales have led to a significant increase in the number of patients with RCC receiving RF ablation. More than 300 patients with RCC treated with RF ablation have been described in the peer review literature. At some larger institutions, such as Beth Israel Deaconess Medical Center and Massachusetts General Hospital, patients with RCC have now eclipsed patients with tumors in the liver as the largest patient population referred for RF ablation. The


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rapid adoption of RF ablation despite limited comparative and long-term efficacy studies attests to the scope of the clinical need and dearth of alternative treatment options for these patients. We provide herein a review of recent clinical studies using RF ablation to treat RCC, including a synopsis of patient selection and tumor factors, efficacy, and complications. In addition, we review the obstacles of RF ablation for RCC and note current research aimed at overcoming these limitations.

BASICS OF RADIOFREQUENCY ABLATION

RF delivers a high-frequency (460–500 kHz) alternating current into the tumor by means of a RF electrode, a thin needle (usually 21–14 gauge) that is electrically insulated along all but the distal 1 to 3 cm of the shaft. The application of RF current produces resistive friction in the tissue that is converted into heat (37). Heat, in turn, induces cellular destruction and protein denaturation at temperatures above 50°C when applied for 4 to 6 minutes and almost instantaneous destruction above 60°C (36). Temperatures above 105°C may result in gas formation, which retards efficient creation of the RF current. Therefore, the goal of RF ablation is to induce temperatures of 50°C to 100°C throughout the tumor tissue without exceeding 105°C near the active electrode (37). Most RF systems used for the kidney are monopolar and require a grounding system that is usually a pad placed on the patient’s back or thigh. Electrodes can be placed directly into tumors using ultrasound, computed tomography (CT), or magnetic resonance guidance.

Although early RF systems used single monopolar needle electrodes, efforts to increase RF-induced coagulation have led to modifications in the original design, including the development of various RF applicators such as multitined applicators (3, 4), pulsed energy delivery (38, 39), and others (40). Although not ideal, multiple ablations and multiple sessions can be used for large tumors. Currently, there are three RF devices with 510-K FDA approval for soft tumor ablation (Radionics Inc., Burlington, MA; RadioTherapeutics Corp., Sunnyvale, CA; and RITA Medical Systems, Mountain View, CA). No study has yet demonstrated a clear advantage of any one device (37).

ASSESSING FOR SUCCESSFUL RADIOFREQUENCY ABLATION

The success of RF ablation is usually assessed by postprocedural imaging, typically by CT at least 1 month after treatment. Imaging immediately after the procedure can be difficult to interpret because peripheral inflammation may mimic the appearance of viable tumor (41). On CT, viable tumor maintains its enhancement (>10-HU after contrast injection), whereas successfully ablated tumor loses its attenuation (Fig. 1; ref. 31). There are fewer data available with recurrence as an outcome measure, although longer-term follow-up suggests that inadequate treatment can occur in up to 35% of cases of colorectal liver metastases, leading to tumor progression (1). Recurrence rates for RCC after RF ablation are sparse, and more data comparing postprocedural imaging with local rates of recurrence will be necessary. It is clear, however, that essential 5-year outcome data are still unavailable, given the newness of RF ablation for RCC. The studies here report treatment outcomes up to a mean of 17 months and thus should be interpreted with appropriate reserve.

A handful of investigational studies performing nephrectomies after RF ablation have yielded mixed results regarding pathological assessment of ablation. Michaels et al. (42) reported that the vast majority of their 15-patient series revealed residual tumor viability acutely after ablation, whereas Matlaga et al. (43) reported complete treatment in 8 of 10 patients after just a single 12-minute RF ablation treatment. In addition to different methodologies used to perform RF ablation, other factors including possible uncertainties as to the true area ablated may play a role in these discrepant results. For example, we have previously shown in liver tumors that specialized stains are required to identify ablated tumor, particularly in the acute postablation period (2). Hence, the precise role of pathological assessment after RF ablation patients has been questioned (44).

PATIENT SELECTION

At our institution, patient selection includes those with known contraindications to partial or complete nephrectomy as
a result of comorbid conditions or advanced age. The gold standard of treatment remains surgical resection and should always be preferred when tolerable, except for patients with VHL syndrome or patients with multiple bilateral RCCs. In addition, RF ablation may be indicated for patients with RCC in a solitary kidney to prevent the need for hemodialysis (31, 45, 46).

Contraindications may include a poor life expectancy of <1 year (7–13), multiple metastases, or difficulty for successful treatment due to size or location of tumor. Tumor factors as a predictor of treatment success are discussed separately, but in general, large tumors (>5 cm) or tumors in the hilum or central collecting system are not typically recommended for RF ablation. In addition, tumors located so that thermal injury may occur to the proximal ureter, resulting in urine extravasation and urinoma production, are usually deferred until an intrarureteral stent has been placed by a urologist. However, the only absolute contraindications include irreversible coagulopathies or severe medical instability such as sepsis (36). Patients are jointly evaluated by a urologist and radiologist. The extent of disease should be well established with sufficient abdominal and nonabdominal imaging to verify the location and extent of local tumor and any metastatic involvement. In addition, pretreatment imaging is important for planning the ultrasound, magnetic resonance, or CT-guided electrode placement. Important laboratory values include prothrombin time, partial thromboplastin time, and creatinine, and screening for intravenous sedation or anesthesia. A biopsy before the procedure is not imperative but should be strongly considered because imaging does not always accurately differentiate benign from malignant disease (7). Given current debate on the issue, a discussion between the urologist and radiologist concerning a tumor biopsy is prudent.

**CLINICAL STUDIES**

In 2002 and 2003, seven studies together reported on a total of 195 RCCs in 159 patients (Table 1). Numerous smaller studies and case reports have also been published recently, with notable contributions for percutaneous RF techniques and indications for RCC. The largest study, by Gervais et al. (7), examined RF ablation of 42 RCC tumors in 34 patients. Of the 42 tumors, 29 were exophytic, 2 were parenchymal, 4 were central, and 7 were mixed. All 29 exophytic tumors (mean size, 3.2 cm; size range, 1.1–5.0 cm) and 2 parenchymal tumors were ablated successfully. One of four central tumors (25%) and four of seven mixed tumors (57%) were treated with technical success, although these tumors were all large. The authors report that a significant negative predictor of technical success is a tumor larger than 3.0 cm with a component in the renal sinus ($P = 0.004$), although 5 of 11 tumors of this type were treated successfully.

Su et al. (9) published the results of 29 patients with a total of 35 small renal tumors (mean size, 2.2 cm; range, 1.0–4.0 cm). The authors reported that 33 of 35 (94%) renal lesions required just a single RF ablation treatment during a mean follow-up of 9 months, whereas the 2 remaining tumors were successfully retreated with a second session. Mayo-Smith et al. (11) reported on the outcomes of 32 tumors in 32 patients (mean size, 2.6 cm; range, 1.0–5.0 cm). After either one or two sessions, 31 of the 32 tumors (97%) were treated successfully by CT. Six patients (19%) required a second session because of incomplete treatment during the first session. Roy-Choudhury et al. (12) examined eight patients with 11 renal tumors (mean size, 3.0 cm; range, 1.5–5.5 cm; 9 tumors were exophytic, and 2 tumors were central). Seven of the eight patients (88%) showed no recurrence at follow-up (mean, 17.1 months; range, 10–26 months). The only failure was a patient with VHL syndrome who had two separate metachronous nodules of enhancement noted during follow-up, although the treated tumors were unenhanced. However, at autopsy 3 months after the procedure, two large tumors were identified, both engulfing previous sites of ablation. This made it difficult to exclude the possibility of recurrence.

**COMPPLICATIONS**

Reported outcomes reveal a very low complication associated with RF ablation of renal masses. Of 159 patients, only 3 experienced complications from direct thermal effects of RF ablation, including two ureteral strictures (7, 47), a small liver burn (9), and some thermal injury to the psoas muscle (12) in 1 patient. Of these, only the ureteral strictures required intervention. Gross hematuria led to uretal obstruction (7) in two additional patients who required intervention. There was one death (9) reported from aspiration pneumonia in a severely compromised pulmonary patient. Small perirenal hematomas that resolved spontaneously were also reported, along with flank numbness in a small number of patients. In one series (11), a 5-mm skin metastasis at the electrode insertion site was reported in one patient (which was resected without recurrence). One case report identified a patient who developed flank pain, fol-

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lowed by hydronephrosis, ureteropelvic junction obstruction, and eventual loss of function in the treated kidney (48). It is important to note that the very low complication rate associated with RF ablation is reported in patients who were already deemed too high risk for surgical intervention because of advanced age or medical comorbidities. Thus, even in high-risk patients, RF ablation for RCC is associated with a very low complication rate. Nevertheless, greater multicenter experience is likely required to define complication rates, as has been performed for liver (49).

TUMOR FACTORS

Tumor size and location are the two most important factors that govern whether RCCs can be treated successfully. Because heat decreases exponentially from the RF source, large tumors (>5 cm) pose a significant challenge for RF ablation, especially because a 0.5- to 1.0-cm “ablation margin” surrounding the tumor is also preferred (6). In general, RCC tumors that are ≤3 cm in diameter are ideal for ablation, with near-perfect success rates on postprocedural imaging (7–13). Most tumors smaller than 3 cm can also be treated successfully in a single session (7–13). Tumors between 3.0 and 3.5 cm in diameter can also be treated successfully with confidence, but multiple ablations and sessions may be required (7–13).

The location of the tumor (exophytic, parenchyma, or central) also influences ablation results. Even larger exophytic tumors are almost always treated successfully, with ≥70% requiring only a single RF session (7–13). Parenchymal tumors may be more difficult to treat, but centrally located tumors represent the largest obstacle for successful ablation. The presence of a central component in a tumor larger than 3 cm is reported to be a significant predictor of failure (7).

OTHER INDICATIONS OF RADIOFREQUENCY ABLATION FOR RENAL CELL CARCINOMA

In addition to ablation of solid tumors within the kidney, there have been other notable uses of RF ablation for patients with RCC, including intractable hematuria (50) and tumor recurrence in the surgical bed after nephrectomy (51). In addition, RF ablation has been used to palliate lung and symptomatic bone metastases from RCC (17, 33). Such a minimally invasive method with low morbidity to treat metastases could conceivably have therapeutic and palliative benefits in appropriately selected patients (34, 35, 52).

LIMITATIONS AND FUTURE DIRECTION

Although there may be many potential benefits to using RF ablation for the treatment of RCC, the technique still has many limitations. Although data demonstrate >90% efficacy for primary RCCs smaller than 3 cm, the efficacy is much lower for lesions of 3 to 5 cm (7–13). In general, ablation of lesions larger than 4 to 5 cm is currently avoided, and patients are considered for surgical resections. In addition, even small tumors located in the more vascular central areas of the kidney cannot be treated with certainty. Therefore, strategies that increase the uniformity and completeness of RF tumor destruction, even for small lesions, are needed.

The reduced efficacy of RF ablation in larger and centrally located renal tumors in part reflects the in vivo biophysiologic limitation imposed by perfusion-mediated vascular cooling, which limits heat-induced coagulation necrosis (37). We and other investigators (53, 54) have demonstrated experimentally the negative impact that blood flow and tissue vascularity have on the extent of coagulation induced by RF ablation in normal tissues, multiple animal tumor models, and human intrahepatic tumors. For example, coagulation created by RF power during mechanical vascular inflow occlusion is significantly larger than coagulation created with normal blood flow (53). Although surgical or angiographic techniques (i.e., mechanical occlusion) can be used to reduce blood flow (55), they require a second and more invasive procedure, increasing the complexity and morbidity of tumor ablation. On the other hand, antivascular and antiangiogenic agents have been shown to preferentially reduce tumor neovascularity (56, 57) and theoretically represent the least invasive and potentially the most renal cancer-specific means for reducing blood flow. One such agent, arsenic trioxide, has received increasing attention as a novel antineoplastic agent for use in several solid and hematologic malignancies refractory to standard treatments, including tumors of the kidney, bladder, cervix, and prostate (57). Our studies in a renal tumor model in the rabbit revealed that arsenic trioxide preferentially decreased tumor blood flow (44 ± 16%) and significantly increased RF-induced coagulation (58). This finding suggests that pharmacological modulation of tumor blood flow may provide a noninvasive way to decrease blood flow during thermally mediated ablation therapy, potentially enabling the successful treatment of large and centrally located malignant renal tumors.

Again, most importantly, studies demonstrating the long-term efficacy of RF ablation of RCC are still needed. Such data will likely enable us to define appropriate indications and may lead to better justification for widespread adoption of the procedure. Positive data may also lay the groundwork for future comparative trials between RF ablation and surgery as well as permit the changing of the status of RF ablation from an investigational procedure to one with specific FDA approval for RCC. Furthermore, larger volumes of data are necessary for the treatment of metastatic RCC, given the variable complication rates and variable treatment outcomes in specific organ tissue environments.

SUMMARY

Image-guided percutaneous RF ablation is posed for significant growth in the treatment of RCC, in part due to the increased incidental detection of small RCCs in an elderly population not ideally suited for surgical resection. RF ablation is a viable option for nonsurgical patients and is safe, with a very low complication rate. Tumor size and location are the two most important factors that govern whether a RCC can be treated successfully. RF ablation cannot yet reliably treat most tumors larger than 5 cm, although exophytic tumors of this size can be successfully treated. Centrally located tumors represent the largest obstacle for successful ablation, in part because of perfusion-mediated vascular cooling. Current studies with antivascular agents, such as arsenic trioxide, suggest that pharmacological modulation of tumor blood flow may provide a noninvasive way to decrease blood flow during thermally mediated ablation ther-
apy, potentially enabling the successful treatment of large and centrally located malignant renal tumors. Further clinical follow-up is required from ongoing clinical studies to provide key information, such as 5-year relapse-free and overall survival data and expected complication rates.

OPEN DISCUSSION

Dr. Andrew Novick: What concerns me about radiofrequency ablation (RFA) is that there are now three published studies involving patients treated with RFA where at some point afterward, the surgeons went back and excised the treated area with a total or partial nephrectomy. In many of those cases, there was a residual microscopic carcinoma still present. And in many of those, the areas of residual disease didn’t enhance on a contrast imaging study, which I think is a very gross assessment of recurrent malignancy. There are two or three other published studies, one from the National Cancer Institute entailing patients treated with RFA, where there is residual contrast enhancement afterward, which I think is pathognomonic for recurrent malignancy. This isn’t to denigrate RFA. There are going to have to be refinements in the technique, how it’s applied, and the duration of therapy, but this is an approach that’s not ready for prime time.

Dr. S. Nahum Goldberg: Much of these data come from the liver, and there is no question that one can achieve heat preservation and mummification of the cells that are in fact dead, but because they don’t show signs of coagulative necrosis or the absence of the nuclei, many pathologists have originally called these cells live. It often requires pathological study beyond hematoxylin and eosin staining, which is a major criticism of the three papers you mentioned. Although, in the Toronto paper, I think they had quite a bit of residual tumor, because they were using small electrodes, and it was impossible for those electrodes to cover that tumor area. But the reality is that a histopathologic assessment of a single cell is insufficient proof that those cells are alive. In regard to the RCCs not completely shrinking, although they tend to shrink a little bit, we need to realize that the body will wall off heat-damaged tissue in a fashion that is different from cryoablation. In cryoablation, the cells are shattered, and in the liver and kidney, those areas will shrink much greater than in the thermal therapies. However, with thermal therapies, lesions appear to shrink. Can I guarantee you that every single cell is ablated? No, I can’t, but what I can say is that “the baby should not be thrown out with the bath water” based on prior experience with a different pathophysiology.

Dr. Novick: Regarding those published studies that showed recurrent microscopic malignancy, are you saying that if a pathologist does a photomicrograph of renal tissue and sees cancer, that it may not be cancer?

Dr. Goldberg: No, I’m saying that the histopathologic changes that occur, particularly at the lower thermal doses, are subtle enough that without special stains or an intense amount of training, it cannot be said that you have a viable tumor.

Dr. Robert Figlin: In the population of elderly patients with comorbid disease and lesions less than 3 cm in size, what’s the natural history, and what justifies treatment at all?

Dr. Goldberg: About 10% to 15% of those patients will go on to have metastatic disease over 10 to 15 years. So, indeed there are many people who in the past have gone the route of expectant waiting, especially in the more elderly or more comorbid population.

Dr. Figlin: What percentage of the patients who you have described had benign tumors that didn’t require any therapy?

Dr. Goldberg: One of the issues that I didn’t address is the issue of biopsy. There is a big debate even among the urologic referral community as to whether or not these lesions should be biopsied before ablation.

Dr. Novick: There’s no risk of inducing any harmful changes. I would suggest that when you’re in the process of evaluating a new approach or a new technology that it is advantageous to gather as much information as possible.

Dr. Figlin: Once you identify a ≤3-cm lesion in a population of patients who have comorbidity and who might not be candidates for more standard surgical approaches, one could take an approach of observation until such time as the lesion defines itself as requiring something other than just observation. Would that be a fair statement?

Dr. Goldberg: That’s a very fair statement. One of the studies that we’ve proposed is to randomize patients in that way. However, patients are reading all of the information and misinformation on the internet. So, if you’re a 75-year-old and somebody has promised you a 90% chance of ablating something and then not having to worry about it except for a couple of CTs, which route would you take? Unfortunately, there is also a bit of push from the patient side toward this. The typical urologist calls me up and says, “I’ve got a patient who is pushing me to do something: I don’t want to operate on him.”

Dr. Walter Stadler: I’m very concerned that this is being developed not because of patient push but because of financial pressures in the community. You have already noted the internet issue, and it is also advertised on radio shows. Every patient comes in with, “Can you radiofrequency ablate my tumor?” Yet there are great limitations in the data. How many commercial companies are selling this?

Dr. Goldberg: To my knowledge, there are three radiofrequency companies. Some are more aggressive than others, and some are marketing to surgeons more than to the radiologist. I share your concern about this being overused, and I don’t want that message to be diluted. However, I also even more strongly don’t want to potentially criticize something that may ultimately prove to be useful if there is appropriate study.

Dr. Novick: There are several companies out there, because RFA is only one technology. You’ve got the cryosurgical companies, you’ve got the high and sensory focused ultrasound, you’ve got local radiosurgery and the gamma knife, but let me just share with the group a situation that I’ve seen in my practice now several times. This is a story of a 50-year-old, young, otherwise healthy patient with a tumor that needs to be treated with a partial nephrectomy. It’s in a solitary kidney, it’s 4 cm, it’s in a difficult location, it’s in the center of the kidney, but it’s something that could be dealt with with an open partial nephrectomy in experienced hands. The patient sees the urologist, who, prior to the availability of these ablative forms of therapy, would have done one or two things: take the kidney out or send the patient to someone who is able to do the operation. Now what’s being done is the urologist tells the patient, “I’m
going to operate on you and do the best that I can to take care of the cancer. I will try to do an open partial nephrectomy, but if I can’t I’ll do something else.” So, he opens the patient up, he is not able to do the open partial nephrectomy, and he freezes it or ablates it. So, 8 or 9 months later, the patient is seeing me in need of further therapy; tissue planes have now been violated, and the chance of developing metastatic disease has significantly increased. I’ve probably seen 10 patients like this over the last 2 or 3 years. A couple of them have come to me with metastatic disease. This just shouldn’t happen.

Dr. Goldberg: That’s right, and that’s why we need augment groups like this directing how and when these procedures are performed. We need developmental technology and working hand in hand to further the research elements of this to try to band together and prevent things like that happening.

Dr. Allan Lipton: Does positron emission tomography scanning play any role in selection of patients or following-up patients after your procedure to look for activity within the tumor?

Dr. Goldberg: There are early preliminary data in this area in regard to the lung but very little currently in the kidney, although there are some folks at the University of California Los Angeles who have started to look at that.

Dr. Michael Gordon: From the radiologist’s perspective, how is this going to be proven as safe and equally effective so that it could reach the mainstream with regard to recommendations in patient populations?

Dr. Goldberg: It’s not only the radiologists; there are quite a number of urologists practicing this as well. But you’re 100% correct.

Dr. Hruszczewycz: I imagine your image-guided approach lends itself to aspiration. What to degree do you exploit that opportunity to evaluate this tumor before and after ablation? Are you able to do aspiration cytology?

Dr. Goldberg: This has not been done yet. People have been concerned about the concept of morcellation and spreading cells, but it is something that should be pursued down the line.

Dr. Atkins: It sounds like there’s a role for responsible development of these treatments, and I think responsible development means cooperation of urologists and medical oncologists in potentially identifying appropriate use of these treatments and appropriate ways of investigating them. That is all of our responsibility.

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