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Abbreviations:

RCC = renal cell carcinoma
RF = radio frequency
VHL = von Hippel-Lindau disease

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Renal Cell Carcinoma: Clinical Experience and Technical Success with Radio-frequency Ablation of 42 Tumors¹

PURPOSE: To evaluate clinical experience with percutaneous image-guided radio-frequency (RF) ablation of renal cell carcinoma (RCC) and to assess factors that may influence technical success.

MATERIALS AND METHODS: Thirty-four patients who underwent RF ablation of 42 RCC tumors during a 3.5-year period were evaluated. Overlapping ablations were performed on the basis of tumor size and geometry. Technical success was defined as elimination of areas that enhanced at imaging within the entire tumor. With the exception of those patients with renal insufficiency, who were followed up with unenhanced and gadolinium-enhanced magnetic resonance imaging, patients were followed up with unenhanced and contrast material-enhanced computed tomography. Univariate analysis of the results was performed with the Fisher exact test to assess the effect of tumor size and location on technical success. $P \leq .05$ was considered to represent a significant difference. Complications and the management and outcomes of the complications were recorded.

RESULTS: All 29 exophytic tumors (mean size, 3.2 cm; size range, 1.1–5.0 cm) were completely ablated, as were two parenchymal tumors. The remaining 11 tumors had a component in the renal sinus. For large (>3.0 cm) tumors, presence of a tumor component in the renal sinus was a significant negative predictor of technical success ($P = .004$); only five of these 11 tumors were completely treated, compared with 11 of 11 tumors without a renal sinus component. A similar analysis was not possible for small tumors because no small tumors involved the renal sinus. Four complications occurred in a total of 54 ablation sessions: one minor hemorrhage, two major hemorrhages, and one ureteral stricture.

CONCLUSION: RF ablation of RCC can be successful in exophytic RCC tumors up to 5.0 cm in size. Tumors larger than 3.0 cm with a component in the renal sinus are more difficult to treat but can be ablated successfully.

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The incidence of renal cell carcinoma (RCC) continues to increase; there were over 30,000 new cases in the United States in 2000 (1). Many cases are incidentally found at cross-sectional imaging examinations such as ultrasonography (US) and computed tomography (CT) (2). With the current interest in screening CT, this trend is likely to continue. Moreover, the incidence of RCC appears to be increasing independently of the use of cross-sectional imaging (3). At the same time, there have been numerous developments in minimally invasive treatments for RCC, as compared with the traditional standard of open complete nephrectomy (4,5). These developments include partial nephrectomy, laparoscopic complete or partial nephrectomy, and ablation therapies such as cryoablation and radio-frequency (RF) ablation (4,5).

RF ablation has been available for treatment of soft-tissue tumors since the early 1990s, and results of extensive assessment of RF ablation of primary and metastatic hepatic tumors have been reported (6–11). Investigations have shown that in the liver, tumor size

influences technical success, with smaller tumors significantly more likely than larger tumors to be completely treated (10). Recently, new uses of percutaneous image-guided RF ablation for treating tumors of the kidney, lung, adrenal gland, and spleen have been reported (12–18).

Although there have been a few reports of RF ablation for human RCC (12–14,19), to our knowledge, no study has yet been performed to evaluate long-term follow-up of treated tumors left in situ to assess for metastatic disease or local recurrence, and the small number of tumors in previous reports has precluded a statistical analysis of factors influencing technical success. The purpose of this study was to evaluate our clinical experience with percutaneous image-guided RF ablation of RCC and to assess factors that may influence technical success.

MATERIALS AND METHODS

Patients

Over a 3.5-year period, 34 consecutive patients who underwent RF ablation for treatment of RCC were evaluated for technical success and clinical outcome. The first eight patients were prospectively evaluated with approval of the human studies committee at our institution, and informed consent was obtained from all patients for research evaluation of RF ablation. Subsequently, RF ablation of soft-tissue tumors was performed as a clinical service without the requirement for enrollment in protocols approved by the human studies committee. However, human studies committee permission was obtained for review of the medical records of these patients. Informed consent is not required for medical records review at our institution. Informed consent was obtained for the procedure itself in all cases.

Forty-two RCCs in 34 patients (24 men, 10 women; age range, 22–86 years; mean age, 69 years) were treated. Tumor size ranged from 1.5 to 8.9 cm in women, 1.1–7.1 cm in men, and 1.1–8.9 cm (mean, 3.2 cm) overall. Two of the 42 RCC tumors had cystic, as well as solid components. Diagnosis of RCC was confirmed at needle biopsy of 41 tumors. One tumor was treated because it appeared to have enlarged on images obtained at serial magnetic resonance (MR) imaging studies. Indications for RF ablation initially were comorbid conditions that rendered surgery highly risky, life expectancy longer than 1 year and shorter than 10 years, and/or presence of

a solitary kidney. Exclusion criteria initially were metastatic disease from RCC, life expectancy longer than 10 years without a comorbid condition that limited surgical options, and lack of a safe percutaneous path.

As our experience with the technique increased, the inclusion criteria were changed so that subsequent patients with von Hippel-Lindau disease (VHL) were allowed to undergo ablation. These patients typically present with symptoms of RCC at a young age and develop multiple and bilateral RCC tumors that require multiple resections and, ultimately, result in the need for dialysis. For patients with VHL or a large tumor in a solitary kidney, the goal of RF ablation was to treat the target lesions with a nephron-sparing procedure to delay the need for dialysis.

In addition, two patients with metastatic disease were treated. One patient had had a kidney removed because of RCC 9 years before RF ablation and an isolated ipsilateral adrenal metastasis removed 4 months before RF ablation of the new contralateral RCC. The goal in this case was to preserve renal function and to limit the spread of the target lesion. The other patient with metastatic disease who was treated with RF ablation had two isolated small pancreatic metastases that were present before RF ablation but that were appreciated only in retrospect after ablation. This patient is included in the analysis of the technical success of this procedure.

One of two staff urologists (F.J.M., W.S.M.) in collaboration with one of two staff radiologists (D.A.G., P.R.M.) evaluated all patients to determine each patient's suitability for RF ablation and to ensure that all surgical alternatives had been assessed. Prothrombin time, partial thromboplastin time, and complete blood count were assessed before ablation in all cases.

RF Ablation

All RF ablation procedures were performed with intravenous sedation consisting of 2–5 mg of midazolam (Versed; Baxter, Deerfield, Ill), 100–300 µg of fentanyl (Sublimaze; Janssen, Titusville, NJ), and 0.625 mg of droperidol (Inapsine; Akorn, Buffalo Grove, Ill). RF ablation was performed as an outpatient procedure in 26 patients. Of the eight inpatients, three were admitted before RF ablation so that coagulopathy could be corrected. One of these eight patients had undergone heart transplantation

and was admitted by the cardiac service for monitoring after ablation. One patient was an inpatient recovering from a urinary tract infection at the time the RCC was diagnosed; she was treated prior to discharge. One patient was admitted for assessment of complete recovery from the intravenous sedation, and two patients were admitted after developing hemorrhagic complications.

All ablations were performed by two of three staff radiologists (D.A.G., R.S.A., P.R.M.); the choice of generator system and electrode size and type was up to the discretion of the senior staff radiologist (P.R.M., D.A.G.). At least one of two staff radiologists with extensive experience in tumor ablation (P.R.M., D.A.G.) was involved in all ablations. Most tumors ($n = 38$) were ablated with internally cooled electrodes with impedance-controlled pulsed current from a 200-W generator (Radionics, Burlington, Mass) (20–22). A 12-minute treatment was performed with either a cluster (three-prong, 2.5-cm active tip) or single (2- or 3-cm active tip) needle electrode, depending on the size of the tumor. In three tumors, ablation was performed with an umbrella-shaped electrode (Starburst XL, 3–5 cm) and a 150-W generator (RITA Medical Systems, Mountain View, Calif).

For this system, the timing of individual ablations was determined by means of temperature control, with a target temperature of 105°C. One tumor was ablated with both systems during two separate visits to the radiology suite.

Ablations were performed with either CT (33 tumors) or US (eight tumors) guidance at the discretion of the senior radiologist. One tumor was treated with US guidance at the first visit and with CT guidance at the second visit. The choice of CT versus US for imaging guidance was generally made on the basis of the visibility of the entire mass and adjacent structures at US. Lesions easily and clearly seen at US were ablated with US guidance and all others were ablated with CT guidance.

On the basis of the size and geometry of the lesion, overlapping ablations were performed by repositioning the needle to ablate the entire tumor. As previously reported, CT and US imaging findings during ablation do not help predict the result or guide treatment (13). Therefore, the operators compared tumor diameter in the plane of imaging to the expected in vivo burn diameter of the electrode in use and adjusted electrode positions accordingly. In the orthogonal plane, electrode adjustments were likewise per-

Technical Success of RF Ablation of 42 RCC Tumors, with Further Breakdown by Size in Each Location

Tumor Location	Technical Success		
	All Tumors	Large Tumors	Small Tumors*
Exophytic	29/29	10/10	19/19
Parenchymal	2/2	1/1	1/1
Central	1/4 [†]	1/4	NA
Mixed	4/7 [‡]	4/7	NA

Note.—Data are numbers of tumors successfully treated/numbers of tumors in each location.

* NA = not applicable (there were no small tumors with a central or mixed location).

[†] Two of the three patients in whom RF ablation was not technically successful were still undergoing treatment at the time of this writing.

[‡] One of the three patients in whom RF ablation was not technically successful was still undergoing treatment at the time of this writing.

formed on the basis of the expected burn diameter and tumor size. Whenever possible, the electrode was initially placed strategically to enable ablation of the portion of tumor at the interface with normal kidney. Theoretically, this strategy results in larger burn diameters by stopping or slowing blood flow from adjacent parenchymal vessels.

If the axis of the tumor parallel to the electrode was longer than the expected burn length, overlap was achieved by pulling the electrode back for the appropriate distance and performing another ablation. Each positioning of the needle electrode into a different portion of tumor was recorded as a separate treatment or ablation. Patients made additional visits to the radiology department for more ablations if CT or MR imaging revealed incomplete treatment. This was continued until either the tumor was completely treated or the treatment was stopped by the urologist on the basis of a combination of clinical assessment of the patient's overall condition and the failure to eradicate tumor despite multiple ablation sessions.

Six patients had solitary kidneys, and three patients had atrophic minimally functioning contralateral kidneys. Three patients had RCC in the contralateral kidney. These three patients included two patients with VHL and one patient who had a contralateral RCC. The latter was treated first with RF ablation of the smaller tumor and then with resection of the contralateral kidney. In patients with multiple tumors being treated with RF ablation, ipsilateral tumors were treated during a single visit as time allowed. Contralateral tumors were treated in separate visits to avoid placing both kidneys at simultaneous risk for complications.

Imaging and Clinical Follow-up

All patients underwent contrast material-enhanced imaging before and after RF ablation. In patients with a creatinine level of less than or equal to 2.0 mg/dL (177 $\mu\text{mol/L}$) ($n = 30$), unenhanced and contrast-enhanced CT (Lightspeed; GE Medical Systems, Milwaukee, Wis) was performed. Patients with a creatinine level greater than 2.0 mg/dL (177 $\mu\text{mol/L}$) ($n = 4$) were evaluated with MR imaging (Signa; GE Medical Systems) (T1 weighted, T2 weighted fast spin echo, gradient echo before and after gadolinium enhancement [gadopentetate dimeglumine, Magnevist; Berlex, Montville, NJ]). Follow-up CT or MR abdominal imaging was first performed within 1 month, and then at approximately 3 months and 6 months after ablation. Patients were then followed up at 6-month to yearly intervals, depending on the kind of comorbid condition or conditions they had. The treated tumors were assessed for residual enhancement and size changes (13,23). All follow-up images were also assessed for the development of new metastatic disease and ancillary peritumoral changes.

Technical success was defined as the absence of enhancement in any area of tumor on images from the 1-month follow-up study. This definition is based on radiologic-pathologic correlation research on liver tumors (23). Objective measurements of enhancement were performed on images from all follow-up studies, and the criteria described previously by Gervais et al (13) were used to assess for persistent enhancement. Residual disease was defined as persistent enhancement in an area or areas of tumor after ablation, as determined on the 1-month follow-up study. Recurrent disease was defined as new tumor enhancement after at least one imaging study had demonstrated complete

eradication of enhancement (ie, technical success). Assessment of images was performed in consensus by two staff radiologists (D.A.G., P.R.M.).

Complications of RF ablation, management of the complications, and outcomes of the complications were recorded. Creatinine levels were not evaluated as part of the study, but reports of laboratory tests performed within 6 months after the procedure were evaluated for any change, with an increase of 0.5 mg/dL (44 $\mu\text{mol/L}$) considered to be clinically important.

Data Analysis and Statistics

Univariate analysis was performed by using the Fisher exact test to assess tumor size and location as predictors of technical success. $P \leq .05$ was considered to represent a significant difference. The t test was used to evaluate differences between group means. Results are reported according to size and location. Large tumors were defined as those larger than 3 cm, and small tumors were defined as those 3 cm or smaller.

Exophytic tumors were defined as those with a component extending into the perirenal fat but no component extending into the renal sinus fat. Parenchymal tumors were defined as those limited to the confines of the renal parenchyma, without extension into either the perirenal fat or the renal sinus fat. Central tumors were defined as those with extension into the renal sinus fat. Mixed tumors had components extending into both the renal sinus fat and the perirenal fat.

To evaluate the importance of tumor location, statistical analysis was performed to assess the influence of the presence or absence of any component of tumor within the renal sinus adjacent to large blood vessels. Thus, central and mixed tumors were considered a single category to provide a number large enough to allow meaningful statistical analysis when compared with exophytic and parenchymal tumors as a separate single group.

RESULTS

Technical Success

Results of the evaluation of the technical success of the procedure are summarized in the Table; results are broken down by tumor size and location. The 42 tumors were treated with a total of 140 ablations during 54 patient visits. Several

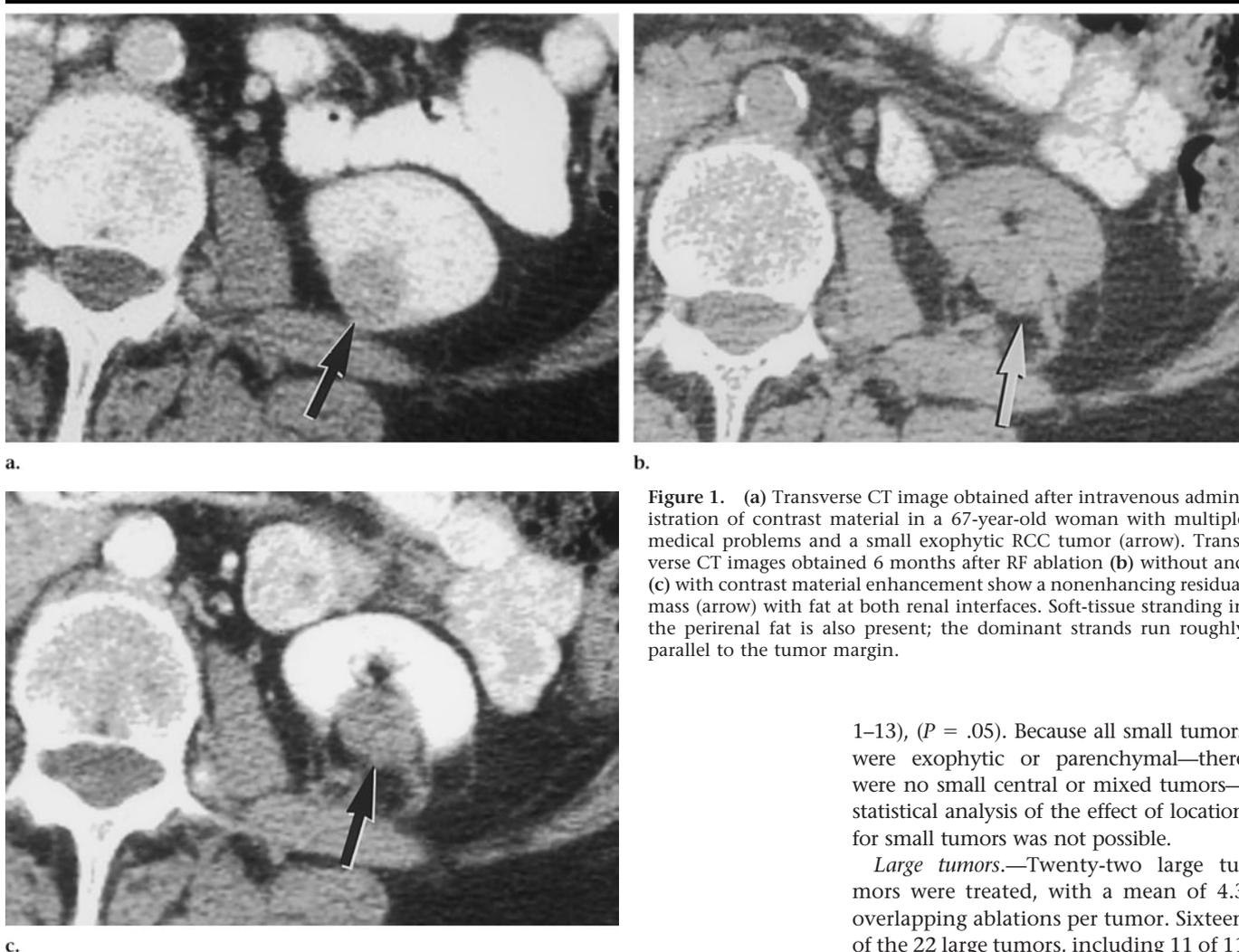


Figure 1. (a) Transverse CT image obtained after intravenous administration of contrast material in a 67-year-old woman with multiple medical problems and a small exophytic RCC tumor (arrow). Transverse CT images obtained 6 months after RF ablation (b) without and (c) with contrast material enhancement show a nonenhancing residual mass (arrow) with fat at both renal interfaces. Soft-tissue stranding in the perirenal fat is also present; the dominant strands run roughly parallel to the tumor margin.

observations are worth emphasizing; further detail is provided next.

Tumor Location

Exophytic and parenchymal tumors.—All exophytic tumors, small or large (mean, 3.2 cm; range, 1.1–5.0 cm), were treated with technical success. Technical success was achieved in 29 of 29 exophytic tumors and in two of two parenchymal tumors, regardless of small or large size. Technical success was achieved in most cases with one visit, but a few patients, especially those with large tumors, required two visits. Seventeen (89%) of the 19 small exophytic tumors (Fig 1) were treated in a single visit, whereas the other two tumors (11%) each required a second ablation session before technical success was achieved. Seven of the 10 (70%) large exophytic tumors were completely treated with one visit, whereas the other three

(30%) required two visits for complete treatment.

The two parenchymal tumors, one small (1.1 cm) and the other large (3.1 cm), were both completely treated with one visit. Thus all 31 tumors that lacked a component in the renal sinus fat were treated with technical success, with 26 tumors requiring a single visit for complete treatment and five tumors requiring two visits.

Central and mixed tumors.—Since all central and mixed tumors were large, these results are detailed in the section on large tumors.

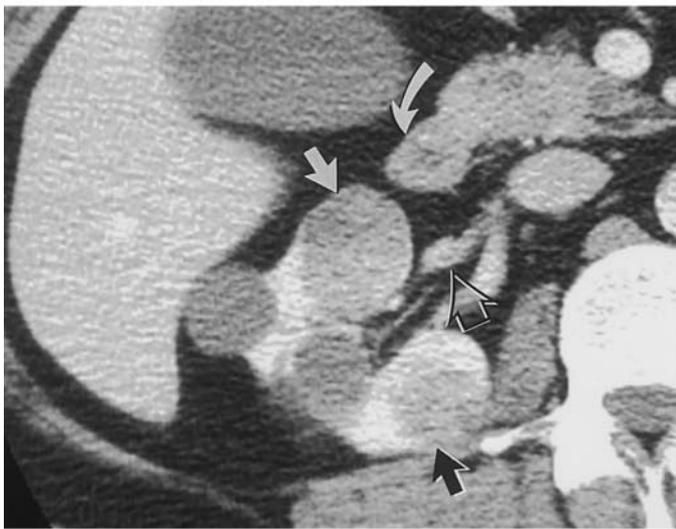
Tumor Size

Small tumors.—All small tumors were treated with technical success. As expected, small tumors required significantly fewer overlapping ablations (mean, 2.3; range, 1–6) for technically successful treatment than did large tumors (mean, 3.5; range,

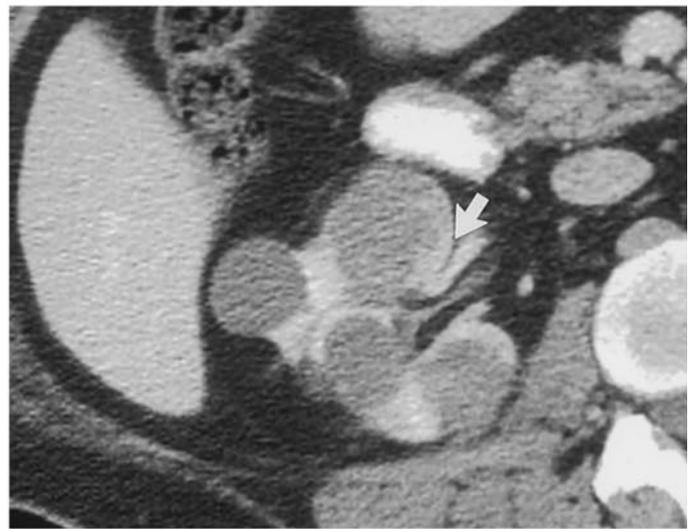
1–13), ($P = .05$). Because all small tumors were exophytic or parenchymal—there were no small central or mixed tumors—statistical analysis of the effect of location for small tumors was not possible.

Large tumors.—Twenty-two large tumors were treated, with a mean of 4.3 overlapping ablations per tumor. Sixteen of the 22 large tumors, including 11 of 11 large exophytic or parenchymal tumors, were treated with technical success. Among the mixed or central tumors (Fig 2), one of four central tumors and four of seven mixed tumors were treated with technical success. Thus, for large tumors, statistical evaluation of the effect of location was possible.

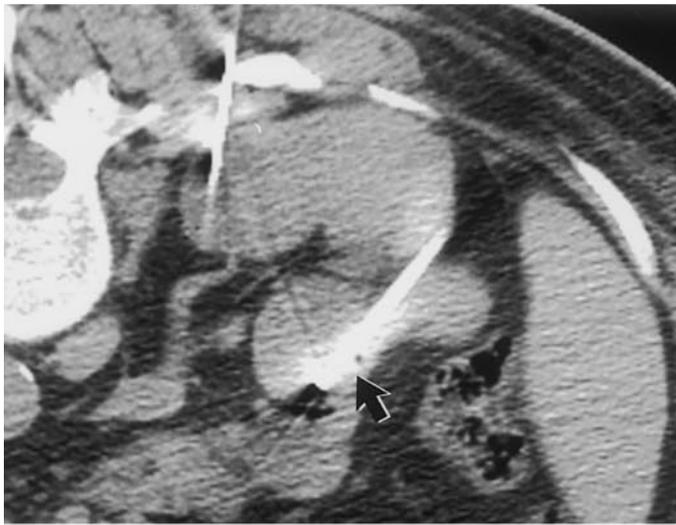
Location of all or part of a tumor in the renal sinus adjacent to large vessels was a significant negative predictor of technical success for tumors larger than 3.0 cm ($P = .01$). Of the 22 large tumors, 11 (100%) of the 11 large exophytic or parenchymal tumors were treated with technical success, whereas only five (45%) of the 11 central or mixed tumors were treated with technical success. Of the five mixed or central tumors treated with technical success, two (40%) were completely treated with a single visit, and the other three required a second visit. The largest tumor that was treated with technical success was a 5.3-cm mixed tumor.



a.



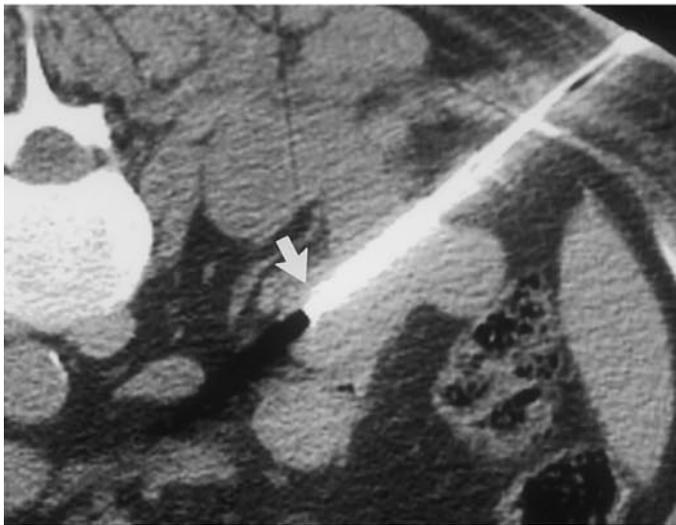
d.



b.



e.



c.

Figure 2. (a) Transverse CT image obtained after intravenous administration of contrast material in a 32-year-old man with VHL shows two enhancing RCC tumors (straight solid arrows). A fat plane separates the anterior tumor from the duodenum (curved arrow). The anterior tumor has a component in the perirenal fat but also juts into the renal sinus adjacent to the renal vein (open arrow). (b) Transverse CT image obtained during RF ablation performed with this patient in a prone position shows a cluster electrode (arrow) in the anterior tumor. The needle electrode was advanced slightly to abut the medial edge of the anterior tumor during RF ablation. The posterior tumor contains a biopsy needle that was removed before RF ablation was performed. (c) Transverse CT image obtained during RF ablation. The cluster electrode (arrow) was repositioned into the more posterior aspect of the anterior tumor. Again, the electrode was advanced until it abutted the medial edge of the tumor. (d) Transverse follow-up CT image obtained after intravenous administration of contrast material 1 month after RF ablation shows a small crescent of residual enhancement (arrow) in the anterior tumor at the interface with the renal vein. This region was ablated at a second visit. (e) Transverse follow-up CT image obtained after intravenous administration of contrast material 6 months after complete ablation shows that the anterior tumor (arrow) does not enhance and is 1.2 cm smaller than it was on images obtained in the previous studies.

Status of Patients with Incompletely Treated Tumors

At the time of this writing, of the six patients with incompletely treated tumors, three remained in the treatment protocol awaiting further ablation sessions or imaging examinations, whereas the other three patients were no longer undergoing treatment. Of the three patients no longer undergoing treatment, two were excluded after two ablation sessions because of worsening metastatic disease from another primary cancer. One patient opted to return to being followed up with imaging after four ablation sessions failed to result in technically successful treatment.

Follow-up

Overall length of follow-up ranged from 3.0 to 42.6 months (mean, 13.2 months; median, 9.9 months). During the 3.5-year interval after RF ablation, four patients died of other causes (leukemia [$n = 1$], cirrhosis [$n = 1$], metastatic disease from another primary cancer [$n = 2$]) between 3 and 22 months after ablation. RF treatment of RCC in two of these four patients had been technically successful; two had residual disease at the time of their deaths. Exclusion of the patients who died leaves a mean follow-up period of 13.4 months (median, 9.9 months; range, 3.7–42.6). Among the 30 patients alive at the time of this writing in whom RF ablation was technically successful, the follow-up period ranged from 3.0 to 42.6 months, with a mean of 12.7 months (median, 9.7 months). Of the 30 patients alive at the time of this writing, 20 were alive 6 or more months after the achievement of technically successful RF ablation treatment of RCC.

The 20 patients alive 6 or more months after RF ablation had undergone RF ablation of 23 tumors. At 6 months, all but three of these tumors were only slightly smaller, with a decrease of 1 cm or less in axial diameter. Thus, most tumors remain relatively stable after RF ablation in the 1st few months. However, three tumors showed a decrease in size of more than 1 cm. All three had been larger than 3 cm on pretreatment CT images. Two of these three tumors were followed up with imaging beyond 6 months. One of these two tumors was observed to have decreased in size from 3.4 to 2.3 cm at 6 months and, at the time of this writing, had remained stable for an additional 2.5 years. The other tumor was also followed up for 2.5 years and decreased from 3.4 to

1.5 cm during that time. In addition, at the time of this writing, the size of all other tumors followed up for at least 1 year remained relatively stable compared with that observed on CT images obtained at 6-month follow up.

Ancillary CT findings in many patients included fatty replacement within the tumor, often at the interface with normal kidney, soft-tissue stranding in the perirenal and/or pararenal fat that usually coalesced over time into a dominant band or halo roughly parallel to the tumor. This halo did not correspond to the pretreatment location of the outer margin of the tumor but extended beyond the pretreatment margin. Therefore, this finding likely represents a demarcation of an inflammatory reaction within the surrounding fat and does not represent the capsule of the tumor. Seven tumors treated with technical success were seen at preablation imaging to have adjacent cysts. In five of these seven tumors, the cysts adjacent to the tumors regressed after RF treatment. The nature of all the ancillary findings evolved with time, indicating an ongoing reaction to the remote thermal injury.

There were no cases of locally recurrent disease following a technically successful treatment, and no successfully treated tumor showed subsequent growth. Furthermore, no patients developed metastatic disease during treatment. No patients required dialysis during their postablation clinical course.

Results of postablation creatinine level testing were available for 26 patients and showed no clinically important change in 22 patients. Three of these 22 patients had had baseline creatinine levels above 2.0 mg/dL (177 $\mu\text{mol/L}$). In the four patients with increases in creatinine levels, these increases were associated with complications of RF ablation.

Complications

Four complications occurred during or after 54 patient visits to the radiology department for ablation. The 50 uncomplicated patient visits included the visits of five patients who underwent RF ablation of multiple tumors. All five patients had two ipsilateral tumors treated during the same visit. Two of these were the patients with VHL who also had contralateral tumors treated during different visits. One patient with VHL has had four tumors treated and at the time of this writing is continuing to undergo treatment for residual disease left only in a large central lesion. The second patient

had three tumors treated successfully and will return for treatment of two small enhancing lesions that have not yet been treated.

Three of the four complications occurred in patients with solitary kidneys; two of these kidneys contained large central tumors. One patient experienced a minor complication consisting of gross hematuria after a second visit for treatment of a 7.1-cm central tumor in a solitary kidney. A cluster electrode was used during this second visit; the patient's first visit had been uncomplicated. This patient became anuric because prostatic hyperplasia in combination with the hematuria resulted in bladder outlet obstruction. The bladder obstruction resolved promptly after placement of a bladder catheter. This patient was discharged from the hospital with the catheter in place; it was removed a week later. However, this patient's creatinine level did not return to baseline up from 3.3 to 5.2 mg/dL (292–460 $\mu\text{mol/L}$).

Another patient with a solitary kidney experienced gross hematuria obstructing the ureter and required hospital admission and treatment with ureteral stent placement after two RF treatments of a 6.2-cm central tumor with a cluster electrode. This patient's creatinine level returned to a baseline of 1.8 mg/dL (159 $\mu\text{mol/L}$) after an increase to 2.8 mg/dL (248 $\mu\text{mol/L}$), and the patient returned for a subsequent ablation session that was uneventful. A third patient developed a perirenal hematoma after a single ablation session in which a cluster electrode was used to treat a 3.4-cm exophytic tumor. This patient's creatinine level returned to a baseline of 2.5 mg/dL (221 $\mu\text{mol/L}$) after an increase to 3.5 mg/dL (309 $\mu\text{mol/L}$).

In another patient with a solitary kidney, a proximal ureteral stricture occurred after treatment of a 3.0-cm exophytic tumor with a single ablation, for which a cluster electrode was used. Treatment initially required a nephrostomy, but subsequent management of this patient's condition was possible with the placement of internal ureteral stents, and the patient's creatinine level returned to a baseline of 2.1 mg/dL (186 $\mu\text{mol/L}$) after an increase to 3.9 mg/dL (345 $\mu\text{mol/L}$). This tumor was in an exophytic location off the lower pole of the kidney near the ureter, and the ureter was injured despite the presence of an intervening fat plane between the ureter and the tumor. Of the four tumors in these four patients, the two smaller tumors were treated with technical success, whereas residual dis-

ease persisted in the two large central tumors after two ablation sessions each; these tumors subsequently were not treated with RF ablation.

DISCUSSION

Although several investigators have reported their experience with RF ablation of RCC (12–14,19), to our knowledge, the present report describes the most extensive experience with and the longest cumulative follow-up of percutaneous image-guided RF ablation of RCC left in situ reported to date. Most prior reports consist of case reports or describe a series of tumors removed after RF ablation performed laparoscopically. While laparoscopic partial nephrectomy is becoming more common as surgical expertise with the technique grows (4), percutaneous therapy remains less invasive. In our series, 42 tumors were ablated with a total of 140 overlapping ablations with acceptable morbidity and no procedure-related mortality. Moreover, the number of ablated tumors in our series allowed statistical analysis of the effect of tumor location on results of RF ablation of large tumors, and we were able to achieve complete ablation of all exophytic tumors up to 5.0 cm in size.

Although the mean follow-up period in our study (13.2 months) is short with respect to the natural history of RCC, the results observed during the longest follow-up period (3.5 years) are encouraging in terms of the continued long-term evaluation of this technique. The absence of tumor recurrences over the time course of this study is also very encouraging. Still, because many small RCC tumors can be expected to grow at a rate of 1–3 mm per year, longer-term follow-up of surviving patients to assess rates of local recurrence and occurrence of possible metastatic disease is needed.

Our results regarding the influence of tumor size and location on the outcome of RF ablation of RCC are as expected, given the characteristics of tissue in and around the kidney. With respect to size, ablation systems can produce burn diameters ranging from 1 to 5 cm in a single ablation (24). Depending on the ablation system used, the geometry of the burn is that of an irregular cylinder or sphere, which may not perfectly coincide with the tumor geometry (25). Therefore, overlapping ablations are usually required. With respect to tissue characteristics, the kidney is surrounded by fat that serves as a heat insulator; this allows

higher ablation temperatures to be achieved and maintained in tumors surrounded at least in part by fat (24). Consequently, exophytic tumors appear to be more easily treatable. This so-called oven effect has been described in hepatic tumors, in which the tumor capsule and surrounding cirrhotic liver perform this insulating function (9). Maintenance of higher temperatures during ablation results in improved tumor necrosis. On the other hand, near the renal sinus, the central portion of the kidney contains large vessels that serve as heat sinks because of the constant inflow of cool (ie, body temperature) blood. This limits the temperature achieved, and the time to return to body temperature is more rapid, thus limiting tumor necrosis (26).

Therefore, on the basis of their size and location, small exophytic RCC tumors are the ideal tumors for treatment with RF ablation. Our results support this theory and provide strong encouragement for the use of RF ablation in exophytic tumors as large as 5.0 cm. In our study, 17 (89%) of 19 small exophytic tumors were treated in a single visit, and two required a second visit. As tumor size increased, there was a greater chance that tumor treatment would require a second visit, but seven (70%) of 10 large exophytic tumors were still completely ablated during one visit. All exophytic tumors up to 5 cm in size were successfully ablated. Therefore, when one is assessing a tumor for possible RF ablation, one can select exophytic tumors up to 5 cm in size with a high certainty that the procedure will be successful. In the future, more accurate intraprocedural monitoring of tumor necrosis with MR imaging may facilitate complete ablation in a single session and obviate multiple visits. Early experience with experimental MR imaging-guided RF ablation systems is encouraging, but for now these systems remain experimental, and the RF systems currently commercially available in the United States are not compatible for use with MR imaging (27,28).

As expected, our study results have shown that for large RCC tumors, location is a significant predictor of the technical success of RF ablation. Among tumors larger than 3 cm, those with a central component near large vessels are less likely to be treated with technical success than are those without such a component. A limitation of our data set is that there were no small tumors that had a central component. Thus, we were unable to assess the significance of loca-

tion in the outcome of RF ablation of small tumors.

Of nine patients in our study who had a solitary kidney or compromised renal function, none has required dialysis. Thus, for patients with an actual or functionally solitary kidney who undergo complete ablation of RCC, RF ablation provides a treatment option that does not subject them to the inconvenience and morbidities of dialysis. Even in the absence of complete ablation, RF ablation may play a role in palliation of disease in patients who find dialysis unacceptable. This palliative role of RF ablation in the treatment of RCC is an interesting area for further study, especially for large tumors with a central component.

Uzzo and Novick (4), in a review of reports of nephron-sparing surgical procedures published during the past decade, established complication rates and outcomes for these procedures (4). Survival data for nephron-sparing surgical procedures are similar to those for radical nephrectomy (4). In their review, Uzzo and Novick (4) found that rates of major complications ranged from 4% to 30% in nine series, with a cumulative total of 155 (13.7%) complications in 1,129 procedures (4). Among these complications were 14 deaths, three splenic injuries, 78 urinary fistulas, 19 infections or abscesses, 27 hemorrhages, and 18 instances in which patients had to undergo postoperative dialysis (4). Our results are favorable compared with this standard, especially when one considers that many patients in our series were ineligible for or would be at extremely high risk during anesthesia and surgery. The most frequent complication we encountered (in three cases) was hemorrhage, with management involving placement of a ureteral stent in one patient and a bladder catheter in another. A third patient required supportive care. One minor and two major hemorrhages, with none requiring surgery, are acceptable considering the 140 separate ablations, some of which were performed with triple punctures (when the cluster electrode was used). The case of ureteral stricture formation observed in our study provides an opportunity to review the approach to tumors close to the ureter. Ureteral protection should be considered when RF ablation is to be performed in a tumor near the ureter. Options include placement of a ureteral stent with cold saline perfusion before ablation, laparoscopic ablation with separation of the ureter from the tumor, and percutaneous abla-

tion with instillation of saline or carbon dioxide to separate the ureter and tumor.

In conclusion, percutaneous image-guided RF ablation of RCC is a very promising technique and is most successful in treating small (<3 cm) exophytic tumors, although tumors up to 5.0 cm can be completely ablated. Tumors with a central component in the renal sinus require more ablations but can be successfully treated with multiple visits for repeated ablations. Longer-term studies of RF ablation of RCC left in situ will provide additional guidance for the most appropriate selection of patients for this treatment.

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