

# Reporting Standards for Percutaneous Thermal Ablation of Renal Cell Carcinoma

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Abbreviations: RCC = renal cell carcinoma, RF = radiofrequency

WITH the increasing incidence of renal cell carcinoma (RCC) in the United States and the increasing proportion of patients with tumors detected at an early stage (1–5), nephron-sparing approaches are becoming more popular. These alternatives to radical nephrectomy include partial nephrectomy, wedge resection, and, more recently, in situ thermal ablation.

Five-year survival rates after partial nephrectomy are equivalent to those after radical nephrectomy (6–8), supporting the rationale of in situ tumor destruction to further reduce morbidity and invasiveness. In situ thermal destruction of RCC uses techniques that destroy tumor tissue through heating (eg, radiofrequency [RF] ablation, microwave ablation, laser interstitial therapy, high-intensity focused ultrasound [US]) or freezing (eg, cryotherapy). Each of these techniques relies on controlled energy delivery to minimize collateral damage to normal renal parenchyma and other surrounding structures. In the United States, RF ablation and cryoablation are currently the most widely used techniques for in situ RCC destruction. Thermal ablation of RCC may be performed percutaneously, laparoscopically, or through open surgery.

Our current understanding of the role of percutaneous thermal ablation in the management of primary RCC is limited by a paucity of prospective studies (9,10). Given the relative newness of this technology, most series to date report short-term or midterm outcomes, with no reports extending to 5 years of survival outcomes. No randomized trials have been performed to date comparing thermal ablation against a gold standard (ie, partial nephrectomy) or against other thermal ablation techniques. The optimal size range of RCC amenable to

thermal ablation has not been clearly defined and is closely related to anatomic factors that influence the ability to deposit sufficient thermal dose to coagulate tissue, including proximity to major vessels and the urinary collecting system, which can act as a heat sink. The kidney has approximately four times the blood flow of the liver, so convective heat loss during thermal ablation is potentially significant (11). The role of percutaneous thermal ablation compared with laparoscopic or open thermal ablation also remains a topic of controversy. The combination of thermal ablation with other image-guided therapies (eg, transcatheter embolization) and adjuvant therapies such as chemotherapy and antiangiogenic agents for larger RCCs in patients who are poor operative candidates is another potential use of this technique.

Although most recent reports of percutaneous RCC ablation have involved RF ablation, other ablation technologies are now available with percutaneous applicators (eg, cryoablation, microwave, laser interstitial therapy), and reporting standards should be uniform for all forms of energy-based ablation. This document provides recommended reporting standards for physicians performing percutaneous thermal ablation of primary RCC and will serve as a template in the design of clinical trials to further evaluate this technology.

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## PATIENT SELECTION

### Clinical Criteria

Potential candidates for thermal ablation fall into two general categories: (i) patients who are poor operative candidates as a result of inadequate renal function and/or comorbid disease and (ii) patients at high risk for the development of additional RCC in the future in whom the least invasive nephron-sparing approach is desirable.

Patients in the first category include those with RCC detected in a solitary functional or anatomic kidney in whom surgical resection would likely result in the need for dialysis. Individuals with marginal renal function, who would also have a high likelihood of requiring dialysis after resection, may also be suitable candidates for thermal ablation. Comorbid disease such as coronary artery disease, cardiomyopathy, or chronic obstructive pulmonary disease may introduce an unacceptably high risk with general anesthesia and make a patient unsuitable for operative resection. In these patients, percutaneous thermal ablation may be an appropriate alternative.

Patients in the second category include those with genetic syndromes associated with RCC, including von Hippel-Lindau syndrome, hereditary papillary cell carcinoma, or hereditary clear-cell carcinoma. These are patients who are screened for RCC at regular intervals, and therefore an incident RCC may be detected at an early stage. They are also more likely to require eventual nephrectomy, so thermal ablation of early-stage RCC may provide a longer interval before nephrectomy becomes necessary. Patients with synchronous RCC—sporadic or associated with a genetic predisposition—also represent a category of patients who may benefit from thermal ablation. In these patients, surgical resection of a dominant RCC followed by thermal ablation of the smaller contralateral RCC followed by close observation may enable a longer period before nephrectomy or partial nephrectomy becomes necessary.

### Anatomic Criteria

Multiple anatomic considerations should be taken into account when se-

lecting patients for thermal ablation, including tumor size, proximity to the collecting system, and proximity to adjacent viscera. These are discussed in more detail in the Pretreatment Evaluation section.

### Exclusion Criteria

Imaging of the chest (with computed tomography [CT]) and the skeletal system (with a nuclear medicine bone scan) should be performed in each patient within 3 months before ablation to confirm that disease is limited to the kidney (ie, T1N0M0). Thermal ablation may play a role in patients with limited metastatic disease (eg, a solitary pulmonary nodule) if the metastatic disease is amenable to potentially curative resection or ablation. Patients undergoing thermal ablation should have an adequate functional status, and each patient's functional status at baseline and at each point during follow-up should be documented according to an accepted grading system such as Eastern Cooperative Oncology Group score. Ablation should be limited to patients with a reasonable life expectancy ( $\geq 6$ –12 months), in whom the risk/benefit ratio for the procedure is believed to be favorable.

### Recommendations

The clinical indication for percutaneous thermal ablation must be clearly specified. Genetic syndromes or chromosomal abnormalities, when present, must be recorded. A history of RCC in the ipsilateral or contralateral kidney must be noted. To enable determination of the effect of RF ablation on long-term renal function, serum creatinine levels and glomerular filtration rate (measured directly or estimated according to the Cockcroft and Gault equation) must be reported at baseline and at each point during follow-up. Subgroups of patients with impaired or marginal renal function should be reported separately. The functional status of each patient should be recorded at baseline and during follow-up with an established scoring system such as Eastern Cooperative Oncology Group score.

## PRETREATMENT EVALUATION

### Patient Evaluation

Pretreatment evaluation of patients for thermal ablation must include assessment of demographics (eg, age, sex, ethnicity). Any known or putative risk factors for RCC should be noted, such as smoking; occupational exposure to cadmium, asbestos, or aniline dyes; hereditary predisposition to RCC; cystic disease of the kidney; and history of dialysis. In addition to comorbid medical renal or renovascular disease, additional comorbidities must be reported, including coronary artery disease, essential hypertension, cerebrovascular disease, diabetes mellitus, chronic obstructive pulmonary disease, and other malignancies. In addition to risk stratification for future treatment algorithms, this enables identification of patients who may be at a lower tolerance for procedural complications. For example, a patient with chronic obstructive pulmonary disease in whom a pneumothorax develops from transpleural transgression of an RF electrode will be more likely to require a chest tube than a patient without underlying lung disease. Patients with cardiac pacemakers require additional planning before RF ablation and may require temporary deactivation of the device during RF ablation. Patients with mechanical cardiac valves will require temporary conversion from warfarin to unfractionated or low-molecular-weight heparin for the thermal ablation procedure, followed by resumption of oral anticoagulation.

### Tumor Characteristics

Patients who are candidates for thermal ablation will generally harbor T1N0M0 disease (Tables 1,2, available at [www.jvir.org](http://www.jvir.org)) (12). Currently, tumor size should be recorded as the maximum tumor diameter in a single dimension, in accordance with the Response Evaluation Criteria In Solid Tumors adopted by the National Cancer Institute (13). When more detailed assessment of tumor size is recorded, including dimensions in three orthogonal axes, tumor volume estimated from the orthogonal diameters, or measurement of tumor volume with use of volume-rendering software, the

method of volume estimation should be specified. Although no established threshold of tumor diameter is associated with RF ablation treatment success or failure, our current understanding of renal thermal ablation indicates that an RCC with a greatest unidimensional diameter of 4 cm or less (T1a) has a higher probability of complete ablation than does an RCC larger than 4 cm (14).

Nevertheless, tumor diameter is only one of several important determinants of technical success of thermal ablation. RCC location is an important factor that determines the safety and efficacy of thermal ablation and should be recorded according to the classification of Gervais et al (14), in which RCC is classified as exophytic, parenchymal, central, or mixed with central and exophytic components. For patients with multiple RCCs, each lesion must be described individually. Perirenal fat can produce a thermally insulating effect, resulting in more efficient thermal ablation. Therefore, exophytic RCC may be more likely to be completely ablated than parenchymal or central RCC. Tumor proximity to a major renal vessel can result in residual viable tumor after thermal ablation as a result of heat-sink effects. Proximity to the central collecting system (ureteropelvic junction or ureter), bowel, pancreas, adrenal, liver, or gallbladder may be relative contraindications to percutaneous thermal ablation or may require adjunctive techniques to prevent off-target heating of adjacent structures during the ablation procedure.

### Recommendations

Patient demographics, occupational exposure, genetic history, and comorbidities must be reported. Comorbid conditions that may place a patient at additional risk for percutaneous thermal ablation must be noted and justified. Tumor characteristics including stage, size, number, and location must be recorded. Adjacent organs at risk for perforation or thermal injury must be noted when present.

## TREATMENT DESCRIPTION

### Biopsy before Ablation

Whenever possible, biopsy should be performed before ablation (15,16).

**Table 3**  
**Classification of Renal-cell Tumors (18)**

Benign
Papillary adenoma
Angiomyolipoma
Oncocytoma
Malignant
Conventional (clear-cell) carcinoma
Papillary carcinoma
Chromophobe carcinoma
Collecting duct carcinoma

This determination of RCC subtype may become relevant to the option of systemic chemotherapy if the patient experiences metastatic disease in the future. A biopsy also ensures that the tumor ablated was actually RCC and not a benign lesion such as an oncocytoma, metanephric adenoma, papillary adenoma, or angiomyolipoma devoid of fat (17). A classification of renal cell neoplasms is shown in Table 3 (18).

### Method of Targeting and Monitoring

Thermal ablation of RCC may be performed with CT, US, or magnetic resonance (MR) guidance; the imaging method of targeting must be provided. Some operators prefer to perform initial applicator placement with US and then use CT to perform precise final positioning. When multitined expandable electrode systems are used for RF ablation, final tine position before the application of RF energy should be verified with imaging. The imaging modality used for initial applicator placement will usually be the same modality used for monitoring during ablation and electrode repositioning. If not, a description of additional imaging must be provided. The goal of renal thermal ablation is to achieve a treatment margin that extends just beyond the margin of the tumor. CT-guided cryoablation has the ability to monitor ice ball formation during ablation; instances in which ice ball formation dose not extend beyond the margins of the tumor should be recorded because the edge of the ice ball represents sublethal temperatures. Some authors advocate extension of the ice ball 6–8 mm beyond the margin of the tumor for this reason (19).

Experience from nephron-sparing surgery of RCC indicates that long-term disease progression is not related to width of the resection margin; patients with narrow resection margins have the same long-term outcomes as patients with wide margins (20). The exact distance of adequate treatment margins remains to be established; until further data become available, a circumferential treatment margin of 5–10 mm should be used.

### Ablation Description

As specified in published standardization guidelines (21), a description must be given of the ablation device (energy source and applicator) and treatment protocol used for thermal ablation. Adherence to the manufacturer's recommended treatment protocol and/or precise details and modification by the operator must be stated. The total procedure time and duration of energy application must be recorded. For RF ablation, this includes the energy source (ie, power and current) and algorithm used (eg, impedance based, pulsed), the number of overlapping ablations, the number of ablation sessions, and the treatment endpoint (ie, time, target temperature, maximum impedance). Details as to whether the electrode used was a single-tip, triple-cluster, or multitined electrode must also be given. When bipolar electrodes become available, a distinction between monopolar and bipolar devices must be made. The number of grounding pads, skin positioning, and skin preparation must be stated.

For cryoablation, probe size, isotherm characteristics, probe positioning, duration of active freezing, duration of active thawing, and number of freeze/thaw cycles must be recorded. The method and frequency of monitoring ice ball formation (CT, US, or MR imaging) must be provided. When thermocouples are used, the number, positioning, and minimum temperature reached must be stated.

Other thermal ablation modalities (eg, microwave, laser interstitial therapy, high-intensity focused US) must have applicator and energy source characteristics and energy delivered as recorded parameters.



### Adjunctive Techniques

Adjunctive techniques may be used in some circumstances to displace at-risk viscera away from the intended ablation zone or to provide cooling of the urinary collecting systems to prevent urothelial thermal injuries. These techniques include so-called hydrodissection (22), in which a window of sterile water or similar nonionic solution (eg, dextrose in water) is injected through a fine needle inserted between the tumor and the organ deemed at risk. The use of balloons positioned between the kidney and adjacent viscera has also been described (23). Deliberate pneumothorax is another adjunctive technique described for the treatment of upper-pole RCC with thermal ablation, in which a transpleural window is created for applicator insertion. This technique involves percutaneous instillation of air into the pleural space without producing injury to the lung surface (24). Retrograde or percutaneous antegrade infusion of chilled water during ablation is a potential method to protect the adjacent collecting system from thermal injury during ablation of central tumors (25).

### Anesthesia and Hemodynamic Monitoring

Thermal ablation of RCC may be performed with use of moderate sedation or general anesthesia. All patients will require hemodynamic monitoring in compliance with national hospital accreditation standards and local institutional standards. When moderate sedation is used, airway evaluation before and throughout the procedure is necessary because almost all patients will be in a prone position during the procedure. The method of anesthesia or sedation must be recorded. When endotracheal intubation is performed, this should be stated.

### Recommendations

Biopsy should be performed before ablation, and the biopsy results must be reported. The imaging method of targeting (CT, MR imaging, US) must be provided. A description of the ablation electrodes and energy source must be stated, along with the treatment algorithm. When adjunctive per-

cutaneous techniques are used for the protection of adjacent viscera from perforation or thermal injury, sufficient detail must be provided to enable another operator to perform the same maneuver. The type of anesthesia used and hemodynamic monitoring must be provided.

### POSTTREATMENT IMAGING

Residual or recurrent disease (ie, local tumor progression) is most common at the margin of the ablation zone. For a detailed description of general imaging findings after thermal ablation, the reader is referred to the recommended reporting guidelines of Goldberg et al (26). Imaging after thermal ablation to detect viable tumor can include contrast medium-enhanced CT or MR imaging. CT characteristics of residual or recurrent tumor remain to be clearly defined. Farrell et al (27) used an arbitrary criterion of 10 HU of enhancement or less in a series of 35 tumors treated with RF ablation for complete ablation. Low signal of the ablation zone on T2-weighted images and lack of enhancement after gadolinium administration are the general characteristics of completely ablated RCC. Merkle et al (28) prospectively evaluated the conditions of 18 patients with gadolinium-enhanced MR imaging after RF ablation and found that tumors gradually decreased in size but retained a thin rim of T2-hyperintense tissue, which enhanced with gadolinium. Gill et al (29) monitored a cohort of 56 patients with MR imaging after laparoscopic cryoablation and observed a gradual involution in the size of the ablation zone. By 3 years, there was a 75% reduction in cryolesion size, and 38% of cryolesions were undetectable on imaging. Two patients had enhancing areas of nodularity on MR imaging at 6 months, which were biopsy-proven recurrence. Cestari et al (19) monitored 37 patients with MR imaging after laparoscopic cryoablation and also observed a progressive reduction in size.

When MR imaging is used to detect residual or recurrent disease of small tumors (<3 cm), high spatial resolution is necessary. With current MR imaging technology, most open magnets are unable to achieve the needed resolution to detect early local tumor pro-

gression. There is currently no role for conventional US in the detection of residual or recurrent disease, although US contrast agents may play a future role in patient surveillance after thermal ablation. Experience with positron emission tomography has thus far been limited to the characterization of renal masses as benign or malignant and in the detection of residual metastatic disease in patients treated with systemic chemotherapy (30,31). However, as the technology of positron emission tomography and CT/positron emission tomography continues to evolve, these modalities may play a greater role in the preablation evaluation and posttreatment surveillance of RCC after thermal ablation.

### Frequency of Imaging

The necessary frequency of imaging after thermal ablation is related to the natural history of small RCCs (<3 cm), which is approximately 6 mm growth per year. For this reason it may be appropriate to perform imaging at 6-month intervals after an early scan (at 1–3 months) documenting that absence of viable enhancing tumor has been obtained. Others will perform imaging more frequently within the first year after ablation (every 3–4 months), with the rationale that the first year is when recurrent disease is most likely. The timing of the first scan varies among institutions from as early as 1 week to as late as 1 month. Although the optimal frequency of follow-up imaging remains to be defined from a cost-effectiveness standpoint, for the purposes of study design, all patients within a study must undergo imaging follow-up with the same frequency.

### Follow-up of Clinical Status

Evaluation of each patient's clinical status should be performed with at least the same frequency as follow-up imaging. These assessments should record the patient's general medical condition, renal function, and any late complications possibly related to thermal ablation, including stricture of urinary collecting system, lumbar radiculopathy, and skin paresthesias.

**Functional Status**

The potential benefit of thermal ablation in the treatment of patients with RCC needs to be defined in the context of an individual patient’s functional status. Each patient’s functional status should be recorded during every follow-up encounter according to the same grading system used in the pre-treatment evaluation.

**Duration of Follow-up**

To become established as a curative technique for small RCC, percutaneous thermal ablation needs to achieve disease-free survival rates that are equal to those of surgical resection. Therefore, similarly to any resection approach to a solid organ malignancy, a follow-up period of at least 5 years is necessary after ablation.

**Recommendations for Imaging and Clinical Follow-up**

Imaging after thermal ablation must be performed at a regular frequency with CT or MR imaging. Clinical factors may influence the choice of imaging (eg, pacemaker precluding MR imaging or contrast agent allergy or renal insufficiency precluding CT); otherwise, within a clinical trial, the use of imaging modality should be uniform among longitudinal imaging sessions. Standardized definitions of residual disease must be used according to recent recommendations (26). The clinical status and functional status of patients after thermal ablation should be evaluated during each follow-up encounter. The results of imaging and clinical follow-up must be reported. The duration of follow-up should be sufficient to detect progression of disease.

**ANALYSIS OF OUTCOMES**

The natural history of small RCC (<3 cm) involves slow growth, making survival difficult to use as a distinguishing outcome, because in all but long-term follow-up studies, survival rates will be high. Therefore, the primary outcome of percutaneous thermal ablation should be disease-free survival. Most clinical studies report-

**Table 4**  
**Classification of Complications of Percutaneous Renal RF Ablation**

Complication	Class
Abscess	Infectious/inflammatory
Allergic/anaphylactoid reaction	Contrast agent-related
Angina/coronary ischemia	Cardiac
Death related to procedure	Death
Death unrelated to procedure (30-day mortality)	Death
Hypotension	Cardiac
Hematoma bleeding	
Perirenal	Vascular
Subcapsular	Vascular
Retroperitoneal	Vascular
Puncture site	Vascular
Hematuria	General nonvascular
Idiosyncratic reaction	Medication-related
Lumbar radiculopathy	Neurologic
Myocardial infarction	Cardiac
Pleural effusion	Respiratory/pulmonary
Pneumothorax	Respiratory/pulmonary
Pulmonary embolism	Vascular
Renal failure	General nonvascular
Renal infarct	Vascular
Sepsis	Infectious/Inflammatory
Skin burn	Device-related
Stricture	
Collecting system	General nonvascular
Ureteral	General nonvascular
Stroke	Neurologic
Tumor seeding	General nonvascular
Urinary fistula	General nonvascular
Unintended perforation of hollow viscus	General nonvascular
Vagal reaction	Cardiac

ing survival data use Kaplan-Meier estimates or life tables. Many investigators refer to these techniques interchangeably; however, they have important differences. Failure and censoring events in life-table analysis are clustered into fixed intervals of time, typically 3-month or 6-month windows. In small trials (<200 patients), this clustering can produce inaccuracy in survival estimates, because a patient who survives 3 months plus 1 day has the same statistical effect as a patient who survives 5 months plus 29 days. By contrast, the Kaplan-Meier technique calculates survival from the actual time of the failure or censoring event. For this reason, all studies reporting survival data except for very large trials should use the Kaplan-Meier technique. Inter-group comparisons of survival estimates should be performed with an appropriate nonparametric technique, such as the log-rank test.

**Intent-to-Treat Analysis**

Patients in studies of thermal ablation of RCC should be considered to have undergone ablation if this was the intended treatment after randomization. For example, if a patient experiences a subcapsular hematoma during insertion of an RF electrode, resulting in abandonment of the procedure, the patient should still be included as a patient in the RF ablation arm during subsequent outcome analyses.

**Comparison with Other Nephron-sparing Therapies**

To become established as a curative technique for small RCC, thermal ablation needs to (i) achieve equivalent safety and efficacy to nephron-sparing surgery and (ii) be cost effective. Whenever possible, randomized trials should include economic evaluation of

**Table 5**  
Society of Interventional Radiology  
Definition of Complications (32)

Minor complications
No therapy, no consequence
Nominal therapy, no consequence; includes overnight admission for observation only
Major complications
Require therapy, minor hospitalization (<48 hours)
Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours)
Permanent adverse sequelae
Death

thermal ablation compared with alternative treatment. Because thermal ablation of renal tumors is significantly influenced by size and proximity to major vessels and the collecting system, prospective trials should also consider stratification of randomized patients by tumor size and location.

Blinding of patients and observers to the form of nephron-sparing therapy (eg, RF ablation vs cryoablation) may not be feasible. However, follow-up imaging can be evaluated in a core laboratory with observers blinded to therapy.

**Complications**

All complications of the ablation procedure should be reported, including those that do not appear related to the procedure. Recognized and/or potential complications of renal thermal ablation are given in **Table 4**. Late complications that develop outside of this window, such as tract seeding or lumbar radiculopathy, must also be reported. The classification system used by the Society of Interventional Radiology for grading complications must be used (**Table 5**) (32).

**Quality of Life**

A validated instrument for the measurement of quality of life should be used at baseline and during each follow-up encounter, such as the Short Form-36, European Organisation for the Research and Treatment of Cancer QLQ-C30 instrument, or Functional Assessment of Cancer Therapy-General questionnaire. These instruments

**Table 6**  
Recommendations for Reporting Standards

	Required	Highly Recommended	Recommended
Evaluation before ablation			
Patient population	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Age, sex, race	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Clinical indication for RF ablation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anatomic location of tumor	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tumor staging	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Biopsy	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Study design			
Inclusion criteria	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Exclusion criteria	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comorbid diseases	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Functional status	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Ablation description			
Ablation device description	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Treatment endpoint	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Energy and duration of RF ablation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Number of ablation zones	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Method of targeting and monitoring	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Adjunctive techniques	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anesthesia	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hospital days	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Complications			
Immediate	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30-Day	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Late complications	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Evaluation after ablation			
Follow-up imaging at regular intervals	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Follow-up of clinical status	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Survival	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Disease-free survival	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Quality of life assessment	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Uniform duration of follow-up	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Need for additional ablation/resection	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Costs	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Cost effectiveness	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

have the advantage of having been extensively validated in oncology patient populations, and they have been used in quality-of-life evaluation after nephron-sparing surgery for RCC (33-35).

**Costs and Cost Effectiveness**

When reporting costs of renal ablation, authors should report direct costs associated with the procedure (eg, thermal applicators, CT interventional suite time, length of hospitalization) and indirect costs (eg, need for increased imaging follow-up to detect residual or recurrent disease). These costs are then combined for a study patient cohort as a cumulative numerator for measurement of cost effective-

ness. The denominator of cost effectiveness is the number of quality-adjusted life years derived for the study population, which yields the cost-effectiveness ratio of dollars per quality-adjusted life years. This should also include sensitivity analysis and discounting. These cost-effectiveness data will become critical in comparing percutaneous thermal ablation with other ablative and nephron-sparing therapies.

**Recommendations**

Disease-free and overall survival should be determined with the Kaplan-Meier technique. An intent-to-treat basis should be used for the evaluation of patient outcomes after randomization. Comparison with other



nephron-sparing approaches is ideal, rather than case series of patients treated only with thermal ablation. A thorough description of complications in the immediate periprocedural period and within 30 days of the procedure is needed. Measurement of quality of life should be performed with a previously validated instrument, preferably one that has been developed for oncology patients. Determination of costs and cost effectiveness is recommended.

## CONCLUSION

Percutaneous ablation has the potential to become an established minimally invasive therapy for small RCC. To reach this potential, percutaneous thermal ablation must be supported by compelling randomized, prospective trials comparing it with other nephron-sparing approaches for RCC. The goal of this document is to provide recommended definitions to enable uniform reporting of these trials (Table 6).

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## References

- American Cancer Society. Cancer Facts and Figures 2005. Atlanta: American Cancer Society, 2005. Available at: <http://www.cancer.org/downloads/STT/CancerFacts&Figures2005TM.pdf>. Accessed January 15, 2006.
- Levine E, Huntrakoon M, Wetzel LH. Small renal neoplasms: clinical, pathologic, and imaging features. *AJR Am J Roentgenol* 1989; 153:69-73.
- Smith SJ, Bosniak MA, Megibow AJ, et al. Renal cell carcinoma: earlier discovery and increased detection. *Radiology* 1989; 170:699-703.
- Ozen H, Colowick A, Freiha FS. Incidentally discovered solid renal masses: what are they? *Br J Urol* 1993; 72:274-276.
- Chow WH, Devesa SS, Warren JL, et al. Rising incidence of renal cell cancer in the United States. *JAMA* 1999; 281:1628-1631.
- Butler BP, Novick AC, Miller DP, et al. Management of small unilateral renal cell carcinomas: radical versus nephron-sparing surgery. *Urology* 1995; 45:34-40.
- Hafez KS, Fergany AF, Novick AC. Nephron sparing surgery for localized renal cell carcinoma: impact of tumor size on patient survival, tumor recurrence and TNM staging. *J Urol* 1999; 162:1930-1933.
- Fergany AF, Hafez KS, Novick AC. Long-term results of nephron sparing surgery for localized renal cell carcinoma: 10-year followup. *J Urol* 2000; 163:442-445.
- Pavlovich CP, Walther MM, Choyke PL, et al. Percutaneous radio frequency ablation of small renal tumors: initial results. *J Urol* 2002; 167:10-15.
- Hwang JJ, Walther MM, Pautler SE, et al. Radiofrequency ablation of small renal tumors: intermediate results. *J Urol* 2004; 171:1814-1818.
- Brown DB. Concepts, considerations, and concerns on the cutting edge of radiofrequency ablation. *J Vasc Interv Radiol* 2005; 16:597-613.
- Kidney. In: American Joint Committee on Cancer Staging Manual, 6th ed. New York: Springer, 2002;323-328.
- Therasse P, Arbuck SG, Eisenhauer EA, et al. New guidelines to evaluate the response to treatment in solid tumors. European Organization for Research and Treatment of Cancer, National Cancer Institute of the United States, National Cancer Institute of Canada. *J Natl Cancer Inst* 2000; 92:205-216.
- Gervais DA, McGovern FJ, Wood BJ, et al. Radio-frequency ablation of renal cell carcinoma: early clinical experience. *Radiology* 2000; 217:665-672.
- Mai KT, Alhalouly T, Lamba M, et al. Distribution of subtypes of metastatic renal-cell carcinoma: correlating findings of fine-needle aspiration biopsy and surgical pathology. *Diagn Cytopathol* 2003; 28:66-70.
- Crapanzano JP. Fine-needle aspiration of renal angiomyolipoma: cytological findings and diagnostic pitfalls in a series of five cases. *Diagn Cytopathol* 2005; 32:53-57.
- Tuncali K, vanSonnenberg E, Shankar S, et al. Evaluation of patients referred for percutaneous ablation of renal tumors: importance of a preprocedural diagnosis. *AJR Am J Roentgenol* 2004; 183:575-582.
- Kumar V, Abbas AK, Fausto N. Robbins and Cotran Pathologic Basis of Disease, 7th ed. Philadelphia: Saunders/Elsevier, 2005.
- Cestari A, Guazzoni G, dell'Acqua V, et al. Laparoscopic cryoablation of solid renal masses: intermediate term followup. *J Urol* 2004; 172:1267-1270.
- Castilla EA, Liou LS, Abrahams NA, et al. Prognostic importance of resection margin width after nephron-sparing surgery for renal cell carcinoma. *Urology* 2002; 60:993-997.
- Goldberg SN, Charboneau JW, Dodd GD Jr, et al. Image-guided tumor ablation: proposal for standardization of terms and reporting criteria. *Radiology* 2003; 228:335-345.
- Gervais DA, Arellano RS, McGovern FJ, et al. Radiofrequency ablation of renal cell carcinoma: part 2, lessons learned with ablation of 100 tumors. *AJR Am J Roentgenol* 2005; 185:72-80.
- Kam AW, Littrup PJ, Walther MM, et al. Thermal protection during percutaneous thermal ablation of renal cell carcinoma. *J Vasc Interv Radiol* 2004; 15:753-758.
- Ahrar K, Matin S, Wallace MJ, et al. Percutaneous transthoracic radiofrequency ablation of renal tumors using an iatrogenic pneumothorax. *AJR Am J Roentgenol* 2005; 185:86-88.
- Schultze D, Morris CS, Bhave AD, et al. Radiofrequency ablation of renal transitional cell carcinoma with protective cold saline infusion. *J Vasc Interv Radiol* 2003; 14:489-492.
- Goldberg SN, Grassi CJ, Cardella JF, et al. Image-guided tumor ablation: standardization of terminology and reporting criteria. *J Vasc Interv Radiol* 2005; 16:765-778.
- Farrell MA, Charboneau WJ, DiMarco DS, et al. Imaging-guided radiofrequency ablation of solid renal tumors. *AJR Am J Roentgenol* 2003; 180:1509-1513.
- Merkle EM, Nour SG, Lewin JS. MR imaging follow-up after percutaneous radiofrequency ablation of renal cell carcinoma: findings in 18 patients during first 6 months. *Radiology* 2005; 235:1065-1071.
- Gill IS, Remer EM, Hassan WA, et al. Renal cryoablation: outcome at 3 years. *J Urol* 2005; 173:1903-1907.
- Ramdave S, Thomas GW, Berlangieri SU, et al. Clinical role of F-18 fluorodeoxyglucose positron emission tomography for detection and manage-

- ment of renal cell carcinoma. *J Urol* 2001; 166:825–830.
31. Safaei A, Figlin R, Hoh CK, et al. The usefulness of F-18 deoxyglucose whole-body positron emission tomography (PET) for re-staging of renal cell cancer. *Clin Nephrol* 2002; 57:56–62.
  32. Burke DR, Lewis CA, Cardella JF, et al. Quality improvement guidelines for percutaneous transhepatic cholangiography and biliary drainage. *J Vasc Interv Radiol* 2003; 14(suppl): S243–S246.
  33. Poulakis V, Witzsch U, de Vries R, et al. Quality of life after surgery for localized renal cell carcinoma: comparison between radical nephrectomy and nephron-sparing surgery. *Urology* 2003; 62:814–820.
  34. Shinohara N, Harabayashi T, Sato S, et al. Impact of nephron-sparing surgery on quality of life in patients with localized renal cell carcinoma. *Eur Urol* 2001; 39:114–119.
  35. Bacik J, Mazumdar M, Murphy BA, et al. The functional assessment of cancer therapy-BRM (FACT-BRM): a new tool for the assessment of quality of life in patients treated with biologic response modifiers. *Qual Life Res* 2004; 13:137–154.