Thermoablation of Renal Masses: The Urologist's Perspective

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ABSTRACT

Thermoablation (TA) has become an increasingly popular treatment for small renal masses (SRMs). Although long-term outcomes are not currently reported, TA may have a role in being an alternative to radical or partial nephrectomy. This review gives a broad overview of TA and discusses current controversies in the field.

KEYWORDS: Ablation, thermoablation, renal malignancy, renal cell carcinoma, interventional radiology

Objectives: Upon completion of this article, the reader should be able to explain the medical benefits of thermoablation.

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The incidence of small renal masses (SRMs) is increasing.^{1,2} As a large percentage of these masses represent malignancies, excision is the preferred approach.³ The American Urological Association (AUA) places partial and radical nephrectomy as the two main treatment options, and ablation is considered a secondary option for selected patients. Nevertheless, active surveillance is also a possibility, as SRMs grow slowly, and elderly patients may be able to avoid intervention.

TREATMENT VERSUS ACTIVE SURVEILLANCE FOR SMALL RENAL MASSES

There has been an extensive literature defining the natural history of untreated SRMs or SRMs where curative therapy was deferred.^{4–15} When documented, most of the patients in these retrospective cohorts have

significant comorbidities that would increase the risk of perioperative cardiovascular complications or lead to postsurgical dialysis-dependence if NSS were entertained. The average age of patients in all but two cohorts that we identified is greater than 70 years old. In active surveillance series, the rate of metastasis in patients with renal masses is less than 1%. It is important to note that some of these retrospective studies include patients with not small but large renal masses undergoing active surveillance, even patients with caval tumor thrombi or masses up to 14 cm.^{4,5} Also noteworthy is that no patients undergoing active surveillance have a T1a SRM at the time of metastasis.⁶ In other words, as long as the mass remains small, there is no risk of metastasis. To our knowledge, only Nguyen et al have shown metastasis in patients with T1a SRMs, and these metastases were present at the time of diagnosis.⁷ Thus, active surveillance is usually precluded in that population.

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Based on these studies, active surveillance is a possible option in patients, particularly if comorbid conditions warrant a conservative approach.

PATIENT SELECTION IN THERMOABLATION

Selection of a patient for thermoablation (TA) hinges on an informed understanding of the oncologic outcomes, potential complications, and alternative therapies. Generally speaking, oncologic outcomes are not as robust as partial or radical nephrectomy, with an increased local recurrence or retreatment rate (discussed later). However, in certain patients, TA may be an alternative to traditional excision, provided the patients understand the risks and benefits.

Besides comorbid conditions, size seems to be an important criterion for determination of successful outcomes. In one series of TA failures, 97% of failures were 2 cm or larger.⁸ In another study, all failures were in patients with tumors larger than 3 cm.⁹ Other factors include location and nearness to surrounding structures. For percutaneous approaches, posterior or lateral masses are preferable to anterior masses, although, for laparoscopic or open TA, posterior location may be less desirable. Exophytic masses are preferable to endophytic masses.

ONCOLOGIC OUTCOMES AFTER THERMOABLATION AND POSTTHERMOABLATION FAILURE

Oncologic outcomes after TA are clouded by the lack of pre- and postablation biopsies. Preablation biopsy was made a standard-of-care in the AUA guidelines, but prior to the development of the guidelines, many of these lesions were not biopsied. In fact, no pathologic diagnosis was present for 18% and 43% of such SRMs undergoing cryoablation and radiofrequency ablation (RFA), respectively, in a meta-analysis by Kunkle et al.¹⁰ Furthermore, as a significant percentage of SRMs are benign, it is difficult to assess true oncologic outcomes. Hence, the outcomes are largely based on pre- and postablation imaging, the validity of which is not completely known.

Nevertheless, imaging is the workhorse of post-TA followup. All series show that on a long enough time scale, the successfully ablated mass should either shrink or remain stable in size.^{11–15} Late enlargement or new enhancement after no enhancement should be taken as a sign of recurrence. Several series show that post-TA cross-sectional imaging can show enhancement, which decreases with time as described below.

A few series have evaluated imaging of SRMs after RFA. Davenport et al evaluated 28 such SRMs, which were presumed recurrence-free on imaging and

were proven so by biopsy of the postablation bed.¹² All patients had percutaneous approaches. They showed that SRMs with volume < 3 cm³ actually increase in size in the short term. With computed tomography (CT), no enhancement is seen at any point during post-RFA surveillance in successful procedures. However, a halo sign (defined as soft tissue scar around a cushion of fat surrounding the residual mass) was often seen with post-RFA magnetic resonance imaging (MRI) or CT. This was not indicative of recurrence, but was thought to be a sign of inflammation as it was very common and described in several series. Davenport et al also note that often fat invagination into the renal parenchyma can be seen, typically 1 year after RFA. Masses were typically hyperintense to renal parenchyma on T1-weighted magnetic resonance images (MRIs) and hypointense on T2-weighted MRIs.

In contrast, Matsumoto et al showed that no masses increased in size in 64 tumors on CT after RFA.¹³ However, the first surveillance imaging study was performed at 3 months, in contrast to the Davenport study, which occurred at 1 month. Any persistent enhancement seen on CT was defined as recurrence and did occur in two masses. These masses were not pathologically evaluated and were retreated successfully. Matsumoto et al also show that a halo sign was common. In agreement, one group evaluated 101 consecutive patients after RFA and showed that the halo sign was present in 75% of cases in post-RFA surveillance regardless of imaging modality.¹⁶

Postcryoablation imaging also does not necessarily follow a straightforward path of evolution. Persistent enhancement within the mass occurs in ~20% of patients after cryoablation both with CT and MRI, but SRMs universally stop enhancing within 1 year.^{11,14,15,17,18} These studies typically describe rim enhancement as normal radiologic evolution of a post-cryoablation tumor. Thus, persistent enhancement cannot be interpreted as residual or recurrent disease, but central or nodular enhancement should be. Any enhancement after nonenhancement should also be taken as recurrent disease, regardless of TA modality. In contrast to post-RFA SRMs though, most cryoablated masses regress in size; many will disappear.

Post-TA imaging clearly has its shortcomings. Interpretation can be complicated and imaging may not always guide the clinician in identifying the biology of remaining tissue. This is evident in a well-done study¹⁴ where 311 SRMs in 264 patients were subjected to either laparoscopic cryoablation or percutaneous RFA followed by 6-month biopsy of the post-TA mass in a significant proportion of the cohort. One hundred thirty-four patients were biopsied representing 45% of the entire cohort. Although imaging showed that 85% of RFA cases were successful at eradicating tumor, biopsy was positive for malignant or atypical cells in 35% of cases

(13 of 37 biopsied specimens were positive). By imaging, the postcryoablation group had only a 10% failure rate, and after postcryoablation there was suspicion of persistent tumor in only 6% of biopsied tumors (6 of 101 biopsied specimens were positive). Additionally, four cases were positive for recurrence/persistent tumor by imaging alone (three post-RFA SRM, one cryoablated SRM) and were removed by radical nephrectomy, demonstrating renal cell carcinoma.

It is worthwhile to review the patterns seen on imaging with the biopsy results that Weight et al reported. Of patients treated with RFA, 25 patients had no enhancement on postprocedural imaging, yet six of these patients had biopsy-proven renal cancer cells. In other words, 24% of patients in whom no suspicion of residual/recurrent malignancy was present by imaging had malignant biopsies. This is a significant false-negative rate. Seventy-one percent of patients with central enhancement after RFA had positive biopsies. Conversely, nonenhancement of postcryoablation beds was 100% predictive of negative biopsy and all positive postcryoablation biopsies came from tumors with some degree of enhancement.

Although imaging may suggest whether treatment was successful, clearly more tools are required to determine ultimate outcome. This is further substantiated by an early study where patients underwent nephrectomy either immediately after or one week after RFA.¹⁹ Malignant cells were still detectable in a small volume of 7 of 11 tumors. Another study demonstrated viable tumor cells in all 20 specimens when they were treated with RFA immediately before extirpation.²⁰ The clinical significance of a small volume of residual disease, which can often be treated by active surveillance anyway, is still in question.

CRYOABLATION VERSUS RFA FOR SRMs

Cryoablation and RFA have different mechanisms of energy delivery. With cryoablation, ice crystals both inside and outside cells disrupt cellular membranes and architecture, causing tissue destruction and cell death by apoptosis and/or necrosis.²¹ Chosy et al showed that the temperature of the tissue is directly related to the degree of necrosis.²² Temperatures below -19.4°C are required for 100% tissue necrosis, whereas temperatures between -19.4 and 0°C showed that only 80% of tissue is destroyed. The temperature can be monitored at several distinct foci within the kidney, both within the tumor and in normal parenchyma, to ensure that the procedure is going as planned. It is important to note that the temperature at a distance from the cryoprobe is predictable as a function of radius.²³ The radius that correlates with a temperature of -20°C is ~ 3 mm inside the visible edge of the ice ball. It is also known that the temperature at the edge of the ice ball is $\sim 0^{\circ}\text{C}$, which is thought to be safe.

RFA on the other hand, heats tissue resulting in coagulative necrosis by denaturation of proteins and disintegration of membranes. In an analogous manner to monitoring tissue temperature and ice ball formation for cryoablation, tissue temperature or tissue impedance can be measured during RFA. A goal temperature, commonly in excess of 80°C , is achieved for 10 to 15 minutes. Impedance, commonly 100, signifies denaturation and destruction of tissue and is thought to be a more reliable marker for necrosis than temperature. Of note, RFA is hemostatic as it cauterizes tissue and blood vessels, whereas cryoablation is not hemostatic and the most common complication of cryoablation is postprocedure bleeding, described below. Technology has been brought to the RFA platform, which infuses saline into the tissue as the tissue is ablated. "Wet RFA" prevents the tissue from becoming desiccated so quickly and creates a larger zone of ablation.

No study has prospectively and randomly evaluated RFA versus cryoablation. One study retrospectively compared the two ablative modalities at a single institution.²⁴ 164 One hundred sixty-four patients underwent laparoscopic cryoablation, and 82 patients underwent percutaneous RFA. The authors found that there were no significant differences in tumor size, patient body mass index (BMI), comorbidity, or preablation creatinine. However, some important tumor characteristics were different between the treatment groups: Most tumors in the laparoscopic cryoablation group were anterior, whereas most tumors in the percutaneous RFA group were posterior and lateral; 6% of tumors abutted the collecting system in the cryoablation group, whereas 37% of tumors abutted the collecting system in the RFA group. These characteristics may have predisposed the oncologic outcomes in the two groups: 3% of cryoablation-group patients had radiologic evidence of persistence or recurrence, whereas 11% of RFA-group patients had such evidence.

It is important to note such differences in tumor characteristics when reviewing a large meta-analysis comparing RFA and cryoablation outcomes.²⁵ This meta-analysis of almost 1400 masses treated with TA showed that outcomes favored cryoablation over FA in every meaningful metric analyzed: local recurrence (5% vs. 13%), repeat ablation (1% vs. 9%), and metastasis (1% vs. 3%). All differences were statistically significant. Tumor size, age of patient, and length of follow-up were not significantly different between groups, but presumably, tumor location did play a role in the decision regarding which TA modality to use. Note that the approach for RFA was almost exclusively percutaneous (94%), whereas 35% of cryoablations were performed percutaneously. Lastly, the approach alone (laparoscopic vs. percutaneous) may have predisposed to disparate oncologic outcomes in the two previously mentioned studies. Enhanced vision of the mass laparoscopically or

the ability to place the ultrasound probe directly onto the kidney intracorporeally would probably lead to better tumor destruction. To this end, Pirasteh et al also retrospectively reviewed 111 patients who underwent percutaneous RFA or cryoablation and found similar rates of recurrence as defined by imaging among the groups.²⁶

SURGICAL VERSUS PERCUTANEOUS TA FOR SRMs

One might envision that percutaneous and surgical approaches may lead to different oncologic efficacy secondary to the ability to visualize the tumor more easily, either by indirect vision (a laparoscope) or with ultrasonography.

One retrospective case series describes outcomes of cryoablated tumors dichotomized by approach.²⁷ Ninety-nine and 97 masses were treated by percutaneous and laparoscopic cryoablation, respectively. All percutaneous approaches were done on posterior lesions. Laparoscopic approaches were for posterior, anterior, or central masses. Tumor size, median follow-up, and serum creatinine were statistically identical between groups. Although no statistical tests for significance were performed to determine if efficacy was different between groups, the laparoscopic cryoablation group had fewer cases of residual tumor on follow-up imaging (1% vs. 9%), but the percutaneous treatment group had fewer recurrences (0% vs. 2%).

One metaanalysis describes outcomes for >1400 masses after cryoablation, again, dichotomized by approach.²⁸ In this analysis, there was no significant difference in age, tumor size, duration of follow-up, or residual or recurrent tumor. However, in another metaanalysis by the AUA Guidelines Committee on T1 SRMs, there was an 11% rate of incomplete ablation when cryoablation was performed percutaneously, but only a 2% rate when performed laparoscopically.²⁹

COMPLICATIONS FROM THERMOABLATION

The AUA guidelines for SRM management include a very thorough analysis of the types and rates of complication from all modalities of SRM treatments.³ The complete version of the guidelines is available in web-based format and describes specific complications and rates in even more detail.²⁹ We shall highlight those findings and several studies from the literature.

The AUA Guidelines Committee evaluated major urologic and major nonurologic complications, as well as complications requiring transfusion or reintervention and compared rates among TA modalities and surgical therapies. Based on this metaanalysis, laparoscopic partial nephrectomy had a statistically significant

higher urologic complication rate (9%) compared with cryoablation (5%) and RFA (6%). Major nonurologic complications were similar between these modalities (~5%) and meaningful statistical comparison was thought to be not valid. Rate of transfusion requirement was also statistically significantly higher in laparoscopic partial nephrectomy patients (6%) compared with cryoablation (3%) and RFA (2%). Interestingly though, the rate of reintervention was statistically similar among laparoscopic partial nephrectomy and TA treatments (3%).

It is important to keep in mind when deciding whether to perform a surgical or percutaneous TA procedure that the complication rate will inevitably be higher when surgery is performed due to the need for anesthesia and renal exposure. Despite data regarding complication rate and oncologic outcome, it is likely that the driving factor in the decision regarding whether to perform surgical or percutaneous TA is probably largely driven by availability. When a physician who is skilled enough to perform percutaneous TA is available to perform the procedure percutaneously, this is probably the preferred choice.

Injury to the collecting system has been evaluated in swine models. Sung et al subjected pigs to bilateral open cryoablation of the lower pole, with the intention of freezing the renal pelvis.³⁰ Renal pelvis injury was confirmed by pyelography freezing and reevaluated at necropsy. Right kidneys received continuous retrograde infusion of warm saline while left kidneys did not. In all cases, the collecting system healed without any evidence of leak or scar. However, when an RFA probe is placed directly into the renal pelvis or a major calyx, a fistula from the collecting system and subsequent urinoma will be created.³¹ Interestingly, no injury was identified on pyelography or pathologic examination after direct cryoablation of the renal pelvis or a calyx.

The other major concern during TA is bleeding from the SRM or from the hilar vessels. Fracture of the frozen parenchyma has been described in cryoablation and can cause significant bleeding. This is the most common complication from cryoablation.³²⁻³⁶ All cases of parenchymal bleeding requiring transfusion after TA that we could identify occurred in tumors larger than 3 cm.^{32-34,36} Retroperitoneal bleeding in these series led to some significant complications in these reported cases including shock and the need for dialysis.

Parenchymal fracture is probably most dependent on the size of the tumor, but is also dependent on size of the cryoprobes in animal models³⁷ and has been associated with the number of cryoprobes inserted.³⁶

One case series stratified 52 patients who underwent laparoscopic renal cryoablation into two groups based on size of SRM with a 3 cm cutoff.³³ The group with larger tumors was older (70 vs. 78 years old), had a higher rate of malignancy on precryoablation biopsy

(47% vs. 68%), and a higher American Society of Anesthesia comorbidity score (1.8 vs. 2.1), but only age was statistically significant. All complications reported in this series were in the group with larger SRMs. There were five Clavien grade 4 complications including two deaths, myocardial infarction, pulmonary embolism, and a cerebrovascular event.

Several surrounding structures must be accounted for during percutaneous TA to prevent serious injury. For right-sided SRMs, specifically the hepatic flexure of the colon, duodenum, and liver must be kept out of the zone of ablation. In the case of a left-sided SRM, the spleen, splenic flexure of the colon, and pancreas also must be kept out of the zone of ablation. Some authors have used hydrodissection or hydrodisplacement of critical structures to prevent undesired injury.^{38–41} This can be accomplished using a 19- or 20-G needle inserted between the SRM and the overlying structure, followed by infusion of sterile fluid or gas to displace the structure. Fluid or gas is continually infused because if it is not, it can diffuse out into tissue causing reapproximating the SRM with the critical overlying structure. Critical structures can also be protected by inserting an angioplasty balloon into the tissue.^{42,43} This acts as a thermal barrier in cryoablation. Using sterile fluid to displace critical structures can, however, obscure the SRM and make intraprocedural imaging harder to interpret. To overcome this potential obstacle, recently authors have instilled iodinated contrast into the hydrodissection media to better differentiate the mass from displacement media.³⁹ This results in obvious differences in the attenuation of fluid and SRM, with presumed decreased risk of incomplete ablation and complication.

CONCLUSIONS

Thermoablation for renal masses is an evolving technology. Although oncologic outcomes, postprocedure imaging, and complications differ in large series, it does appear to be a viable alternative to extirpation in selected patients.

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