Society of Interventional Radiology Position Statement on Percutaneous Radiofrequency Ablation for the Treatment of Liver Tumors

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Focal tumor ablation—whether applied percutanously, laparoscopically, or by means of open surgery—is an effective therapy for selected liver tumors. The choice of liver ablation as well as the choice between percutaneous and surgical approaches is dependent on tumor factors, patient factors, and other viable treatment options. Currently, the largest cumulative reported experience is with radiofrequency (RF) ablation of hepatocellular carcinoma and colorectal metastases. This document is a position statement of the Interventional Oncology Task Force and the Standards Division of the Society of Interventional Radiology regarding the use of percutaneous RF ablation for the treatment of liver tumors.

INTRODUCTION

SMALL primary and secondary liver tumors have increasingly been the focus of minimally invasive percutaneous therapies for patients ineligible for

surgery or as a bridge to liver transplantation. The incidence of hepatocellular carcinoma (HCC) is increasing worldwide and in the United States (1). Worldwide, HCC is the fifth most common malignancy, with more than 500,000 deaths annually (2). In the United States, between 8,500 and 11,500 new cases of HCC occur annually (1). Far more common in North America are secondary tumors—especially from colorectal carcinoma, for which improved survival, from 20% to 40% at 5 years, is well documented for patients who undergo surgical resection of hepatic metastases (3,4).

Surgical resection remains the gold standard for eligible patients with colorectal metastases. For selected patients with HCC, orthotopic liver transplantation (OLT) has become the standard therapy because most patients with HCC are ineligible for surgery due to a limited hepatic reserve in the setting of hepatic cirrhosis (5). Moreover, HCC is often a progressive and multifocal disease, whether at presentation and/or during the course of long-term follow-up. Patients ineligible for OLT often undergo multiple sequential treatments aimed at achieving local control—whether percutaneous, endovascular, or surgical.

Given the lack of widely effective chemotherapy for HCC, patients ineligible for surgery have few therapeutic options other than minimally invasive endovascular or percutaneous therapies. In recent years, the use of percutaneous ablative therapies such as radiofrequency (RF) ablation to treat primary and secondary liver tumors has increased as the underlying technology has improved in its ability to achieve adequate volumes of tumor necrosis. In situ thermal destruction of liver tumors uses techniques that destroy tumor tissue through heating (RF ablation, laser ablation, microwave ablation, or high-intensity focused ultrasound) or freezing (cryotherapy). Each of these techniques relies on controlled energy delivery to minimize collateral damage to normal hepatic parenchyma and other surrounding structures. In the United States, RF ablation is currently the most widely used technique for in situ liver tumor destruction.

This document presents a position statement from the Interventional Oncology Task Force and the Standards

Division of the Society of Interventional Radiology regarding the use of percutaneous RF ablation for the treatment of liver tumors.

COMPARISON OF RF ABLATION WITH OTHER ABLATION TECHNIQUES

Our current understanding of the role of percutaneous RF ablation in the management of HCC stems from comparative studies with percutaneous ethanol ablation, a well-established therapy for small HCC in Asia, Europe, and the United States (6). For small tumors (≤3 cm), Huang et al (7) have shown in a prospective comparison no significant survival difference between surgical resection and percutaneous ethanol ablation. RF ablation has been shown to be equal to or better than percutaneous ethanol ablation and achieves therapeutic efficacy in fewer sessions (8,9). Nevertheless, there is only a single prospective randomized trial comparing RF ablation favorably with a gold standard such as surgery for HCC and none for liver metastases (10). The paucity of prospective randomized trials is in part related to the ethical reservations of many investigators. These reservations are due to the potential randomization of patients to a procedure other than the gold standard of surgery as well as the potential for RF ablation to leave tumor in situ.

Although most recent reports of percutaneous liver tumor ablation use RF ablation, new ablation technologies are now available with percutaneous applicators (cryoablation, microwave, laser, high-intensity focused ultrasound). The preponderance of the literature documenting efficacy and survival after percutaneous thermal ablation of liver tumors currently supports this position statement for RF ablation. Further studies are needed to determine equivalence or superiority, whether generalized or indication-specific, of one or more of the other thermal ablation technologies with respect to success rates and complications. It is likely that key issues such as indications and contraindications will not vary between the various types of thermal ablation when used by experienced operators. Thermal ablation of liver tumors may be performed percutaneously, laparoscopically, or by means of open surgery.

INDICATIONS FOR PERCUTANEOUS, LAPAROSCOPIC, OR SURGICAL RF ABLATION

The choice of a percutaneous, laparoscopic, or open surgical approach remains controversial, although clear advantages of one over the other may apply in specific clinical circumstances. The percutaneous approach remains the least invasive and allows for the fastest recovery. For most cirrhotic patients with small HCC as well as for many other patients with HCC or metastases, the percutaneous route is clearly the preferred approach because it avoids surgery and potentially avoids general anesthesia.

Nevertheless, there remain clear instances where open RF ablation is clearly in the patient's best interest. When open liver resection is planned for colorectal metastases, for example, preoperative magnetic resonance imaging or computed tomography may not depict all metastases. Intraoperative ultrasonography improves detection, and open detection of additional metastases may render the patient unresectable, or at least incompletely resectable. In this circumstance, Abdalla et al (11) have demonstrated that when complete resection of colorectal metastases cannot be performed, then partial resection and ablation of the remaining metastatic burden, when possible, prolongs survival compared with ablation alone. However, survival is diminished compared to that of patients who are completely resectable.

In centers with skilled laparoscopic surgeons, the laparoscopic approach may facilitate mobilization of adjacent structures, thereby minimizing the risk of thermal injury. However, recent advances and dissemination of skills in percutaneous displacement of adjacent structures by using fluids, carbon dioxide, or balloon catheters render many of these cases amenable to a percutaneous approach (12,13).

Finally, the surgical approaches offer the potential advantage of the direct control of hepatic perfusion, with temporary hilar clamping diminishing perfusion-mediated tissue cooling and thereby resulting in a more effective ablation (14). For many small tumors, an operative approach with this maneuver is not necessary for an adequate ablation. For larger tumors, temporary percutaneous transhepatic balloon occlusion of the portal vein or transcatheter occlusion of the inferior vena cava or hepatic veins have been advocated as methods of diminishing hepatic blood flow during ablation (15). Transarterial embolization is another proposed mechanism of diminishing tumor blood flow, and its use in combination with RF ablation will be covered in more detail later.

HCC

Results of RF ablation for HCC vary depending on tumor size and, to a lesser extent, on whether the HCC is encapsulated (16–34). The optimal size range of liver tumors amenable to RF ablation has not been clearly defined and is closely related to anatomic factors, such as proximity to major vessels, that influence the ability to deposit sufficient thermal dose to coagulate tissue (16). Likewise, the number of tumors in a single patient that can undergo ablation is difficult to specify because the size of each tumor will also play a role in effectiveness.

Although there is no established threshold of tumor diameter or tumor number that is associated with RF ablation treatment success or failure, our current understanding of hepatic tumor RF ablation indicates that HCCs 5 cm or less in diameter have a higher probability of having complete ablation compared to those greater than 5 cm in diameter (17). Indeed, this size stratification has been taken further to show superior results with tumors smaller than 3 cm, intermediate but acceptable results for those measuring 3–5 cm, and fairly dismal results for tumors larger than 5 cm (17). For HCC, the presence of a well-defined capsule has been shown to improve the efficacy of thermal ablation, whereas more infiltrative nonencapsulated HCCs respond less completely (17). HCC arising in the background of a cirrhotic liver has a more favorable ablation profile due to the insulating effect of the cirrhotic liver, the so-called *oven effect*, allowing both higher temperatures to be achieved and longer cytotoxic temperature duration (9).

In a recent prospective randomized trial, survival data up to 4 years were equivalent between RF ablation (95.8%, 82.1%, 71.4%, 67.9% at 1, 2, 3, and 4

years) and surgical resection for HCCs 5 cm or less (10). Long-term survival data are also available from other series for HCC patients treated with RF ablation. The 1-, 3-, and 5- year survival from other trials (18,19,21,32) range from 82% to 97%, from 54% to 77%, and from 33% to 54%, respectively.

Colorectal Metastases

Colorectal carcinoma metastatic disease to the liver is the next most widespread use of RF ablation. As with HCC, local control after RF ablation of colorectal carcinoma metastases varies with tumor size (35–40). Colon metastases 3–4 cm or less are more likely than larger tumors to result in a favorable outcome (39). Local control can be achieved in up to 98% of small tumors (39).

Resection of colorectal carcinoma metastases remains the gold standard for eligible patients. For patients not eligible for surgery, RF ablation offers an alternative means of local control.

Survival data following percutaneous RF ablation of colorectal carcinoma metastases in general are not as good as those for patients who undergo resection. Even patients who undergo resection combined with RF ablation do better (11). For percutaneous RF ablation, the 1-, 3-, and 5-year survival rates range from 91% to 93%, from 28% to 69%, and from 25% to 46%, respectively (36,38,39).

Other

There are reports of limited numbers of patients who have undergone RF ablation of liver metastases from breast cancer or sarcomas (41–45). Although a rationale could be advanced to treat limited hepatic metastases in nonsurgical candidates with any tumor where surgical resection would be considered, the current literature is insufficient to support any recommendations supporting or refuting the use of RF ablation in these other diseases.

Another less common group of patients present for palliative treatment. In this group of patients, the goal is not necessarily to achieve local control of the entire hepatic tumor burden but to mitigate the symptoms from the tumor. Such symptoms are generally either pain from a rapidly growing surface tumor or hormonal symptoms from hormonally active neuroendocrine tumors (41).

PATIENT SELECTION FOR RF ABLATION

Potential candidates for RF ablation for treatment of liver tumors fall into four general categories: (*a*) patients who are poor surgical candidates due to inadequate liver function from underlying cirrhosis or prior hepatectomy, (*b*) patients who are poor surgical candidates due to comorbid conditions, (*c*) patients who are ineligible for surgical resection due to the anatomic distribution of the liver tumors, (*d*) patients who are surgical candidates but for whom the "test of time" approach is favored to limit unnecessary hepatectomies, and (*e*) patients undergoing RF ablation to control local tumor burden as a "bridge" to liver transplantation (8–45). The first category defines the vast majority of patients presenting with HCC. Co-morbid disease such as coronary artery disease, cardiomyopathy, or chronic obstructive pulmonary disease may incur an unacceptably high risk of general anesthesia and make a patient unsuitable for operative resection. In these patients, percutaneous RF ablation may be an appropriate alternative. Patients with two or more metastases in different lobes may not be eligible for surgery because of the large volume of liver that would have to be removed, or they may be eligible for resection of one or more tumors with RF ablation of the remaining tumors. Finally, for some patients with limited metastatic liver disease who are eligible for surgery, RF ablation has been advocated as a means of avoiding unnecessary hepatectomies—applying the so-called "test of time" approach. Advocates point out that (*a*) for those patients in whom RF ablation achieves local control of limited metastatic disease, no hepatectomy may be needed; (*b*) for those patients who blossom multiple bilobar metastases shortly after ablation, likely reflecting microscopic metastases at presentation, unnecessary and likely unbeneficial hepatectomy is avoided; and (*c*) for those patients in whom RF ablation fails to achieve local control but multiple new metastases do not develop, close imaging surveillance allows prompt detection of local viable tumor, thereby allowing the patient to undergo hepatectomy without adverse effects from the "delay" needed for RF ablation and short-term follow-up imaging (37).

Patients awaiting OLT form a unique category of patients. In regions where the waiting time for a donor liver may be several months to a year, local-regional therapy has been advocated to limit tumor growth (46). The rationale stems from the HCC size criteria used to allow patients with limited HCC to undergo OLT. The most commonly applied are the Milan criteria (47). The Milan criteria allow OLT for patients with a single HCC up to 5 cm or those with up to three HCCs with no single HCC larger than 3 cm. To expand the pool of eligible OLT patients, the UCSF (University of California at San Francisco) criteria have been proposed, although they remain controversial and are not widely accepted (48). The UCSF criteria allow for (*a*) a single HCC up to 6.5 cm or (*b*) up to three HCCs with none larger than 4.5 cm and total tumor diameter no larger than 8 cm. Should existing tumor(s) grow while a patient awaits a donor liver, the patient could become ineligible for OLT, which is potentially curative. Percutaneous as well as transcatheter techniques have been applied in this setting. Percutaneous ablation has engendered more controversy due to concerns about possible tract seeding of the peritoneum, which would then render the patient ineligible for transplantation (46,49). A recent report on the risk of tumor seeding suggests that, in general, surface lesions are at greatest risk, implying that perhaps risk can be mitigated by including some nontumorous liver parenchyma in the needle applicator path to the tumor (50). Despite early concerns about tumor seeding, several centers have performed percutaneous RF ablation for patients awaiting OLT, with an acceptable safety record (46,49, 51,52). Nevertheless, a prospective study of patients with HCC awaiting transplantation comparing percutaneous ablation to no intervention failed to show improvement in outcomes—including overall survival, disease-free survival, and cancer mortality—for those undergoing ablation (49). The wait times to OLT in this study were short to moderate at 2–6 months. This area re-

mains controversial. The utility of RF ablation in minimizing drop out from the transplant wait list will in part be determined by the median wait time for a transplant once listed. There is wide variation in wait times among different regions in the United States. Thus, individual centers will vary in their approach to patients on the transplant wait list with small HCC.

USE OF RF ABLATION IN CONJUNCTION WITH TRANSARTERIAL EMBOLIZATION

Although there is emerging evidence that improved local control may be achieved with RF ablation combined in close sequence with transarterial chemoembolization or bland embolization, long-term survival data are minimal (53,54). In theory, combined RF ablation and transarterial chemoembolization or bland embolization would be expected to result in synergistic improvement in response and time to progression. This choice of combination therapies is often used for tumors that are larger than ideal for RF ablation alone (53,54). Currently, there is insufficient evidence to support or refute any recommendation as to the appropriate use of RF ablation and transcatheter chemoembolization for large tumors, although we expect evidence will likely continue to accumulate.

COMPLICATIONS OF RF ABLATION

Complications of percutaneous hepatic RF ablation are reported in approximately 7% of patients (50,55–59). By far the most common complication is hemorrhage (55), but major hemorrhage, defined as that requiring transfusion and/or an additional procedure, has been reported in less than 1% of cases. Undoubtedly the risk will be related to tumor size and location, but substratified data are lacking. About equally common is abscess and less common is bowel perforation. Abscess risk following RF ablation is markedly increased in patients after biliary enteric anastomosis or other manipulation such as stent placement or sphincterotomy (56). The possibility of tract seeding has received attention but appears to remain under 1% of

HCC ablated with straight electrodes (58). Other investigators have reported a rate of 2.7% with expandable electrodes, but these investigators did not routinely perform tract coagulation, which may decrease risk, upon electrode removal (50). Surface tumors appear to be at highest risk (50). Death is rare, at less than 1% (55,59). The risk of these complications compares favorably with open liver resection, which has complication rates as high as 22% (60).

SUMMARY

It is the position of the Society of Interventional Radiology that percutaneous RF ablation of hepatic tumors is a safe and effective treatment for selected patients with HCC and colorectal carcinoma metastases.

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