Radiofrequency Thermal Ablation as Tumor Therapy: An Overview for the Oncology Team

by Bradford J. Wood, M.D., and Mary T. Winkler

Recent developments in radiofrequency thermal ablation (RFA) have expanded the treatment options for certain oncology patients. Minimally invasive, image-guided therapy may now provide effective local treatment of isolated or localized neoplastic disease, and can also be used as an adjunct to conventional surgery, systemic chemotherapy, or radiation.

RFA expands the medical application of heat, which for decades has been used as a cautery device to cut tissue. In the procedure, the tumors are located with ultrasound, computed tomography (CT), or magnetic resonance (MR) imaging devices. Then, essentially the patient is turned into an electrical circuit by placing grounding pads on the thighs. A small needle-electrode with an insulated shaft and an uninsulated distal tip is inserted through the skin and directly into the tumor. Ionic vibration at the needle tip leads to frictional heat. After 10 to 30 minutes of contact with the tumor, the radiofrequency energy kills a 2.5- to 5-cm sphere.[1] The dead cells are not removed, but become scar tissue and eventually shrink.

RFA continues to play a time-tested, major role in the treatment of patients with painful osteoid osteomas in the bone[2] and heart arrhythmias. In addition, RFA has been used to treat painful trigeminal neuralgia for 25 years.[3] Today, the mainstream applications of RFA are increasing. In particular, this minimally invasive, percutaneous technique is showing promise as a treatment option for patients with primary or metastatic liver cancer.

Worldwide, primary liver cancer is the most common solid cancer, causing an estimated one million deaths annually.[4] In the United States, 15,300 people were expected to be diagnosed with the disease in 2000, and 13,800 were expected to die. Hepatocellular carcinoma accounts for about 84 percent of primary liver cancers in the U.S.[5] The number of people expected to die from colorectal carcinoma metastases to the liver is even greater than that of people expected to die from primary liver cancer. Twenty to 25 percent of patients with colorectal carcinoma liver metastases are eligible for surgery, and of those, the five-year survival rate is approximately 30 to 40 percent.[6,7] RFA may provide a safe and effective option for patients with inoperable or recurrent liver cancer who have failed to respond to conventional methods.[8] Given the lack of effective treatment options for the majority of patients with primary liver cancer and metastases to the liver, the oncology team should be aware of this relatively new treatment.

In addition to treatment of patients with liver cancers, clinical applications of RFA include treatment of kidney, adrenal, and prostate tumors; benign prostatic hyperplasia; painful or abnormal neural tissue; and painful soft tissue or bone masses that are unresponsive to conventional therapy.

Many times RFA can be an alternative to risky surgery, and sometimes it can change a patient from having an inoperable tumor to being a candidate for surgery. The procedure is proving useful as an adjunct to conventional treatments and as a palliative treatment. What's more, the cauterizing effect of the heated needle prevents excessive bleeding, leading to low complication rates. Although RFA may not be a magic bullet, it clearly can be a cure in some cases.

Multiple techniques have been studied and used to kill tumor cells. These techniques include laser, focused ultrasound, and microwave,[9] as well as RFA, cryotherapy, and percutaneous ethanol injection (PEI). PEI has proven especially useful in treating primary liver tumors.[10] In PEI, ethanol is injected directly into the tumor in multiple treatment sessions. Prospective, randomized clinical trials comparing PEI and RFA for the treatment of liver tumors are currently in progress. Cryotherapy is an ablation method that has been used primarily during open surgery, after mobilizing the liver. It has limited applications due to the size of the treatment probe, expense, and excessive complications, such as liver capsule fracture.[9] Cryotherapy may be less effective and more prone to complications than RFA for liver tumors,[11] although this is controversial. While these multiple technologies can each destroy tissue, RFA has emerged as safe, cheap, and predictable, and is becoming

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the treatment of choice for small but inoperable tumors of the liver.[1,12,13]

LIVER CANCER AND RFA

RFA may be most effective in primary liver cancer (hepatocellular carcinoma or hepatoma). Primary tumors are often soft and encapsulated, and usually occur in a cirrhotic liver, allowing for effective dissemination and retention of the heat.

Although surgery and liver transplant are considered the only curative treatment for hepatocellular carcinoma, few patients are eligible.[6] Eligibility criteria tend to vary by institution and physician. Contraindications include multiple tumors, decreased liver function, or multiple medical problems. While controlled, long-term studies of RFA have not been done, survival rates are likely to be similar to that of patients undergoing surgery or PEI treatment.[13]

With a median follow-up of only 15 months, Curley and colleagues reported 1.8 percent short-term recurrence rate following RFA of 169 tumors (median diameter 3.4 cm) in 123 patients with primary or metastatic liver cancer.[14] RFA clearly can provide short-term local control of small, early, or focal liver cancer. The question remains if this finding of a low short-term recurrence rate will translate into prolonged survival. Extrapolation of data from the surgical literature for resection of solitary liver tumors suggests that successful local control may lead to prolonged survival. Combination therapies need to be further studied for impact upon survival as well.[15]

Current studies are underway to evaluate the long-term efficacy of RFA for liver tumors. As yet, there have been no long-term, randomized studies, and the long-term benefits are thus somewhat speculative. Still, preliminary, short-term

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One Patient's Experience with RFA

When Steven H. Feldman, 53, was diagnosed with liver metastasis following colon cancer surgery, a major cancer institution in New York recommended removing 35 percent of his liver. Uncomfortable with the idea of a resection and the dismal prognosis of such surgery, Feldman sought another opinion. He went to North Shore Surgical Oncology in Great Neck, N.Y., a seven-person surgical oncology practice affiliated with North Shore University Hospital in Manhasset and St. Francis Hospital in Roslyn, N.Y. There, he was told that because he had more than three bilobar metastases, he was not a good candidate for surgical resection. However, he could be considered for radiofrequency thermal ablation (RFA) or cryotherapy.

Jim Sullivan, M.D., F.A.C.S., F.A.S.C.R.S., a surgical oncologist at North Shore Surgical Oncology, told Feldman about RFA. He explained that although RFA is effective at local disease control at the site of the tumors (with about a 10 percent local recurrence rate), other liver metastases may develop outside the ablated area. However, the RFA treatment in combination with adjuvant hepatic artery infusion (HAI) chemotherapy would offer the chance to live disease-free for months and even years.

"I felt like I didn't have a choice," said Feldman, "so I agreed to this new treatment modality."

Feldman had the RFA procedure performed in the North Shore-affiliated hospital's operating room. He was given medication intravenously to relieve any post-operative incisional pain and discomfort. Shortly thereafter, he was given general anesthesia in order to undergo the RFA operative procedure, which would "microwave" the tumors on his liver.

During the procedure, a representative from one of the three companies that manufactures the RFA units provided the surgical oncologist with technical support, if needed.

As part of the RFA procedure, a hepatic arterial infusion port was implanted. The port will allow chemotherapeutic agents to be delivered to the liver through a catheter placed in the hepatic artery. The port, placed under the skin and secured to the abdominal wall, uses a side pump mechanism and allows direct catheter injection. Feldman is on a chemotherapy regimen, which is scheduled for two weeks on and two weeks off. When he is on treatment, his chemo drug is in a fanny pack, which he wears 24 hours a day. Effective chemotherapy treatment depends in large part on the dynamic interplay of dosage, scheduling, and toxicity.

The RFA treatment modality in combination with HAI chemotherapy has given Feldman what he terms "a better outlook on life... My years have been extended, and I have gone back to work." He maintains a positive attitude.

Since the RFA procedure almost seven months ago, Feldman has experienced no significant operative surgical complications, and "is satisfied" with the outcome. Only the chemotherapy treatment has caused him occasional fatigue, sometimes resulting in lost work time.

As part of his follow-up care, Feldman had an abdominal CT scan done within 30 days of the operation, prior to initiation of HAI chemotherapy and prior to discharge from the hospital. Liver function tests are checked prior to each cycle of HAI chemotherapy, and dosing adjustments are evaluated. Feldman is then evaluated every three months with history and physical examination, CT scan of the abdominal and pelvic areas, and liver function tests. The carcinoembryonic antigen (CEA) level is checked for the first two years and at least every six months thereafter.

Feldman said his insurance plan in New York has paid all the costs (the evaluation, the ablation, preoperative, operative, postoperative and hospital-based charges) related to his RFA procedure. His only out-of-pocket expense was a minimal deductible.

results are promising and suggest that this therapy can impact certain patients' survival.

TREATMENT FOR KIDNEY CANCER...AND MORE

RFA is being studied as a minimally invasive treatment for patients with kidney cancer.[16,17] An effective, minimally invasive therapy could postpone kidney failure and prolong kidney function in patients with multiple or hereditary kidney cancer, such as von Hippel-Lindau disease, which causes multiple, recurrent, and diffuse tumors. RFA may also provide a useful option for patients who are not operative candidates or have solitary kidneys, multiple medical problems, or unresectable tumors.

Surgery for benign prostate hyperplasia and prostate cancer is not without morbidity. RFA may provide a safer option for removing abnormal prostate tissue,[18] as well as predictably destroying the entire gland with a low complication rate to the adjacent rectum, sphincter, bladder base, and urethra.[19,20]

RFA may also provide a method for alleviating pain that is unresponsive to conventional treatment,[21] or to complement treatments that have a delayed response. For example, radiation therapy for painful bone metastases can average four weeks to show effect.[22] Studies are underway to investigate the efficacy of RFA in the palliation of painful bone tumors and painful peripheral soft tissue tumors that are unresponsive or poorly responsive to conventional treatment. Preliminary data suggest that RFA may provide rapid pain relief for many tumors in the days following treatment and thus may decrease dependence on sedating painkillers.

Ablation of nerve and nerve ganglia continues to be used safely and effectively in the treatment of multiple pain syndromes, including trigeminal neuralgia, cluster headaches, chronic segmental thoracic pain, cervicobrachialgia, and plantar fasciitis.[3,23-26]

Patients with functional or tumorous disorders of the brain, such as Parkinson's disease, and benign or malignant lesions may also be candidates for RFA,[27,28] although it is experimental for brain tumors. One feasibility series on RFA for breast cancer in five patients suggests that it might play a role in select patient populations;[29] however, this is also experimental.

RFA

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WHAT ARE THE COMPLICATIONS?

Although RFA is relatively safe and minimally invasive, the benefits do not come without slight risks. The reported complication rate has been estimated at nearly 2 percent,[14,30,31] and may include bleeding, effusion, fever, and infection. The proximity to vital structures may influence the risk for collateral damage. The risks are kept to a minimum by attention to detail as well as continuous monitoring of vital signs and oxygenation and pre-procedural blood tests. Complications are usually managed nonoperatively.

The heating treatment inherent to RFA actually stops bleeding. The 14 to 17.5 gauge needles are very small; they are the same size needles used for biopsy, with the added benefits of cauterization and coagulation. The low rate of bleeding seen with RFA is likely the result of this cauterization effect, which is similar to electrocautery used to stop bleeding during surgery. This same treatment of the needle track should minimize the risk of needle-track seeding in the systems that are capable of cauterizing the track. The predictable nature of RFA allows for little collateral damage during treatments situated near vital structures. In fact, the "heat sink effect" actually preserves the vessels near a treatment area. However, with this effect, the inflow of "cool" blood at body temperature (cool relative to the cooked tissue) may impair the heating of the tumor cells closest to the vessels. The protected vessel often harbors an adjacent tumor that may regrow adjacent to large vessels.

Combining RFA therapy with chemoembolization can selectively block blood flow to a tumor, and thus may provide more effective treatment for larger tumors. Combining local radiation or local chemotherapy infusion with RFA could also be more effective than any one treatment alone. Doxorubicin has been shown in mice to enhance the effects of RFA by increasing the volume of tumor treated.[32] Early reports of combining RFA with chemotherapy infusion and chemoembolization should lead to larger studies of such combination therapies.[33-35]

FINAL THOUGHTS

A wide variety of clinical applications for RFA are being developed. If a target can be seen with CT, MR, or ultrasound, then a needle can be placed into it. If a needle can be placed, then the target tissue or tumor can be ablated and destroyed. If a clean margin is created, then the tumor will not recur at that site. Recent developments in RFA allow this treatment process to be done in a safe, predictable, and cheap fashion with low complication rates and minimal discomfort, on an outpatient basis. Further study is required to assess which patients will benefit from this new treatment, and most cancer patients will not be candidates due to the size or location of the tumor. Although long-term data have yet to be reported, early results suggest that RFA may prove to be an effective treatment option or adjunct for many oncology patients.

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The RFA Treatment Session

Radiofrequency thermal ablation can usually be performed as an outpatient procedure under general anesthesia or conscious sedation. Alternatively, RFA may be performed laparoscopically or during open surgery.[36]

Under light sedation, lidocaine or bupivacaine is administered subcutaneously at the needle entry site and down to the liver capsule. A needle is placed through the skin and into the tumor with imaging guidance. Treatment sessions of percutaneous RFA are easily monitored using real-time ultrasound imaging, computed tomography, or magnetic resonance imaging. Most patients feel little pain during the procedure and go home the same day or the day after the procedure, usually with minimal to no pain or soreness, although there is a spectrum, and some patients will experience severe pain the day of the procedure.

During a 10- to 30-minute treatment session, nitrogen microbubbles gradually create a hyperechoic area on ultrasound that provides a rough estimation of the treated tissue, which is 2.5 to 5 cm per 10- to 30-minute treatment sphere. CT, MR imaging, or positron emission tomography (PET) imaging may provide more exquisite detail for follow-up verification of the treatment zone and for finding residual or recurrent neoplastic tissue. Although real-time MR imaging and CT are available, they are not in widespread use. Ultrasound is a safe, common, and easy guidance method, although it is somewhat operator dependent.

Once the needle has been properly positioned within the tumor, the tissue is heated. At temperatures exceeding 50° C, cells are destroyed. To treat tumors of different size and shape, the needle is available in different lengths and shapes of exposed tips.[37]

Energy is transferred from the uninsulated distal tip of the needle to the tissue as current rather than as direct heat. The circuit is completed with grounding pads placed on the patient's thighs. As the alternating current flows to the grounding pads, it agitates ions in the surrounding tissue, resulting in frictional heat. The tissue surrounding the needle is desiccated, creating an oval or spherical lesion of coagulation necrosis, typically 2.5 to 5 cm in diameter for each 10- to 30-minute treatment. These spheres are added together in three dimensions to overlap and completely envelop the tumor. Ideally, the treated tissue will contain the entire tumor plus a variable rim of healthy tissue as a safety margin.

Failure to ablate the entire tumor with clean edges results in regrowth of the tumor. Depending on the size and configuration of new growth, the patient may or may not be suited for another treatment session. Over months to years, as the dead necrotic cells are reabsorbed and replaced by scar tissue and fibrosis, the size of the thermal lesion shrinks, although the remaining cells are ideally dead. The possibility of successful surgical resection may be augmented by decreasing the number of tumors.[38] Treatment of a tumor in one lobe may broaden the surgical indications of a tumor in the other lobe. Due to the natural course of the disease, new or recurrent tumors may be suited for additional treatment sessions as well.

Various methods of increasing the volume of treated tissue have been explored. One type of ablation needle-electrode consists of a coaxial system, or an expandable needle within a needle. The inner hooks are deployed once properly situated within the tumor.[39] Different configurations allow for treatment of various shapes and locations of tumors. Another ablation system utilizes a triple parallel needle array, which synergistically increases the treated volume.[40]

At temperatures exceeding 100° to 110° C, the tissue surrounding the needle vaporizes. The gas from the vaporization insulates the area immediately around the needle, limiting energy deposition in the target zone and decreasing the volume of tissue treated. Overcooking or charring around the outside of the needle also insulates and causes incomplete destruction of target tissue remote from the needle, much like a hamburger cooked too fast on a grill, charred on the outside and raw in the middle.

The deleterious effects of charring and vaporization may be decreased by monitoring temperature and/or impedance during treatment, and adjusting the current accordingly. The generators have computer chips or treatment algorithms to assist in optimizing this process. One system perfuses chilled saline within a closed-tip needle in order to deposit more energy without increasing the temperature.[41] This system allows an increase in the lesion diameter, while keeping the temperatures below the vaporization point.

At the end of a treatment session, the active needle is slowly retracted to heat and cauterize the needle pathway. This action prevents bleeding and tumor seeding of the needle track by destroying any cell that becomes attached to the needle or dislodged in the needle tract.

Three companies (RITA Medical Systems, Radionics, and RadioTherapeutics) market RFA systems. They currently have FDA 510-K clearance for soft tissue ablation, and have or are pursuing FDA 510-K clearance for unresectable liver tumor ablation. Although it is in its infancy as a technique, RFA is no longer a completely experimental procedure.

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