

Medical Policy



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Title: Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

See also: Treatment of Liver Tumors policy

Professional

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DESCRIPTION

Radiofrequency ablation (RFA) is being evaluated to treat various tumors, including inoperable tumors or to treat patients ineligible for surgery due to age, presence of comorbidities, or poor general health. Goal(s) of RFA may include 1) controlling local tumor growth and preventing recurrence; 2) palliating symptoms; and 3) extending survival duration for patients with certain tumors. The procedure kills cells (normal and abnormal) by applying a heat-generating, rapidly alternating current through probes inserted into the tumor. The effective volume of RFA depends on the frequency and duration of applied current, local tissue characteristics, and probe configuration (e.g., single vs. multiple tips). RFA can be performed as an open surgical procedure, laparoscopically, or percutaneously with ultrasound or computed tomography (CT) guidance.

Potential complications associated with RFA include those caused by heat damage to normal tissue adjacent to the tumor (e.g., intestinal damage during RFA of kidney), structural damage along the probe track (e.g., pneumothorax as a consequence of procedures on the lung), or secondary tumors if cells seed during probe removal.

RFA was developed initially to treat inoperable tumors of the liver. Recently, reports have been published on use of RFA to treat renal cell carcinomas, breast cancer, pulmonary (primary lung cancers or metastatic tumors), bone, and other tumors. For some of these, RFA is being investigated as an alternative to surgery for operable tumors. Well-established local or systemic treatment alternatives are available for each of these malignancies. The hypothesized advantages of RFA for these cancers include improved local control and those common to any minimally invasive procedure (e.g., preserving normal organ tissue, decreasing morbidity, decreasing length of hospitalization).

Renal cell carcinoma. Localized renal cell carcinoma (RCC) is treated by radical nephrectomy or nephron-sparing surgery. Prognosis drops precipitously if the tumor extends outside the kidney capsule, since chemotherapy is relatively ineffective against metastatic RCC.

Breast tumors. Early-stage primary breast cancers are treated surgically. The selection of lumpectomy, modified radical mastectomy, or another approach balances the patient's desire for breast conservation, the need for tumor-free margins in resected tissue, and the patient's age, hormone receptor status, and other factors. Adjuvant radiation therapy decreases local recurrences, particularly for those who select lumpectomy. Adjuvant hormonal therapy and/or chemotherapy are added, depending on presence and number of involved nodes, hormone receptor status, and other factors.

Fibroadenomas are benign tumors of the breast, which may present as a palpable mass or a mammographic abnormality. Fibroadenomas are typically surgically excised.

Pulmonary tumors. Primary lung cancers are resected if they are small, solitary masses. Adjuvant radiation and chemotherapy usually are added, most often using a platinum compound combined with 1 or more other drugs such as a taxane, alkylating agent, vinca alkaloid, or topoisomerase inhibitors. Patients with metastatic pulmonary lesions are also treated with chemotherapy, but with palliative intent or to relieve symptoms. Surgical resection of isolated metastatic lung lesions is an option, but is not used very often due to generally poor patient health, inoperability of most metastatic lesions, and lack of evidence for benefit to patients.

Osteoid osteomas. Osteomas are benign tumors of the bone typically seen in children and young adults. They cause inflammation, local effects on normal tissue from tumor expansion, and secondary effects and complications (e.g., scoliosis, osteoarthritis). Open excision is the accepted treatment and is generally successful. However, it is associated with increased risk of fracture, recurrence of larger tumors, and incomplete resection of anatomically inaccessible tumors.

Bone metastases. After lung and liver, bone is the third most common metastatic site and is relatively frequent among patients with primary malignancies of the breast, prostate, and lung. Bone metastases often cause osteolysis (bone breakdown), resulting in pain, fractures, decreased mobility, and reduced quality of life. External beam irradiation often is the initial palliative therapy for osteolytic bone metastases. However, pain from bone metastases is refractory to radiation therapy in 20% to 30% of patients, while recurrent pain at previously irradiated sites may be ineligible for additional radiation due to risks of normal tissue damage. Other alternatives include hormonal therapy, radiopharmaceuticals such as strontium-89, and bisphosphonates. Less often, surgery or chemotherapy may be used for palliation, and intractable pain may require opioid medications. RFA has been investigated as another alternative for palliating pain from bone metastases.

POLICY

1. Radiofrequency ablation may be considered **medically necessary** to palliate pain in patients with osteolytic bone metastases who have failed or are poor candidates for standard treatments such as radiation or opioids.
2. Radiofrequency ablation is considered **medically necessary** as an alternative to surgical resection for debulking of primary and metastatic neoplasms.
3. Radiofrequency ablation is considered **medically necessary** for removal of primary or metastatic malignant neoplasms when removal of the neoplasm may be curative and surgery cannot be tolerated.
4. Radiofrequency ablation is considered **experimental/investigational** for curative treatment of primary or metastatic malignant neoplasms in surgical candidates because the effectiveness of radiofrequency tumor ablation in improving clinical outcomes has not been established.
5. Radiofrequency tumor ablation, excluding the liver, is considered **experimental/investigational** for all other indications.

RATIONALE

The following sections summarize the evidence for those applications of RFA with evidence available from at least 1 case series of 10 or more patients.

Renal cancers. The outcomes of RFA procedures in more than 550 patients with a total of nearly 700 lesions have been described in 21 uncontrolled studies. (1-21) The characteristics of the patients and RFA procedures varied widely within and across the studies in terms of tumor type (e.g., exophytic, parenchymal, central, with or without history of von Hippel-Lindau disease), tumor size (from <1 cm to >8 cm), length of follow-up (from <1 month to 48 months), imaging modality used for guidance, and reason for using RFA. Overall, 88%–100% of procedures were considered successful shortly after 1 or 2 ablations (i.e., no signs of residual tumor by histologic analysis after excision or by post-RFA radiologic imaging). Significant but nonfatal complications were reported in 8%–13% of patients in 7 studies, including perinephric hematomas, hemorrhage, and ureteral strictures.

In general, available data were inadequate or lacked appropriate statistical analyses to estimate duration of survival or quality of life. Follow-up duration in most studies was insufficient to determine recurrence rates after RFA from viable tumor cells remaining *in situ* at ablation sites. A particular concern with the available data is that patient selection criteria and rationale for using RFA were not well described or did not provide a compelling argument to use the technique in lieu of potentially curative surgical resection or extirpation. In total, the available evidence is insufficient to permit conclusions on net

health outcomes of RFA for renal cancers. Moreover, the guidelines of the National Comprehensive Cancer Network (NCCN) regarding the treatment of renal cancer do not address RFA.

Breast cancer. Four uncontrolled pilot studies published through June 2004 enrolled 77 patients given RFA to treat primary breast cancer. (22-25) One of these reported preliminary data from an ongoing trial (23). In each study, RFA was performed no more than 2 weeks before definitive surgery (e.g., lumpectomy, quadrantectomy, modified radical mastectomy). In many patients, RFA was performed immediately before surgery. (24) Complete coagulation necrosis was reported in 90% of the excised tumors, with no reported complications from RFA. None of the studies reported that presurgical RFA altered surgical decisions of either the patient or surgeon. Investigators of each study acknowledged the preliminary nature of their reports and the pilot status of their studies on effectiveness of RFA as a potential alternative to excision. No new published studies were identified in a literature search updated through December 2005. The available evidence is insufficient to permit conclusions on net health outcomes of RFA for breast cancer.

Pulmonary cancer . RFA has been used to treat pulmonary tumors in more than 500 patients worldwide (26-40). One of the larger recent studies reported the use of RFA in 30 patients with a spectrum of primary (n = 18) and secondary (n = 11) lung tumors, mesothelioma (n = 1), and 5 secondarily eroded, painful ribs who underwent ablation for 36 total lesions (40). Patients were not considered surgical candidates because they had medical comorbidities or extensive disease; they had exhausted chemotherapy and radiotherapy options; or they had "refused" surgery or undergone "unsuccessful" surgery. All ablations were deemed "technically successful." Contrast-enhanced CT or enhanced magnetic resonance imaging (MRI) studies demonstrated necrosis of 90% or better in 26 of 29 (89.7%) patients with lung lesions; pain was ameliorated in 11 of 11 (100%) patients who reported painful lesions. The longest follow-up without recurrence was 26 months. Complications included hemoptysis (n = 4) pneumothorax (n = 8), atrial fibrillation (n = 1), respiratory difficulty (n = 2), hoarseness (n = 1), and a small third-degree skin burn in 1 case. Post-procedure [18F]-2-fluoro-deoxy-D-glucose positron emission tomography (PET-FDG) showed loss of virtually all FDG activity in 9 of 10 (90%) previously positive tumors that were examined with this technology.

There is ongoing interest in using RFA in pulmonary cancers. However, the identified studies are all small case series or uncontrolled cohort studies, which focused primarily on technical feasibility and initial tumor response. Study quality concerns include lack of long-term follow-up; significant interstudy heterogeneity in terms of study design, patient populations, and RFA methods used; and non-uniformity of reporting and efficacy scoring criteria. In total, the available evidence is insufficient to permit conclusions on net health outcomes of RFA for pulmonary cancers.

Osteoid tumors. Rosenthal et al (41) retrospectively compared outcomes for a consecutive series of osteoid osteoma patients treated by operative excision (n=87; 68 primary, 19 recurrent) or by RFA (n=38; 33 primary, 5 recurrent). With an average time to last follow-up of almost 9 years, the study reported “no significant difference with regard to the rate of clinical success” for the 2 approaches (rates of recurrence: 11% RFA, 9% surgery), no difference in complications (0% RFA, 2% surgery), and lesser need for hospitalization with RFA. Based on these results, the investigators concluded, “the percutaneous method is preferred for the treatment of extraspinal osteoid osteomas.”

Methodologic issues raise questions regarding the validity of this conclusion. Up to one third of each patient group may not have had osteomas, since only 60% and 66% of those in the surgery and RFA groups, respectively, underwent a biopsy preoperatively, and pathologic examination on operative specimens failed to confirm the diagnosis for an unspecified number. Nevertheless, results were aggregated for all who received each treatment. Furthermore, patients included in this retrospective analysis were treated between 1978 and 1995, but those given RFA were treated in 1990 or later, and few (i.e., <10% annually) were treated surgically in the study’s final years. Comparisons to historical rather than concurrent controls can bias conclusions, particularly since operative techniques have evolved over time. Also, the authors did not report selection criteria for assigning treatment during years when both treatments were used in this non-randomized study. Thus, patient selection bias further threatens the validity of this comparison.

Finally, long-term clinical success (i.e., after 2 years of initial follow-up) was measured using patient responses to a mailed survey with questions on the need for additional procedures, pain medications, and presence of symptoms. The authors reported only a 31% response rate for operative patients, compared with a 68% response rate for those given RFA. They ascribe this difference to the longer time since operative treatment, yet did not limit their analysis to the period when both treatments were in use. They also did not report efforts to increase survey response rates by telephone contact or other measures. The differences in response rates also threaten the validity of their conclusions.

In 2004, Cioni and colleagues reported on a case series of 38 patients with osteoid osteoma diagnosed clinically, and by radiography, scintigraphy, contrast-enhanced MRI, and CT. A total of 30 of the 38 patients reported prompt pain relief. Six of the remaining 8 patients underwent successful retreatment, and 2 underwent surgical excision. (42)

Another recent case series reported primary success in 37 of 38 (97%) patients (25 males, 8 females, age range 5–43 years) who underwent CT-guided percutaneous RFA to treat clinically and radiologically suspected osteoid osteoma. (43) Lesions were located in the proximal femur (n = 13), tibia (n = 5), foot (n = 5), spine and fibula (n = 3 each), acetabulum and humerus (n = 2 each), and 5 in other sites. (43) All patients experienced

sufficient pain relief to permit resumption of normal activities within 24 hours of the procedure. During follow-up ranging from 3–24 months, no major complications were reported.

In total, while promising, the available evidence is insufficient to permit conclusions on net health outcomes of RFA for osteoid osteomas.

Palliation of pain from bone metastases Goetz et al (44) reported on an international study (n=43) conducted at 9 centers in which patients with painful osteolytic bone metastases were treated palliatively with RFA. The study's primary outcome measure was the Brief Pain Inventory-Short Form, a validated scale from 0 for no pain to 10 for worst pain imaginable. Patient eligibility required baseline values > 4 from < 2 painful sites. Thirty-nine (91%) of the patients had previously received opioids to control pain from the lesion(s) treated with RFA, and 32 (74%) had prior radiation therapy to the same lesion. Mean pain score at baseline was 7.9 (range, 4 to 10). At 4, 12, and 24 weeks after RFA, average pain scores decreased to 4.5, 3.0, and 1.4, respectively (all $p < 0.0005$). Forty-one (95%) of the patients achieved a clinically significant improvement in pain scores, prospectively defined as a decrease of 2 units from baseline. Investigators also reported statistically significant ($p=0.01$) decreases in opioid use at weeks 8 (by 59%) and 12 (by 54%).

An earlier case series showed that palliative RFA provided significant pain relief in 9 of 10 (90%) patients with unresectable, osteolytic spine metastases who had no other treatment options. (45) Pain was reduced by an average of 74%; back pain-related disability was reduced by an average of 27%. Neurologic function was preserved in 9 patients and improved in 1.

These uncontrolled studies included only a limited number of cases. However, the patient populations comprised individuals with limited or no treatment options, for whom short-term pain relief is an appropriate outcome. Therefore, the use of RFA as palliative therapy in patients with painful metastatic bone lesions is considered medically necessary. Because data were unavailable on use of RFA as initial therapy for pain from bone metastases, this indication remains investigational. Neither setting is addressed in the NCCN guidelines for the treatment of bone cancers.

Miscellaneous One case series of 13 patients with adrenal neoplasms treated with RF ablation was identified. Eleven of the 13 lesions were treated successfully with RF ablation, defined by follow-up CT scans, and normalization of preprocedural biochemical abnormalities. (46)

Another single-arm, retrospective, paired-comparison study evaluated the short-term efficacy of RFA in relationship to pain and functional impact in patients with unresectable, painful soft tissue neoplasms recalcitrant to conventional therapies. (47) Patients had tumors located in a variety of sites including the chest wall, pelvis, breast, perirectal,

renal, aortocaval, retroperitoneal, and superficial soft tissues. All had exhausted conventional methods of palliation or experienced dose-limiting adverse effects from pain medication. Although not all Brief Pain Inventory scores were statistically significant, all mean scores trended down with increased time after ablation. Complications from RFA were minor or insignificant in all but 1 patient who had skin breakdown and infection of the ablated superficial tumor site.

Finally, a recent case series showed palliative CT-guided RFA provided subjective improvement with regard to pain, appearance, and function in 12 patients who had recurrent and advanced head and neck malignancies and were not candidates for radiation or surgery. (48) The procedure was deemed reasonably safe and feasible for this indication, but further study is needed.

In total, the available evidence is insufficient to permit conclusions on net health outcomes of RFA for any of the miscellaneous benign or malignant tumors discussed in this section.

2007 Update

A literature search was performed in May 2007 to identify new publications on RFA for miscellaneous tumors. No randomized trials were reported since the last update of this policy, but a few reports of studies were identified.

One retrospective study reported long-term (up to 5 years of follow-up) efficacy and safety of RFA in patients (n = 153 total) with primary or metastatic pulmonary cancers. (49) A 5-year survival rate of 27% for RFA in stage IA or B non-small cell lung cancer and 57% for metastatic colorectal cancer lesions suggests this technique holds promise for treatment of non-resectable pulmonary lesions. However, these results are compromised by the retrospective nature of the data; the potential confounding effects of undefined prior and adjuvant chemo- or radiotherapy; lack of histopathologic proof of treatment completeness; substantial patient and disease heterogeneity; and failure to separate overall survival rates according to disease. Other case series were reported for RFA of primary and metastatic pulmonary lesions, but none provide convincing evidence for its efficacy. (50-52)

Several review articles and small case series summarized specific results of RFA in renal tumors (53, 54), breast cancer (55, 56), pancreas (57), painful metastatic bone tumors (58), and, osteoid osteoma (59). Additional reviews of RFA examined its use in solid malignancies. (60, 61) Although most authors suggest RFA may have a role in treatment of solid non-hepatic malignancies, none provides sufficient evidence to alter the existing policy statements.

CODING**CPT**

20982	Ablation, bone tumor(s) (e.g., osteoid osteoma, metastasis) radiofrequency, percutaneous, including computed tomographic guidance
32998	Ablation therapy for reduction or eradication of one or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, radiofrequency, unilateral (new code effective 1/1/07)
50542	Laparoscopy, surgical; ablation of renal mass lesion(s)
50592	Ablation, one or more renal tumor(s), percutaneous, unilateral, radiofrequency
76940	Ultrasound guidance for, and monitoring of, parenchymal tissue ablation

ICD-9 Diagnosis

These diagnoses are otherwise subject to medical policy as stated above.

162.9	Malignant neoplasm of bronchus and lung, unspecified
174.0 - 174.9	Malignant neoplasm of female breast code range
189.0 – 189.9	Malignant neoplasm of kidney and other and unspecified urinary organs code range
213.9	Malignant neoplasm of bone and articular cartilage site unspecified

ICD-9 Procedure

32.29	Other local excision or destruction of lesion or tissue of lung
55.32	Open ablation of renal lesion or tissue (effective 10/1/06)
55.33	Percutaneous ablation of renal lesion or tissue (effective 10/1/06)
55.34	Laparoscopic ablation of renal lesion or tissue (effective 10/1/06)
55.35	Other and unspecified ablation of renal lesion or tissue (effective 10/1/06)
77.6	Local excision of lesion or tissue of bone
85.20	Excision or destruction of breast tissue, not otherwise specified

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