

Musculoskeletal Tumor Society Novel Practice Assessment

Radiofrequency Ablation for Skeletal Metastases

In these occasional Novel Practice Assessments, the Musculoskeletal Tumor Society (MSTS) Guidelines and Evidence Based Medicine committee will assess the evidence underlying novel diagnostics and therapies entering clinical practice in musculoskeletal oncology. The goal is to assist MSTS members make more informed decisions for their patients. As evidence is expected to change rapidly, articles will be rewritten or removed after one year.

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Summary

Pros

1. Single treatment with rapid onset of pain relief
2. It can be performed concurrently with percutaneous stabilization procedures, such as cementoplasty
3. It can be used at sites that cannot receive further radiation
4. Low complication rate

Cons

1. Requires anesthesia
2. Inadequate evidence comparing efficacy and durability versus radiation therapy, with limited evidence suggesting more durable pain relief when radiation is added

Background

The majority of patients with carcinomas will eventually develop skeletal metastases, which may be painful and, in some cases, lead to fracture. The primary modality for alleviation of pain from skeletal metastases is external beam radiation. However, some patients may have failed radiation therapy or have mechanical instability at the site of metastasis requiring treatment. In these and other cases, other modalities to address the metastatic disease may be indicated.

What is new?

Percutaneous radiofrequency ablation (RFA) is a minimally invasive procedure that be done in the outpatient setting and has been shown to be effective in reducing pain from skeletal metastases. RFA is not new, but there has recently been a more vigorous interest in expanding its utilization for skeletal metastases. Thus far, the bulk of the evidence is in the spine, but there are increasing reports of its successful use in the pelvis and extremities.

What is the evidence in favor?

Methods

A search of PubMed and Ovid online databases was performed on June 1, 2022. The search terms were deliberately kept broad. The primary inclusion terms were “radiofrequency ablation” and “secondary malignancy”. We excluded citations that specifically addressed osteoid osteoma and head and neck sites, as well as case reports and review articles. The search was limited to English language articles published since 2012. Search term specifics can be seen in figures # and #.

The search resulted in 124 citations. Excluded from these were the following: 19 reviews, 9 reports on treatment of visceral metastases, 38 not relevant for other reasons, such as technique papers, case reports, etc. The remaining 57 citations are summarized below.

Results

Of the 57 included citations, only 8 (14%) reported prospectively collected data. More than half (34/57 or 60%) reported radiofrequency ablation of spinal metastases. In an equal number of citations, patients received cementoplasty/vertebroplasty in addition to RFA. However, only two citations attempted to compare the outcomes of RFA vs. RFA with cementoplasty. Twelve citations (21%) reported treatment of non-spinal metastases, mostly in the pelvis, while three reported treatment of sacral lesions. Other forms of percutaneous thermal therapy were also provided to patients, cryoablation in 8 papers and microwave ablation in 2 citations.

In only 4 citations (7%) was there an attempt to elucidate the role of external beam radiation therapy in addition to RFA, all of which were studies of spinal lesions. One of these retrospective studies showed similar pain relief but improved durability of pain control when RFA and radiation therapy (RT) are combined compared to RFA alone. In this study, there were more local failures (8 of 17 lesions) with RFA alone, compared to 1 of 11 in the combination group. This included three lesions treated with RFA alone, which were subsequently treated with RT for local progression at a median of 11.0 months post-RFA. One center is initiating a prospective, randomized, controlled trial comparing RFA/vertebroplasty and RT vs. RT alone.

Several studies compared cryoablation to radiofrequency ablation. Cryoablation seems to be more suited to larger tumors and those closer to critical structures, as the ice-ball can be visualized. Compared to radiofrequency ablation, it is associated with less post-procedural pain but a small but increased fracture risk.

For more details, see annotated bibliography of selected references below.

What is the evidence against?

Thus far, the available evidence is almost entirely from practitioners of radiofrequency ablation and, not surprisingly, there are few provided arguments against RFA.

In the multi center “Opus One” study which prospectively collected on 100 patients undergoing spinal RFA, there were four adverse events reported, two of which required hospitalization (pneumonia, respiratory failure).

Future Directions

A prospective study randomizing patients with symptomatic non-mobile spine bone metastases to RFA vs. RFA plus external beam radiation should be feasible and would be very helpful in making treatment recommendations. It could also help provide comparative cost data.

Annotated Bibliography

Anchala PR, Irving WD, Hillen TJ, Friedman MV, Georgy BA, Coldwell DM, et al. Treatment of metastatic spinal lesions with a navigational bipolar radiofrequency ablation device: a multi-center retrospective study. *Pain Physician* 2014;17(4):317-27.

- multi-center retrospective study, 2012-2013, using “STAR” tumor ablation system
- senior author and 2nd author consultants for company making system, which “is an articulating, navigational and bipolar radiofrequency electrode containing a pair of thermocouples positioned along the length of the electrode, 10 and 15 mm from the center of the ablation zone”
- 92 patients, 96 lesions
- decrease in pain medications in 54% of patients

Bagla S, Sayed D, Smirniotopoulos J, Brower J, Neal Rutledge J, Dick B, et al. Multicenter Prospective Clinical Series Evaluating Radiofrequency Ablation in the Treatment of Painful Spine Metastases. *Cardiovascular & Interventional Radiology* 2016 Sep;39(9):1289-97.

- Single arm, prospective multi-center study
- 50 patients, 69 thoracolumbar lesions, nearly all (96%) also received cement augmentation
- significant improvement in pain scores and QOL measurements from 3 to 90 days time intervals
- no reported complications

De Marini P, Cazzato RL, Auloge P, Koch G, Dalili D, Garnon J, et al. Percutaneous image-guided thermal ablation of bone metastases: a retrospective propensity study comparing the safety profile of radio-frequency ablation and cryo-ablation. *Int J Hyperthermia* 2020;37(1):1386-94.

Single center retrospective study, 2008-2018, 274 patients

- goal was to compare different treatments for similar lesions (and demographics)
- at baseline, cryo was used more often for sclerotic/mixed lesions, larger lesions, lesions closer to critical structures and patients with lower performance scores, more likely previously radiated
- 53 patients/66 lesions with RFA, 221 patients/301 lesions with cryoablation
- overall 2.5% major complication rate, similar in both RFA/cryo
- 1/2 of major cryo complications were fracture
- 11% minor complications for RFA group vs 6% in cryo group ($p < 0.001$), most commonly (90%) post-procedural pain
- with propensity score matching, similar rates of major complications, but persistent higher rate of minor complication with RFA (33%) vs cryo (3%), of which post-procedural pain was 90%
- “This may be partially attributed to the analgesic properties of the ice-ball [in cryoablation], which may significantly contribute to lowering post-procedural pain after bone tumor CA”

Burgard CA, Dinkel J, Strobl F, Paprottka PM, Schramm N, Reiser M, et al. CT fluoroscopy-guided percutaneous osteoplasty with or without radiofrequency ablation in the treatment of painful extraspinal and spinal bone metastases: technical outcome and complications in 29 patients. *Diagnostic and interventional radiology (Ankara, Turkey)* 2018 May;24(3):158-65.

- Used combination of CT & fluoroscopy
- single institution retrospective study 2002-2016
- total 40 lesions: 14 iliac/acetabular, 8 sacral, 11 spinal lesions
- seven lesions received prior radiation, 3 particle embolization
- Six minor complications
- no pain scores recorded

English DI, Lea WB, King DM, Tutton SM, Neilson JC. Minimally Invasive Stabilization with or without Ablation for Metastatic Periacetabular Tumors. *Journal of bone and joint surgery.American volume* 2021 Jul 7;;103(13):1184-92.

- High quality retrospective study entirely of peri-acetabular lesions
- single institution, retrospective, 38 patients, 2011-2017
- “Periarticular cortical dehiscence” was not contraindication
- Ablation not performed for breast cancer, lymphoma, or myeloma lesions
- 45% patients also received radiation therapy
- Larger lesions with soft tissue component underwent cryoablation

- Mean follow up 9 mos
- Narcotic usage decreased 80%, mean MSTS score improved from 7.8 to 19.6 out of 30
- Two patients had nerve injuries, which resolved
- three patients had repeat treatment, 3 underwent total hip arthroplasty

Guenette JP, Lopez MJ, Kim E, Dupuy DE. Solitary Painful Osseous Metastases: Correlation of Imaging Features with Pain Palliation after Radiofrequency Ablation—A Multicenter American College of Radiology Imaging Network Study. *Radiology* 2013 Sep;268(3):907-15.

- Prospective multi center trial, 2001-2006
- 49 patients, solitary bone mets
- Previous radiation not contraindication, no RT allowed for 30 days after
- Follow-up CT or MRI performed 1 and 3 mos later
- smaller tumor size and proximity to neurovascular structures were correlated with higher rate of successful palliation
- Interestingly, existing pathologic fracture was associated with better pain relief
- Presence of irregular rim and rim thickness correlated with increased pain after treatment, while treatment of a larger percentage of the bone tumor interface was correlated with improved pain relief

Kotecha R, Schiro BJ, Sporrer J, Rubens M, Appel HR, Calienes KS, et al. Radiation therapy alone versus radiation therapy plus radiofrequency ablation/vertebral augmentation for spine metastasis: study protocol for a randomized controlled trial. *Trials* 2020 Nov 23;21(1):964-x.

- Published study protocol from Miami Cancer Institute, Baptist Health
- single-center, prospective, randomized, controlled trial in patients with spine metastasis, stratified radio-resistant vs. radiosensitive, patients will be randomized in a 2:1 ratio to either RFA/vertebroplasty and EBRT or EBRT alone

Lee FY, Latich I, Toombs C, Mungur A, Conway D, Alder K, et al. Minimally Invasive Image-Guided Ablation, Osteoplasty, Reinforcement, and Internal Fixation (AORIF) for Osteolytic Lesions in the Pelvis and Periarticular Regions of Weight-Bearing Bones. *Journal of vascular and interventional radiology* 2020 Apr;31(4):649,658.e1.

- Single center, prospective trial, 23 patients, 2017-2019
- 26 osteolytic lesions: 19 pelvis, 7 lower extremity
- VAS decreased 8.32 ± 1 . To 2.36 ± 2.23 at two weeks, MSTS scores increased 45%-68%
- all patients underwent RFA, balloon osteoplasty and cementation
- cannulated screws used for instrument access were left in place
- one patient with hip joint cement extravasating without “no further complications”

Levy J, Hopkins T, Morris J, Tran ND, David E, Massari F, et al. Radiofrequency Ablation for the Palliative Treatment of Bone Metastases: Outcomes from the Multicenter OsteoCool Tumor Ablation Post-

Market Study (OPuS One Study) in 100 Patients. Journal of vascular and interventional radiology 2020 Nov;31(11):1745-52.

- Major paper which brought attention to Medtronic's "OsteoCool" device which uses circulating water to maintain 70° C at electrode tip
- Seven of the thirteen authors, including first author, are paid consultants of Medtronic
- 14 international centers, treated from 2017-2019
- excluded osteoblastic lesions, but not previous RT
- 100 patients total – 87 thoracolumbar spine, 13 in pelvis/sacrum, 134 total ablations - nearly all (97%) underwent immediate cementoplasty
- no patient received radiation therapy before radiofrequency ablation, 16% received RT after radiation
- 40 patients exited study, outcomes reported in 22 patients ("differences ... because of subjects who were still actively being followed at the time of manuscript preparation"), 30% died before 1 month - Mean worst pain score decreased from 8.2 ± 1.7 to 3.5 ± 3.2 at 6 mos
- 4 adverse events, 2 (pneumonia, respiratory failure) requiring hospitalization
- Authors concede "the difficulty to discern the impact of RF ablation alone as a result of the use of PMMA augmentation"
- Updated, "final" results of 206 patients at 12 months presented at 2021 meeting of Society of Interventional Radiology (SIR) with minimal change in pain & QOL scores

Pellerin O, Medioni J, Vulser C, Déan C, Oudard S, Sapoval M. Management of painful pelvic bone metastasis of renal cell carcinoma using embolization, radio-frequency ablation, and cementoplasty: a prospective evaluation of efficacy and safety. Cardiovasc Intervent Radiol 2014 Jun;37(3):730-6.

- Single institution, prospective study, 2018-2013
- 52 patients, 58 pelvic lesions of which 17 were in the sacrum
- Patients underwent embolization 1 day before RFA/cementoplasty
- Visual Analog Pain scores (VAS) decreased from median 7 (± 1.4) to 3 (±1.5) at discharge and 2 (±1.5) at 6 months
- Prezzano KM, Prasad D, Hermann GM, Belal AN, Alberico RA. Radiofrequency Ablation and Radiation Therapy Improve Local Control in Spinal Metastases Compared to Radiofrequency Ablation Alone. American Journal of Hospice & Palliative Medicine 2019 May;36(5):417-22.
- Single institution, retrospective study, 2016-2017
- compared combined radiofrequency ablation with radiation therapy compared to RFA alone
- 26 patients/28 lesions treated RFA alone
- 10 patients/11 lesions treated with RFA + RT
- more lung primaries in RFA alone group, more breast primaries in combination group
- No difference in pain scores at median 8.2 months follow-up
- More local failures (8 of 17 lesions)with RFA alone, compared to 1 of 11 in combination group
- Three lesions treated with RFA alone subsequently treated with RT for local progression at a median of 11.0 months post-RFA

- Authors suggest “it is unlikely there would exist clinical equipoise to initiate a clinical trial randomizing patients to RFA alone without radiation.”

Tanigawa N, Arai Y, Yamakado K, Aramaki T, Inaba Y, Kanazawa S, et al. Phase I/II Study of Radiofrequency Ablation for Painful Bone Metastases: Japan Interventional Radiology in Oncology Study Group 0208. *Cardiovasc Intervent Radiol* 2018 Jul;41(7):1043-8.

- Prospective multi-center trial, 33 patients to evaluate safety of RFA and pain relief at 1 week
- Four patients with adverse events, one severe pain, 2 hypotension and 1 skin burn
- No patients received RT, no cementoplasty reported
- response was “excellent” (decrease in VAS score >5) in 61% patients, good (VAS decrease >2) in 9% patients, and no improvement in 30%

Tomasian A, Madaeil TP, Wallace AN, Wiesner E, Jennings JW. Percutaneous thermal ablation alone or in combination with cementoplasty for renal cell carcinoma osseous metastases: Pain palliation and local tumour control. *Journal of Medical Imaging & Radiation Oncology* 2020 Feb;64(1):96-103.

- Single center, retrospective study, 2011-2016
- 23 patients, 59 RCC lesions, including 14 pelvis, 5 sacrum, 20 thoracic spine, 17 lumbar spine
- 27% underwent cryoablation, 73% RFA
- Cementoplasty/vertebral augmentation performed “if patient reported mechanical pain or imminent risk of pathologic fracture...”
- self reported pain (scale 1-10) measured at 1 week, 1,3 and 6-month intervals
- median pain scores decreased from 8 to 4 at 1 week, 3 at 1, 3 and 6 months
- 44 tumors had post procedure imaging available at 3 months, in these radiographic control was 100%, while 20% demonstrated systemic progression
- at 12 months, tumor control was 85% (28/33 cases with available imaging)

Tomasian A, Marlow J, Hillen TJ, Jennings JW. Complications of Percutaneous Radiofrequency Ablation of Spinal Osseous Metastases: An 8-Year Single-Center Experience. *AJR.American Journal of Roentgenology* 2021;216(6):1607-13.

- Single center retrospective study of RFA complications, 2012-2019
- 166 patients, 266 lesions
- different forms of passive and active thermal protection, e.g., thermocouples, epidural injections of saline
- total complication rate 3% (8/266)
- 1 was major – spinal venous infarct with LE weakness, GU dysfunction
- 4 minor – transient radicular pain requiring steroid injections
- self reported pain reduction at all intervals 1 week to 6 mos, local tumor control 79%

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