

# RF ABLATION FOR PALLIATIVE TREATMENT OF BONE METASTASES

Clinical Summary

**Medtronic**  
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## INTRODUCTION

Cancer invades bone in 60% to 80% of patients with metastatic disease<sup>1</sup> — most frequently among patients with primary malignancies of the breast, prostate, and lung.<sup>2</sup> Pain, usually refractory, is the most frequent complaint, occurring in 79% of these patients.<sup>3</sup>

Bone metastases can significantly impact patients' quality of life with pain,<sup>4</sup> fractures, decreased mobility, depression,<sup>5</sup> and anxiety.<sup>6</sup> And with patients living longer with their cancer, more are suffering from metastatic disease pain.<sup>1,2</sup>

# EARLY AND LASTING PAIN RELIEF IS A PRIMARY GOAL IN MANAGING BONE METASTASES.

*This guide is intended to provide a summary of three studies which share retrospective clinical data on the use of the OsteoCool™ RF Ablation system for the palliative treatment of bone metastases. These publications were not sponsored by Medtronic.*

Radiation therapy (RT) is the gold standard palliative treatment for patients with bone metastases. While radiofrequency ablation (RFA) is not meant to oppose or replace standard treatments, it may complement RT.

A feasibility study by Di Staso, et al.,<sup>7\*</sup> measured pain scores and time to response with RT vs. RT + RFA\*. Patients who received the combined therapy had overall better pain scores and faster palliation.<sup>7</sup>

With low-power, bipolar RFA, energy is delivered through internally cooled electrodes to a precise ablation zone. Where indicated, subsequent augmentation during the RFA procedure, using the same access tools, stabilizes the fracture.

*\*RFA therapy used: Leveen Needle Electrode (Boston Scientific Corp.)*

# Low-power bipolar radiofrequency ablation and vertebral augmentation for the palliative treatment of spinal malignancies

Cazzato RL, Garnon J, Caudrelier J, et al. *Int J Hyperthermia*. 2018;Jan 18:1-7. doi: 10.1080/02656736.2017.1422557. Epub 2018. PMID: 29347855.

## OBJECTIVE

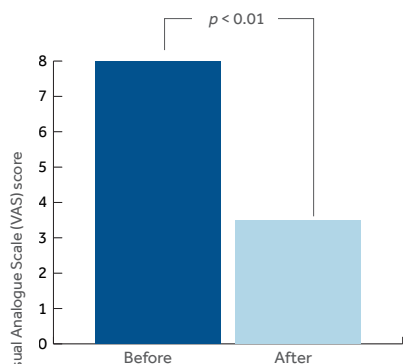
To assess pain management and safety of bipolar radiofrequency ablation (RFA) with internally cooled electrodes (OsteoCool™ RF ablation, Medtronic) combined with vertebral augmentation, for painful bone metastases.

## DESIGN

- Retrospective study
- 11 consecutive patients with painful spinal tumor (visual analogue scale [VAS]  $\geq 4/10$ )
- Treated with RFA and vertebral augmentation
- Followed up one to two months post-procedure to assess intensity of focal pain

## RESULTS

### *Significant pain relief with RFA + vertebral augmentation*



Mean Visual Analogue Scale (VAS) score  
Last clinical follow-up: 1.9 ± 1.4 months  
Mean pain score: 3.5 ± 2 at follow-up versus 7.8 ± 1.1 at baseline  
N=11

- Statistically significant pain reduction in 11/11 (100%) at follow-up (mean 1.9 ± 1.4 months)
- Double electrode approach used in 10/11 (90.9%) of cases
- Following RFA, all treated levels received vertebral augmentation
- Metastatic epidural involvement was noted in 81.8% (9/11) cases
- Technical success achieved in 100% of cases

## COMPLICATIONS

Two reported complications (18.2%) were not RFA-related.

## CONCLUSION

- OsteoCool™ RF ablation, paired with vertebral augmentation, achieved early pain management in this patient population with painful spinal metastases.

## STUDY LIMITATIONS

- Small sample size
- Retrospective design
- Absence of a control group receiving vertebral augmentation alone

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# Initial single center experience: radiofrequency ablation assisted vertebroplasty and osteoplasty using a bipolar device in the palliation of bone metastases

David E, Kaduri S, Yee A, et al. *Ann Palliat Med.* 2017;6(2):118-124.

## OBJECTIVE

To assess safety and clinical outcomes of bipolar radiofrequency ablation (RFA) with internally cooled electrodes (OsteoCool™ RF ablation, Medtronic) combined with vertebroplasty (VP) or osteoplasty (OP), for pathological and insufficiency fractures in patients with painful bone metastases.

## DESIGN

- Retrospective study
- 26 patients treated with RFA followed by VP and/or OP (RFA-VP/OP)
- 56 patients treated with VP only (traditional technique)
- Clinical and radiological outcomes evaluated post procedure

## RESULTS

- Statistically significant pain reduction was achieved in RFA-VP/OP group post procedure
- Significantly reduced rate of posterior and venous cement leaks in the RFA-VP group vs. VP-only group
- No difference in rate of cement leakage into disc space in RFA vs. traditional technique
- Improved cement filling in cases using bi-pedicular approach compared to uni-pedicular approach ( $p < 0.0001$ )
- Technical success was achieved in 100% of RFA-assisted VP and OP cases

## COMPLICATIONS

No morbidity was reported. Any mortality was unrelated to the procedure.

## CONCLUSIONS

- Study demonstrated no damage to adjacent structures with use of the OsteoCool™ RF ablation bipolar technology.
- RFA allows for a controlled cement injection into what may be a thermal cavity, with a significant decrease in posterior and venous cement leaks vs. VP alone.
- The use of RFA combined with VP and/or OP produced significant pain relief and consistent reduction in post operative pain scores.

## STUDY LIMITATIONS

- Retrospective design
- Lack of a control group to assess whether RFA alone enhanced pain relief vs. traditional VP

# Percutaneous radiofrequency ablation for painful spinal metastases resulting in resolution of epidural disease: a case report

Holbert JA, Nguyen DT. *Cureus*. 2018;10(5): e2579. DOI 10.7759/cureus.2579.

## OBJECTIVE

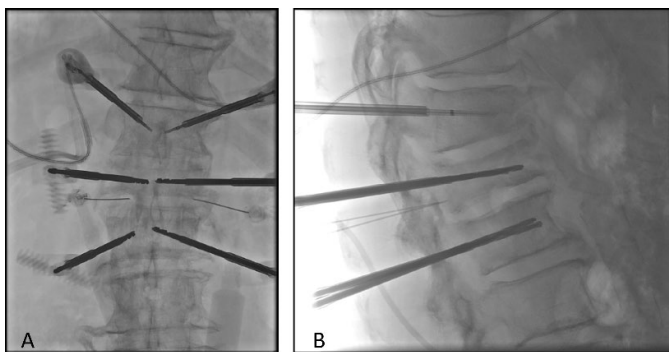
To present a case of metastatic prostate cancer with epidural extension, treated with percutaneous image-guided radiofrequency ablation (RFA) and vertebral augmentation.

## BACKGROUND

- 81-year-old male
- Pathologic involvement of T11, T12, and L1
- Metastatic involvement of the epidural component, resulting in 40% spinal canal stenosis
- Patient wheelchair bound due to debilitating back pain, not controlled with NSAIDs or opioids
- The lytic component of metastatic prostate cancer creates a local bone weakening effect, which contributes to severe pain and increased risk of vertebral collapse.

## PROCEDURE

Using fluoroscopic-guided imaging, 10-gauge introducer needles were advanced into the T11, T12, and L1 vertebral levels using a bilateral transpedicular approach.



**Figure 1: Intraoperative AP (A) and lateral (B) radiographic views.**

Images from JA Holbert and DT Nguyen. *Cureus*. 2018;10(5): e2579. DOI 10.7759/cureus.2579.

## OUTCOME

### Post-op follow-up

#### Three weeks

- No pain
- Ambulating without assistance
- Increasing daily activities

#### Eight weeks

- No pain
- Stable vertebral changes (MRI)
- Complete resolution of epidural disease at T12 and L1

#### Nine months

- No pain
- Return to normal activities

## CONCLUSIONS

- In this case, RFA (OsteoCool™ RF ablation, Medtronic) followed by vertebral augmentation provided significant pain relief and stabilized affected vertebra.
- One complicating factor in the treatment of spinal metastases is the involvement of epidural tissue. In this case, the epidural involvement reduced in size, secondary to the RF ablation of the vertebrae.

## STUDY LIMITATION

- Single patient case study

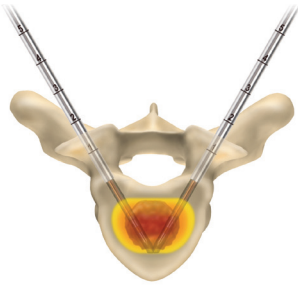
## About OsteoCool™ RF Ablation

The OsteoCool™ RF Ablation System is cooled radiofrequency ablation technology. It offers simultaneous, dual probe capabilities for the treatment of metastatic malignancies in bone.

Internally cooled probes create large volume lesions without excessive heating at the active tip, minimizing potential for char and risk of iatrogenic nerve damage.

At a target temperature of 70° C at the distal tip, the probes ablate for the pre-set time and yield predictable ablation zones.

Where indicated, use the same bone access for subsequent physician-directed procedure such as cementoplasty (i.e., kyphoplasty or vertebroplasty).



Simultaneous ablation allows two probes to be positioned closely enough to produce large ablation zones.

## INDICATIONS AND RISKS

The OsteoCool™ RF Ablation System is intended for ablation of benign bone tumors such as osteoid osteoma and for the palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body. It is also intended for coagulation and ablation of tissue in bone during surgical procedures, including palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy. Risks of the system include damage to surrounding tissue through iatrogenic injury as a consequence of electrosurgery, pulmonary embolism, nerve injury including thermal injury, puncture of the spinal cord or nerve roots potentially resulting in radiculopathy, paresis, and paralysis. The OsteoCool™ bone access kits are indicated for percutaneous access to bone.

Kyphon™ BKP and vertebroplasty is a minimally invasive procedure for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesion. Risks of acrylic bone cements include cement leakage, which may cause tissue damage, nerve or circulatory problems, and other serious adverse events, such as: cardiac arrest, cerebrovascular accident, myocardial infarction, pulmonary embolism, or cardiac embolism.

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2. Kurup AN and Callstrom MR. Ablation of Skeletal Metastases: Current Status. *J Vasc Interv Radiol*. 2010;21(8 Suppl):S242-50.
3. Janjan N, Lutz ST, Bedwinek JM, et al. Therapeutic guidelines for the treatment of bone metastases. *J Palliat Med*. 2009;12(5):417-426.
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# Medtronic

**Medtronic**  
Spinal and Biologics Business  
Worldwide Headquarters

2600 Sofamor Danek Drive  
Memphis, TN 38132



**Medtronic Sofamor Danek USA, Inc.**  
1800 Pyramid Place  
Memphis, TN 38132

(901) 396-3133  
(800) 876-3133  
Customer Service: (800) 933-2635

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