Radiation therapy alone versus radiation therapy plus radiofrequency ablation/vertebral augmentation for painful spine metastasis: a randomized controlled trial

Rupesh Kotecha, MD1,2,*; Omer Gal, MD1; Haley Appel, BA1; Maria Carolina Avendano, BS3; Antoinette M Pimentel, BS3; Amy K Starosciak, PhD3; Muni Rubens, PhD3; Mukesh Roy, PhD3; Dilanis Perche, MD3; Cristina I Pow-Sang, BS3; Fabiana Milosevic3; Ramon F Cruz, BSN3; Alex Kudryashev, MS3; Matthew D Hall, MD1,2; Ana Botero, MD1,2; Minesh P Mehta, MD1,2; Justin M Sporrer, MD4; Brian Schiro, MD2,5

1Department of Radiation Oncology, Miami Cancer Institute, Miami, FL, USA; 2Herbert Wertheim College of Medicine, Florida International University, Miami, FL, USA; 3Office of Clinical Research, Miami Cancer Institute, Miami, FL, US; 4Department of Neurosurgery, Miami Neuroscience Institute, Miami, FL, USA; 5Department of Vascular and Interventional Radiology, Miami Cardiac and Vascular Institute, Miami, FL, USA.

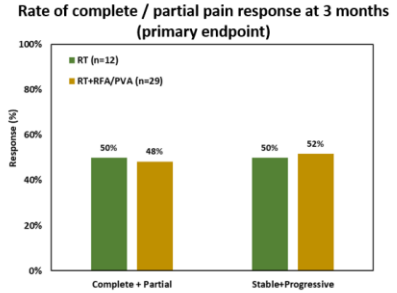
Purpose

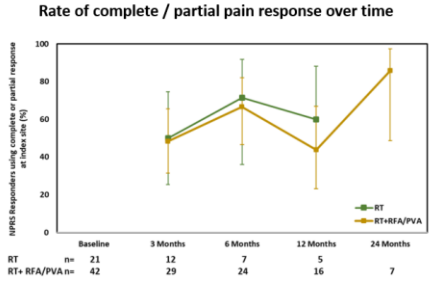
- External beam radiation therapy (EBRT) offers modest pain relief for patients with symptomatic spine metastases; efforts to improve upon this with image-guided thermal ablative approaches remain understudied.
- This study aimed to prospectively compare pain response rates and corresponding quality of life (QoL) between EBRT alone and EBRT + radiofrequency ablation/percutaneous vertebral augmentation (RFA/PVA).

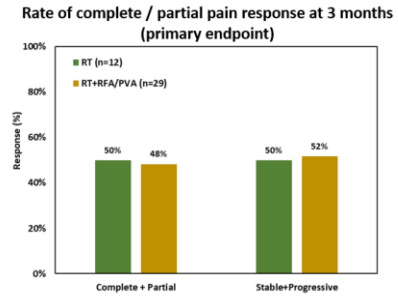
Methods

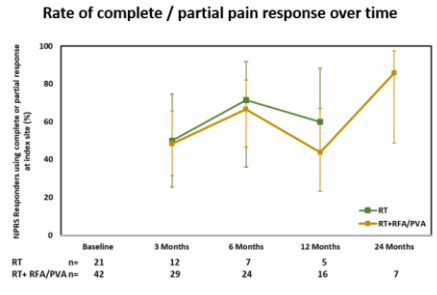
- Single-center, prospective, randomized phase 2 trial
- Patients with spine metastasis from T5-L5, with 1-2 index sites amenable to RFA and a minimum Numeric Pain Rating Scale (NPRS) of 5
- Patients were stratified according to tumor type (radioresistant vs. radiosensitive) and randomly assigned in a 1:2 ratio to receive either EBRT (20-30 Gy in 5-10 fractions) alone or with the addition of RFA/PVA (RFA/PVA arm)
- Primary endpoint was 3-month pain response (complete or partial), defined as a reduction in the worst NPRS score of ≥3 points from baseline at the index sites
- Adverse events and patient-reported QoL measures were secondary objectives.

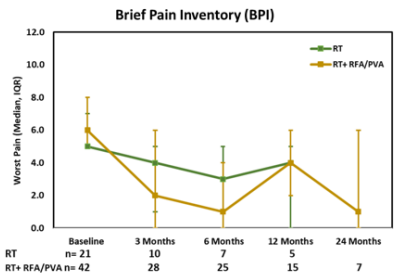
Results

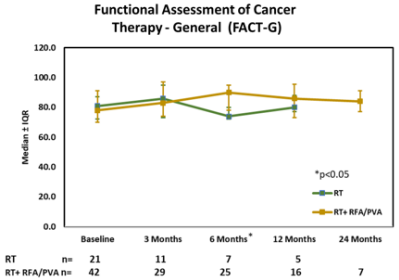


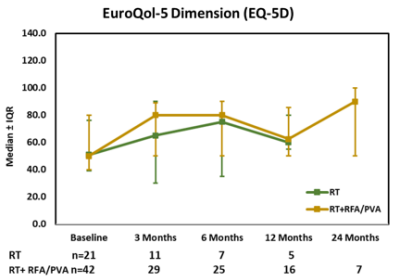












- The study was terminated early after enrolling and randomizing 63 patients (79% of planned accrual; 21 EBRT, 42 RFA/PVA)
- The median age was 68 (IQR: 61-77), 65% were female, 70% ECOG 1, and 60% Hispanic
- The median baseline NPRS was 10 (interquartile range [IQR] 8-10) for EBRT alone and 9 (7.5-10) for the RFA/PVA arm
- The primary endpoint of pain response 3 months after treatment was similar between EBRT alone and RFA/PVA arms (50.0% vs. 48.3%, p-value= 0.92)
- Complete pain response rates at 3 months were also similar between the EBRT alone arm and the RFA/PVA arm (16.7% vs. 20.7%, p-value =0.77). The median 3-month NPRS reduction was -4 (IQR, -6 to -1) in both treatment arms
- Adverse events were comparable between the arms, as were QoL measures including FACT-G, BPI, and EQ-5D scores. There were no grade 4 or higher adverse events in either arm
- Only one patient in the RT+RFA/PVA arm (2%) had a grade 3 spinal fracture and back pain related to the intervention

Conclusion

The addition of RFA/PVA to RT for patients with symptomatic spine metastases did not improve pain control or QOL measures at 3 months