Radiofrequency Ablation in Radiation Naïve Patients for Palliation of Osseous Metastases: An OPuS One Sub-analysis

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PURPOSE

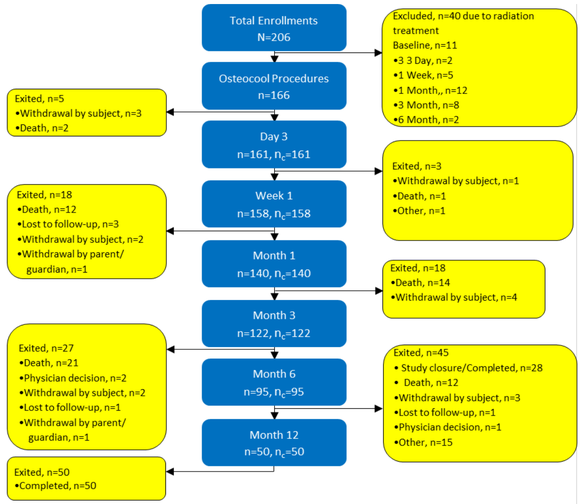
To report the results from a prospective multicenter study of Radiofrequency Ablation (RFA) for the palliation of painful bone metastases for subjects that did not receive radiation therapy at the site of RFA before or after RFA treatment.

MATERIALS and METHODS

Two-hundred six subjects were enrolled and treated with RFA across 15 sites (NCT03249584). Subject inclusion required worst pain ≥4/10 within 24 hours as measured by BPI (Brief Pain Inventory) at the target site. RFA was to be conducted with imaging guidance at 1-2 levels and subsequent cementoplasty was optional. Pain and EQ-5D-5L index score were assessed at baseline and 3 days through 12 months. Adverse events (AEs) related to device, procedure, and/or therapy were recorded. Subjects were included in the present sub-group analysis if they did not receive radiation therapy at the site(s) of RFA treatment from pre-RFA baseline through up to 12 months of follow-up.

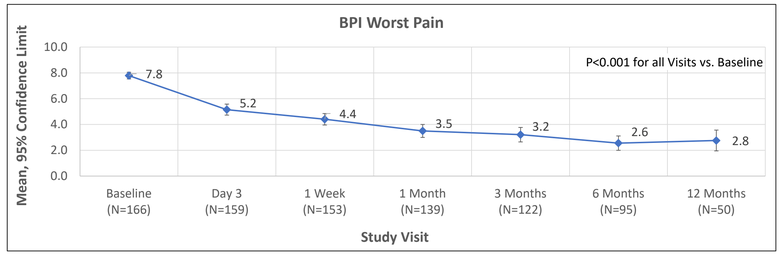
RESULTS

Eighty-one percent of RFA-treated subjects were free from radiation therapy at the index site (166/206). For this cohort, mean age ± SD was 63.5±13.6 years and 55.4% were female. The prevailing cancer pathologies were lung (23.5%), breast (21.7%), and renal (10.2%).

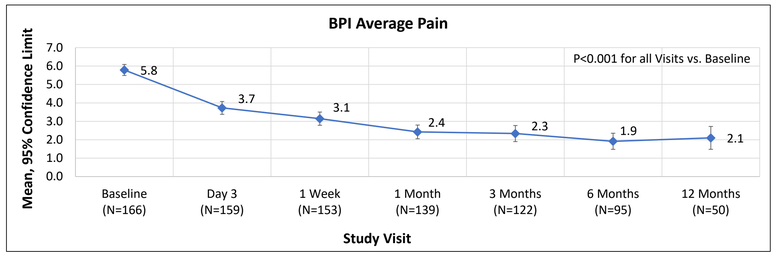


Note: n in the blue boxes represents the number of subjects who were followed at the visit or at a later visit. n_c is the number of subjects who completed the visit.

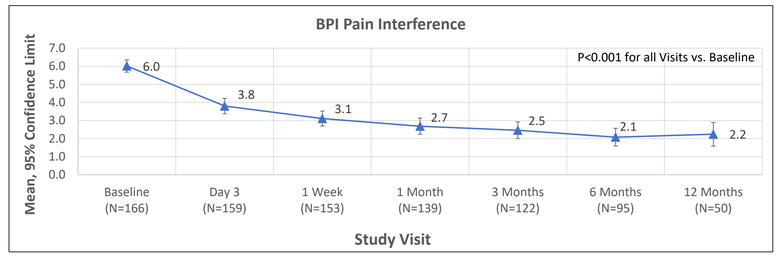
Eighty-nine percent of subjects were treated for metastatic lesions involving the lumbar/thoracic spine; 11% were treated for metastatic lesions located in the iliac crest, peri-acetabulum, sacrum or mixed vertebral and pelvic location. Ninety-nine percent (209/210) of RFA procedures were technically successful and 97% were followed by cementoplasty.



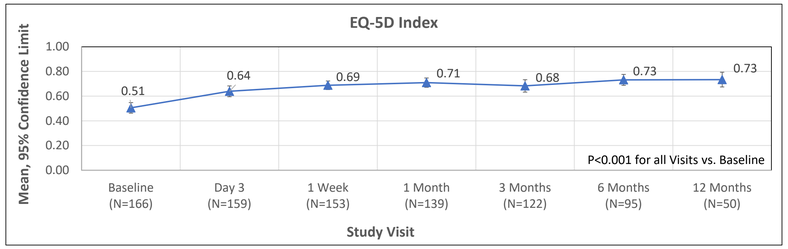
Significant improvements in worst pain relief as rapid as 3 days post-RFA and durable up to 12 months post-RFA.



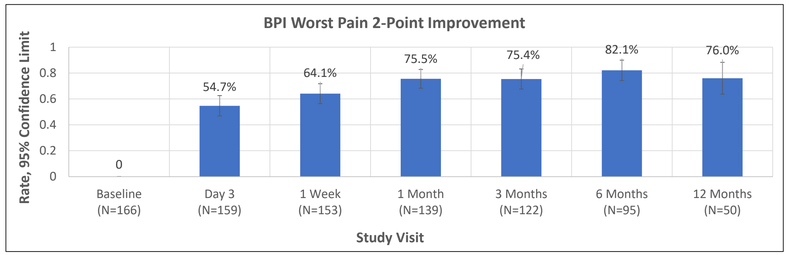
Significant improvements in average pain as rapid as 3 days post-RFA and durable up to 12 months post-RFA.



Significant improvements in pain interference with patient functionality as rapid as 3 days post-RFA and durable up to 12 months post-RFA.



Significant improvement in quality of life as rapid as 3 days post-RFA and durable up to 12 months post-RFA



Clinically meaningful pain relief (≥2 point change in worst pain, BPI) was observed in 54.7% and 76.0% of patients at 3 days and 12 months post-RFA.

SAFETY

- 6 device, therapy, and/or procedure-related adverse events in 6 patients (3.6%; 6/166) were reported of which 3 were considered serious: respiratory failure, intra-abdominal fluid collection, and pneumonia.
- 62 deaths (37.3%; 62/166) deaths were reported, but all were attributed to an underlying malignancy by an independent Clinical Events Committee.

CONCLUSION

The results of this subgroup analysis from the OPuS One clinical study show swift and significant pain reduction and improved quality of life for up to 12 months after RFA treatment for metastatic bone disease, without radiation therapy.

Disclosure: OPuS One was sponsored by Medtronic.