

## ABSTRACT

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Initial results of a phase II trial of (18)F-DOPA PET-guided re-irradiation for recurrent high-grade glioma.

Breen WG(#)(1), Youland RS(#)(2), Giri S(3), Jacobson SB(3), Pafundi DH(4), Brown PD(1), Hunt CH(5), Mahajan A(1), Ruff MW(6), Kizilbash SH(6), Uhm JH(6), Routman DM(1), Jones JE(1), Brinkmann DH(1), Laack NN(7).

### Author information:

(1)Department of Radiation Oncology, Mayo Clinic, 200 First Street SW, Rochester, MN, 55905, USA.

(2)Minnesota Oncology, St. Paul, MN, USA.

(3)Department of Biomedical Statistics and Informatics, Mayo Clinic, 200 First Street SW, Rochester, MN, 55905, USA.

(4)Department of Radiation Oncology, Mayo Clinic, Jacksonville, FL, USA.

(5)Department of Radiology, Mayo Clinic, Rochester, MN, USA.

(6)Division of Medical Oncology, Mayo Clinic, Rochester, MN, USA.

(7)Department of Radiation Oncology, Mayo Clinic, 200 First Street SW, Rochester, MN, 55905, USA. Laack.Nadia@mayo.edu.

(#)Contributed equally

**PURPOSE:** In-field high-grade glioma (HGG) recurrence is a common challenge with limited treatment options, including re-irradiation. The radiotracer 3,4-dihydroxy-6-[18F]-fluoro-L-phenylalanine (18F-DOPA) crosses the blood brain barrier and demonstrates high uptake in tumor, but low uptake in normal tissue. This study investigated whether 18F-DOPA positron emission tomography (PET) and MRI guided re-irradiation for recurrent HGG may improve progression free survival (PFS).

**METHODS:** Adults with recurrent or progressive HGG previously treated with radiation were eligible. The primary endpoint was a 20% improvement from the historical control PFS at 3 months (PFS3) of 20% with systemic therapy alone. Re-RT dose was 35 Gy in 10 fractions. The target volume was MRI T1 contrast-enhancement defined tumor plus 18F-DOPA PET defined tumor.

**RESULTS:** Twenty patients completed treatment per protocol. Diagnosis was most commonly glioblastoma, IDH-wildtype (60%). MRI-defined volumes were expanded by a median 43% (0-436%) by utilizing 18F-DOPA PET. PFS3 was 85% (95% CI 63.2-95.8%), meeting the primary endpoint of PFS3  $\geq$  40%. With 9.7 months median follow-up, 17 (85%) had progressed and 15 (75%) had died. Median OS from re-RT was 8.8 months. Failure following re-RT was within both the MRI and PET tumor volumes in 75%, MRI only in 13%, PET only in 0%, and neither in 13%. Four (20%) patients experienced grade 3 toxicity, including CNS necrosis (n = 2, both asymptomatic with bevacizumab initiation for radiographic findings), seizures (n = 1), fatigue (n = 1), and nausea (n = 1). No grade 4-5 toxicities were observed.

**CONCLUSION:** 18F-DOPA PET-guided re-irradiation for progressive high-grade glioma appears safe and promising for further investigation.

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