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A Phase III Study of Conventional Radiation Therapy Plus Thalidomide versus Conventional Radiation Therapy for Multiple Brain Metastases (RTOG 0118)

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Corrected Proof

Purpose
To compare whole-brain radiation therapy (WBRT) with WBRT combined with thalidomide for patients with brain metastases not amenable to resection or radiosurgery.

Patients and Methods
Patients with Zubrod performance status 0–1, MRI-documented multiple (>3), large (>4 cm), or midbrain brain metastases arising from a histopathologically confirmed extracranial primary tumor, and an anticipated survival of >8 weeks were randomized to receive WBRT to a dose of 37.5 Gy in 15 fractions with or without thalidomide during and after WBRT. Prerandomization stratification used Radiation Therapy Oncology Group (RTOG) Recursive Partitioning Analysis (RPA) Class and whether post-WBRT chemotherapy was planned. Endpoints included overall survival, progression-free survival, time to neurocognitive progression, the cause of death, toxicities, and quality of life. A protocol-planned interim analysis documented that the trial had an extremely low probability of ever showing a significant difference favoring the thalidomide arm given the results at the time of the analysis, and it was therefore closed on the basis of predefined statistical guidelines.

Results
Enrolled in the study were 332 patients. Of 183 accrued patients, 93 were randomized to receive WBRT alone and 90 to WBRT and thalidomide. Median survival was 3.9 months for both arms. No novel toxicities were seen, but thalidomide was not well tolerated in this population. Forty-eight percent of patients discontinued thalidomide because of side effects.

Conclusion
Thalidomide provided no survival benefit for patients with multiple, large, or midbrain metastases when combined with WBRT; nearly half the patients discontinued thalidomide due to side effects.

[Brain metastases](#), [Whole-brain radiotherapy](#), [thalidomide](#), [Phase III trial](#), [antiangiogenesis](#)

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Conflict of interest: none.

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