Results of a phase II trial of the GliaSite Radiation Therapy System for the treatment of newly diagnosed, resected single brain metastases.

Clinical Articles


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OBJECT. The aim of this study was to evaluate the effectiveness of brachytherapy using the GliaSite Radiation Therapy System in patients with a newly diagnosed resected single brain metastasis. The primary end point of the study was local tumor control. The secondary end points included patient survival, distant brain recurrence, quality of life, and treatment toxicity.

METHODS. The authors conducted a prospective multiinstitutional phase II study of GliaSite brachytherapy prescribed at a 60-Gy dose administered to a 1-cm depth after resection of a single brain metastasis. No whole-brain radiation therapy was given. Patients were assessed at 1 and 3 months after brachytherapy and every 3 months thereafter for up to 2 years. Seventy-one patients were enrolled at 13 centers. A GliaSite balloon catheter was implanted in 62 patients. Fifty-four patients received brachytherapy. The median patient age was 60 years. The most common tumor (54%) was non–small cell lung cancer. Fifty-seven percent of patients had brain metastasis only, whereas 43% had extracranial metastasis. The median final
administered dose was 60 Gy. The magnetic resonance imaging–determined local control rate, based on several different methods, was 82 to 87%. Both the median patient survival time and the median duration of functional independence were 40 weeks. Among the 35 patients who died, the cause of death was neurological in 11%. Thirteen patients underwent reoperation for suspected tumor recurrence or radiation necrosis, and histological diagnoses included radiation necrosis without tumor (nine patients), radiation necrosis mixed with tumor (two patients), and tumor only (two patients). Extracranial metastasis, tumor size, and radiation necrosis were significant factors affecting patient survival.

**CONCLUSIONS.** In patients with a resected single brain metastasis, GliaSite brachytherapy leads to a local control rate, median patient survival time, and duration of functional independence similar to those achieved with resection plus whole-brain radiation therapy.

**KEYWORDS:** metastasis, brachytherapy, GliaSite, local tumor control