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# A Phase II study of anti-epidermal growth factor receptor radioimmunotherapy in the treatment of glioblastoma multiforme.

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### Abstract

**Object** This single-institution Phase II study tests the efficacy of adjuvant radioimmunotherapy with (125)I-labeled anti-epidermal growth factor receptor 425 murine monoclonal antibody ((125)I-mAb 425) in patients with newly diagnosed glioblastoma multiforme (GBM). **Methods** A total of 192 patients with GBM were treated with (125)I-mAb 425 over a course of 3 weekly intravenous injections of 1.8 GBq following surgery and radiation therapy. The primary end point was overall survival, and the secondary end point was toxicity. Additional subgroup analyses were performed comparing treatment with (125)I-mAb 425 (RIT, 132 patients), (125)I-mAb 425 and temozolomide (TMZ+RIT, 60 patients), and a historical control group (CTL, 81 patients). **Results** The median age was 53 years (range 19-78 years), and the median Karnofsky Performance Scale score was 80 (range 60-100). The percentage of patients who underwent debulking surgery was 77.6% and that of those receiving temozolomide was 31.3%. The overall median survival was 15.7 months (95% CI 13.6-17.8 months). The 1- and 2-year survivals were 62.5 and 25.5%, respectively. For subgroups RIT and TMZ+RIT, the median survivals were 14.5 and 20.2 months, respectively. No Grade 3 or 4 toxicity was seen with the administration of (125)I-mAb 425. The CTL patients lacked Karnofsky Performance Scale scores, had poorer survival, were older, and were less likely to receive radiation therapy. On multivariate analysis, the hazard ratios for RIT versus CTL, TMZ+RIT versus CTL, and TMZ+RIT versus RIT were 0.49 ( $p < 0.001$ ), 0.30 ( $p < 0.001$ ), and 0.62 ( $p = 0.008$ ), respectively. **Conclusions** In this large Phase II study of 192 patients with GBM treated with anti-epidermal growth factor receptor (125)I-mAb 425 radioimmunotherapy, survival was 15.7 months, and treatment was safe and well tolerated.

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