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A Phase I Dose-Escalation Study (ISIDE-BT-1) of Accelerated IMRT with Temozolomide in Patients with Glioblastoma.

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PURPOSE: To determine the maximum tolerated dose (MTD) of fractionated intensity-modulated radiotherapy (IMRT) with temozolomide (TMZ) in patients with glioblastoma. **METHODS AND MATERIALS:** A Phase I clinical trial was performed. Eligible patients had surgically resected or biopsy-proven glioblastoma. Patients started TMZ (75 mg/day) during IMRT and continued for 1 year (150-200 mg/day, Days 1-5 every 28 days) or until disease progression. Clinical target volume 1 (CTV1) was the tumor bed +/- enhancing lesion with a 10-mm margin; CTV2 was the area of perifocal edema with a 20-mm margin. Planning target volume 1 (PTV1) and PTV2 were defined as the corresponding CTV plus a 5-mm margin. IMRT was delivered in 25 fractions over 5 weeks. Only the dose for PTV1 was escalated (planned dose escalation: 60 Gy, 62.5 Gy, 65 Gy) while maintaining the dose for PTV2 (45 Gy, 1.8 Gy/fraction). Dose limiting toxicities (DLT) were defined as any treatment-related nonhematological adverse effects rated as Grade ≥ 3 or any hematological toxicity rated as ≥ 4 by Radiation Therapy Oncology Group (RTOG) criteria. **RESULTS:** Nineteen consecutive glioblastoma were treated with step-and-shoot IMRT, planned with the inverse approach (dose to the PTV1: 7 patients, 60 Gy; 6 patients, 62.5 Gy; 6 patients, 65 Gy). Five coplanar beams were used to cover at least 95% of the target volume with the 95% isodose line. Median follow-up time was 23 months (range, 8-40 months). No patient experienced DLT. Grade 1-2 treatment-related neurologic and skin toxicity were common (11 and 19 patients, respectively). No Grade > 2 late neurologic toxicities were noted. **CONCLUSION:** Accelerated IMRT to a dose of 65 Gy in 25 fractions is well tolerated with TMZ at a daily dose of 75 mg.

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