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### **Phase I/II Trial of Hyperfractionated Concomitant Boost Proton Radiotherapy for Supratentorial Glioblastoma Multiforme.**

[Mizumoto M](#), [Tsuboi K](#), [Igaki H](#), [Yamamoto T](#), [Takano S](#), [Oshiro Y](#), [Hayashi Y](#), [Hashii H](#), [Kanemoto A](#), [Nakayama H](#), [Sugahara S](#), [Sakurai H](#), [Matsumura A](#), [Tokuuye K](#).

Proton Medical Research Center, University of Tsukuba, Tsukuba, Ibaraki, Japan.

**PURPOSE:** To evaluate the safety and efficacy of postoperative hyperfractionated concomitant boost proton radiotherapy with nimustine hydrochloride for supratentorial glioblastoma multiforme (GBM). **METHODS AND MATERIALS:** Twenty patients with histologically confirmed supratentorial GBM met the following criteria: (1) a Karnofsky performance status of  $\geq 60$ ; (2) the diameter of the enhanced area before radiotherapy was  $\leq 40$  cm; and (3) the enhanced area did not extend to the brain stem, hypothalamus, or thalamus. Magnetic resonance imaging (MRI) T(2)-weighted high area (clinical tumor volume 3 [CTV3]) was treated by x-ray radiotherapy in the morning (50.4 Gy in 28 fractions). More than 6 hours later, 250 MeV proton beams were delivered to the enhanced area plus a 10-mm margin (CTV2) in the first half of the protocol (23.1 GyE in 14 fractions) and to the enhanced volume (CTV1) in the latter half (23.1 GyE in 14 fraction). The total dose to the CTV1 was 96.6 GyE. Nimustine hydrochloride (80 mg/m<sup>2</sup>) was administered during the first and fourth weeks. **RESULTS:** Acute toxicity was mainly hematologic and was controllable. Late radiation necrosis and leukoencephalopathy were each seen in one patient. The overall survival rates after 1 and 2 years were 71.1% and 45.3%, respectively. The median survival period was 21.6 months. The 1- and 2-year progression-free survival rates were 45.0% and 15.5%, respectively. The median MRI change-free survival was 11.2 months. **CONCLUSIONS:** Hyperfractionated concomitant boost proton radiotherapy (96.6 GyE in 56 fractions) for GBM was tolerable and beneficial if the target size was well considered. Further studies are warranted to pursue the possibility of controlling border region recurrences.

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