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# A phase I clinical trial of sonodynamic therapy combined with radiotherapy for brainstem gliomas

Linkuan Huangfu<sup>1</sup>, Boya Zha<sup>1</sup>, Peihong Li<sup>1</sup>, Long Wang<sup>1</sup>, Xiaohao Liu<sup>1</sup>, Haiyang Cui<sup>1</sup>, Yuxin Li<sup>1</sup>, Jingjing Wu<sup>1</sup>, Shuling Shi<sup>1</sup>, Yuchuan Yang<sup>1</sup>, Xiaocong Sun<sup>1</sup>, Shibo Gao<sup>1</sup>, Huizhen Li<sup>1</sup>, Daoke Yang<sup>1</sup>, Yingjuan Zheng<sup>1 2</sup>

Affiliations

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## Abstract

Brainstem gliomas (BSGs) are a class of clinically refractory malignant tumors for which there is no uniform and effective treatment protocol. Ultrasound and radiation can activate hematoporphyrin and produce sonodynamic and radiodynamic effects to kill cancer cells. Therefore, we conducted the first phase I clinical trial of sonodynamic therapy (SDT) combined with radiotherapy (RT) for the treatment of BSGs to verify its safety and efficacy. We conducted a study of SDT combined with RT in 11 patients with BSGs who received SDT and RT after hematoporphyrin administration. Magnetic resonance imaging was performed during this period to assess the tumor, and adverse events were recorded. All adverse events recorded were grade 1-2; no grade 3 or more serious adverse events were observed. Treatment was well tolerated, and no dose-limiting toxicities were observed. There were no treatment-related deaths during the course of treatment. 8 of 11 patients (72.7%) maintained stable disease, 2 (18.2%) achieved partial response, and the tumors were still shrinking as of the last follow-up date. The median progression-free survival (PFS) for patients was 9.2 (95% confidence interval [CI] 6.2-12.2) months, and the median overall survival (OS) was 11.7 (95% CI 9.6-13.8) months. Therefore, SDT combined with RT has a favorable safety and feasibility and shows a preliminary high therapeutic potential.

**Keywords:** brainstem glioma; hematoporphyrin; radiodynamics; radiotherapy; sonodynamic therapy.

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