

Wearable medical device improves survival for patients with glioblastoma

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Patients with glioblastoma who wore a medical device that delivers alternating electrical fields in addition to being treated with the chemotherapeutic temozolomide had significantly improved median overall survival compared with those treated with temozolomide only, according to final results from a randomized phase III clinical trial presented here at the AACR Annual Meeting 2017, April 1-5.

"Glioblastoma is the deadliest primary malignancy of the central nervous system for adults," said Roger Stupp, MD, professor of Neurological Surgery at Northwestern University Feinberg School of Medicine and associate director for strategic initiatives at the Robert H. Lurie Comprehensive Cancer Center of Northwestern University. "The last time any form of treatment was shown to improve survival for patients with this disease was more than 10 years ago, when adding temozolomide to radiotherapy was shown to improve the two-year survival rate from 10 percent to 27 percent.

"It is very exciting to see that the magnitude of benefit from adding tumor-treating fields (TTFields) to temozolomide is similar to that seen from adding temozolomide to radiotherapy; the two-year survival rate for those in the TTFields plus temozolomide arm was 43 percent," continued Stupp. "These data show the power of this new treatment modality, and we look forward to learning the results of trials testing it in patients with other forms of cancer."

TTFields are low-intensity electric fields alternating at an intermediate



frequency (200kHz) that are thought to exert anticancer effects by blocking cell division, explained Stupp. For patients with glioblastoma, the TTFields are delivered continuously to the brain by a patient-operated, wearable medical device. "We found that patients learned how to operate the device very quickly, often in less than an hour," said Stupp.

From July 2009 to November 2014, Stupp and colleagues enrolled 695 patients newly diagnosed with glioblastoma in the phase III clinical trial; 466 patients were randomly assigned TTFields delivered by the Optune medical device and temozolomide and 229 were randomly assigned to receive maintenance temozolomide alone.

Interim data from the first 315 patients enrolled in the trial led the U.S. Food and Drug Administration to approve the Optune medical device for newly diagnosed glioblastoma. "Now we are reporting the final results for all 695 patients enrolled on the trial, including long-term outcome. Our data firmly establish the survival benefit of treatment with TTFields," said Stupp.

The median overall survival for patients randomly assigned TTFields and temozolomide was 21 months, compared with 16 months for those randomly assigned temozolomide alone.

The two-, three-, four-, and five-year survival rates for patients who received TTFields and temozolomide were significantly improved compared with those for patients who received temozolomide alone: 43 percent versus 31 percent; 26 percent versus 16 percent; 20 percent versus 8 percent; and 13 percent versus 5 percent. TTFields showed an effect in all subgroups of patients treated, including the patients who have the most unfavorable prognostic factors.

The hazard ratio for overall survival was 0.63, meaning that patients



randomly assigned TTFields and temozolomide had a 37 percent lower risk of death than those randomly assigned temozolomide alone.

"TTFields are an entirely new treatment modality," said Stupp. "We need to continue to think outside the box to find other new treatments and then we need to learn how best to combine them with existing treatment modalities to ensure maximum patient benefit."

More information: Andreas F. Hottinger et al. Tumor treating fields: a novel treatment modality and its use in brain tumors, *Neuro-Oncology* (2016). DOI: 10.1093/neuonc/now182

Roger Stupp et al. Radiotherapy plus Concomitant and Adjuvant Temozolomide for Glioblastoma, *New England Journal of Medicine* (2005). DOI: 10.1056/NEJMoa043330

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