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A prospective, randomized, open-label, phase III clinical trial of NovoTTF-100A versus best standard of care chemotherapy in patients with recurrent glioblastoma.

Sub-category:
CNS Tumors

Category:
Central Nervous System Tumors

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2010 ASCO Annual Meeting

Session Type and Session Title:
Oral Abstract Session, Central Nervous System Tumors

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Abstract:

Background: The NovoTTF is a portable, medical device delivering low intensity, intermediate frequency, alternating electric fields by means of noninvasive, disposable scalp electrodes. These tumor treatment fields (TTF) physically interfere with cell division and assembly of organelles. **Methods:** Adult pts (KPS≥70%) with recurrent GBM were randomized (stratified by surgery for recurrence and center) to either NovoTTF administered continuously (20-24h/day, 7 days/week) or the best standard chemotherapy (BSC) at each physicians' discretion. Number of prior therapies was not limited. Primary endpoint was overall survival (OS). The study was powered (80%) to detect a 60% increase in OS with a two tailed a of 0.05. **Results:** 237 pts were randomized (28 centers in the United States and Europe) to either TTF alone (120 pts) or BSC (117 pts). Patient characteristics were balanced, median age was 54 years (range 23-80), median KPS 80% (50-100). All had prior TMZ/RT, and the majority at least one prior therapy for recurrence. One-quarter had surgery for recurrence. Mean treatment duration was 4.4 mo (0-40) vs. 2.3 mo (0-15), median OS was 6.6 vs. 6.0 months for TTF and BSC, respectively (p=0.23, hazard ratio 0.84 [95% CI 0.63-1.12]), the 1-year survival rate 23.6% versus 20.8% (ns). PFS6 was 17.6% in both groups. Time to treatment failure favored the TTF group (HR 0.76 [0.57-1.02], p=0.07). Objective responses were more common in the TTF arm (12%) versus the BSC (6%). Related adverse events were mild-to-moderate skin rash beneath the electrodes in 17% of TTF treated pts. Hematological and other toxicities were observed at a significantly higher incidence in the BSC arm depending on the type of chemotherapy, no treatment-related deaths occurred. Treatment compliance with TTF was excellent with a median duration 20 hours/day. **Conclusions:** This is the first phase III,

controlled clinical trial testing TTF, an entirely novel treatment modality. TTF had minimal toxicity, long-term treatment proved feasible. TTF as a single modality showed a higher response rate and longer time to treatment failure compared to best available chemotherapy. Overall survival also favored TTF, but did not reach statistical significance. In view of the above, TTF should be considered a valid novel treatment modality.

Abstract Disclosures

Faculty & Discussant Disclosures

Annual Meeting Planning Committee Disclosures

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Associated Presentation(s):

1. A prospective, randomized, open-label, phase III clinical trial of NovoTTF-100A versus best standard of care chemotherapy in patients with recurrent glioblastoma.

Meeting: 2010 ASCO Annual Meeting
Presenter: Roger Stupp
Session: Central Nervous System Tumors (Oral Abstract Session)

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1. Multicenter randomized phase II trial of methotrexate (MTX) and temozolomide (TMZ) versus MTX, procarbazine (PCB), vincristine (VINC), and cytarabine (Ara-C) for primary CNS lymphoma (PCNSL) in elderly patients.

Meeting: 2010 ASCO Annual Meeting Abstract No: TPS144 First Author: A. M. Omuro
Category: Central Nervous System Tumors - CNS Tumors

2. Phase II trial of chemotherapy with temozolomide in combination with topotecan for central nervous system (CNS) metastases of solid tumors.

Meeting: 2010 ASCO Annual Meeting Abstract No: TPS145 First Author: P. Z. New
Category: Central Nervous System Tumors - CNS Tumors

3. Phase I study of bendamustine and fractionated stereotactic radiotherapy (FSRT) in patients with one to three brain metastases from solid malignancies.

Meeting: 2010 ASCO Annual Meeting Abstract No: TPS146 First Author: J. C. Grecula
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Abstracts by R. Stupp:

1. A prospective, randomized, open-label, phase III clinical trial of NovoTTF-100A versus best standard of care chemotherapy in patients with recurrent glioblastoma.

Meeting: 2010 ASCO Annual Meeting Abstract No: LBA2007 First Author: R. Stupp
Category: Central Nervous System Tumors - CNS Tumors

2. Cilengitide in newly diagnosed glioblastoma with *MGMT* promoter methylation: Protocol of a multicenter, randomized, open-label, controlled phase III trial (CENTRIC).

Meeting: 2010 ASCO Annual Meeting Abstract No: TPS152 First Author: R. Stupp
Category: Central Nervous System Tumors - CNS Tumors

3. Glioblastoma (GBM) in elderly patients: A randomized phase III trial comparing survival in patients treated with 6-week radiotherapy (RT) versus hypofractionated RT over 2 weeks versus temozolomide single-agent chemotherapy (TMZ).

Meeting: 2010 ASCO Annual Meeting Abstract No: LBA2002 First Author: A. Malmstrom
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Presentations by R. Stupp:

1. A prospective, randomized, open-label, phase III clinical trial of NovoTTF-100A versus best standard of care chemotherapy in patients with recurrent glioblastoma.

Meeting: 2010 ASCO Annual Meeting
Presenter: Roger Stupp, MD
Session: Central Nervous System Tumors (Oral Abstract Session)

2. Cilengitide in newly diagnosed glioblastoma with *MGMT* promoter methylation: Protocol of a multicenter, randomized, open-label, controlled phase III trial (CENTRIC).

Meeting: 2010 ASCO Annual Meeting
Presenter: Roger Stupp, MD
Session: Trials in Progress Poster Session (Trials in Progress Poster Session)

3. Phase II trial of the epothilone analog sagopilone (ZK219477; ZK EPO) in patients with recurrent glioblastoma: Initial report of the EORTC study 26061.

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