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## Efficacy of nitrosourea-based chemotherapy in recurrent malignant glioma according to time to adjuvant temozolomide failure: A pooled analysis.

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### Abstract Disclosures

### Abstract

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**Background:** Concomitant and adjuvant temozolomide (TMZ) is the standard of care of the first-line treatment in glioblastoma (GBM) patients. At recurrence patients have few therapeutic options and the use of nitrosoureas, alternative schedule of TMZ and new target therapy have been widely studied. Recently Perry and colleagues (JCO 2010;28:2051-2057) have demonstrated that time to adjuvant temozolomide failure seems to be predictable to dose-intense TMZ treatment. The aim of our pooled analysis was to assess the efficacy of nitrosourea in recurrent GBM patients according to time to adjuvant TMZ progression.

**Methods:** Patients with GBM who failed the standard Stupp regimen have been treated with a nitrosoureas based regimen of fotemustine (FTM) 75-100mg/sqm at day 1, 8, 15 (induction phase) and after 4/5 weeks of rest 100 mg/sqm every 21 days. The primary endpoint of the study was 6-months progression free survival (PFS-6m). Overall survival at 1 year (OS1y), response rate (RR) and toxicity were secondary endpoints. Patients were stratified in 3 groups according to time to TMZ failure: GBM patients failing during the first 6 months of adjuvant TMZ (B1), those who failed after more than 6 months of therapy (B2) and GBM patients who recurred after a treatment-free interval (B3).

**Results:** Six Italian centers participated in this study. At that time preliminary results are available: 119 patients with recurrent GBM have been evaluated. Results have been summarized in the table.

**Conclusions:** Nitrosourea is a valuable therapeutic option for patients with recurrent GBM, not depending on time to adjuvant temozolomide failure and also patients recurred after 6 cycles of adjuvant TMZ (B2) seem to get a benefit from FTM treatment. A prospective randomized trial is warranted to define if TMZ and FTM have a different pattern of response in recurrent GBM.

	B1 (%)			B2 (%)			B3 (%)		
	PSF-6m	OS1y	RR	PSF-6m	OS1y	RR	PSF-6m	OS1y	RR
<b>FTM</b>	24.5	24.5	12.2	31.3	31.3	18.8	34.2	28.9	7.9
<b>TMZ*</b>	27.3	27.3	3	7.4	14.8	0	35.7	28.6	11.1