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
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Meeting: [2005 ASCO Annual Meeting](#)
Category: [Central Nervous System Tumors](#)
SubCategory: [CNS Tumors](#)

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Phase II trial of thalidomide (TD), tamoxifen (TX), and temozolomide (T) for patients with advanced malignant gliomas (MG).

Abstract No: 1575

Author(s): T. Ahmed, B. Chen, G. Rabbani, M. N. Wallam, D. Benzil

Abstract: **Background:** Patients with MG have a poor survival despite surgery, radiation therapy (RT). Chemotherapy (CTX) is often used but the overall impact on survival is poor. **Methods:** We studied the combination of TD, TX and T in a phase II trial for patients with MG. Standard response criteria and NCI toxicity criteria were used. We also assessed quality-of-life (QoL). Eligibility criteria included histologic confirmation of Glioblastoma (GBM) or Anaplastic astrocytoma (AA), no chemo or RT for 3 weeks and ECOG PS of ≤ 2 . 20 patients entered the trial: 8 were female; median age 51 years (r 24-84); 17 had GBM and 3 had AA. 9 patients had prior RT and 5 prior CTX. 28-day treatment cycles consisted of daily TD 100 mg PO and TX 100 mg PO for the full duration of each cycle and T 75 mg/m² PO) for the first 21 days of each cycle. Treatment continued until disease progression. Primary outcomes measures were patient survival, response, toxicity and changes in QoL. **Results:** 6 patients discontinued therapy prior to response evaluation. 9 of 14 patients had disease stabilization and response (64%, 95% CI, 39%-89%), lasting 8-135 weeks (median 12 weeks) documented by MRI scan. No CR was seen. One patient remained progression free for 2 years. By Kaplan Meier analysis, mean survival was 75 \pm 18 weeks (95% CI, 41-110 weeks) with a median time to progression of 47 weeks (95% CI, 15-79 weeks). One patient had a sustained decrease in WBC and T was held. Mean WBC was 9.4 x10e3/ul, which fell to a mean of 5.58 x 10e3/ul. Hgb and platelets were not significantly affected. 4 patients developed deep vein thrombosis (DVT): subsequent patients were given prophylactic warfarin. 2 patients had pulmonary embolism. No other grade 3 or 4 toxicities were noted. Changes in QoL scores during treatment did not significantly correlate with disease progression. **Conclusions:** Outpatient therapy with temozolomide, thalidomide, and tamoxifen is well tolerated and results in stabilization/response in 64% of patients. Prophylaxis with warfarin may prevent DVT in patients on tamoxifen. The overall impact on survival will require further study. Supported by the ZA Arlin Cancer Research Institute, Schering-Plough Corp. and Celgene Corp

Associated Presentation(s):

A presentation was not made on this abstract

Other Abstracts in this Sub-Category:

1. **[RTOG 0118: A Phase III Study of Conventional Radiation Therapy Alone vs. Conventional Radiation Therapy Plus Thalidomide for Multiple Brain Metastases](#)**

Meeting: 2005 ASCO Annual Meeting Abstract No: 1500 First Author: J. P. Knisely

2. **[Prognostic factors for patients with newly diagnosed low-grade oligodendroglial tumors: molecular genetics, histopathology, and neuroimaging](#)**

Meeting: 2005 ASCO Annual Meeting Abstract No: 1501 First Author: L. S.



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3. **NCCTG 94-72-53: Diagnostic and prognostic significance of 1p and 19q deletions in patients (pts) with low-grade oligodendroglioma and astrocytoma.**
Meeting: 2005 ASCO Annual Meeting Abstract No: 1502 First Author: J. C. Buckner
4. **First analysis of EORTC trial 26951, a randomized phase III study of adjuvant PCV chemotherapy in patients with highly anaplastic oligodendroglioma**
Meeting: 2005 ASCO Annual Meeting Abstract No: 1503 First Author: M. J. van den Bent
5. **Results from phase II trial of Enzastaurin (LY317615) in patients with recurrent high grade gliomas**
Meeting: 2005 ASCO Annual Meeting Abstract No: 1504 First Author: H. A. Fine
6. **N997B: Phase II Trial of CCI-779 in Recurrent Glioblastoma Mutiforme (GBM): Updated Results and Correlative Laboratory Analysis**
Meeting: 2005 ASCO Annual Meeting Abstract No: 1505 First Author: E. Galanis
7. **Final results of Phase I/II studies of IL13-PE38QQR administered intratumorally (IT) and/or peritumorally (PT) via convection-enhanced delivery (CED) in patients undergoing tumor resection for recurrent malignant glioma**
Meeting: 2005 ASCO Annual Meeting Abstract No: 1506 First Author: M. Prados
8. **Phase II study of erlotinib in recurrent GBM: Molecular predictors of outcome**
Meeting: 2005 ASCO Annual Meeting Abstract No: 1507 First Author: T. Cloughesy
9. **NCCTG N047D: Relationship between Phase II Endpoints of 12 Month Overall Survival and 6 Month Progression-free Survival for Glioblastoma Multiforme (GBM) Phase II trials**
Meeting: 2005 ASCO Annual Meeting Abstract No: 1508 First Author: K. V. Ballman
10. **Prognostic factors for survival in adult patients with recurrent glioma enrolled on New Approaches to Brain Tumor Therapy (NABTT) CNS Consortium phase I and II clinical trials**
Meeting: 2005 ASCO Annual Meeting Abstract No: 1509 First Author: K. Carson

Other Abstracts by Author: T. Ahmed

1. **Comparison of aprepitant combination regimen with 3-day ondansetron + 4-day dexamethasone for prevention of acute and delayed nausea/vomiting after cisplatin chemotherapy**
Meeting: 2005 ASCO Annual Meeting Abstract No: 8007 First Author: H. J. Schmoll
2. **High-dose therapy with autologous stem cell rescue in patients with breast cancer at high risk for relapse**
Meeting: 2005 ASCO Annual Meeting Abstract No: 824 First Author: S. Farjami

1. PET scan-positive cat scratch disease in a patient with T cell lymphoblastic lymphoma.

Leuk Res, England

Vol 29, No 5 (3/10/2005): pp. 591-4

PMID: 15755513 [PubMed - in process]

2. Phosphodiesterase 4B (PDE4B) and cAMP-level regulation within different tissue fractions of rat hippocampal slices during long-term potentiation in vitro.

Brain Res, Netherlands

Vol 1041, No 2 (4/15/2005): pp. 212-22

PMID: 15829230 [PubMed - in process]

3. Long-term survival of patients with resistant lymphoma treated with tandem stem cell transplant.

Leuk Lymphoma, England

Vol 46, No 3 (12/29/2004): pp. 405-14

PMID: 15621831 [PubMed - in process]