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Pilot study of dronabinol for adult patients with primary malignant gliomas

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Abstract

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Background: Chemotherapy-induced nausea and vomiting (CINV) are common adverse effects from chemotherapy. While most treatments administered in patients with primary gliomas are not highly emetogenic, up to 50% of neuro-oncology patients report CINV despite 5HT₃ or steroid therapies. Adjuvant benzodiazepines frequently alter mental status. Dronabinol may provide a safe alternative option without compromise of neurological status. This study seeks to describe toxicities (TOX) associated with dronabinol administration in neuro-oncology patients. A secondary aim is to describe the impact that dronabinol has on their quality of life (QOL). **Methods:** This is an exploratory study of adult patients with WHO Grade III/IV primary gliomas on adjuvant chemotherapy. Power analysis determined a sample size of 34 subjects for 0.80 effect size. Enrollment is ongoing with 18/34 adult patients accrued. Patients take dronabinol 5 mg BID 24 hours prior to, during, and 48 hours after completion of oral/IV chemotherapy. Patients continue their established antiemetic regimen. Between chemotherapy doses, dronabinol is reduced to 2.5 mg daily. Intolerance of dronabinol is defined as 2 or more Grade 3 or greater non-hematologic TOX according to the CTC v.3 definition handbook. Modified Functional Living Index-Emesis (FLIE), Functional Assessment of Cancer Therapy-Brain Tumor (FACT-Br), Mini Mental Status Exam (MMSE), and CINV visual analog scales are collected at specific points for 2 cycles for TOX and QOL data. **Results:** Subjects are predominately male (n=10); mean age of 45.2 years. Four withdrew due to Grade 3 neurologic TOX of cognitive changes (n=3) despite decreasing dosages; Grade 3 persistent CINV (n=1) despite increasing dronabinol dosage. Increased dosages were required in 4 subjects to better manage CINV. Two required decreased doses for Grade 2 neurologic TOX. Most subjects (n=14) reported stable or improved QOL by FACT-Br and FLIE while the 4 withdrawn subjects reported worsening QOL related to TOX. **Conclusions:** Dronabinol is safe and effective for administration as an adjunct to standard antiemetic therapy during treatment for primary glioma. The dose may be titrated with minimal toxicities and improvement in QOL.

No significant financial relationships to disclose.