A Randomized Trial on the Efficacy of Topical Anesthesia on Pain Reduction during Frame Placement for Stereotactic Radiosurgery

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Abstract

Objectives: Frame application for stereotactic radiosurgery may be perceived as painful by patients. Topically applied EMLA (2.5% Lidocaine/2.5% Prilocaine) has been used to alleviate pain caused by injection of local anesthetic before frame placement. This study was designed to assess the efficacy of EMLA for pain reduction.

Methods: This was a prospective, randomized and controlled trial approved by our IRB. Pre-study statistical analysis indicated that we would need to enroll 54 patients in 2 groups of 27. The study was designed to observe a difference of 1.0 on the VAS scale at a power of 95%. All patients were having outpatient radiosurgery for a variety of intracranial neoplasms. They were pretreated with oral narcotic and benzodiazepine medication the morning of the procedure. Fifteen minutes before frame application either EMLA or placebo cream was applied to the patient’s forehead. Neither the patients nor providers knew if EMLA or placebo was applied. Patients used a VAS scale to rate their experience during frame fixation at four separate intervals – during the two frontal injections, the two occipital injections, placement of the two frontal screws, and overall level of discomfort during the fixation procedure.

Results: Study and control groups were controlled for age and diagnosis of metastatic tumors or benign intracranial neoplasms. The VAS for EMLA vs. placebo on the front injections (5.2±2.7 vs. 5.7±2.0 respectively, p<.45), the back injections, (6.5±2.2 vs. 5.9±2.3 respectively, p<.30), the two front pins (4.6±2.7 vs. 4.6±2.2 respectively, p<.99) and the overall level of discomfort (4.2±2.8 vs. 3.4±2.5 respectively, p<.29) was not significantly different between the two groups. Comparison between back and front injections for EMLA (6.54 vs. 5.19 respectively, p<0.16) and placebo (5.89 vs. 5.68 respectively, p<0.69) did not show significant difference between group and location (p<0.21).

Conclusions: Use of EMLA did not result in significant pain reduction when used as a preoperative supplement for stereotactic frame fixation. EMLA is no longer used as part of our routine for patients undergoing frame-based stereotactic radiosurgery.