

A Double-Blind, Placebo-Controlled Study of Transnasal Sphenopalatine Ganglion Blockade with Tx360[®] in the Treatment of Chronic Migraine: Evaluation of Clinical Outcomes

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Background

The Sphenopalatine Ganglion (SPG) is a small concentrated structure of neuronal tissue that resides within the pterygopalatine fossa (PPF) in close proximity to the sphenopalatine foramen. The SPG is innervated by the maxillary division of the trigeminal nerve and has a sensory, parasympathetic, and sympathetic component. It has been implicated in several orofacial pain conditions including migraine. Access to this structure can be gained via a small area of mucosa just posterior and superior to the tail of the middle turbinate on the lateral nasal wall. Blocking the SPG using local anesthetics may relieve pain associated with chronic migraine. Unfortunately, many current interventions are cumbersome, invasive, and expensive. Some are associated with significant and sometimes serious adverse events.

The purpose of this study is to evaluate the safety and efficacy of 0.5% bupivacaine sphenopalatine ganglion blockades for the treatment of chronic migraine delivered via the Tx360[®] device. This device contains a small, flexible, soft plastic tube that is advanced below the middle turbinate just past the pterygopalatine fossa. The plastic tube can then be rotated laterally on a preset track and extended into the intranasal space. A total of 0.3 cc of anesthetic (0.5% bupivacaine) is injected through the tube and directed to the mucosa covering the SPG. The procedure is performed similarly in each nostril.

Objectives

This pilot study aimed to evaluate the Tx360[®] device through the review of clinical outcomes in a chronic migraine population.

Primary Objective

- To compare the Numeric Rating Scale (NRS) score between bupivacaine and saline.

Secondary Objectives

- Compare the change in the number of headache days between bupivacaine and saline.
- Patient's Global Impression of Change (PGIC) score for bupivacaine vs. saline.
- Acute Medication usage between bupivacaine and saline.
- Adverse events of subjects receiving SPG block with bupivacaine vs. saline.

Demographic Characteristics

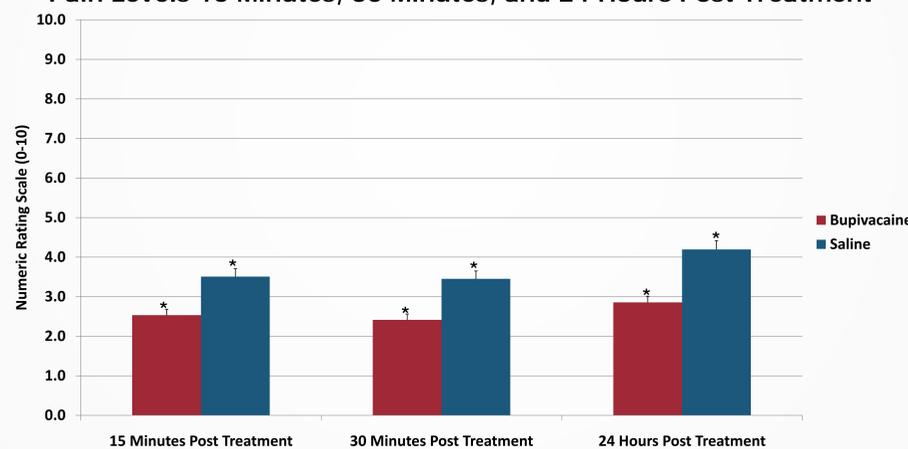
Fifty-five subjects were screened for this study, meeting the proposed sample size of 42 subjects. The study population consisted of 41 subjects randomized per protocol. Subjects included 10 males and 31 females between the ages of 18-67 and a mean age of 41.30 with a diagnosis of ICHD-II definition of chronic migraine. The average length of chronic migraine diagnosis was 8.58 years. Subjects, on average, experienced 15.24 migraines and 23.63 headaches in a month during baseline. Of the randomized population, 34 were Caucasian, 4 were African American, and 3 Other. Forty subjects completed treatment, although 3 subjects had protocol violations and were therefore removed from the study. A total of 38 subjects were analyzed; 26 subjects treated with bupivacaine and 12 with saline.

Methods

This was a 2 center, randomized, double-blind, placebo controlled study consisting of 55 screened subjects, 18 to 67 years of age, meeting the definition of chronic migraine. Subjects were asked to complete a daily baseline headache diary for 28 days. Following the baseline period, subjects meeting the diagnostic criteria for chronic migraine per diary analysis were randomized 2:1 receiving either 0.3 cc of 0.5% bupivacaine or saline delivered to the mucosal surface of the SPG through each nares with the Tx360[®] device. The procedure was repeated twice weekly for 6 weeks. Subjects continued to complete a daily headache diary throughout the treatment period and 1 month post treatment. Also during the treatment period, subjects completed a battery of questionnaires 15 and 30 minutes post treatment, as well as 24 hours post treatment.

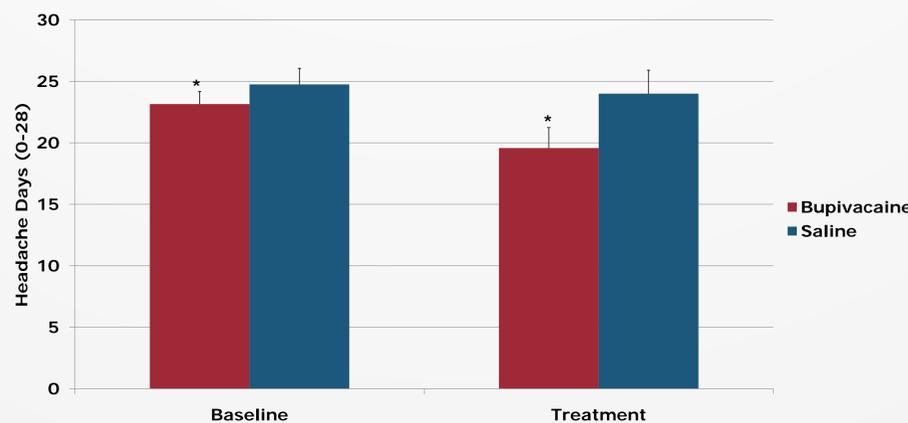
Results

Subjects Treating with Bupivacaine Had Significant Reductions in Pain Levels 15 Minutes, 30 Minutes, and 24 Hours Post Treatment



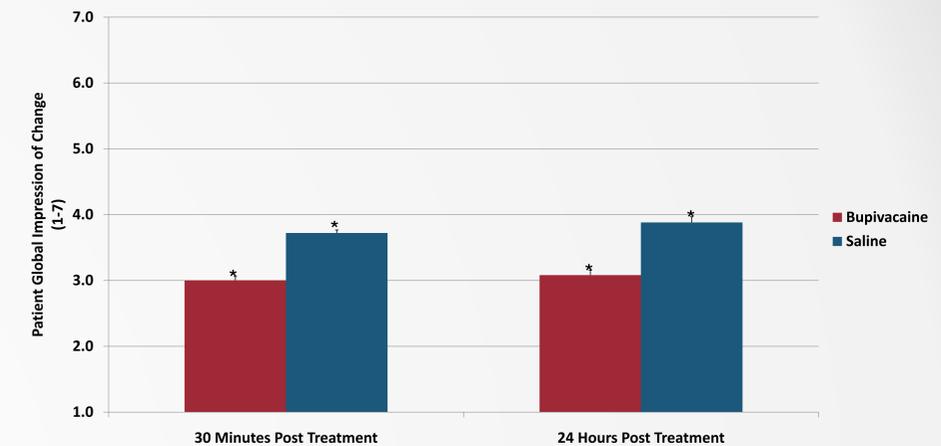
There was a reduction in the NRS in subjects receiving bupivacaine compared to saline at 15 min (3.51 vs 2.53, $p < .001$), 30 min (3.45 vs 2.41, $p < .001$), and 24 hours post treatment (4.20 vs 2.85, $p < .001$) when pooling all twelve treatments. Subjects in the treatment group had a reduction in the number of headache days per month from baseline to the end of treatment period while the sham group did not (-3.58 days vs. -0.75 days, $p < 0.01$).

Subjects Treated With Bupivacaine Had a Significant Decrease in the Number of Headache Days From Baseline



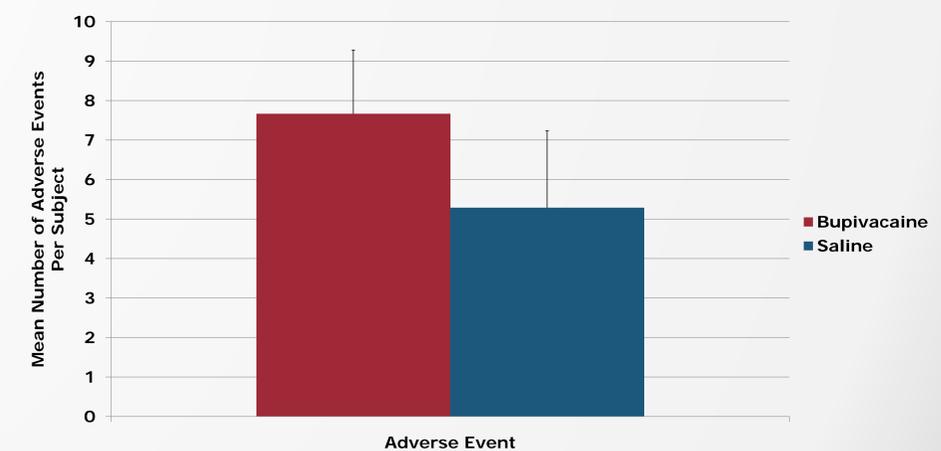
Results

Subjects Treating with Bupivacaine Reported Greater Levels of Change Than Those Treating with Saline



Subjects receiving bupivacaine reported significantly improved levels of Patient Global Impression of Change (PGIC) scores compared to those treating with saline, ($p < .001$) at both 30 minutes and 24 hours post treatment. Total acute medication usage was similar between the two groups. However, the average usage of opioids per subject during the treatment phase was lower in the bupivacaine group compared to the saline group (8.33 vs. 45.7). There was no difference in non-serious and serious adverse events between groups.

Adverse Event Reporting Was Similar for Both Groups



Conclusion

SPG blocks using the Tx360[®] device provide rapid and sustained migraine relief for a population of patients with chronic migraine. Importantly, subjects in the treatment group experienced a significant reduction in headache days during the treatment. This study provides evidence for the effectiveness and tolerability of treating chronic migraine with the Tx360[®] device.