Zolmitriptan Quickly Aids Acute Cluster Headache

BY DIANA MAHONEY
New England Bureau

Intranasal zolmitriptan is an effective, well-tolerated treatment for acute cluster headache, a study has shown.

Both 5-mg and 10-mg doses of the selective serotonin (5-HT) receptor agonist demonstrated significantly higher rates of headache relief 30 minutes after administration than did placebo in a randomized, placebo-controlled, double-blind crossover trial, according to lead investigator Dr. Elizabeth Cittadini of London's National Hospital for Neurology and Neurosurgery and colleagues.

Already proved an effective treatment for acute migraine, intranasal zolmitriptan has been shown to be effective for acute cluster headache in an earlier preliminary single-blind study. In the present study, investigators sought to assess the drug's efficacy compared with placebo in the acute treatment of cluster headache attacks lasting at least 45 minutes using a crossover study design intended both to facilitate recruitment and to provide homogeneity for comparisons, the authors wrote (Arch. Neurol. 2006 Sept. 11 [Epub doi:10:1001/archneur.63.11.nct60002]).

Of those attacks treated with the 5-mg and 10-mg doses of zolmitriptan nasal spray, significantly more patients reported headache relief at 30 minutes.

Of 92 patients recruited for the study, 69 were available for an intention-to-treat analysis; their mean age was 40 years. Each patient was asked to treat three cluster headache attacks at least 24 hours apart using placebo for one attack and 5 mg and 10 mg of zolmitriptan nasal spray for each of the other two attacks.

For purposes of the study, participants first rated their pain at the time of the attack on a scale of 1-5, ranging from no pain to very severe pain. They then applied one dose of either active agent or placebo in the contralateral nostril when the headache reached moderate severity and then reassessed their pain at 5, 10, 15, and 30 minutes. The primary study outcome was the combined headache response at 30 minutes, compared with placebo.

Patients in the study were allowed to use either oxygen or analgesic as escape medication at 30 minutes post dose if necessary; investigators did not allow use of either a triptan or an ergotamine derivative. Use of escape medication within 30 minutes was considered a treatment failure.

A total of 65 attacks were treated with 5-mg zolmitriptan nasal spray, 63 were treated with the 10-mg dose, and 61 were treated with placebo. Of those attacks treated with the 5-mg and 10-mg doses, 27 and 38 patients, respectively, reported headache relief at 30 minutes, significantly more than the 14 patients who reported headache relief with placebo. Additionally, with the 5-mg and 10-mg doses, 18 and 31 patients, respectively, were pain free at 30 minutes, significantly more than the 10 patients with placebo.

The investigators also evaluated the impact of zolmitriptan on associated symptoms occurring immediately before treatment, including, most frequently, conjunctival injection/lacrimation, nasal congestion/rhinorrhea, and ptosis/eyelid edema. Although no statistical analysis was performed because of multiple comparison issues, numerically more patients reported relief from associated symptoms when treated with either dose of zolmitriptan, the authors wrote.

Study participants used escape medication in 30 placebo-treated attacks, compared with 23 of the 5-mg treatment and 17 of the 10-mg treatment attacks.

No serious adverse events were reported in either zolmitriptan- or placebo-treated attacks. One withdrawal occurred in a patient treated with 5-mg zolmitriptan who reported shortness of breath, vomiting, and rheumatic pain.

The findings suggest that zolmitriptan nasal spray can be used as a first-line abortive therapy for managing cluster headache. Because there is good evidence of safety with the 15-mg daily dose of the drug for migraine, it may be safe to give three 5-mg doses of the agent in a 24-hour period for patients who do not respond to oxygen and subcutaneous sumatriptan.

AstraZeneca provided support for the study but did not initiate or design it or analyze the data, said the authors. ■