Frovatriptan as Preemptive Treatment for Fasting-Induced Migraine

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OBJECTIVE:

To examine frovatriptan's efficacy as preemptive treatment for fasting-induced migraine.

BACKGROUND:

Fasting is a common trigger of migraine. Since it cannot always be avoided, the development of a short-term preemptive approach would benefit migraineurs. Frovatriptan, because of its longer half-life, has been effectively used for short-term daily use to prevent menstrually related migraines, and might prove useful in the prevention of fasting-induced migraine.

METHODS:

- Double-blind, placebo-controlled, randomized, parallel-group trial.
- Subjects with a history of fasting-induced episodic migraine were randomly assigned to receive either frovatriptan 5.0 mg. or placebo (ratio 1:1).
- Subjects took a single dose of study medication at the start of their 20-hour fast.
- Headache development, severity, and rescue use were captured at defined time points from the start of the fast through 20 hours after the start of the fast.

RESULTS:

- 75 subjects screened; 74 randomized.
- All subjects who took study drug were included in safety analyses (N=71).
- 67 subjects included in efficacy analyses.
- There was no statistical difference between the 2 treatment groups with respect to the development of a headache (Pearson Chi-Square, p=0.172).
- Kaplan-Meier (KM) survival analysis showed no difference between the 2 treatment groups with respect to the time of onset of a headache of any intensity (Log Rank, p=0.264). There was also no difference between the 2 groups with respect to the time of onset of a headache of moderate or severe intensity (Log Rank, p=0.634).

Demographic and Headache Characteristics of the Two Treatment Groups

	Frovatriptan (N=33)	**Placebo** (N=34)	
Gender	26 (78.8%) female	26 (76.5%) female	p=0.820
Age: Mean ± SD (Range)	40.15 ± 11.8 (21-65)	38.7 ± 12.7 (22-65)	p=0.625
# migraine attacks/month Mean ± SD (Range)	3.88 ± 1.47 (1-6)	3.85 ± 1.42 (2-6)	p=0.942
Preventive use	16 (45.4%)	14 (41.2%)	p=0.580

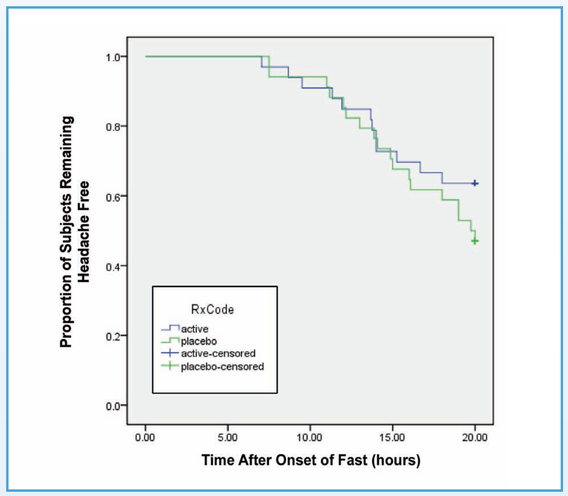
Development of Headache at 6 to 20 Hours After Onset of Fast

Treatment Group	No Headache	Mild Headache	Moderate or Severe*
Frovatriptan	21 (63.6%)	1 (3.0%)	11 (33.3%)
Placebo	16 (47.1%)	4 (11.8%)	14 (41.2%)

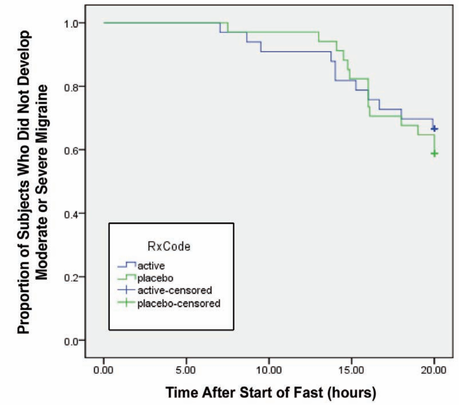
p=0.172 NS

*Subject developed headache of moderate to severe intensity, or developed a mild headache after a minimum of 6 hours that became moderate or severe within 20 hours.

Time to Development of Headache of Any Intensity



Development of Headache of Moderate or Severe Intensity



CONCLUSION:

- More subjects on placebo developed a headache than did those on frovatriptan.
- Our pilot study did not achieve statistical significance, perhaps because of the small number of subjects.
- Because of frovatriptan's effectiveness as a short-term preventive for menstrual migraine, a larger study to address the effectiveness of frovatriptan for the prevention of fasting-induced migraine may be warranted.

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