

Gender and triptan efficacy: a pooled analysis of three double-blind, randomized, crossover, multicenter, Italian studies comparing frovatriptan vs. other triptans

E. Franconi¹, S. Omboni², D. Zava³, A. Casini⁴

¹Farmacologia Cellulare e Molecolare, Facoltà di Farmacia dell'Università di Sassari; ²Clinical Research Unit, Italian Institute of Telemedicine, Varese, Italy; ³Istituto Lusofarmaco d'Italia, Peschiera Borromeo, Milano, Italy; ⁴Menarini Industrie Farmaceutiche Riunite, Firenze, Italy.

Background: migraine is twice as common in females as in males, and attacks may be more severe and difficult to treat in women. However, no study specifically addressed possible gender differences in response to antimigraine therapy although some triptans such as frovatriptan, rizatriptan, zolmitriptan but not almotriptan may have higher C_{max} in women than in men (Ferrari A. et al J Headache Pain 2011;12:5-12).

Objective: to review the efficacy of frovatriptan vs. other triptans, in the acute treatment of migraine in subgroups of subjects classified according to gender (males vs. females) through a pooled analysis of three individual randomized Italian studies.

Methods: 346 patients suffering from migraine with or without aura were randomized to frovatriptan 2.5 mg or rizatriptan 10 mg (study 1), frovatriptan 2.5 mg or zolmitriptan 2.5 mg (study 2), frovatriptan 2.5 mg or almotriptan 12.5 mg (study 3). All studies had a multicenter, randomized, double-blind, crossover design. After treating 1 to 3 episodes of migraine in no more than 3 months with the first treatment, patients switched to the other treatment for the next 3 months. In this analysis traditional migraine endpoints were compared between males (n=66, mean age±SD: 39±10 years) and females (n=280, mean age±SD: 38±10 years) of the intention-to-treat population.

Results: at baseline, long-term and debilitating migraine attacks were more frequently reported by females than males. During the observation period, the proportion of pain free attacks at 2 hours did not significantly differ between males and females for either frovatriptan (30% vs. 30%) or the comparators (37% vs. 34%). Pain relief was also similar between males and females (53% vs. 56% frovatriptan and 60% vs. 58% for comparators). Rate of relapse at 48 hours with frovatriptan was significantly lower in males than females (16% vs. 29%) and significantly larger with the comparators (39% males and 40% females, $p<0.05$ vs. frovatriptan). No difference in the occurrence of adverse events was reported between triptan-treated males and females.

Conclusions: our study confirms that migraine is more difficult to treat in females than in males and that, at variance from other triptans, frovatriptan retains its favorable sustained antimigraine effect regardless of the gender.