

Suggested randomized, controlled trial for frovatriptan: a reply

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Dear Sir,

We read with interest the comments of Dr. Tfelt-Hansen [1] regarding our three recently published randomized controlled trials comparing patients' preference (primary endpoint) and efficacy (secondary endpoints) of frovatriptan 2.5 mg versus zolmitriptan 2.5 mg [2], rizatriptan 10 mg [3] and almotriptan 12.5 mg [4], and the meta-analysis of pooled individual data from the three studies [5]. In all studies frovatriptan showed similar preference and short-term efficacy outcomes (pain relief and pain-free episodes at 2 h) with respect to the other three triptans.

The questions put by Dr. Tfelt-Hansen sound appropriate. Doubts are raised on the usefulness of head-to-head preference trials of triptans and on the actual translation of their results into the clinical practice. We agree that patients may probably switch over time from one triptan to

another because of individual preference, which might not be in line with results of randomized, controlled, comparative studies. However, the availability of results of head-to-head preference and efficacy trials may help physicians to make a first choice which might be very close to the actual patient's preference. We should remind that some evidence on triptan preference in clinical practice does exist, even if we recognize that a tighter link between trials and clinical practice might be developed, for instance, by appropriate surveys [6, 7].

It is true that some guidelines usually refer to simple (and cheaper) oral analgesics and anti-emetics or prokinetic as the first line treatment of acute migraine, escalating to a (more expensive) triptan if this approach fails [8, 9]. This might sound reasonable in terms of the efficacy, because, as mentioned by Dr. Tfelt-Hansen, a meta-analysis showed that aspirin and sumatriptan act similarly in migraineurs [10]. More recently a publication from the same group showed a good efficacy of aspirin in treatment of acute migraine of moderate or severe intensity [11]. However, we think that a comparative study with sumatriptan, namely the oldest among triptans, might not be ideal, because newer triptans have been proved to be more effective than sumatriptan, with differences in the onset time of headache relief according to the characteristics of the studied triptan [12, 13]. Even though the efficacy of some triptans and aspirin might be similar in the acute phase of migraine, it is undisputable that triptans have a more definite place in treatment of chronic and recurrent migraine attacks in the most published guidelines. In addition, oral analgesics, like aspirin, are not an exempt from adverse events, as shown by a recent meta-analysis [14]. At the light of the current evidence we think that choice of use of non-steroidal anti-inflammatory-drugs or triptans for treatment of migraine headache should be

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based on several considerations, including characteristics of migraine, drug efficacy, patient's preference and drug safety in the individual subject. Unfortunately, only a few of these aspects are taken into account in the current recommendations.

Conflict of interest All authors have occasionally served as scientific consultants for manufacturers of frovatriptan, zolmitriptan, rizatriptan or almotriptan.

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References

1. Tfelt-Hansen P, Steiner TJ (2011) Suggested randomized, controlled trial with frovatriptan. *J Headache Pain*. doi:10.1007/s10194-011-0381-x
2. Tullo V, Allais G, Ferrari MD, Curone M, Mea E, Omboni S, Benedetto C, Zava D, Bussone G (2010) Frovatriptan versus zolmitriptan for the acute treatment of migraine: a double-blind, randomized, multicenter, Italian study. *Neurol Sci* 31(Suppl 1): S51–S54
3. Savi L, Omboni S, Lisotto C, Zanchin G, Ferrari MD, Zava D et al (2011) A double-blind, randomized, multicenter, Italian study of frovatriptan versus rizatriptan for the acute treatment of migraine. *J Headache Pain* 12:219–226
4. Bartolini M, Giamberardino MA, Lisotto C, Marteletti P, Moscato D, Panascia B et al (2011) A double-blind, randomized, multicenter, Italian study of frovatriptan versus almotriptan for the acute treatment of migraine. *J Headache Pain* 12:361–368
5. Cortelli P, Allais G, Tullo V, Benedetto C, Zava D, Omboni S, Bussone G (2011) Frovatriptan versus other triptans in the acute treatment of migraine: pooled analysis of three double-blind, randomized, cross-over, multicenter, Italian studies. *Neurol Sci* 32(Suppl 1):S95–S98
6. Lipton RB, Cutrer FM, Goadsby PJ, Ferrari MD, Dodick DW, McCrory D, Liberman JN, Williams P (2005) How treatment priorities influence triptan preferences in clinical practice: perspectives of migraine sufferers, neurologists, and primary care physicians. *Curr Med Res Opin* 21:413–424
7. Sheftell FD, Feleppa M, Tepper SJ, Volcy M, Rapoport AM, Bigal ME (2004) Patterns of use of triptans and reasons for switching them in a tertiary care migraine population. *Headache* 44:661–668
8. World Health Organization (2010) WHO model list of essential 78 medicines, 16th list. WHO, Geneva. http://www.who.int/medicines/79publications/essentialmedicines/Updated_sixteenth_adult_list_80en.pdf
9. Guidelines for All Healthcare Professionals in the Diagnosis and Management of Migraine, Tension-Type Headache, Cluster Headache, Medication-Overuse, Headache. 3rd edition (1st revision) (2010). http://217.174.249.183/upload/NS_BASH/2010_BASH_Guidelines.pdf
10. Lampl C, Voelker M, Diener HC (2007) Efficacy and safety of 1,000 mg effervescent aspirin: individual patient data meta-analysis of three trials in migraine headache and migraine accompanying symptoms. *J Neurol* 254:705–712
11. Lampl C, Voelker M, Steiner TJ (2011) Aspirin is first-line treatment for migraine and episodic tension-type headache regardless of headache intensity. *Headache*. [Epub ahead of print]
12. Tfelt-Hansen P, De Vries P, Saxena PR (2000) Triptans in migraine: a comparative review of pharmacology, pharmacokinetics and efficacy. *Drugs* 60:1259–1287
13. Ferrari MD, Goadsby PJ, Roon KI, Lipton RB (2002) Triptans (serotonin, 5-HT_{1B/1D} agonists) in migraine: detailed results and methods of a meta-analysis of 53 trials. *Cephalalgia* 22:633–658
14. Lanas A, McCarthy D, Voelker M, Brueckner A, Senn S, Baron JA (2011) Short-term acetylsalicylic Acid (aspirin) use for pain, Fever, or colds—gastrointestinal adverse effects: a meta-analysis of randomized clinical trials. *Drugs R D* 11:277–288