MEDICATION-OVERUSE HEADACHE MANAGEMENT: DATA FROM A MULTICENTRIC CLINICAL STUDY

Angela Verzina[1], Ilenia Corbelli[1], Paolo Eusebi[1], Letizia Maria Cupini[2], Stefano Caproni[3], Paola Sarchielli[1] and Paolo Calabresi[1]

[1] Neurological Clinic, Department of Medicine, University of Perugia, Italy; [2] Headache Center and Cerebrovascular Disease, S. Eugenio Hospital, Roma, Italy; [3] Neurological Clinic, Department of Neuroscience, University of Terni, Italy

Medication Overuse Headache (MOH) is a chronic disabling disorder. It's prevalence is of 1-2% with a peak of 5% in women aged 40-50 years [1]. There is no established consensus concerning MOH standard of care, but advice and educational intervention has proved to be effective likewise structured inpatient/outpatient detoxification programmes in reducing medication overuse in uncomplicated MOH[2]. This multicentre study aimed to assess any differences in phenotypical characteristics, type and amount of drugs overused and comorbidities between MOH patients who respond to an advice and educational intervention and who did not.

Materials and methods

Data from our multicenter placebo-controlled SAMOHA study [3] previously highlighted the efficacy and tolerability of sodium valproate (VPA) in a 12-week treatment period of MOH patients after detoxification. In the present study we collected demographic and clinical data of the patients at V1. Then, they filled out a daily headache diary for an observational period of 4 weeks. At V2, therefore, all of them were divided in two subgroups: patients who could continue the study (randomized group-R group) and drop-out patients (non-randomized group-NR group).

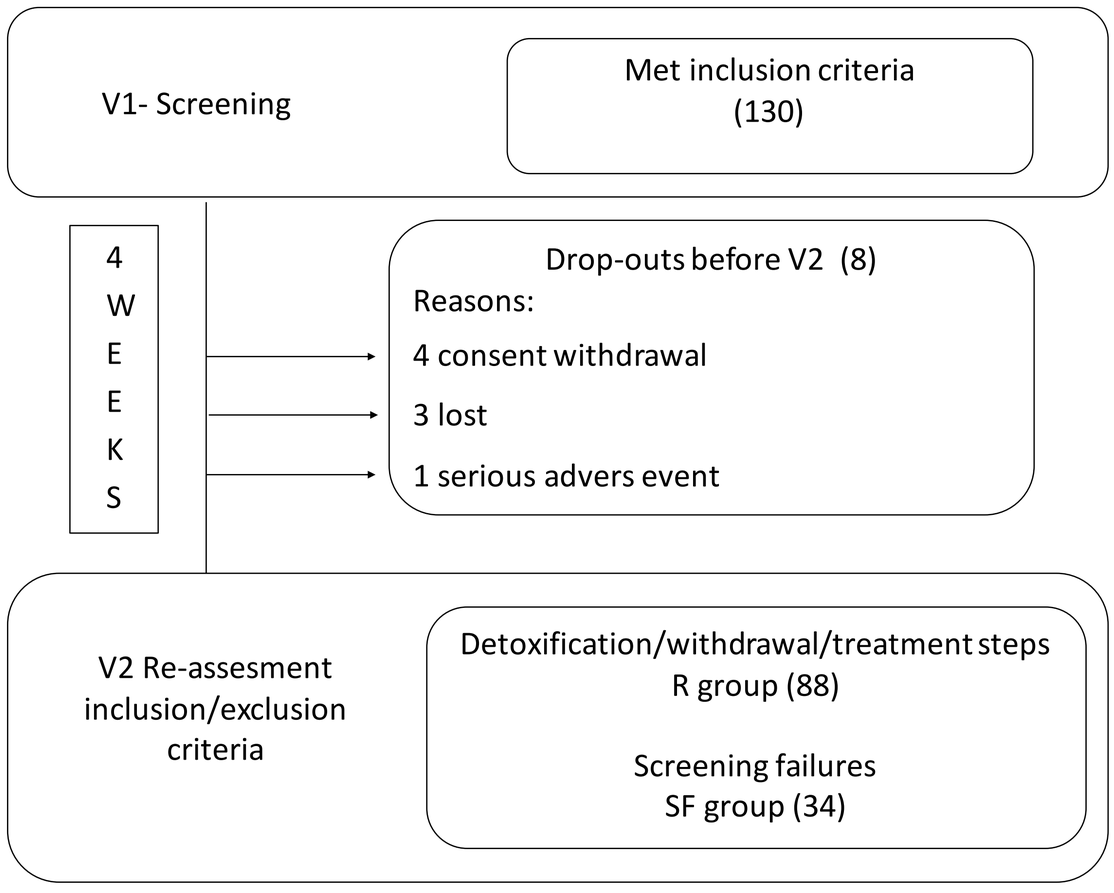
Results

From nine participating centers we screened 130 patients [104 (80%) women; mean age was 42 years old]. At V2, 88 (67.7%) of them continued meeting the inclusion/exclusion criteria and were, then, randomized to placebo/VPA (R group). 42 patients, instead, drop-out the study (NR-group). Analyzing in detail the drop-out reasons, we find that 34 of the 42 NR patients left the study at V2 because they were no more satisfying the inclusion/exclusion criteria (screening failure group-SF group). The remaining 8 patients left the study before reaching V2 for other reasons. Comparing the clinical and demographic differences between the R and SF groups, R group was significantly older and with more years of migraine in history than SF group. Moreover, in R group, the headache has become chronic for more than twice of years, compared to SF group.

Conlcusions and discussion

From our data appear that, in every MOH trial, in order to confirm the diagnosis, it is crucial, after an educational section (simple advice) on the disease, an observational period preceding the assignment to any type of treatment. Obtaining a sample representative of "pure" MOH will certainly improve the reliability of the results. On the other hand, in the clinical field, our findings demonstrate that early diagnosis (young age and/or few years of episodic and chronic migraine in history) of MOH is needed to ensure a high remission rate. Furthermore we consider essential that an early diagnosis come from the general practitioner and, before him, from the pharmacist.

Figure 1. Flow-chart of enrolled patients, R and SF groups, according to SAMOHA protocol.



R group = Randomized group; SF group = Screening Failures group

Table 1. Compared demographic and clinical details of R and SF groups [means ± standard deviations (SD)].

	R group N=88	SF group N=34	*p*-value
Sex (Females/Males)	69/19	27/7	1.000
Age	43.23±9.50	37.71±9.41	**0.005**
BMI	24.50±4.12	23.43±3.61	0.165
Years behind Migraine how long Migraine has become chronic	25.41±11.43	18.59±9.87	**0.002**
Chronic Headache (years)	5.51±4.68	2.05±2.41	**<0.001**
Days with Headache/month (last 3 months before enrollment)	23.59±5.87	23.88±5.56	0.515
Attack prevailing intensity (last 3 months before enrollment)			
Mild	3 (3.4%)	2 (5.9%)	0.400
Moderate	32 (36.4%)	16 (47.1%)	
Severe	53 (60.2%)	16 (47.1%)	
Abused Drugs (according to ICHD III beta groups [1]) (last 3 months before enrollment)			
Simple analgesics	30 (34.1%)	19 (55.9%)	0.115
Combination-analgesics	12 (13.6%)	1 (2.9%)	
Multiple drug classes not individually overused	22 (25.0%)	7 (20.6%)	
Triptans	24 (27.3%)	7 (20.6%)	
Ergotamine	0	0	
Opioids	0	0	

R group = Randomized group; SF group = Screening Failures group; BMI = Body Mass Index; ICHD III beta = International Classification of Headache Disorders, 3rd edition (beta version).

References

[1]. Westergaard ML, Hansen EH, Glümer C, Olesen J, Jensen RH. Definitions of medication-overuse headache in population-based studies and their implications on prevalence estimates: a systematic review. Cephalalgia. 2014 May;34(6):409-25. doi: 10.1177/0333102413512033. Epub 2013 Nov 29.

[2]. Rossi P, Faroni JV, Nappi G. Short-term effectiveness of simple advice as a withdrawal strategy in simple and complicated medication overuse headache. Eur J Neurol. 2011;18:396-401.

[3]. Sarchielli P, Messina P, Cupini ML, et al. Sodium Valproate in Medication Overuse Headache Treatment: a placebo-controlled randomized trial. Eur Neuropsychopharmacol 2014; 24: 1289-1297