### BRIEF REPORT

# New appendix criteria open for a broader concept of chronic migraine

Headache Classification Committee: J Olesen, M-G Bousser, H-C Diener, D Dodick, M First, PJ Goadsby, H Göbel, MJA Lainez, JW Lance, RB Lipton, G Nappi, F Sakai, J Schoenen, SD Silberstein & TJ Steiner

### <u>Cephalalgia</u>

Headache Classification Committee: Olesen J, Bousser M-G, Diener H-C, Dodick D, First M, Goadsby PJ, Göbel H, Lainez MJA, Lance JW, Lipton RB, Nappi G, Sakai F, Schoenen J, Silberstein SD & Steiner TJ. New appendix criteria open for a broader concept of chronic migraine. Cephalalgia 2006; 26:742–746. London. ISSN 0333-1024

After the introduction of chronic migraine and medication overuse headache as diagnostic entities in The International Classification of Headache Disorders, Second Edition, ICHD-2, it has been shown that very few patients fit into the diagnostic criteria for chronic migraine (CM). The system of being able to use CM and the medication overuse headache (MOH) diagnosis only after discontinuation of overuse has proven highly unpractical and new data have suggested a much more liberal use of these diagnoses. The International Headache Classification Committee has, therefore, worked out the more inclusive criteria for CM and MOH presented in this paper. These criteria are included in the appendix of ICHD-2 and are meant primarily for further scientific evaluation but may be used already now for inclusion into drug trials, etc. It is now recommended that the MOH diagnosis should no longer request improvement after discontinuation of medication overuse but should be given to patients if they have a primary headache plus ongoing medication overuse. The latter is defined as previously, i.e. 10 days or more of intake of triptans, ergot alkaloids mixed analgesics or opioids and 15 days or more of analgesics/NSAIDs or the combined use of more than one substance. If these new criteria for CM and MOH prove useful in future testing, the plan is to include them in a future revised version of ICHD-2.  $\square$  *Migraine, primary headaches, drug* dependency, triptans, ergot alkaloids, opioids, disease classification

Jes Olesen, Professor, Department of Neurology, University of Copenhagen, Glostrup Hospital, DK-2600 Glostrup, Copenhagen, Denmark. Tel. +45 4323 3036, e-mail: jeol@glostruphosp.kbhamt.dk Received 13 February 2006, accepted 7 March 2006

### Introduction

Chronic headaches continue to be the most disputed part of the International Headache Classification (1, 2). In the 2nd Edition (ICHD-2), the concept of chronic migraine (CM) was introduced (3). It was meant to include many of the patients seen in tertiary headache referral centres, patients with a history of migraine who experience headache more than half the time. However, it has subsequently been shown that the CM criteria that were proposed are fulfilled by very few patients in clinical practice and clinical trials (4, 5). This most suffering segment

of headache patients therefore still do not have their own diagnostic category. They can be classified using the multiple diagnosis system of the international headache classification, but since it can often be difficult to distinguish which of the headache episodes are migraine and which are not, these patients have generally been excluded from drug trials. The result: little evidence-based medicine available to help physicians who care for these patients. In order to amend this situation, the Headache Classification Committee decided to develop criteria which more accurately reflect the large majority of this population of patients who are seen in clinical practice.

### Deliberations of the committee

In addition to a need for diagnostic criteria allowing entry of these patients into clinical trials, a number of arguments have accumulated suggesting that classifying the episodes in these patients as either migraine without aura or tension-type headache is not easy and may sometimes be impossible. The ICHD-1 and 2 define headache entities from the characteristics of each attack. In order to do so, attacks have to be untreated or unsuccessfully treated since efficient early treatment may obviously obscure the characteristics of an attack. Most attacks of migraine without aura develop in a matter of hours and often go through a phase where they phenomenologically fulfill the criteria for tension-type headache before the headache gets worse, becomes unilateral and has associated symptoms. Early intake of a triptan may, thus, abort the attack before the typical characteristics of migraine develop. From a purely phenomenological point of view, such attacks might easily be classified as tension-type headaches. When patients have few attacks, it is quite easy for them to avoid treatment for one or two attacks in order to collect the characteristics of the untreated attack. However, when patients suffer from frequent migraine and other headaches and are very disabled, it is usually not possible to stay medication free for more than a couple of attacks. The ICHD-2 criterion for CM demands that patients fulfill criteria for 1.1 migraine without aura on ≥15 days per month. This would require that patients stay off treatment for an entire month, which is usually possible only when patients have medication overuse headache and need a drug-free period as part of their treatment. Furthermore, new evidence has shown that when patients with migraine treat attacks that phenomenologically fulfill criteria for tension-type headache, the response to triptans is robust (6). This is in contrast to previous studies showing that, in pure tension-type headache, the effect of triptans is modest or non-existent (7). These two facts suggest that a number of headaches in migraineurs fulfilling tension-type headache criteria may in fact be mild migraine attacks. Prophylactic trials in migraine patients that have separated the effect on tension-type headaches and migraine headaches have given divergent results, some concluding that tension-type headaches diminishe to the same extent or even more than migraine attacks, whereas others have demonstrated that only migraine attacks diminish in frequency.

## Chronic daily headache, transformed migraine or chronic migraine

These three terms have often been used interchangeably in the past. However, the term chronic daily headache has been recognized to be a collective description of patients with very frequent headache rather than a diagnostic category (4, 8). The term transformed migraine is based on the evolution of headache over time but has the problem that patients are often diagnosed several years after a presumed transformation has happened (9). Studies of patients with chronic tension-type headache (CTTH) have revealed that as many as 50% do not remember clearly how the headaches started (10). Furthermore, to introduce the longitudinal aspect into the headache classification would be to introduce a new principle that goes across existing categories. CTTH might then also be called transformed tension-type headache, as the great majority of cases begin as episodic tension-type headache and tension-type headache may transform into migraine. A diagnosis of transformed migraine would have to be reserved exclusively for those patients who were able to give a very precise history of how their headaches had changed and who were not transformed by the overuse of drugs. For these reasons, the term transformed migraine was not favoured by the majority of the Classification Committee.

Chronic migraine is a term introduced into the ICHD-2 and is thus part of the main body of the classification. However, already during the work of the 2nd International Headache Classification Committee, the term chronic migraine was severely criticized. However, the terms chronic cluster headache and chronic tension-type headache were also criticized because the word chronic is used with different meanings in different headache disorders. For CM and CTTH the term implies that headache is present ≥15 days per month. For cluster headache, the term means that patients remain in a cluster period for ≥1 year with no or only brief remissions. In addition, all the primary headaches are chronic in the sense that they are present for many years. Despite these problems, no better word than chronic could be found during 4 years' deliberation of the 2nd International Headache Classification Committee. For these reasons, and since disease classification by its nature must be conservative because changes have so many implications in different fields of science and medicine, it was decided to keep the term chronic migraine and to make the criteria less restrictive. After several months of e-mail exchange of opinion, the Chairman and several members of the

Table 1 Revised International Headache Society criteria for chronic migraine

Appendix 1.5.1 Chronic migraine

- A. Headache (tension-type and/or migraine) on ≥15 days per month for at least 3 months\*
- B. Occurring in a patient who has had at least five attacks fulfilling criteria for 1.1 Migraine without aura
- C. On ≥8 days per month for at least 3 months headache has fulfilled C1 and/or C2 below, that is, has fulfilled criteria for pain and associated symptoms of migraine without aura
  - 1. Has at least two of a-d
    - (a) unilateral location
    - (b) pulsating quality
    - (c) moderate or severe pain intensity
    - (d) aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs) and at least one of a or b
    - (a) nausea and/or vomiting
    - (b) photophobia and phonophobia
  - 2. Treated and relieved by triptan(s) or ergot before the expected development of C1 above
- D. No medication overuse† and not attributed to another causative disorder‡

†Medication overuse as defined under 8.2 Medication-overuse headache.

‡History and physical and neurological examinations do not suggest any of the disorders listed in groups 5–12, or history and/or physical and/or neurological examinations do suggest such a disorder but it is ruled out by appropriate investigations, or such disorder is present but headache does not develop in close temporal relation to the disorder.

International Headache Classification Committee met during the International Headache Congress in Kyoto for half a day, debating criteria for CM. A proposed version had already been distributed and through fruitful discussion, further amendments and improvements were made. A further prolonged e-mail debate caused further minor modifications and resulted in the criteria presented in Table 1. It was decided to place these new criteria in the Appendix so they could be available for future research. Once these criteria had been field-tested, the aim would be to introduce them into the main body of the classification. It was agreed that a revised edition of the International Headache Classification should be presented perhaps in 2009 or 2010. At that time there should be sufficient evidence to allow the inclusion or abolition of these new criteria for CM. Until then, the International Headache Classification Committee extends an invitation to the headache community to study these new criteria and to generate clinical trials for this severely affected segment of headache patients.

#### Medication overuse headache

There has been general dissatisfaction with ICHD-2 in relation to the diagnosis of medication overuse headache. The concept itself is excellent and perhaps the greatest achievement of ICHD-2, but the problem is that medication overuse headache cannot be diag-

nosed until the overuse has been discontinued and the patient has been shown to improve. This means that when patients have it, it cannot be diagnosed. It can be diagnosed only after the patient does not have it any more. This slightly awkward system was introduced because it was pointed out that not all patients improve after discontinuation of overuse of acute headache medication(s). In the meantime, evidence has suggested that those patients who do not improve after withdrawal nevertheless become responsive to prophylactic medication, something they were not during medication overuse (unpublished data by the group of the Chairman). Furthermore, patients could become chronic due to medication overuse, but this effect might be permanent. In other words, it may not be reversible after discontinuation of medication overuse. Finally, a system whereby medication overuse headache became a default diagnosis in all patients with medication overuse would encourage doctors all over the world to do the right thing, namely, to take patients off medication overuse as the first step in a treatment plan. The conclusion of the committee was that, with the introduction of more inclusive criteria for CM, also the criteria for medication overuse should be changed and that the diagnosis of probable CM should be deleted. This would also eliminate the problem that the word 'probable' has taken on different meanings within ICHD-2. In relation to medication overuse headache and CM, it means that

<sup>\*</sup>Characterization of frequently recurring headache generally requires a headache diary to record information on pain and associated symptoms day-by-day for at least 1 month. Sample diaries are available at http://www.i-h-s.org

Appendix 8.2 Medication overuse headache Diagnostic criteria:

- A. Headache present on ≥15 days/month
- B. Regular overuse for >3 months of one or more acute/symptomatic treatment drugs as defined under sub forms of 8.2.
  - 1. Ergotamine, triptans, opioids, or combination analgesic medications on ≥10 days/month on a regular basis for >3 months
  - 2. Simple analgesics **or** any combination of ergotamine, triptans, analgesics opioids on ≥15 days/month on a regular basis for >3 months without overuse of any single class alone
- C. Headache has developed or markedly worsened during medication overuse

response to withdrawal has not been shown while, usually, it means that one subcriterion in the explicit diagnostic criteria for a disorder is not fulfilled. The new Appendix criteria for medication overuse headache are shown in Table 2.

### General principles of headache classification

Discussion of the above-mentioned items led to considerations about headache classification in general. As previously mentioned, classification should be a conservative art because changes in a classification have so many implications. On the other hand, classifications are not fool-proof. Mistakes and suboptimal solutions become disclosed as the wider headache community starts to examine a classification system. Not least, the application of computerized diagnostic algorithms is able sometimes to show inconsistencies in a classification. This discovery of mistakes and/or new possibilities is an ongoing process and it should be possible for a classification to absorb these changes as they emerge. The general scheme for accommodation of changes agreed by the Classification Committee was that whenever part of the classification needs change, the Classification Committee will discuss it and, when appropriate, develop new criteria. These will go into the Appendix for a testing period of several years. At intervals somewhat shorter than those between new editions of the headache classification, changes that have been published in the Appendix and tested could then be included in a revised version of the same edition of the classification. The next revised version of the classification (ICHD-2R) is expected to be published in 2009 or 2010.

### Concluding remarks

The classification of chronic headache has been the most difficult part of the International Headache Classification. The International Headache Classification Committee hopes that, with the criteria for CM revised to reflect the majority of patients seen in practice with this disorder, they will be properly field-tested and final revisions, if necessary, may be made in the ICHD-2R. This paper has been voted and endorsed by the Chairman and subcommittee chairs of the ICHD-2 Classification Committee.

It has been a tremendous strength for headache as a research field and as a clinical discipline to have the International Headache Classification as a common platform. A consequence is of course that chronic daily headache and transformed migraine should no longer be used as diagnostic entities. Severely affected migraine patients can be diagnosed as chronic migraine and remaining patients must be diagnosed using the general system of multiple diagnoses. As members of the International Headache Classification Committee, we, the authors, shall at least from now on avoid using non-International Headache Society terms and we suggest that scientific journals will accept this principle. That does not mean, however, that concepts should not be challenged and examined scientifically, but changes to diagnostic criteria should be proposed only if sufficient data are present to indicate their validity.

### References

- 1 Bigal ME, Rapoport AM, Sheftell FD, Tepper SJ, Lipton RB. Chronic migraine is an earlier stage of transformed migraine in adults. Neurology 2005; 65:1556–61.
- 2 Bigal ME, Rapoport AM, Tepper SJ, Sheftell FD, Lipton RB. The classification of chronic daily headache in adolescents—a comparison between the second edition of the international classification of headache disorders and alternative diagnostic criteria. Headache 2005;45:582–9.
- 3 Headache Classification Committee of the International Headache Society. The International Classification of Headache Disorders: 2nd edition. Cephalalgia 2004;24 (Suppl. 1):9–160.
- 4 Silberstein SD, Lipton RB, Sliwinski M. Classification of daily and near-daily headaches: field trial of revised IHS criteria. Neurology 1996; 47:871–5.

- 5 Bigal ME, Tepper SJ, Sheftell FD, Rapoport AM, Lipton RB. Chronic daily headache: correlation between the 2004 and the 1988 International Headache Society diagnostic criteria. Headache 2004; 44:684-91.
- 6 Cady RK, Lipton RB, Hall C, Stewart WF, O'Quinn S, Gutterman D. Treatment of mild headache in disabled migraine sufferers: results of the Spectrum Study. Headache 2000; 40:792-7.
- 7 Brennum J, Brinck T, Schriver L, Wanscher B, Sørensen PS, Tfelt-Hansen P, Olesen J. Sumatriptan has no clinically
- relevant effect in the treatment of episodic tension type headache. Eur J Neurol 1996; 3:23-8.
- 8 Silberstein SD, Lipton RB. Chronic daily headache. Curr Opin Neurol 2000; 13:277-83.
- 9 Mathew NT. Transformed migraine. Cephalalgia 1993; 13 (Suppl. 12):78-83.
- 10 Langemark M, Olesen J, Poulsen DL, Bech P. Clinical characterization of patients with chronic tension headache. Headache 1988; 28:590-6.