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What's a migraine day? Towards a consensus definition for clinical care and research – a Delphi panel-based study

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Abstract

Background Although guidelines for controlled trials have proposed a definition for a migraine day, substantial variability remains across clinical trials, highlighting the need for a universally adopted definition.

Methods Through three survey rounds using an eDelphi method, a panel of 18 headache experts evaluated clinical scenarios to achieve consensus on a standardized definition of a migraine day. The first two rounds provided clear-cut cases with the question whether a clinical scenario should be labelled as a migraine day and the third round proposed a migraine day definition. Consensus was predefined at 70% agreement.

Results A consensus was reached on a proposed definition of a migraine day across three distinct situations: (1) without acute treatment, (2) with acute treatment, and (3) in the presence of aura. If untreated, a headache day can be labelled as a (probable) migraine day when the following criteria are met: headache lasting ≥ 4 h having at least two out of four headache characteristics, regardless of the presence of any associated symptom or at least one out of four headache characteristics combined with one associated symptom. If treated, a headache day can be labelled as a migraine day when the following criterion is met: lasting ≥ 30 min, regardless of drug (class) taken, the presence of any headache characteristic or associated symptom. In the presence of aura, a migraine day can be defined as any calendar day on which the following criterion is met: an aura, fulfilling the ICHD-3 criteria for migraine with aura, is experienced regardless of the presence of headache.

Conclusions We suggest the Classification Committee considers this eDelphi survey based consensus definition as a possible definition both for clinical trials and clinical care in the new edition of the International Classification of Headache Disorders.

Clinical trial number Not applicable.

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Keywords Migraine, Migraine day, Classification, ICHD

Background

The diagnosis of migraine is purely clinical [1], using the International Classification of Headache Disorders (ICHD) from the Headache Classification Committee of the International Headache Society (IHS). The first criteria were introduced in 1988 [2]. ICHD-3 criteria are the most recent available criteria, published in 2018 [3]. The ICHD-4 criteria are currently in development [4].

Clinical trials in migraine patients with preventive agents often use the reduction in monthly migraine days as a primary endpoint. However, the ICHD-3 was designed to diagnose migraine and its (sub)types on a patient level, but not on the level of every individual headache day [5]. The IHS has proposed a definition of a migraine day in the 2020 guidelines for controlled trials of episodic migraine [6] and in the 2018 guidelines for chronic migraine [7]. However, these definitions are not universally used. Also, the ICHD-3 encompasses the concept of 'probable migraine' but this entity is more related to the concept of the polythetic criteria used throughout the classification where the 'probable' label is applicable when one criterion is missing, similar to all other primary and secondary headache disorders outlined in the classification [3]. A previous study showed that in 23 phase III trials with drugs targeting the calcitonin gene-related peptide pathway, 12 different definitions of a migraine day were used [8].

The aim of the present study was to propose a consensus definition of a migraine day in adults for the use either in clinical trials or any automated labelling of headache days into migraine days e.g. by means of digital headache calendars. This study was performed by means of an electronic survey amongst an international panel of migraine experts, using an eDelphi method [9, 10].

Methods

Survey design and participants

This study was conducted as a closed electronic survey, in accordance with the CHERRIES (CHEcklist for Reporting Results of Internet E-Surveys) guidelines. An eDelphi method was used to reach consensus among a panel of experts [9, 10]. The survey was sent to a target population of 18 headache experts: all board members of the European Headache Federation (EHF) at the time of study initiation, supplemented with clinical experts associated with the International Headache Society (IHS) or clinicians having a particular interest in the headache classification (see Supplementary Table for details of survey participants).

Survey structure and completion

The first eDelphi round started with 16 clinical cases containing either 'yes or no' or closed questions, pertaining to whether a headache day should be labelled as a migraine day in individuals with an established diagnosis of migraine. These clinical cases were mostly based on the differences in definitions of a migraine day across phase III trials with drugs targeting the CGRP pathway identified in a previous study [8], focused on either the duration of a headache day, the timing of drug use, whether non-specific drugs can be taken into account and the inclusion of probable migraine (see Supplementary Materials). Participants had the opportunity to provide comments after each question. Although across both clinical trials and clinical practice definitions of a 'headache day' tend to vary as well, the present study only considered the definition of a migraine day.

The first survey was completed by 17 participants. Following the eDelphi method, the results of the survey were compiled into a report, accompanied by key discussion points. Consensus in all three survey rounds was a priori considered reached when more than 70% of respondents agreed on a question [10]. Based on the results of the first round, a second survey was created including eight questions for which consensus had not yet been reached (see Supplementary Materials). The report of the first survey, together with the second survey, was sent out to 18 participants, of whom all completed this second survey.

Based on the results of the two surveys, a third and final survey was conducted (18 participants, all responded), containing a proposal of a definition of a migraine day in adults with an established diagnosis of migraine. Since survey one and two made clear that a single definition capturing every possible clinical scenario would be impossible, a definition was presented across three distinct situations: (1) without acute treatment, (2) with acute treatment, and (3) in the presence of aura (see Supplementary Materials and Table 2). Each proposed definition was accompanied by a brief rationale explaining the choices made, followed by a yes/no question whether the experts agreed on the presented definition. Similar to the first and second survey rounds, participants had the opportunity to add comments after each proposal. No adaptive questioning was used. The survey had a completeness check, preventing submission unless all questions were answered, and the experts had the possibility to modify their responses using a back button before final submission. Each survey round was thoroughly tested by the first investigator and reviewed by a steering group of three experts (JV, KP and AMVDB) prior to distribution to ensure clarity, consistency and appropriateness of the

questions, as well as accessibility, maintenance of anonymity and overall layout.

Ethics and informed consent

The experts were informed that the study used an eDelphi methodology consisting of multiple survey rounds, each round requiring approximately 10 min to complete. The purpose of the survey and the identities of the investigators were stated. This survey was not reviewed by an Institutional Review Board, as no patient data was collected.

Recruitment and administration

The survey was available via email invitation. Participants received a personal link that gave access to the survey. Responses were captured automatically through the REDCap platform (version 14.6.3) [11, 12]. If a participant did not complete the survey, a unique code was sent to allow completion. Duplicate entries were prevented. Participation was voluntary, and no incentives were offered.

Data security and anonymity

Survey data were stored by REDCap software and was handled anonymously. Access to the database was password-protected and restricted to the principal investigators (LDL and JV) and REDCap administrators. Investigators could not view responses linked to individual email addresses.

Timeframe

The three survey rounds were conducted over a period of four months.

Results

The questions of the first and second survey with their percentage of agreement are found in Table 1. For questions asked in both surveys, the level of agreement from the second survey is presented.

It was unanimously agreed that when a patient goes to sleep with a migraine and wakes up free of headache the day after, this should be considered as only one migraine day. High consensus (83%) was obtained as to whether non-specific analgesics should be considered to label a treated headache day as a migraine day. Intermediate consensus (50–71%) was reached concerning questions related to the definition of a probable migraine day and a day with aura in the absence of headache. The lowest level of consensus (< 50%) concerned the required minimal duration to constitute a migraine day after acute medication is taken.

Table 2 shows our proposed definition of a migraine day in patients with an established migraine diagnosis, based on the first two surveys.

The three distinct situations each reached a consensus of more than 70% after the third survey. Specifically, the first situation (without acute treatment) reached 83% (15 out of 18 participants), the second situation (with acute treatment) reached 94% (17 out of 18 participants) and

Table 1 Raised questions during the first and second survey with their percentage of agreement (descending order)

Delphi question	% consensus
Migraine resolved when waking up headache-free the next day counts as one migraine day	**100%**
The minimal duration of a migraine day should be the same for chronic and episodic migraine	**94%**
A shortlasting headache resolved 30 min after taking oral sumatriptan 100 mg should be labelled as a migraine day	**94%**
A headache lasting 1 h resolved 2 h after taking ibuprofen 600 mg should be labelled as a migraine day	**94%**
A shortlasting headache resolved 15 min after injecting subcutaneous sumatriptan 6 mg should be labelled as a migraine day	**88%**
Non-specific drugs should be given the same "power" as migraine-specific drugs to label a headache day as a migraine day	**83%**
Without drug intake, a headache should last ≥4 h to be labelled as a migraine day	**78%**
A severe migraine-like headache only lasting 5 min not followed by drug intake should not be labelled as a migraine day	**77%**
A shortlasting headache resolved 30 min after taking oral ibuprofen 600 mg should be labelled as a migraine day	**77%**
A headache with migraine characteristics however without nausea or photophobia, but with phonophobia, should be labelled as a migraine day	**71%**
Premonitory symptoms without a headache leading to the intake of ubrogepant 100 mg do not constitute a migraine day	**71%**
A day with the presence of a typical migraine aura not associated with headache should be labelled as a migraine day	61%
A shortlasting headache with migraine characteristics resolved 5 min after taking oral sumatriptan 100 mg should not be labelled as a migraine day	61%
A headache with migraine characteristics without any associated symptom should be labelled as a migraine day	61%
A pulsating headache with nausea (no other characteristics or associated symptoms) should be labelled as a migraine day	50%
If a headache is treated, any headache duration can constitute a migraine day	39%
If a headache is treated, the duration required to be labelled as a migraine day depends on the drug's pharmacology and pharmacokinetics	39%
If a headache is treated, the headache should last longer than 30 min to be labelled a migraine day	17%
If a headache is treated, the headache should last longer than 4 h to be labelled a migraine day	6%

Table 2 Proposed definition of a migraine day in patients with an established diagnosis of migraine across three distinct clinical situations

1. Untreated headache day	A headache day can be labelled as a (probable) migraine day when the following criteria are met: - Headache attacks lasting ≥ **4h** **AND** - Headache must have at least **two** out of four headache characteristics, regardless of the presence of any associated symptom **OR** - Headache must have at least **one** out of four headache characteristics combined with one associated symptom **Headache characteristics**: 1. unilateral location 2. pulsating quality 3. moderate or severe pain intensity 4. aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs) **Associated symptoms**: • Nausea and/or vomiting • Photophobia AND phonophobia
2. Treated headache day	A headache day can be labelled as a migraine day when the following criterion is met: A headache lasting **≥ 30 min**, regardless of drug (class) taken and the presence of any headache characteristic or associated symptom.
3. Aura	A migraine day can be defined as any calendar day on which the following criterion is met: An aura, fulfilling the ICHD-3 criteria for migraine with aura, is experienced regardless of the presence of a headache.

the third situation (in the presence of aura) reached 83% (15 out of 18 participants).

Discussion

This study aimed to propose a consensus-based definition of a migraine day using the eDelphi method among a panel of clinical experts. After three survey rounds, consensus was achieved on what constitutes a migraine day in adults diagnosed with migraine. The final definition takes into account untreated and treated headache days, as well as days with aura. The application of these 3 definitions may raise concerns about its feasibility for patients when reporting symptoms during trial inclusion or in an e-diary. To address the latter, an e-diary could be designed in two modes: a diagnostic mode with extensive questioning of the patients' symptoms, and a follow-up mode with a more simplified questioning. However, as the current study did not field test the proposed definition, future research should assess the feasibility of implementing the current proposed definition both in clinical trials and real-world clinical practice.

As a rationale for the first situation (an untreated headache day), 78% of respondents agreed that a headache should last more than four hours to qualify as a migraine day in adults. Additionally, 61% considered that a headache with migraine-specific headache characteristics (unilateral location, pulsating quality, moderate or severe pain intensity, aggravation by or causing avoidance of routine physical activity), even without associated symptoms (nausea and/or vomiting, photophobia and phonophobia), should still be labelled as a migraine day. As such, headache characteristics were prioritised over associated symptoms in the final proposed definition. The latter is in line with literature mentioning that, for example, aggravation by or causing avoidance of routine physical activity in migraine might be present in virtually all migraine patients [11, 12]. Moreover, nearly half of the patients mention light or sound sensitivity only during follow-up questioning in patients where the initial question of 'does light or noise bother you during a headache?' was answered negatively [13]. Finally, as for nausea, no validated (follow-up) questions are available. As a clinical aid, the ICHD-3 mentions in its appendix a 'definition of terms' section where items as 'unilateral', 'pulsating', 'moderate or severe', 'photo- and phonophobia' are defined although these individual definitions have not been further validated. Since the survey did not aim to establish a clear hierarchy amongst the specific headache characteristics and this was only questioned once without further in-depth questioning, no specific characteristic or combination of characteristics was prioritised.

The current proposal confirms the concept of a migraine day extending beyond the current ICHD-3 criteria. In line with this, it is already mentioned in the ICHD-3 that, "in patients who already have a migraine diagnosis and where the issue is to count the number of attacks they are having (e.g. as an outcome measure in a drug trial), attacks fulfilling criteria for probable migraine should be counted as migraine. Mild attacks or those treated early may not meet all diagnostic criteria, but still reflect meaningful disease burden and typically respond to migraine-specific treatments" [3]. This inclusion of probable migraine days will always reflect a deliberate trade-off between sensitivity and specificity. Indeed, while this approach may reduce the diagnostic precision for each individual migraine day, it increases the sensitivity by capturing the full clinical spectrum of migraine and more likely is able to reflect disease activity with a higher accuracy in patients with an established migraine diagnosis.

For the second situation (a treated headache day), the rationale backing the proposed definition was derived from the second survey where 83% of respondents agreed that the use of non-specific migraine medication should be given the same weight as migraine-specific treatments when determining whether a headache day qualifies as a migraine day, differing from the ICHD-3 criteria used to diagnose chronic migraine [3]. This finding is especially relevant in light of global variations in access to migraine-specific treatments and highlights the need for inclusive criteria that reflect real-world clinical practice. According to one report, diclofenac is an effective treatment for migraine attacks with an even reported better efficacy and tolerability profile compared to oral sumatriptan [14].

Additionally, a treated headache day does not require the presence of migraine-specific headache characteristics or associated symptoms to be labelled as a migraine day. As patients may abort their attack very early on with acute treatment, the headache can indeed lack headache characteristics or associated symptoms. The aspect that generated the lowest level of consensus concerned how to define the minimal duration of a migraine day, when acute treatment is taken. The final definition proposes adopting a 30-minute threshold, recognizing that creating distinct definitions for each drug or pharmacological class according to their pharmacokinetic properties would be impractical. Removing the duration threshold was not supported, as only 39% of participants agreed with the option 'any duration' and it would also conflict with the outcome of another survey question. In the latter scenario, a patient takes 100 mg of oral sumatriptan 5 min after headache onset and the headache resolves within the following 5 min. The majority of respondents (61%) indicated that this should not be classified as a migraine day. Although 88% of participants agreed that a headache resolving 15 min after injecting subcutaneous sumatriptan 6 mg should be labelled as a migraine day, adopting a 15-minute threshold was not considered appropriate as this cut-off is not commonly used in migraine literature. The final proposed 30-minute threshold therefore represents a compromise consistent with prior definitions used in literature. We acknowledge that, in theory, a 30-minute threshold might be too long for patients who are treated very early with subcutaneous sumatriptan. Evidence shows that after the administration of subcutaneous sumatriptan, 10% of patients report pain relief within 10 min, 63% within 30 min, 72–73% after 1 h, and 70–81% after 2 h [15, 16]. However, onset and complete freedom from pain within a timeframe of 30 min is rather rare. This 30-minute threshold also aligns with a previous study comparing migraine days based on longitudinal E-diary data, where it was found that 97.7% of headache days that did not meet the standard duration criterion in patients who took triptans still experienced a headache duration of ≥ 30 min [5].

Finally, for the third situation (presence of aura), the rationale behind the proposed definition was similarly derived from the second survey, where the majority responded that aura does not need to be associated with a headache to classify as a migraine day. This aligns with the aforementioned study comparing migraine days based on longitudinal E-diary data, where they found that 8.5% of days with migraine with aura consisted of an aura not followed by a headache [5]. However, this point might warrant further consideration. A concern could be that counting aura only-days on equal terms with migraine headache days within a composite migraine day endpoint may compromise interpretability of preventive trials, particularly when the investigational drug primarily reduces the headache phase and has uncertain or no effect on aura. In such cases, a composite migraine day endpoint can either inflate baseline event counts (by adding aura-only episodes that carry limited pain disability) or dilute apparent treatment effects (if aura does not change while headache improves), thereby masking a clinically meaningful pain relief. As such, a solution could be to introduce the term 'aura day' next to 'migraine day' in order to disentangle these two phenomena, where, for example, a day could end up receiving both labels. This would allow for a more precise classification of the clinical spectrum and phenomenology of migraine attacks. From a practical standpoint, including aura within the proposed definition of a migraine day may improve monitoring of disease activity and guidance of preventive treatment. This is particularly relevant since most if not all preventive treatments are indicated both for individuals suffering from migraine with aura and migraine without aura. Finally, no differentiation was made between different types of aura such as visual, sensory, aphasic, or hemiplegic. It is common knowledge that these are often difficult to identify and classify accurately, especially when relying on retrospective patient reports. This was however not further questioned in the eDelphi survey rounds.

The ICHD-3 classification reads "When the patient falls asleep during a migraine attack and wakes up without it, duration of the attack is reckoned until the time of awakening." [3]. This can be interpreted as two migraine days, which contrasts with the answers of the present survey, where there is a 100% consensus that if a patient goes to sleep with a migraine and wakes up headache-free the day after, this should be counted as one migraine day. Since counting in this specific situation might also create problems in patients-filled headache calendars or e-diaries, the ICHD Classification Committee might reconsider the current recommendations concerning this overnight remission of migraine attacks.

Strenghts and limitations

This study included 18 headache experts with substantial clinical experience or a specific interest in the headache classification. All three eDelphi surveys maintained high response rates and enabled the development of a consensus definition. However, although the eDelphi method is a widely used approach designed to create consensus among experts around clinical issues, it lacks well-defined guidelines [10]. Any Delphi study has an inherent bias in the choice of experts. In the present study, the experts are mostly working in Europe which limits the geographical diversity possibly reflecting a reduced spread of experiences and perspectives. Another potential bias is the inclusion of three experts who were also members of the steering group. However, no a priori definition was defined and the proposed definition in the third survey was not presented as the final definition in order to speed up the process. To account for this potential bias, an additional analysis was performed excluding their responses where consensus was still achieved in the same order of magnitude (80, 93 and 80% respectively). Another limitation is not using a Likert scale for the response options in the survey where the use of mostly yes/no questioning could have restricted the participants' nuances. However, it did facilitate clear interpretation and the participants did have the opportunity to elaborate on each of their responses. In the third survey round, the exact wording of the proposed definition could have influenced the participants' answers where phrasing the definition as "A migraine day *can* be defined as…" emphasizes a possibility rather than an obligation. Although this choice was intentional, as the definitions were intended to reflect minimal criteria, it cannot be excluded that this phrasing influenced participants.

Conclusions

This Delphi-based process resulted in a consensus definition of a migraine day, applicable to untreated and treated headache days, as well as days associated with an aura. As such, the proposed definition was developed with transparency, expert input, and careful consideration of clinical reality. We propose the ICHD Classification Committee considers the findings of this expert panel in a future edition of the Classification. Adoption of this definition could improve consistency in migraine research and clinical documentation, ultimately enhancing comparability across studies and supporting better patient care.

Abbreviations

ICHD	International Classification of Headache Disorders
IHS	International Headache Society
EHF	European Headache Federation

Supplementary Information

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Supplementary Material 1

Supplementary Material 2

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Author contributions

All authors (except LDL, IP, EE, PH and RF) participated in the Delphi process. LDL wrote the first draft. All authors read and approved the final version of the manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent

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Consent for publication

Not applicable.

Competing interests

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