**Diagnostic and classification tools for chronic headache disorders: a systematic review**

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**Funding statement**

This research was funded by the NIHR Programme Grants for Applied Research programme (RP-PG-1212-20018). The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

**Abstract**

**Background or Aim**

Despite guidelines and the International Classification of Headache Disorders (ICHD-IIIβ) criteria, the diagnosis of common chronic headache disorders can be challenging for non-expert clinicians. The aim of the review was to identify headache classification tools that could be used by a non-expert clinician to classify common chronic disorders in primary care.

**Methods**

We conducted a systematic literature review of studies validating diagnostic and classification headache tools published between Jan 1988 and June 2016 from key databases: MEDLINE, ASSIA, Embase, Web of Knowledge and PsycINFO. Quality assessment was assessed using items of the Quality of Diagnostic Accuracy Studies (QUADAS-2).

**Results**

The search identified 38 papers reporting the validation of 30 tools designed to diagnose, classify or screen for headache disorders; nine for multiple headache types and 21 for one headache type only. We did not identify a tool validated in a primary care that can be used by a non-expert clinician to classify common chronic headache disorders and screen for primary headaches other than migraine and TTH in primary care.

**Conclusions**

Despite the availability of many headache classification tools we propose the need for a tool which could support primary care clinicians diagnose and manage chronic headache disorders within primary care, and allow more targeted referral to headache specialists

**Introduction**

Around 4% of primary care consultations and 30% of neurology outpatient appointments in the UK are due to headache disorders (Latinovic 2006 and Hopkins).

Yet many patients presenting in primary care with headache do not have a formal diagnosis, are misdiagnosed, and can potentially receive inappropriate drug treatment and management ([1](#_ENREF_1)). A study in the UK study found 70% presenting with new onset headache were not formally diagnosed (Kernick) and 88% of patients with a history of sinus headache screened in primary care clinics in the US met International Headache Society criteria for migraine (Schreiber 2004).

Despite deceptively simple diagnostic criteria for different headache types such as the comprehensive headache classification ‘The International Classification of Headache Disorders, 3rd edition’ ([2](#_ENREF_2)) and the National Institute for Health and Care Excellence (NICE) headache guidance ([3](#_ENREF_3)), in reality, it can be challenging for a non-expert clinician to accurately diagnose headache disorders.

The Chronic Headache and Self-management Study (CHESS) is a National Institute for Health Research (NIHR) funded programme grant (project number RP-PG-1212-20018) with the overall aim of developing and testing a self-management programme for people living with chronic headache. As part of the study we want to be able to classify participant’s chronic headache types both for reporting purposes, and as part of the study intervention to allow targeted treatment and advice. Specifically we need a classification tool that can be used by a non-expert clinician to screen for primary headache disorders other than migraine and tension type headache (TTH), distinguish between chronic migraine and chronic TTH and identify medication overuse headache (MOH) in primary care settings. We anticipate that such a tool could also support primary care clinicians diagnose and manage chronic headache disorders within primary care, and allow more targeted referral to headache specialists.

We therefore conducted this systematic review to 1) identify any existing tools used to classify chronic headache disorders and 2) assess the validation of tools identified.

**Methods**

We registered this review prospectively with the International Prospective Register of Systematic Reviews. PROSPERO 2015: CRD42015019863 ([4](#_ENREF_4)) and we followed the PRISMA guidelines for the reporting of systematic reviews. ([5](#_ENREF_5))

***Search strategy and study selection***

We included studies that describe the validation of headache tools intended to diagnose, classify or screen for one or more headache types and compare with a reference standard. We only included studies published in English and published from January 1988, the publication date of the first “International Classification of Headache Disorders (ICHD)”([2](#_ENREF_2)). We excluded studies with participants aged below 18 years and any dissertation and conference proceedings, plus those studies where the sole purpose of the study was to report the validation of a tool in a different language.

With the support of an academic support librarian, we searched key databases: MEDLINE, ASSIA, Embase, Web of Knowledge and PsycINFO. The searches were updated in June 2016. We used free text and MeSH terms based on those used for NICE headache guidelines 2012([6](#_ENREF_6)); search words included:

‘Headache’, ‘headache disorders’, ‘headache disorders primary’, ‘headache disorders secondary’, ‘migraine’, ‘migraine disorders’, ‘migraine with aura’, ‘migraine without aura’, ‘tension headache’, ‘cluster headache’, ‘medication overuse headaches’ combined with ‘classification’, ‘diagnostic’, ‘diagnosis’, ‘diagnostic techniques and procedures’, ‘sensitivity’, specificity’, ‘efficacy’, ‘effectiveness’, ‘efficiency’, ‘predictive value of tests’, ‘likelihood function’, ‘diagnostic odds ratio’, and ‘screening,’ ‘questionnaire,’ ‘survey’, ‘interview as topic’ and ‘tools’, ‘instruments’ and ‘ICHD’.

Results were managed using the Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI Centre) reviewer 4 software, duplicates removed, and titles checked for relevance by two authors (RP, KP). We sought a full copy of possible relevant papers, which were assessed independently for inclusion by two authors and any disagreement resolved by discussion. We checked reference lists of relevant papers for any additional studies.

***Data extraction and quality assessment***

Three authors (RP, CB, KP) independently extracted data from papers included in the review using a predetermined pro-forma to capture both study and tool specific information: study design, characteristics of study participants, a brief description of the diagnostic or classification tool, test characteristics, diagnostic/classification parameters, validation assessment (sensitivity, specificity), how the tool is used (questionnaire, online, interview) and by whom (expert, non-expert, patient).

The same three authors independently assessed the methodological quality of each study using the Quality of Diagnostic Accuracy Studies (QUADAS-2), a validated tool used for the quality assessment of diagnostic accuracy studies ([7](#_ENREF_7)).

The QUADAS-2 assesses four domains for risk of bias: patient selection (sampling and exclusions), index test (conduct and interpretation), reference standard (conduct and interpretation), and flow and timing (interval between index and reference standard, number receiving reference standard and included in the analysis). The sets of signalling questions used for each domain have been tailored to the content of the review as recommended by the authors of the tool.

We assessed risk of bias as low, high or unclear for each domain and calculated an overall risk of bias dependent on the number of domains judged as high risk of bias: 0 domains = Low, 1= Low/medium, 2=Medium, 3=Medium/high, 4=High risk of bias. Where criteria used to judge risk for one of the domains was unclear, the risk was considered ‘high risk’ and this was denoted in the overall risk of bias.

**Results**

***Study selection***

We identified 4348 records from the combined database searches and removed 2459 duplicates. The remaining 1889 records were screened for relevance and 1694 records were excluded because they did not meet the study inclusion criteria. We obtained the full text for 195 records and excluded 157 after reading the full paper that did not meet the inclusion criteria, resulting in a total of 38 papers included in the review (figure 1).

***Study characteristics***

The 38 papers published between 1991 and 2016([8-45](#_ENREF_8)) report validation studies from 18 different countries, with most papers from the US (n=10) and Italy (n=4). The papers report the validation of 30 tools, nine to diagnose or classify more than one headache type and 21 to classify or screen for one headache type only: migraine (n=18), cluster headache (n=2), and probable medication overuse headache (n=1) (Table 1).

The number of participants included in the validation studies ranges from 50 to 9346. The majority of the tools are questionnaires, self-completed (n=17), completed face-to-face with a clinician or researcher (n=8), and self-complete online questionnaires (n=2). The three remaining tools are computerised decision support systems designed to assist clinical diagnosis. The number of items in the questionnaires range from short single item migraine screen tests ([45](#_ENREF_45)) to a longer 76 item questionnaire ([8](#_ENREF_8)) plus the complex computerised diagnostic tools ([11](#_ENREF_11), [12](#_ENREF_12), [32](#_ENREF_32)).

The tools have been validated in headache clinic settings (n=14) as part of general health or household surveys (n=6), neurology clinics or departments (n=5), primary care settings (n=4), emergency care (n=3), community (n=2) and other settings such as ophthalmology departments, temporomandibular joint and orofacial pain clinics, and obstetrics and gynaecology clinics (n=3), with some tools validated in more than one setting.

In most studies the reference standard used to validate the tool is a face-to-face neurological assessment by a headache specialist doctor based on the ICHD criteria used at the time of validation. Exceptions include where the reference standard is conducted by a headache nurse specialist experienced in headache diagnosis ([32](#_ENREF_32)), primary care doctors trained to use IHS criteria for migraine ([28](#_ENREF_28)) and researchers([45](#_ENREF_45)). When reported, the time interval between the index test and reference standard is generally short (conducted on the same day, or within four weeks) although the longest interval reported was between two to three years ([25](#_ENREF_25)).

There is wide variation in the reporting of the psychometric results across studies with some reporting an overall sensitivity and/or specificity only, others reporting results for particular headache types, and with some studies also reporting positive and negative predictive values. We have reported the psychometric results for each study in table 1.

***Study Quality***

The quality assessment for risk of bias for the four QUADAS-2 domains: patient selection, index test, reference standard, flow and timing, plus an overall quality assessment are reported in table 3. The overall risk of bias was low for five studies, low/medium for 16, medium for seven, medium/high for six studies and high for four studies.

***Multiple headache types***

We identified nine tools that diagnose or classify more than one headache type; three computerised decision support tools and six questionnaires. The three computerised diagnostic tools support clinical diagnosis of the common episodic and chronic primary headache disorders migraine and TTH, trigeminal autonomic cephalagia (TAC) and medication overuse headache (MOH) ([11](#_ENREF_11), [12](#_ENREF_12), [32](#_ENREF_32)). The sensitivity of the computerised decision support tools appears to be good for most headache types, the authors report lower sensitivity for probable migraine and probable TTH([12](#_ENREF_12)) and new daily persistent headache (NDPH) ([32](#_ENREF_32)). All three tools have been validated in headache clinic populations; overall risk of bias is lowest for the study by Dong et al (2014) ([12](#_ENREF_12)).

The six questionnaires all classify the common primary headache disorders migraine and TTH plus MOH. The 76 item Italian ICHD-II based questionnaire reports the highest sensitivity and specificity and has low risk of bias ([8](#_ENREF_8)). The HARDSHIP questionnaire, developed as part of a Global Campaign against Headache initiative, has been the most extensively validated, in different languages and cultures and is suitable to be administered by trained lay interviews; examples of studies using the questionnaire are presented in the table. Sensitivity ranges from 63-85 and specificity 82-99 for migraine, and sensitivity 51-64 and specificity 51-64 for TTH across the four studies (India, China, Russia and Pakistan)([46](#_ENREF_46)).

In addition to the common primary headache disorders migraine and TTH, one self-complete questionnaire also screens for Trigeminal Autonomic Cephalagia ([17](#_ENREF_17)), validated in a headache clinic population, authors report sensitivity 63.3 (52.9-72.7) and specificity 98.8 (96-99.8).

***One headache type***

*Cluster headache*

We identified two tools that screen for cluster headache, both self-completed questionnaires validated in headache clinic populations with low/medium risk of bias ([14](#_ENREF_14), [43](#_ENREF_43)). The presence of 5 of 7 features (pain severity and location, duration < 3 to 4 hours, frequency and daily reoccurrence of attacks, rhinorrhoea and restlessness) has high sensitivity 100 and specificity 95.1([43](#_ENREF_43)).

*Probable medication overuse headache*

We found one tool for the screening of probable medication over-use headache (pMOH)([13](#_ENREF_13)), validated in a headache clinic setting with low/medium risk of bias. Based on ICHD-II criteria for pMOH, three items were found to have sensitivity 81 and specificity 100.

*Migraine*

We identified 18 tools designed to classify or screen for migraine: migraine only (n=10), migraine with and without aura (n=5), aura only (n=1), chronic migraine (n=1) and menstrual migraine (n=1).

The majority of the migraine tools are short self-complete screening questionnaires; where authors have published the tool the most frequent items are shown in table 2. Notably there are no questions common to all tools, but questions to identify nausea and/or vomiting related to headache (n=7) and photophobia (n=7) are most frequent across the tools, followed by pain restricting activity (n=6), and phonophobia (n=5).

The most widely used and validated of the migraine tools is the ID Migraine with three questions on headache related disability, nausea and photophobia ([29](#_ENREF_29)). A previous meta-analysis of 13 studies reports sensitivity of 84 (95% CI, 75-90) and specificity 76 (95% CI 69-83)([47](#_ENREF_47)). ID Migraine has been validated in different languages (not reported here) and different settings, including ENT and ophthalmology, and temporomandibular joint and orofacial pain clinics. ([16](#_ENREF_16), [24](#_ENREF_24))

The seven item Asian Migraine Criteria (AMC) reports the highest sensitivity and specificity (99.3 and 84.4), but medium/high\* risk of bias([19](#_ENREF_19)). The eight item Migraine Assessment Tool (MAT) reports good sensitivity and specificity (89 and 79) and low risk of bias.

Not surprisingly the tools developed to identify migraine with or without aura, all self-completed questionnaires, tend to be longer, ranging from 10 questions to 56 questions. The shortest of these, The University of California-San Diego (UCSD) Migraine Questionnaire([42](#_ENREF_42)) report sensitivity and specificity for migraine with aura (71-81 and 100), migraine without aura (100 and 91-94) with low/medium risk of bias. Whereas longer questionnaires where participants are asked to describe aura in their own words , ([23](#_ENREF_23)) report higher sensitivity and specificity for migraine without aura (93-100 and 100) and migraine with aura (88-89 and 95-97) but has medium risk of bias([23](#_ENREF_23)).

The Visual Aura Rating Scale (VARS) ([15](#_ENREF_15)) is intended to supplement the ICHD-II and captures visual aura symptoms and characteristics (e.g. location, scotoma, ziz-zag lines, duration, and gradually development). Validated in a population already diagnosed with migraine with aura, sensitivity and specificity are high (91 and 96) and methodological quality, medium\* risk of bias.

Identify Chronic Migraine (ID-CM) ([48](#_ENREF_48))is an online tool to help clinicians identify patients likely to have migraine, and in particular, chronic migraine. The authors report sensitivity and specificity for migraine (83.5 and 88.5) and for chronic migraine (80.6 and 88.6) risk of bias is low/medium.

**Discussion**

The review identified many papers validating headache diagnostic classification tools. The large number of tools identified indicates the demand for tools that can be used to support the diagnosis of headache disorders clinically and/or allow the classification of headache disorders in research.

More than half of the papers (n=21) were judged to have low or low/medium risk of bias for overall quality. The risk of bias was judged high most frequently for the QUADAS-2 domain ‘flow and timing’ which assesses the interval between collecting the index and reference standard, the number of participants receiving the same reference standard and whether all participants were included in the analysis. The criteria used to judge the risk of bias was unclear for at least one domain in 23 papers and recorded as ‘high risk’, indicating that quality assessment often reflects bias in reporting rather than bias in the conduct of the study. Most of the tools identified in the review have been tested in one setting only, predominantly in headache clinic populations. Exceptions include the Hardship tool, which has been validated in different languages and cultures, and the ID-migraine, which has been validated extensively in different languages and settings.

The overriding purpose of the review was driven by our own research requirements, that is, to identify existing headache classification tools that can be used by a non-expert clinician in primary care to classify chronic headache disorders; and specifically to identify tools that allow the user to screen for primary headache disorders other than migraine and tension type headache (TTH), distinguish between chronic migraine and chronic TTH and identify medication overuse headache (MOH). We anticipated that such a tool could also support primary care clinicians diagnose and manage chronic headache disorders within primary care more effectively.

We identified six tools that allow the user to screen for primary headache disorders other than migraine and TTH; four to identify trigemal autonomic cephalagias (TACs) and two specifically for cluster headache. The three computerised diagnostic tools appear to perform well for identification of TACs, as does the longer of the cluster headache specific questionnaires([43](#_ENREF_43)). Only one of the computerised diagnostic tools was designed and validated for use by a non-expert clinician, but to date has not been validated in primary care (Dong).

The HARDSHIP questionnaire is the most extensively validated of the tools that allows the distinction between chronic migraine and chronic TTH by a non- expert clinician; the questionnaire was not designed to identify other primary headache types. The Identify Chronic Migraine (ID-CM) tool helps clinicians identify patients likely to have migraine, and in particular, chronic migraine; but does not allow the classification of other chronic headache types. More commonly the tools identified in the review classify episodic rather than chronic headache, with 17 screening for episodic migraine. It is interesting to note that where authors have published the tool no question is common to all tools.

The review also identified a number of tools that classify medication overuse headache including a brief self-complete questionnaire adapted from ICHD-II for MOH with sensitivity 81 and specificity 100([13](#_ENREF_13)).

We identified a large number of good quality studies, validating a wide range of different headache classification tools; and the review provides a comprehensive evaluation and summary of tools that researchers and clinicians can use to classify headache disorders. However we did not identify a tool that fully met our own research needs that has been validated in a primary care setting and could be used by a non- expert clinician in primary care to support the diagnosis of common chronic headache disorders and screen for primary headache disorders other than migraine and TTH. We propose that such a tool could potentially support more targeted referral to headache specialists and free up under-resourced neurology departments (Latinovic).

*Strengths*

We searched for tools that diagnose, classify or screen for all headache types rather than restrict the search to tools for chronic headache only.

All data extractions and quality assessments were double coded independently by three reviewers and agreement checked; and we used the established tool QUADAS-2 to assess the quality of studies.

*Limitations*

Our search strategy used MeSH terms based on the search terms used to develop NICE headache guidelines to identify potential validation studies, but it is possible that some studies were missed. Reporting of psychometric results made it difficult to compare across studies.

**Conclusions**

Diagnosis of chronic headache disorders can be challenging for non-expert clinicians.

Depending on the clinical, or research, need there are a number of adequate tools available that could be used in specific contexts. Nevertheless, there are currently no tools validated in primary care that can be used by a non-expert clinicians to classify chronic headache disorders that also allow the user to screen for primary headaches other than migraine and TTH. The availability of such a tool could support primary care clinicians diagnose and manage chronic headache disorders within primary care, and allow more targeted referral to headache specialists.

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