Reviewer's report

Title: Diagnosing migraine in research and clinical settings: Development and validation of the Structured Migraine Interview (SMI)

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Reviewer: Csaba Ertsey

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Please note that the numbers refer to the points in BMC Neurology's recommendations for reviewers

Review:

The manuscript reports the validation of the Structured Migraine Interview, a 10-item questionnaire designed for the identification of migraine. This is an important topic as a tool that could reliably identify migraine would be very helpful both for clinicians and researchers.

1. The purpose of the study is well defined. As the instrument had been used in two studies, mentioning ‘Development’ in the title does not seem fully justified. (Discretionary Revision)

2. Generally speaking, the Methods section is ample and well-written. The SMI and the diagnostic criteria used by the authors are in keeping with the criteria of the International Headache Society. Nevertheless a couple of points need a significant improvement.

   a) Page 7. The method the City of London Migraine Clinic used for selecting patients should be clarified (eg. previous diagnosis of migraine, all patients visiting the Clinic in a given time frame etc). (Major Compulsory Revision)

   b) The diagnosis by the SMI was compared with the migraine diagnosis given by the headache specialist in a sub-sample of 41 randomly selected patients. This is less than 7% of the 646 patients who completed the study. The authors should explain why such a small fraction was chosen for comparison and whether it is safe to suggest that this sub-sample is representative of the whole study population. (Major Compulsory Revision)

   c) Paragraph 4 on page 7: Twenty patients who had been administered the SMI in a face to face interview as part of a previous study were re-interviewed by phone to assess the reliability of the instrument, a mean 2.5 years after the face to face interview. This is a rather small sample size. Also, the time gap is rather long as the test&retest method of testing reliability usually recommends a time span of about 1 month. The authors should clarify whether it is safe to think that reliability can be assessed this way. (Major Compulsory Revision)

   d) Using self-reported migraine and antimigraine drug use as the main (and in the majority of patients, only) means of assessing the SMI's validity seems inadequate as self-reported migraine can be twice as frequent as migraine
diagnosed by the IHS criteria (Svensson et al, The Journal of Headache and Pain, 2004;5(3):171-176). The authors should indicate why they preferred using these data. (Major Compulsory Revision) Also, the authors could add Spearman’s rho values for the SMI diagnosis and self-reported migraine/antimigraine drug use for the sub-sample of patients with a clinically verified diagnosis of migraine in the Results section. (Minor Essential Revision)

e) Finally, the first sentence of paragraph 2 of the Methods section (on page 5), probably referring to the experience of the staff members pilot testing the questionnaire, might be omitted as the info is not relevant for the further use of the questionnaire by migraineurs. Instead, an information on what migraineurs think about the difficulty and time consumption of filling in the SMI would be interesting. As the present study is not suited for posing this question, data from the previous studies (if available) could be mentioned in the Discussion section. (Discretionary Revision)

3. Are the data sound?

The authors have studied a total of 646 patients. Generally speaking this is a more than adequate number. Some parts of the study, however, could benefit from some data improvement:

a) As mentioned above, the number of the subjects in whom the SMI diagnosis was compared to the clinical one (41) is rather small. Also, knowing the time elapsed between the two diagnoses (clinical and SMI) could be important, as well as knowing how many times the headache specialists had seen the patients before they were selected in the study, and whether, in those seen several times, there was a change in the clinical diagnosis. (These data may be important because it is not always possible to establish a correct diagnosis at the first visit and patients’ complaints and symptoms may change over time. Was the diagnosis of migraine still valid at the time when the patient filled in the SMI questionnaire?) (Minor Essential Revision)

b) In the first paragraph after Table 1 the authors report the percentage of patients reporting migraine and receiving migraine pharmacological treatment. As the patients only completed the SMI and reported their demographic details, this information was most likely based on questions 8 and 10 of the SMI. If so, how can we be sure that “migraine pharmacological treatment” refers to specific migraine treatment? For some patients the name of a non-specific drug eg. Migraleve may be misleading, and also people with other conditions such as cluster headache could also use specific antimigraine drugs such as triptans, so this info is not 100% relevant for the diagnosis of migraine. (Minor Essential Revision)

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?

Yes.

5. Are the discussion and conclusions well balanced and adequately supported by the data?

The discussion is thorough and well balanced. Some points were not
self-evident, so these might benefit from re-editing.

a) I agree that the study population was a highly selected one (patients from a specialized headache centre), probably with an increased awareness about their headaches, so the comment about SMI detecting a significant number of migraineurs is not really surprising. (Discretionary Revision)

b) Speaking about the (modest) sensitivity of the SMI the authors state that ‘the validity sample was unbalanced by lack of subjects without headache’. The way sensitivity is defined (see also Table 2 of the manuscript) I can’t see how including headache-free subjects could improve the sensitivity. (Minor Essential Revision)

The conclusion that “a structured interview is a useful and valid tool to use in research for the identification of migraine” holds, as the specificity of the SMI was 1. However, I feel that with a misclassification rate of 29% the SMI should not be recommended for clinical use. (Major Compulsory Revision)

6. Are limitations of the work clearly stated?
I think that more emphasis should be put on the limitations posed by the methods and sample sizes (sections 2b, 2c and 3a of this report). (Major Compulsory Revision)

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?
Yes.

8. Do the title and abstract accurately convey what has been found?
As mentioned above, the ‘Development’ part of the title may be superfluous. The Methods section of the abstract is not informative (the methods of validation are not described). (Major Compulsory Revision)

9. Is the writing acceptable?
Yes. There are some typos as in ‘under diagnosed’ and ‘under treated’ (mentioned in the Abstract), both of which are commonly written as a single word, or “none migraine recurrent headaches” (page 5, paragraph 3). Also, “analgesia” in the last row of page 8 probably refers to analgesics and not a pathological state of the sensory system; for the sake of non-native English speakers I’d recommend the use of the latter, more widely accepted term. (Minor Essential Revision)

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**
I declare that I have no competing interests.