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Translation and validation of an extended German version of *ID Migraine*™ as a migraine screening tool

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Abstract

Background and purpose: Diagnosing a patient with headache as a migraineur is critical for state-of-the-art migraine management. Screening tools are imperative means to improve the diagnostic yield in the primary care settings and specialized clinics. This study aims to translate and assess the diagnostic accuracy of a German version of the *ID Migraine*™ as a widely used and efficient screening instrument.

Methods: The Functional Assessment of Chronic Illness Therapy translation methodology was used to translate the original three-item *ID Migraine*™, including a fourth question for aura, from the English language into the German language. Diagnostic accuracy of the German *ID Migraine*™ and predictors of false screening results were assessed among patients presenting to a headache outpatient clinic of a tertiary care center in Germany over a 6-month period.

Results: The translation procedure yielded a harmonized German *ID Migraine*™ and its diagnostic accuracy was assessed in 105 patients (80 female, 46.5 $\pm$ 17.2 years of age), including 79 patients (75.2%) with migraine. The three-item German *ID Migraine*™ provides a sensitivity of 99%, specificity of 68%, and positive and negative predictive values of 90% and 95%, respectively, using a cutoff of $\geq$2. Positive and negative predictive values in a general headache population are estimated to be 74% and 98%, respectively. The aura question identified 18 out of 20 migraineurs with aura.

Conclusions: The German *ID Migraine*™ is an accurate screening tool for migraine even in a challenging population of a specialized outpatient clinic. Its diagnostic accuracy indicates a potential utility for screening in primary health care.

Keywords

diagnosis, migraine, screening tool

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Introduction

Migraine is a highly prevalent neurological condition, which affects about 10–15% of the world's population and substantially interferes with patients' daily activities and vocational and social life.[1] Furthermore, it is associated with significant costs for the economy, the society, and the health-care system due to loss of productivity, psychiatric comorbidities, and medical complications.[2,3] The availability of novel acute and prophylactic treatment options, including calcitonin gene-related peptide (CGRP) antibodies, and increasing acknowledgment of non-pharmacological treatment strategies lead to a new era of migraine care which enables effective treatment even in the most severely affected patient.[4,5] Unfortunately, the proportion of patients with access to evidence-based management of their migraine is

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Table 1. German version of the *ID Migraine*™ (with original English items).[a]

German translation	English original[b]
Bemerkten Sie während der letzten 12 Monate folgende Begleiterscheinungen zu Ihren Kopfschmerzen:	During the last 12 months, did you have the following with your headache:
(1) Beeinträchtigte Ihr Kopfschmerz für mindestens einen Tag Ihre Fähigkeit zu arbeiten, zu lernen, oder das zu tun, was zu erledigen war?	(1) Your headache limited your ability to work, study, or do what you needed to do for at least 1 day?
(2) Verspürten Sie Übelkeit oder das Gefühl sich übergeben zu müssen?	(2) You felt nauseated or sick to your stomach?
(3) Fühlten Sie sich sehr durch Licht gestört (oder deutlich mehr als ohne Kopfschmerzen)?	(3) Light bothered you (a lot more than when you don't have headaches)?
(4) Hatten Sie kurz vor Beginn dieser Kopfschmerzen Sehstörungen (z.B. Blitze, dunkle Punkte, Flackern)?	(4) Just before these headaches, did you have any visual disturbances (flashes, dark spots, vibrations . . .)?

[a]The left column contains the finalized and harmonized German translations of the instrument. Note that the screening period is extended from 3 months to 12 months and that, in analogy to the French version, the German version includes a fourth question about visual aura phenomena.
[b]Item 4 is not part of the original three-item *ID Migraine*™ and derived from the French version.

limited since two-third of patients are incorrectly diagnosed and only 1 out of 10 migraine patients is seen by a headache specialist.[6] This clearly indicates that comprehensive migraine care does critically depend on not only treatment options but also its access. The first and critical step to improve the situation of these patients is to correctly diagnose migraine. Screening tools are powerful as well as well-appreciated means for this purpose, particularly for the health-care provider in the primary care environment.

The *ID Migraine*™ is an easy-to-use screening tool that identifies migraineurs through three questions with a sensitivity and specificity of about 80% by using the criteria of the second edition of the International Classification of Headache Disorders (*ICHD-2*).[7] *ID Migraine*™ has been translated into several languages and successfully implemented in primary care settings.[7,8] An extended version consists of four items including a question which inquiries about the aura phenomena.[8] Until today, a validated translation of the *ID Migraine*™ into the German language including an assessment of its diagnostic accuracy using *ICHD-3* criteria has not been available. The aim of this study was to fill this gap. Successful validation of this screening tool may enhance its use in German-speaking countries.

Methods

Study population and setting

This prospective study was conducted at the headache outpatient clinic of the University Hospital in Greifswald, Germany, a tertiary care center. Referrals are routinely made by neurologists, general practitioners, and rarely by physicians from other specialties, such as pain specialists. Patients are assessed, diagnosed, and treated by board-certified neurologists with very advanced expertise in headache care. All patients presenting for the first time to the headache clinic within the second half of 2019 were screened and asked to provide written informed consent to participate in this study. Further inclusion criteria were age of ≥18 years and being a native speaker of the German language. There were no exclusion criteria in order to avoid selection bias. The study was approved by the local ethic committee (BB 161/18). Its report adheres to *Standards for Reporting Diagnostic accuracy studies* (STARD).[9]

Translation of the questionnaire

The author of the *ID Migraine*™, Professor R Lipton, kindly authorized its use for the intended purpose of this study. The original version includes three questions about headache characteristics and accompanying symptoms (see Table 1 for original items).[7] In analogy to the French version of the *ID Migraine*™, we included a fourth question about aura symptoms and extended the assessed time period from 3 months to 12 months to account for cases of low attack frequency.[8]

The translation into German was done using the established Functional Assessment of Chronic Illness Therapy (FACIT) translation methodology, which can be found online including a full description of the translation procedure.[10] In brief, three German native speakers (including one with a professional qualification in English language and literature studies) conducted a forward translation from English to German blinded to each other's translations. The three versions were then reviewed by all three and a concerted translation was established. A professional translator, who is also an English native speaker, then performed a back-translation from German into English. The agreement of original *ID Migraine*™ items and back-translated items was assessed by the author of the original English version, Professor R Lipton. Comments were subsequently discussed between the three German translators and a reconciled translation of the established items. The resulting translation was again translated back, evaluated, and approved. The harmonized version finally underwent a cognitive debriefing by 10 individuals, who were asked to rate the clarity and comprehensibility of the German *ID Migraine*™ items.

Data collection and processing

Patients were given the finalized German *ID Migraine*™ as part of their initial assessment at the headache outpatient clinic. They were handed out a printed version including checkboxes to agree or disagree with the four questions about their headaches using a paper-and-pencil method. The results of the questionnaire were pseudonymized and entered along with routine clinical data (patient age, gender, and employment status) and further headache characteristics (disease and attack duration and attack frequency) to an electronic data capture system for statistical analyses.

Statistics

Customized MATLAB scripts (R2018a, Natick, Massachusetts, USA) were used for data preprocessing, which included calculation and storage of binary true and false positive or negative screening results for various cutoffs tested, respectively. Statistical evaluations were done using SPSS (version 25, IBM, Armonk, New York, USA). Results from descriptive statistics are reported as group means $\pm$ standard deviations following confirmation of normal distribution of data. Results from inferential statistics are reported with their appropriate coefficients and, if applicable, odds ratios (OR) including 95% confidence intervals in square brackets and p values denoting the statistical significance. The values of p equal to or lower than 0.05 are considered significant. To address the multiple comparison problem when testing more than one hypothesis, we used the Bonferroni correction method.

Statistical performance of the translated *ID Migraine*™ was evaluated using receiver operating characteristics (ROC). The area under the curve (AUC), sensitivity, specificity, and predictive values were evaluated for the original three- and extended four-item questionnaire using cutoffs of $\geq$2 and $\geq$3 positive answers. Since predictive values critically depend on the disease prevalence in the target population, we additionally calculated predictive values for a migraine prevalence of 48% that is expected in a headache population according to health insurance data.[11,12] Predictors for false positive and negative screening results were evaluated using a generalized linear model with a logit link function and binomial response distribution, and including patient age, gender, attack frequency, disease duration, presence of nausea and/or phono-/photophobia, and employment status as predictive factors. Independence of predictors was confirmed using correlation analyses (see Supplemental Table 1).

Results

The study population consisted of 105 patients (80 female, 46.5 $\pm$ 17.2 years of age). The mean duration of the headache disorder before presentation was 17.9 $\pm$ 13.3 years. Employment status of patients was as follows: 39% employed (n = 41), 2% self-employed (n = 2), 4% unemployed (n = 4), 28% retired (n = 29), 11% students (n = 12), 5% trainees (n = 5), and 11% did not provide an answer (n = 12). Seventy-nine patients (75.2%) were clinically diagnosed with migraine; of these, 27% (n = 21) had a chronic migraine. Other diagnoses were cluster headache (7.6%, n = 8), tension-type headache (4.8%, n = 5), and other headache syndromes (12.4%, including trigeminal neuralgia (n = 3), nummular headache (n = 2), hypnic headache (n = 1), idiopathic intracranial hypertension (n = 2), and other symptomatic headache syndromes (n = 5)).

Translation procedure

The FACIT methodology could be followed without protocol deviations. The finalized translation can be found in Table 1. The introduction sentence was slightly modified in the first reconciliation to better express temporal continuity (use of "während" instead of "in den letzten") and the aspect of conscious perception of headache by the patient ("Bemerkten Sie . . . " instead of "Hatten Sie . . . "). A revision was furthermore necessary concerning the question about nausea and vomiting after the back-translation to properly express the feeling of nausea and/or discomfort in the stomach area in the German language. The remaining three questions could be included without changes after the back-translation. Cognitive debriefing did not reveal any further issues with the translated items but confirmed their intelligibility.

Diagnostic performance of the German *ID Migraine*™

The diagnostic performance and results of the ROC analyses are summarized in Figure 1 and Table 2. The AUC was 0.88 for both, the classic three-item *ID Migraine*™ (excluding the aura question) and the extended four-item version (including the aura question). Further diagnostic measures, however, substantially differed depending on the cutoff and number of items used. A cutoff of $\geq$2 yielded a sensitivity of 99% irrespective of the total number of items while specificity was 68% and thus substantially higher using the three-item instead of the four-item version. Specificity for both, the classic and extended version, was enhanced using a cutoff of $\geq$3 and was 86% while the sensitivity was lower than 80%. Positive and negative predictive values were generally greater than 90% considering the prevalence in the study population, except for negative predictive values using a cutoff of $\geq$3 for both *ID Migraine*™ variants. Calculation of predictive values for a reference population, that is, a general headache population with a migraine prevalence of 48% (see the "Methods" section for details), revealed a positive and negative predictive value of 74% and 98%, respectively, for the three-item *ID Migraine*™ using a cutoff of $\geq$2. Positive predictive values were greater than 80% applying a $\geq$3 cutoff to the classic and

extended version, yet negative predictive values decreased to about 80%. The aura question identified 18 out of 20 patients with migraine with aura. The two unidentified patients suffer from a vestibular and sensory aura with paresthesia, respectively.

Predictors for false positive and negative rates

Neither attack frequency, disease duration, employment status, patient age, nor gender were predictive of false positive or negative screening results. Yet, migraineurs without nausea or vomiting during attacks had higher odds to be classified false negative (OR = 3.66 [1.37–9.74], $p = 0.009$).

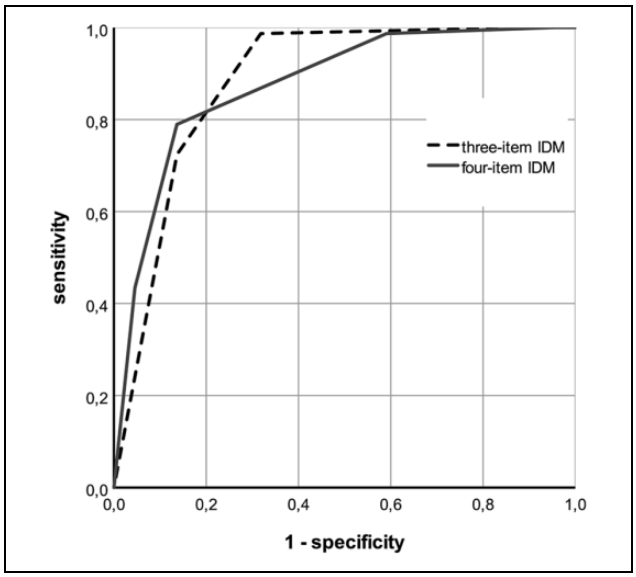

Figure 1. ROC curve illustrating the diagnostic performance of the German *ID Migraine*™ (IDM). Note that ideal operating points of the three- and four-item screening instrument yield a sensitivity of about 80% and specificity of greater than 80%. AUCs are about 0.88 and thus almost equal between both variants. ROC: receiver operating characteristic; AUC: area under the curve.

Discussion

We applied a validated translation methodology to the *ID Migraine*™ as one of the most widely used migraine screening tools and yielded a validated extended German *ID Migraine*™. We furthermore assessed its diagnostic accuracy and found that it is an accurate tool for the detection of migraine, even in a diverse and at times challenging headache population at a specialized headache center. Excellent predictive values, assuming a more general headache population, are encouraging and suggest its use in the primary care setting.

Translation procedure

The FACIT translation methodology is a more rigorous version of the double-back-translation method considered to be superior to single translation and translation by committee.[13] The ultimate goal of any translation is to achieve equivalence between instruments so that any difference detected is the result of true differences and not inherent to the measurement tool.[14] The most difficult item to translate and construct to assess was nausea. This is unsurprising since subjective thresholds for feeling nauseated and its description exist.[15] Multiple quality control measures were implemented to enhance equivalence. Independent review and finally approval of back-translations of the interim and reconciled translations by the author of the original *ID Migraine*™ support the agreement of the versions in both languages (English and German). We furthermore conducted cognitive debriefing interviews of the final German *ID Migraine*™ on an item-by-item basis that did not reveal any translation errors or misinterpretations of the items.

Diagnostic performance

Measures of diagnostic accuracy critically depend on the selection of cutoffs for a positive screening result and the number of items. The original three-item *ID Migraine*™ has shown to provide a sensitivity and a specificity of 81% and 75%, respectively, using a cutoff of ≥2 in a primary care setting.[7] The German *ID Migraine*™ yielded a

Table 2. Diagnostic performance of the German *ID Migraine*™.[a]

					Study population		Reference population	
Items	Cutoff	AUC	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	PPV (%)	NPV (%)
Three items	≥2	0.883	98.7	68.2	90.4	94.5	74.1	98.3
	≥3		72.4	86.4	94.2	50.8	83.1	77.2
Four items	≥2	0.876	98.7	40.9	83.5	91.2	60.1	40.1
	≥3		78.9	86.4	94.6	57.4	84.3	81.6

AUC: area under the curve; PPV: positive predictive value; NPV: negative predictive value.

[a]The diagnostic performance was tested in a specialized tertiary care outpatient headache clinic of a German university hospital. Sensitivities and specificities of the instruments are generally about or greater than 80%, except for a lower specificity when a cutoff of ≥2 is used, particularly in the four-item variant. Predictive values underline the suitability of the three-item German *ID Migraine*™ as a screening tool for migraine in the study population and assuming the migraine prevalence of a general headache population when a cutoff of ≥2 is used. A score lower than 2 in the three-item variant renders a migraine highly unlikely.

Table 3. Comparison of *ID Migraine*™ translations in five different languages, including the present translation into German.[a]

	German	English	French	Italian	Portuguese
Item number	4	3	4	3	3
Considered time frame (months)	12	3	12	3	3
Cutoff	≥2	≥2	No information	≥2	≥2
Sensitivity/specificity	98.7%/68.2%	81%/75%	87.5%/100%	94%/70%	94%/60%

[a]Note that there are differences in the time frame considered. Irrespective of the number of items, that is, whether or not a fourth aura question is included, the cutoff is generally chosen as ≥2, however, uncertainty remains regarding the French version. Sensitivity is higher than 80% in all and higher than 90% in three translations. Specificity, however, varies significantly and is reported to be between 60% and 100%.

substantially higher sensitivity and fairly lower specificity in a more specialized setting. While differences in the population's migraine prevalence provide an intuitive explanation for this difference, test sensitivity and specificity are generally independent of disease prevalence.[12] This does not exclude the possibility that migraine features are more prominent in a severely affected headache population and therefore enhance the patient's ability to recognize symptoms as belonging to their headaches, thereby enhancing test sensitivity. On the other hand, patients with non-migraine headaches may have more debilitating features than average causing a decreased specificity. This interpretation requires validation in primary care settings, which will also yield a more accurate estimation of the true diagnostic accuracy outside a specialized care facility. Reported diagnostic performances of the *ID Migraine*™ in other languages are, however, closer to our findings and thus leave the possibility that our results are already close to that of a more general headache population. To be more precise, versions in other languages provide a sensitivity and specificity of 87.5% and 100% in the French version, 95% and 72% in the Italian, and 94% and 60% in the Portuguese version.[8,16,17] A summary of the translations' characteristics and their diagnostic performance can be found in Table 3.

It is finally possible that the overrepresentation of chronic migraineurs in our population, that is, 27% in our versus 9% in the general migraine population,[18] needs to be taken into account since chronic migraineurs may present with headache features that differ from a classical migraine. This may therefore impede the detection of these individuals through a screening tool.[19] Unfortunately, the proportion of chronic migraineurs is not reported in most of the previous studies which limits comparison.

Potential applications and value for primary headache care

Migraine management has opened a new era of multimodal non-pharmacological approaches and specific pharmacological treatment options, including highly effective antibodies against CGRP.[5,20] Access to state-of-the-art care for migraine is, however, substantially limited and hinders a more widespread application of guidelines. It is well established that about 40% of patients do not know that they actually suffer from migraine. Additionally, about three-quarters of patients are without access to health-care providers for their headaches, which includes access to primary care physicians and headache specialists.[6,21] A recent study reported that about 70% of migraineurs would benefit from specialized treatment for their migraine.[22] In line with this notion, a simple three-item screening tool with a substantial diagnostic performance to rule in and, importantly, rule out migraine as an underlying primary headache disorder provides the intriguing perspective to enhance recognition and improve management of migraine through its widespread application in primary care settings. Based on a previous study, the time required to fill in the screening form is estimated to be lower than a minute, which underlines its applicability in real-world settings.[23] Future studies may address this point in the German health-care system. Another intriguing application of the screening tool would be its implementation in mobile applications or paper-based patient education material. This could facilitate the identification of potential migraineurs and their referral to pain specialists in areas with limited access or during pandemic situations.

Limitations

The study population included patients presenting to a specialized tertiary care center, which may have caused selection bias. Applying the test in primary care center could therefore affect predictive values since it depends on the prevalence in the target population. It is furthermore important to consider that this study was conducted on a German-speaking population in Germany. This leaves the possibility that the comprehensibility and diagnostic accuracy of the German *ID Migraine*™ may differ in Austria and Switzerland, as other German-speaking countries. Confirmatory studies of the German *ID Migraine*™ in these countries may a viable approach to test its validity.

Conclusions

The German version of the *ID Migraine*™ is a valid and easy-to-use screening tool to identify migraineurs, even in a challenging population of a specialized headache clinic.

Clinical implications

- A German *ID Migraine*™ as migraine screening tool is now available.
- The diagnostic accuracy of the German *ID Migraine*™ underlines its potential utility for primary care settings.

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Supplemental material

Supplemental material for this article is available online.

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