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Translation and Transcultural Validation of Migraine Screening Questionnaire (MS-Q)

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ABSTRACT

Introduction: Between 30 to 59% of patients with migraine without aura are undiagnosed and improperly treated, because primary care physicians are either too busy or unfamiliar with criteria for diagnosing migraine. Aim: The aim of our study was to translate the Migraine Screen Questionnaire (MS-Q) to BHS (Bosnian/Croatian /Serbian) language and to test reliability and validity of the translation on a sample of primary care patients. Material and Methods: The study was designed as cross-sectional, multi centric, diagnostic accuracy trial of an instrument for screening patients who visit general practitioners, with an aim to reveal migraine without aura. The instrument was the MS-Q, originally written in English and validated in Spanish population, and in this study being translated to BHS language. Results: Translation of the MS-Q to BHS language showed good diagnostic accuracy (sensitivity 80.0% and specificity 87.2%) and reliability (Cohen kappa 0.648) for migraine without aura, with significant screening yield among previously undiagnosed patients of 72.7%. The study also confirmed high percentage of patients with hidden MWA (52.9%) revealed by the MS-Q and ICH criteria that would otherwise remain undiagnosed. Conclusion: The MS-Q translation to BHS language could be considered as valid and reliable clinical instrument for revealing migraine without aura, similar by its performance to original questionnaire. It has considerable screening yield, discovering majority of patients with previously undiagnosed migraine without aura, whose definite diagnosis should later on be confirmed by the attending physicians using the ICH criteria.

Keywords: migraine without aura, Migraine Screen Questionnaire, translation, transcultural validation.

1. INTRODUCTION

Migraine is severe headache which during the course of an attack make patients incapable of performing any physical or mental work. According to the classification of the International Headache Society (IHS) two types of migraine are dominant: one with and another without aura. In order to establish diagnosis of migraine without aura (MWA) the following criteria established by the IHS have to be met: at least 5 attacks of headache, in the past; duration of the attack 4-72 hours; at least two of the following-unilateral, pulsating, moderate or severe headache, deteriorating with physical activity; and appearance of at least one of these symptoms: nausea and/or vomiting, photophobia and phonophobia. Prevalence of migraine is substantial, making it one of the most frequent diagnosis in primary care: e.g. in

Japan prevalence is 14% in general population, and about 18% in women, while prevalence in United States of America is close to 14.9% in total (20.2% in females and 9.4% in males). About 57% of patients with migraine have diagnosis of 'migraine without aura'.

Between 30 to 59% of patients with MWA are undiagnosed and improperly treated, because primary care physicians are either too busy or unfamiliar with criteria for diagnosing migraine. Although final diagnosis of the migraine without aura could be established only after meticulous checking whether a patient satisfies the IHS criteria or not, simple but reliable and valid screening questionnaires may save the time and efforts of general practitioners directing their attention only to cases with high probability of the MWA. Recently a questionnaire for screening migraine (MS-Q-Migraine Screen Questionnaire) with good diagnostic accuracy (sensitivity 82% and specificity 97%) was developed and validated, showing good screening performance in primary care settings. Since questionnaires designed to screen the patients with MWA in primary care are not available in BHS language to general practitioners from Bosnia & Herzegovina, translation of the MS-Q from English to Bosnian would increase their capacity to reveal and properly treat many of "hidden" MWA cases.

The aim of our study was to translate the MS-Q to BHS language and to test reliability and validity of the translation on a sample of primary care patients from Bosnia and Herzegovina.

2. AIM

The aim of our study was to translate the Migraine Screen Questionnaire (MS-Q) to BHS (Bosnian/Croatian/Serbian) language and to test reliability and validity of the translation on a sample of primary care patients.

3. MATERIAL AND METHODS

Design

The study was designed as cross-sectional, multi centric, diagnostic accuracy trial of an instrument for screening patients who visit general practitioners, with an aim to reveal migraine without aura. The instrument was Migraine Screening Questionnaire (MS-Q), originally written in English and validated in Spanish population, and in this study being translated to BHS language. The study was approved by the Ethics Committee of Clinical Center Kragujevac, and informed consent was obtained from all participants. Permission for translation to BHS language and transcultural validation of the MS-Q was obtained from Dr Javier Rejas, on behalf of all other authors of the MS-Q (e-mail from January the 9th, 2018) .

Population and sample

The study was conducted in the first half of 2018 on primary care outpatients from the following cities in Bosnia & Herzegovina (BiH): Sarajevo, Banja Luka, Zenica, Visoko, Tesanj, Kakanj, Srebrenik, Bijeljina, Mostar and Livno. The inclusion criteria were: the patients visiting general practitioners of the public heath care system in BiH, of both sex, age between 18 and 65 years, with normal cognition as judged by the attending general practitioners, literate and agreed to sign the informed consent. The exclusion criteria were: pregnancy, schizophrenia, major depression, bipolar disorder, epilepsy, acute diseases that distract the attention of a patient, and reporting any type of aura in relation to the headache. The sample was consecutive, i.e. all patients within the study period that fulfilled inclusion criteria and did not met exclusion criteria were enrolled after signing the informed consent.

Translation and transcultural validation of the Migraine Screen Questionnaire (MS-Q)

The Migraine Screen Questionnaire (MS-Q) was translated from English to BHS language according to Good practice of translation and transcultural adaptation set by International Society for Pharmacoeconomics and

Outcome Research (ISPOR) . Steps of this process were as the following: (1) two simultaneous and independent translations of original questionnaire from English to BHS language (the translators were native BHS language speakers); (2) harmonization of the two translations by an independent translator, native BHS language speaker; (3) back-translation of the harmonized BHS language text to English language, by independent, native English speaker (Dr Żan Friščić, othropedic surgeon, born and educated in Australia); (4) comparison of original questionnaire with back-translation by the committee of investigators to identify differences and suggest explanations; (5) an independent committee of three clinicians check all previous steps and suggests corrections of the translations, if any; (6) a team of investigators make final revision, giving comments and identifying potential problems; (7) language coordinator solves potential problems spotted by the team of investigators; (8) proofreading and correcting by two independent experts; (9) pilot validation of the translation on a group of five patients, native BHS language speakers, in order to ascertain whether the patients understand the translated items; (10) formulating final translation in a meeting of investigators with language coordinator.

Testing diagnostic accuracy and reliability of the questionnaire

The questionnaire was self-administered by the study subjects. As a gold standard of diagnosing migraine without aura we used clinical estimate based on the IHS criteria: at least four of them should be present: at least 5 episodes of headache in the past; duration of the attack 4-72 hours; at least two of the following-unilateral, pulsating, moderate or severe headache, deteriorating with physical activity; and appearance of at least one of these symptoms: nausea and/or vomiting, photophobia and phonophobia. The result of the MS-Q was accounted as "positive" (i.e. a patient suffered from migraine without aura) if the score was 4 or more. By comparing results of the MS-Q questionnaire with clinical estimate based on IHS criteria ("gold standard"), the following indexes were calculated: sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, negative likelihood ratio and Cohen Kappa index.

Statistics

Characteristics of the study sample were described using descriptive statistics by rates and percentages when categorical in nature, and by means and standard deviations when continuous. All calculations were made by the Statistical Program for Social Sciences (SPSS), version 18, and by MedCalc online calculator (available at: http://www.medcalc.com/).

4. RESULTS

In total 429 patients visiting general practitioners in primary health care of Bosnia & Herzegovina took part in the study. Characteristics of the study sample are shown in the Table 1. Female patients were more numerous and somewhat younger (46.0 \pm 12.7 years) than male patients (47.6 \pm 12.6 years). According to the International Headache Society (ICH) the criteria for migraine without aura

		The whole group (n=429)		
Age (years, mean \pm SD	46.4 ± 12.7			
Females	312 (72.7%)			
Males		117 (27.3%)		
Education	Elementary school	50 (11.7%)		
	High school	265 (61.8%)		
	Higher education	114 (26.5%)		
Primary reason for visiting a general practitioner	Cardiovascular disorder	78 (18.2%)		
	Respiratory disorder	9 (2.1%)		
	Psychiatric disorder	11 (2.6%)		
	Neurological disorder	226 (52.7%)		
	Gastrointestinal disorder	10 (2.3%)		
	Musculoskeletal disorder	26 (6.1%)		
	Endocrinological disorder	17 (4.0%)		
	Infection	37 (8.6%)		
	Other	15 (3.5%)		
Previous diagnosis	Yes	117 (27.3%)		
of migraine without aura	No	312 (72.7%)		
Family diagnosis of migraine	Yes	142 (33.1%)		
	No	287 (66.9%)		
Cmoking	Yes	151 (35.2%)		
Smoking	No	278 (64.8%)		
Drinking coffee	Yes	370 (86.2%)		
	No	59 (13.8%)		
Diagnosis of migraine	Yes	265 (61.8%)		
without aura accord- ing to International Headache Society (IHS) criteria	No	164 (38.2%)		

Table 1. Characteristics of the study sample. * standard deviation

correctly made diagnosis of the MWA in 112 (72.7%) of the newly diagnosed, suggesting significant screening yield. On the other hand, 6 patients (5.1%) from those who had diagnosis of migraine without aura before the study did not met the criteria of the IHS; the M-SQ correctly classified these patients as not having the MWA, but it also wrongly classified 8 patients (6.8%) as not having the MWA, while they actually met the ICH criteria.

The so-called "hidden migraine without aura", i.e. percentage of patients with de novo diagnosis out of total number of migraine without aura patients diagnosed by both ICH criteria and MS-Q was 52.8%.

5. DISCUSSION

Translation of the MS-Q to BHS language showed good diagnostic accuracy (sensitivity 80.0% and specificity 87.2%) and reliability (Cohen kappa 0.648) for migraine without aura, with significant screening yield among previously undiagnosed patients of 72.7%. The study also confirmed high percentage of patients with hidden MWA (52.9%) revealed by the MS-Q and ICH criteria that would otherwise remain undiagnosed.

When compared to the original questionnaire, the translation of MS-Q performed slightly worse, with somewhat lower diagnostic accuracy than that of the original (sensitivity and specificity of original MS-Q were 82% and 97%, respectively) and significantly lower reliability (Cohen Kappa of original MS-Q was as high as 0.84), but still within the acceptable limits (Cohen Kappa from 0.6 to 0.8 is interpreted as moderate agreement between the MS-Q score \geq 4 and the diagnosis of the MWA

Sample	Sensitivity	Specificity	Positive Pre- dictive Value	Negative Predic- tive Value	Positive Likeli- hood Ratio	Negative Likeli- hood Ratio	Accuracy
Whole sample (n = 429)	80% (74.7%– 84.6%)	87.2% (81.1%– 91.9%)	91.0% (87.1%– 93.8%)	72.9 % (67.8%– 77.6%)	6.3 (4.2–9.4)	0.2 (0.2–0.3)	82.8% (78.8%– 86.2%)
Women (n = 312)	82.6% (76.5%– 87.6%)	83.8% (75.8%– 89.9%)	89.4% (84.8%– 92.8%)	74.2% (67.8%– 79.8%)	5.1 (3.4–7.7)	0.2 (0.2–0.3)	83.0% (78.4%– 87.0%)
Men (n = 117)	72.9% (60.9%– 82.8%)	95.7% (85.5%– 99.5%)	96.2% (86.7%– 99.0%)	70.3% (61.6%– 77.7%)	17.1 (4.4–66.9)	0.3 (0.2–0.4)	82.1% (73.9%– 88.5%)

Table 2. Accuracy of the MS-Q instrument when used for screening of migraine without aura (95% confidence intervals are shown in parenthesis).

were met in 62.5% of women and in 59.8% of men, based on clinical judgment.

Accuracy of the MS-Q instrument when used for screening of migraine without aura (sensitivity, specificity, positive and negative predictive value, likelihood ratio, overall accuracy) is shown in the Table 2, for the whole sample, and separately for women and men. Cohen Kappa coefficient of agreement between diagnosis of migraine without aura by MS-Q score ≥ 4 and diagnosis by the IHS criteria (gold standard) was 0.648 (standard error 0.037, p = 0.000).

Among the patients who did not have diagnosis of migraine without aura before participation in the study (n = 312), 154 (49.4%) met the criteria of IHS and were newly diagnosed ("de novo") as having the MWA. The MS-Q

by the IHS criteria). The same happened when male and female cohorts were analysed separately, i.e. again the original MS-Q had superior performance. However, the same pattern of differences in sensitivity and specificity among sexes observed with the original scale was repeated with the translation: the questionnaire had higher sensitivity, but lower specificity in females than in males. It could be explained by more intense reactivity of females to stress, as they feel more fear, irritability, confusion and less happiness immediately following a stress , like severe headache, what is reflected with less false negatives and more false positives after administering the MS-Q.

Besides having considerable validity and reliability, the MS-Q translation has significant screening yield, since

positive predicted value was high (91%), especially in men (96.2%) in our study, and the test correctly recognized 72.7% of previously undiagnosed MWA cases. Its screening performance was somewhat worse than that of the original MS-Q, which showed positive predicted value of 95% (although less pronounced in men-88%) and correctly recognized 93.4% of previously undiagnosed migraine cases. However, better screening performance of original MS-Q could have been caused by its administration to the sample of patients with all migraine types, including that with aura. On the other hand, prevalence of the MWA was higher in our patient sample than that in general population, which may give an unrealistic estimate of the screening yield, but according to general recommendations for screening tests, prevalence of migraine without aura is high enough to justify use of the MS-Q translation to BHS language for screening purposes. It is illustrated by overall accuracy of the MS-Q translation, which was 82.8% in our study sample, but it even increased to 85.7% when actual prevalence of MWA (8.5%) in general population was taken into account.

Main limitation of our study was use of an non representative sample with high prevalence of MWA to test reliability, validity and screening yield of the MS-Q translation to BHS language, but it was dictated by availability of the study sites, some of them being linked to neurology departments of nearby hospitals. It could contribute to overestimation of the screening yield, which should be taken into account when judging utility of the MS-Q translation for screening purposes.

6. CONCLUSION

The MS-Q translation to BHS language could be considered as valid and reliable clinical instrument for revealing migraine without aura, similar by its performance to original questionnaire. It has considerable screening yield, discovering majority of patients with previously undiagnosed migraine without aura, whose definite diagnosis should later on be confirmed by the attending physicians using the ICH criteria.

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 writing the manuscript and checking the manuscript for important
 intellectual content. Slobodan M. Jankovic contributed to the study

- design, conduct, data processing, statistical analysis, writing the manuscript and checking the manuscript for important intellectual content.
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