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Validation of Malay brief screening instrument for ascertainment of epilepsy

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ABSTRACT

Introduction: Prevalence studies of epilepsy in Asia revealed a prevalence ranging from 1.5 to 14.0 per 1000 among Asian populations. However, the prevalence of epilepsy in Malaysia is not available for comparison with other countries. This study aimed to translate and validate a Malay brief screening instruments for ascertainment of epilepsy.

Method: We translated into Malay a brief screening instrument for ascertainment of epilepsy designed and validated by Ottman et al., using the three-stage cross-cultural adaptation process developed by the International Quality of Life Assessment (IQOLA) project. We then administered the translated questionnaire via online survey to 162 cases (patients with epilepsy under follow-up care at the neurology clinic in University of Malaya Medical Centre, Kuala Lumpur) and 146 controls with no known history of epilepsy for validation.

Results: Applying the most liberal definition for a positive screen, we obtained a sensitivity of 96.3% (95% confidence interval [CI]: 91.8–98.5%), with a specificity of 66.4% (95% CI: 58.1–73.0%) and positive predictive value (PPV) of 2.0%. The most stringent definition for a positive screen (only epilepsy) resulted in a sensitivity of 97.4% (95% CI: 62.0–72.6%), specificity of 98.6% (95% CI: 94.6–99.7%), and PPV of 26.6%. Narrowing the definition of a positive screen decreased sensitivity but improved PPVs. When compared to the original English questionnaire, the sensitivities were similar for all four definitions of a positive screen.

Conclusion: This is the first validated epilepsy screening questionnaire in the Malay language and represents a useful tool for the ascertainment of epilepsy in population-based studies.

1. Introduction

1.1. Prevalence of epilepsy

Although the World Health Organization (WHO) estimates that 8 out of 1000 people have epilepsy, prevalence estimates vary among countries. In Asia, the reported prevalence ranged from 1.5 to 14.0 per 1000 in Asian populations and was found to be higher in developing countries [1]. In Malaysia, however, there is limited epidemiological data on epilepsy, and the national prevalence of epilepsy is not available for comparison.

1.2. Treatment gap

Treatment gap is defined as the difference between the number of people with active epilepsy and the number whose seizures are being appropriately treated in a given population at a given point of time (expressed as a percentage). In Asian countries, the treatment gap is mostly within 50–80%, ranging between 6 and 97% [1]. The epilepsy treatment gap is a major issue in low and middle income countries

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and can be attributed to various factors such as affordability, accessibility, and availability of care and treatment. In Malaysia, treatment gap studies conducted in Sabah and Kuala Lipis, Pahang based on antiepileptic drugs' consumption showed a high treatment gap of more than 90% [2].

1.3. Screening instruments for the ascertainment of epilepsy

A validated measurement tool is an essential component of any large scale population-based prevalence study, with the preferred tool being a multi-item screening questionnaire in the case of epilepsy [3]. In attempting to remedy the lack of epidemiological data on epilepsy in Malaysia, a couple of issues are encountered in selecting a suitable screening instrument. Firstly, there is no internationally standardized screening questionnaire that has been validated for the identification of epilepsy in the general population. Secondly, existing screening questionnaires are available in English, Spanish, French, and Kigiriama but have not yet been translated into Malay [4–9]. A systematic review on the diagnostic accuracy of these questionnaires reported a wide range of sensitivity and specificity with a high risk of bias in patient selection and study flow in the majority of studies [3]. For example, a nine-item questionnaire developed by Ottman et al. had a much higher sensitivity compared to an eight-item questionnaire proposed by Brooks et al. (95.8% vs. 48.6%), though they were comparable in specificity [4,5]. The brief screening tool validated by Ottman et al. using a population-based study had high sensitivity and specificity, and a low risk of bias [3]. This screening instrument has also been translated into French and used by Keezer et al. in the Canadian Longitudinal Study on Aging-Epilepsy Algorithm (CLSA-EA) and by Serrano-Castro et al. into Spanish in the EPIBERIA questionnaire [7,9]. Translation of this validated screening tool is essential for conducting locally relevant epidemiological studies especially in multiethnic, multilingual countries like Malaysia. We aimed to translate this brief screening instrument into Malay and determine the psychometric properties of the Malay translated version.

Table 1
Questions from screening instrument.[a]
Adapted from Ottman et al.

Q1. Did anyone ever tell you that you had a seizure or convulsion caused by a high fever when you were a child?
Q2. [Other than the seizure[s] you had because of a high fever] Have you ever had, or has anyone ever told you that you had, a seizure disorder or epilepsy?[b]
Ask the following questions only if subject said "no" to epilepsy or a seizure disorder in q2. Otherwise go to next part of interview.
Q3. [Other than the seizure[s] you had because of a high fever] Have you ever had, or has anyone ever told you that you had, any of the following…[b]
A. A seizure, convulsion, fit, or spell under any circumstances?
B. Uncontrolled movements of part or all of your body such as twitching, jerking, shaking, or going limp?
C. An unexplained change in your mental state or level of awareness; or an episode of "spacing out" that you could not control?
D. Did anyone ever tell you that when you were a small child, you would daydream or stare into space more than other children?
E. Have you ever noticed any unusual body movements or feelings when exposed to strobe lights, video games, flickering lights, or sun glare?
F. Shortly after waking up, either in the morning or after a nap, have you ever noticed uncontrollable jerking or clumsiness, such as dropping things or things suddenly "flying" from your hands?
G. Have you ever had any other type of repeated unusual spells?

[a] Each question could be answered no, yes, possible, or do not know.
[b] Phrase "Other than the seizure[s] you had because of a high fever" added only if subject responded "yes" or "possible" to question 1.

2. Methodology

A brief nine-item screening instrument validated by Ottman et al. for the ascertainment of epilepsy as shown in Table 1 [4] was selected to be adapted and translated into the Malay language. The sensitivity (the proportion of individuals who screened positive among affected individuals) for this screening instrument was 96% for epilepsy and 87% for isolated unprovoked seizure. The false positive rate (FPR, the proportion who screened positive among seizure-free individuals) was 7%.

The translation process was guided by the three-stage cross-cultural adaptation process developed by the International Quality of Life Assessment (IQOLA) project [10]. The process involves the following stages: Stage 1, evaluating and ensuring conceptual equivalence and acceptability of the translated version (from English to Malay) for cultural adaptation; Stage 2, empirical testing of assumptions underlying the construction and scoring of questionnaire scales; and Stage 3, validation of the translated questionnaire.

2.1. Translation and cultural adaptation

The translation of brief screening instruments for ascertainment of epilepsy was performed based on the framework of the Principles of Good Practice Translation and Culture Adaptation of Patient Reported Outcomes Measures [11]. The translation process is described in further detail as follows.

2.1.1. Participants

A total of 10 Malay-speaking individuals including healthcare professionals and linguistic experts were recruited in the translation process. Purpose of the study were informed to the participants and informed consent were granted before the translation process. This study is approved by University of Malaya Medical Centre (UMMC) Ethics Committee (MREC 2018416-6227).

2.1.2. Translation

Preparation: Permission to use the original screening instrument was obtained from the author, and ethical approval was obtained from the medical research ethics committee of University of Malaya Medical Centre (MREC ID: 2018416-6277). Concepts for the questions in the instrument were developed to ensure conceptual equivalence during translation. *Forward translation*: The original English version questionnaire was translated into Malay by two independent translators who were native Malay speakers. *Reconciliation*: Both forward translated versions were reconciled into a single version after resolving the discrepancies between the two versions and having it reviewed by another independent translator. *Back translation*: The reconciled version of the forward translation was translated back into English by two independent translators. *Expert panel review*: The back-translated version was reviewed against the original English version. The discrepancies between the source and translated version were discussed and resolved by an expert panel consisting of clinicians, translators, and a language expert.

2.1.3. Cognitive debriefing

Ten Malay-speaking participants were interviewed to pretest the questionnaire. The interview explored the participant's comprehension of the questionnaire and identified potential difficulties in responding to the questionnaire.

2.1.4. Finalization

An expert panel reviewed the content of the translated questionnaire to determine the content and face validity. Final agreement

Table 2
Sensitivities, specificities, positive, and negative predictive values of translated version and comparison with the original English version.

Questions	Patients with epilepsy (n = 162)	Presumed seizure-free control (n = 146)	Sensitivity % (95% CI)		Specificity % (95% CI)		PPV (%)	NPV (%)
			Malay	Original[a]	Malay	Original[a]		
a. Any positive responses in screening instrument	156	49	96.3 (91.8–98.5)	95.8	66.4 (58.1–73.0)	33.0	2.0	100.0
b. Any positive excluding febrile seizure (any of Q2 through Q3G)	156	46	96.3 (91.8–98.5)	93.5	68.5 (60.2–75.8)	42.0	2.1	100.0
c. Epilepsy or any seizures (Q2 or Q3A)	139	5	85.8 (79.2–90.6)	91.1	96.6 (91.8–98.7)	67.0	15.0	99.9
d. Epilepsy only (Q2 only)	114	2	70.4 (62.6–77.1)	76.2	98.6 (94.6–99.7)	92.0	26.6	99.8

[a] 95% confidence interval (CI) was not available for comparison.

was made to use the translated questionnaire for further validation testing.

2.2. Validation

2.2.1. Participants

A total of 162 cases and 158 controls with no known history of epilepsy were recruited to answer the Malay-translated version of the brief screening instruments. The cases included Malay-speaking adults aged 18 years old or more and diagnosed as having epilepsy for more than one year. The cases were recruited during their clinic visits in University of Malaya Medical Centre neurology clinic, Kuala Lumpur, Malaysia. All questionnaires were self-administered or via face-to-face interview when the cases had difficulties in reading. Consent was obtained when participants responded to the questionnaire. Demographic information, such as age and gender, was also obtained. The controls were recruited via social networks such as Facebook and mobile messenger application (e.g., WhatsApp) and requested to answer the Malay version of brief screening instruments for ascertainment of epilepsy designed in a "Google form" format, anonymously. Controls who answered yes or possible to any of the questions were asked for consent to undergo a diagnostic interview.

2.2.2. Diagnostic interview

A validated questionnaire for clinical seizure diagnosis derived by Reutens et al., which contained 26-item pertaining to symptoms of seizures and can be administered by trained interviewers directly or via phone, was used for the diagnostic interview [12]. There was a strong agreement between questionnaire- and physician-based diagnoses (Cohen's kappa coefficient, 0.74; asymptotic Standard Error (SE) 0.04) when seizure diagnoses based on information from the questionnaire alone were compared with physician-based diagnoses. Questionnaires were administered either directly or by telephone, by a trained neurologist or a research assistant. If any respondent was diagnosed as having epilepsy and was not on any medical follow-up, they would then be referred to a local hospital for further assessment and management.

2.2.3. Operational definition

For each question in the screening instrument, we classified the response as positive if the subject answered "yes" or "possible". We considered four definitions for a positive screen, consistent with a positive response to:

a. Any question in the screening instrument (any positive),
b. Any Q2 through Q3G (any positive excluding febrile seizure),
c. Q2 or Q3A (epilepsy or any seizures), and
d. Q2 only (epilepsy only).

2.3. Statistical analysis

Upon completion of these questionnaires, responses were tabulated and transferred to SPSS version 23.0 (IBM Corp., Armonk, NY, USA) for further analysis. Sensitivity, specificity, and positive predictive value (PPV) were calculated for each operational definition. Sensitivity was defined as the proportion of patients with epilepsy in our neurology clinic who screened positive, therefore, sensitivity: true positive/(true positive + false negative). Specificity was defined as the proportion of healthy controls who were screened negative, therefore, specificity: true negative/(true negative + false positive). The sensitivities and specificities of the Malay questionnaire were compared against the original English version. To determine the positive and negative predictive values of the questionnaires, we assumed the prevalence of epilepsy in our population would be similar to other countries in Asia. [1]. Thus, we used the following formulas to estimate the PPV and negative predictive value (NPV) based on the assumed prevalence, p of 0.7%:

$$\mathrm{PPV} = \frac{\mathrm{Sensitivity} \times \mathrm{p}}{(\mathrm{Sensitivity} \times \mathrm{p}) + [(1-\mathrm{specificity})(1-\mathrm{p})]}$$

$$\mathrm{NPV} = \frac{\mathrm{Sensitivity}(1-\mathrm{p})}{\mathrm{Sensitivity}(1-\mathrm{p}) + [(1-\mathrm{specificity}) \times \mathrm{p}]}$$

3. Results

The original English version of the epilepsy screening questionnaire designed and validated by Ottman et al. was translated into Malay (see Appendix 1).

3.1. Translation equivalence and acceptability

The translated Malay questionnaire was equivalent to the English version except for items no. 3F and 3G. We generalized the phrase of "seizure, convulsion, fit, or spell" to a single Malay word "sawan" for item 3A, as they were equivalent in the definition of seizure. We also generalized the "strobe lights" and "flickering lights" in item 3E as there were no separate descriptive terms in Malay for these 2 phrases. For item 3G, direct translation of "spells" is "mantra" which is not equivalent to the meaning of seizures/seizure-like events, therefore, in view of the absent of Malay word with equivalent definition, the phrase "repeated unusual spells" was expanded to "kejadian luar biasa dan berulangan" (repeated unusual events). The word "clumsiness" was expanded to "pergerakan kurang cermat yang tidak dapat dikawal" (uncontrollable abnormal movement). The expansion of these words in the translational process aimed to provide more information and clarify its meaning to the respondents. In the reconciliation process, cognitive debriefing, and subsequent review by expert panel, these translations were then finalized to be used in the validation testing.

3.2. Validation testing

In the process of validation of the translated version of screening instruments, there were a total of 162 patients with epilepsy interviewed. This included 82 (50.6%) male and 80 (49.3%) female patients. A total of 158 controls responded to our online survey. However, with subsequent preliminary screening of the responses, we excluded 7 individuals from the control group from further analysis as their responses were incomplete. Another 5 individuals found to have known epilepsy on subsequent diagnostic interview were excluded retrospectively based on the definition of controls as someone without known epilepsy. They were not excluded prior to recruitment because there was no screening in social media recruitment. This left 146 controls for further analysis in which 54 (36.9%) were males and 92 (63.1%) were females. The mean age for epilepsy was 38 years old (27.0 to 60.8) for the patients with epilepsy and 32 years old (25.8 to 35.0) for the controls. The responses from controls were all self-administered. Majority of responses from cases were self-administered, only small proportion were done via face-to-face interview when the patients had difficulties in reading.

The sensitivity, specificity, positive, and negative predictive values for each operational definition are shown in Table 2. Sensitivity was highest (96.3%) in the most liberal definition of a positive screen which included a history of febrile seizures and other symptoms of seizures. However, specificity was lowest in this group (66.4%) with a PPV of 2.0%. In the next most liberal definition of a positive screen which excluded febrile seizures, i.e., any positive response from Q2 through Q3G, the sensitivity remained at 96.3% with a slightly higher specificity of 66.8%. Specificity and PPVs were markedly increased with more stringent definitions that were restricted to “epilepsy or any seizure” and “epilepsy only” in which the specificity was 96.6% and 98.6%, respectively. With less items included, the specificity increased at the expense of decreased sensitivity. When compared to the original English questionnaire, the sensitivities were similar for all four definitions of a positive screen (Table 2). However, the Malay version showed higher specificity than the original English version in all definitions of a positive screen except for the most specific question on epilepsy only (positive for Q2 only). The trend of increasing specificity at the expense of decreased sensitivity was similarly noted in both studies. Positive and negative predictive values of the different operational definitions based on the 0.7% assumed prevalence of epilepsy were shown in Table 2. Similar to the trend of specificity, the PPV increases as the operational definition was narrowed to epilepsy only, and the negative predictive values remained high for all the operational definitions.

4. Discussion

A validated screening instrument that is culturally and linguistically relevant is needed for accurate assessment of the local burden of epilepsy and to assess the adequacy of the current healthcare system in catering for the needs of people with epilepsy. To our knowledge, this is the only screening instrument that has been validated to be used in a Malay-speaking population to identify people with epilepsy or seizures, with similar sensitivity and higher specificity compared to the original English version.

The challenges we faced during English to Malay translation mainly stemmed from the fact that these languages are not from the same language family. We used translation techniques such as borrowing whenever possible in all the items in the questionnaire but also adjusted accordingly with expansion, generalization, and adaptation of the words and phrases when there were no direct equivalent words or phrases in Malay which could be used. The translated items did not affect the sensitivity or specificity as the positive screens which included these items had comparable sensitivity with the source questionnaire, in fact with higher specificity.

The positive screen with the broadest definition, i.e., any positive responses in the questionnaire, was useful to capture patients with confirmed and suspected epilepsy who needs further evaluation. Similar to the original screening instrument, including febrile seizures in the questionnaire did not significantly improve the sensitivity or PPV of the questionnaire. The addition of questions pertaining to specific symptoms of seizures or epilepsy (Q3A to Q3G) allows us to identify patients with epilepsy or suspected epilepsy especially those who have not been diagnosed. However, as the symptoms screened in Q3A to Q3G could be misinterpreted as symptoms of vertigo, migraine, or fatigue, these broad definitions project high sensitivity but low specificity and extremely low PPV. The PPV increased substantially when we narrowed the definition of positive screen to epilepsy or any seizures, i.e., any positive of Q2 or Q3A (epilepsy or any seizures) and Q2 only (epilepsy only). However, with this increased PPV, the sensitivity decreased. Definitions with higher specificity and PPV will be more discriminative in epilepsy diagnosis. However, as a screening tool, it is essential to have high sensitivity but acceptable to have low specificity, and subsequent diagnostic interview will be performed to exclude false positive in the epidemiological study.

5. Limitations

A possible limitation of this validation study was the self-administration of questionnaires to respondents via paper or online forms because of our limited resources, as opposed to face-to-face or telephone interviews as was done in previous similar validation studies [3,4,6,9]. This meant that we were not able to immediately gauge respondents' comprehension of the questionnaire, although we did include a comment section at the end of the questionnaire form asking for respondents' thoughts on the language and wording and if there were any items that they felt needed further clarification. Judging from the feedback we received, the respondents did not have any major problems understanding the questions asked or terms used.

6. Conclusion

This is the first validated epilepsy screening questionnaire in the Malay language and represents a useful tool for the ascertainment of epilepsy in population-based studies.

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Conflicts of interest

There is no conflict of interest relevant to this study.

Appendix 1. Translated Malay version of brief screening instruments for ascertainment of epilepsy

Q1. Pernahkah anda diberitahu bahawa anda pernah mengalami sawan atau kekejangan yang disebabkan oleh demam panas sewaktu kanak-kanak?
□ Ya □ Tidak □ Mungkin □ Tidak tahu

Q2. [Selain daripada sawan yang anda mengalami disebabkan oleh demam panas][a] Pernahkah anda mengalami, atau sesiapa memberitahu bahawa anda mengalami penyakit sawan atau epilepsi?
□ Ya □ Tidak □ Mungkin □ Tidak tahu

Tanya soalan-soalan yang berikut hanya jika peserta kajian menjawab "tidak" bagi soalan Q2 tentang epilepsi atau penyakit sawan. Jika peserta menjawab sebaliknya, langkau ke bahagian temu ramah yang seterusnya.

Q3. [Selain daripada sawan yang anda mengalami disebabkan oleh demam panas][a] Pernahkah anda mengalami, atau sesiapa memberitahu bahawa anda mengalami, mana- mana yang berikut:
A. Sawan dalam mana-mana keadaan?
□ Ya □ Tidak □ Mungkin □ Tidak tahu

B. Pergerakan yang tidak terkawal pada mana-mana anggota atau seluruh badan anda seperti menggerenyet, tersentak-sentak, terketar-ketar atau menjadi lembik?
□ Ya □ Tidak □ Mungkin □ Tidak tahu

C. Perubahan keadaan mental atau tahap kesedaran yang tidak dapat dijelaskan; atau episod melamun yang tidak mampu dikawal oleh anda?
□ Ya □ Tidak □ Mungkin □ Tidak tahu

D. Sewaktu di zaman kanak-kanak , pernahkah anda diberitahu bahawa anda berangan atau termenung lebih kerap daripada kanak-kanak lain?
□ Ya □ Tidak □ Mungkin □ Tidak tahu

E. Pernahkah anda mengalami pergerakan badan atau perasaan yang luar biasa apabila terdedah kepada kelipan lampu, permainan video atau silauan matahari?
□ Ya □ Tidak □ Mungkin □ Tidak tahu

F. Sejurus selepas bangun tidur, sama ada pada waktu pagi atau selepas lelap sebentar, pernahkah anda mengalami sentakan atau pergerakan kurang cermat yang tidak dapat dikawal, seperti barang terlepas atau terpelanting dari genggaman anda?
□ Ya □ Tidak □ Mungkin □ Tidak tahu

G. Pernahkah anda mengalami sebarang kejadian luar biasa dan berulangan yang lain?
□ Ya □ Tidak □ Mungkin □ Tidak tahu

[a]Frasa [Selain daripada sawan yang anda mengalami disebabkan oleh demam panas] hanya disertakan sekiranya responden menjawab "Ya" atau "Mungkin" bagi soalan Q1.

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