Cross-Cultural Adaptation and Linguistic Validation of the Hypoglycaemia Symptom Rating Scale (HypoSRQ) among Malaysian Patients with Diabetes Mellitus

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ABSTRAK

Hypoglycaemia Symptom Rating Questionnaire (HypoSRQ) merupakan soalan kaji selidik bagi mengukur simptom hipoglysaemia dan ia berpotensi untuk kegunaan penyelidikan tempatan. Namun, ia memerlukan adaptasi dan validasi untuk kegunaan tempatan. Kajian ini melaporkan proses dan hasil keputusan adaptasi rentas budaya dan validasi linguistik bagi HypoSRQ dalam Bahasa Melayu dan Bahasa Inggeris di dalam situasi tempatan. HypoSRQ telah melalui proses penterjemahan berbalik dan adaptasi dengan sokongan penterjemah profesional dan pakar psikologi klinikal. Maklum balas kognitif (cognitive debriefing) dilakukan di kalangan pesakit diabetes mellitus jenis 1 dan 2 dengan latar belakang sosiodemografi yang berlainan. Perbincangan bersama pembangun HypoSRQ asal, iaitu Health Psychology Research Ltd (HPR) dilakukan untuk menentukan versi terbaik bagi kegunaan tempatan. Versi akhir disemak dan diformatkan. Maklum balas kognitif melibatkan 7 orang pesakit bagi HypoSRQ-My (versi bahasa Melayu) dan 5 orang pesakit bagi HypoSRQ-EMy (versi bahasa Inggeris). Penterjemahan langsung secara literal kepada bahasa Melayu tidak sesuai disebabkan istilah teknikal yang sukar difahami oleh masyarakat umum. Pindaan dibuat berdasarkan penemuan daripada proses maklum balas kognitif. Peserta kajian mendapati bahawa soal selidik agak mudah untuk difahami selepas pindaan. HypoSRQ-My (versi bahasa Melayu) dan HypoSRQ-EMy (versi bahasa Inggeris) mudah difahami oleh masyarakat tempatan. Soal selidik ini akan melalui penilaian psikometrik untuk kegunaan tempatan pada masa akan datang.

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Kata kunci: hipoglisemia, soal selidik, terjemahan, berpandingan budaya, validasi bahasa

ABSTRACT

The Hypoglycaemia Symptom Rating Questionnaire (HypoSRQ) is potentially useful for local research on hypoglycaemia. However, it requires adaptation and validation in local settings. This study reports the process and results of cross-cultural adaptation and linguistic validation of HypoSRQ for Malay and English versions in our local setting. The HypoSRQ underwent forward and backward translation and adaptation with support from professional translators and a clinical psychologist. Cognitive debriefing was done among patients with Type 1 and Type 2 diabetes mellitus from varying sociodemographic backgrounds. Discussion was done together with the original developers of the HypoSRQ to decide on the best version for local use. The finalised versions were proofread and formatted with the help of Health Psychology Research. Cognitive debriefing for Malay version involved 7 patients and for the English version5 patients. Direct literal translation into Malay language was unsuitable due to technical terms which were difficult for laypersons to understand. Amendments were made based on findings from the cognitive debriefing process. Participants found the questionnaire fairly easy to understand. The HypoSRQ-My (Malay) and HypoSRQ-EMy (English) is easily understood by local participants.   These tools may undergo psychometric evaluation for future use in local settings.

Keywords: hypoglycemia, questionnaires, translations, cross-cultural comparison linguistic validation

INTRODUCTION

Hypoglycaemia is a common complication of diabetes treatment. Studies have shown high prevalence of hypoglycaemia among patients with diabetes on treatment with oral hypoglycaemic agents or insulin (Marrett et al. 2009; Murata et al. 2005). Severe hypoglycaemia is associated with a 3-fold increased risk of mortality compared to non-severe hypoglycaemia (McCoy et al. 2012). Non-severe hypoglycaemia was found to affect patients' well-being negatively, reduce productivity, as well as increase in healthcare utilization (Geelhoed-Duijvestijn et al. 2013). Therefore, it is important for clinicians to assess hypoglycaemia during consultation with patients with diabetes.

Many patients may not realise the presence of hypoglycaemic episodes. Hence, hypoglycaemia may remain unreported. The proportion of Malaysians with Type 2 diabetes who have access to home blood glucose monitoring is also low (Mastura et al. 2007; Mafauzy 2006). Therefore, many suspected hypoglycaemic episodes were either unidentified or unconfirmed.

A good tool to assess episodes of hypoglycaemia may help both clinicians and researchers to identify hypoglycaemia so that treatment can be tailored, accordingly. There are very few questionnaires which were designed to measure symptoms of hypoglycaemia.

The Hypoglycaemia Symptom Rating Questionnaire (HypoSRQ) is a newly developed and validated tool to detect hypoglycaemia among patients with diabetes (Taylor et al. 2013; Taylor 2012) It is a valuable tool because it is one of the very few tools that demonstrated concurrent validity with blood glucose monitoring. The HypoSRQ has been found to be highly reliable with a Cronbach alpha of 0.90. The scores of the HypoSRQ demonstrated significant moderate correlations (r=0.42-0.66, p<0.05) with continuous blood glucose monitoring.

Weinger et al. (1995) used a 40-item Mood and Symptoms Questionnaire and neuropsychological tests to determine the association between hypoglycaemia symptoms with varying levels of blood glucose. From cluster analysis, the Mood and Symptoms Questionnaire was found to have 5 cluster symptoms, which included "autonomic symptoms", "feeling weak and dizzy", "feeling relaxed", "negative moods" and "positive moods". However, there were 17 symptoms which did not fit into any of these clusters. All 5 symptom clusters were present when blood glucose was 2.2mmol/L. However, patients were found to be inaccurate in estimating their own blood sugar based on symptoms (Weinger et al. 1995).

Jaap et al. (1998) validated another questionnaire among elderly diabetic patients who were treated on insulin. The patients were asked to rate 22 symptoms of hypoglycaemia on a 7-point Likert scale. Construct validation of the responses revealed 3 components, which are "impaired coordination and articulation", "neuroglycopenic symptoms", and "autonomic symptoms". However, there was no concurrent validation with blood glucose controls. The Cronbach alpha value for each component was unreported, as well.

Henderson et al. modified the Edinburgh Hypoglycaemia Scale and validated it on insulin-treated patients with Type 2 diabetes (Henderson et al. 2003). The Edinburgh Hypoglycaemia Scale consisted of 20 symptoms of hypoglycaemia. Respondents were required to rate the intensity of the symptoms on a 7-point Likert scale. Construct validation revealed 2 factors which were "autonomic symptoms" and "neuroglycopenic symptoms". Again, there were no concurrent blood glucose measurements.

Brod and her team developed the Diabetes Symptom Measure (DSM) which consisted of 30 items comprising signs and symptoms of diabetes in adults (Brod et al. 2011). The DSM has good internal reliability (Cronbach alpha 0.95). Construct validation revealed 4 components which were "high blood sugar", "low blood sugar", "neuropathy" and "general". The scores were significantly correlated to scores from another validated tool, the Problem Areas in Diabetes (PAID).

Vexiau developed an 11-item questionnaire to measure symptoms of hypoglycaemia among diabetic

patients (Vexiau et al. 2008). The 11 symptoms included sweating, confusion / disorientation, shakiness, clumsy or jerky movements, dizziness, sudden moodiness or behaviour changes, hunger, tingling sensations around the mouth, difficulty concentrating, headache, and pale skin colour. Respondents were required to rate these symptoms according to severity (mild, moderate or severe) over the past 6 months. Unfortunately, construct validation was not done. There was no comparison with actual blood sugar levels as it was based on recall. However, the scores were found to be significantly associated with fear of hypoglycaemia and lower quality of life.

In summary, the Hypoglycaemia Symptom Rating Questionnaire (HypoSRQ) has much potential as it was validated to detect hypoglycaemia among diabetic patients alongside blood glucose monitoring (Taylor 2012; Taylor et al. 2013). In order to use the HypoSRQ in the Malaysian setting, it needs to be translated and culturally adapted for use in our local setting (Hambleton & Patsula 1998). The present study reports the process of cross-cultural adaptation and linguistic validation of the original English version of the HypoSRQ into Malay and to linguistically validate both the Malay and English versions in our local setting.

MATERIALS AND METHODS

This was a linguistic validation study conducted between January 2014 until June 2015. The permission to conduct linguistic validation on the HypoSRQ was obtained from the copyright holder of the original questionnaire, Health Psychology Reesarch (HPR). The validation process was done with close support from HPR. The linguistic validation process was guided by the recommendations of the ISPOR Task Force for Translation and Cultural Adaptation (Wild et al. 2005). Ethical approval to conduct the study was obtained from Medical Research and Ethics Committee of UKMMC.

TRANSLATION AND ADAPTATION PHASE

The original English version of the HypoSRQ underwent two independent translations into Malay language by a certified translator and an academic clinician who was a native speaker of Malay language. The translator and the clinician were requested to produce a conceptually equivalent Malay version. The two Malay versions were then compared and reviewed by the research team for suitability of the wordings. A detailed report with comments was prepared and clarifications were provided regarding reasons for the choice of words to be used in the Malay version. Amendments were made for terms that were felt inappropriate or difficult to understand by the members of the research team who were native Malay speakers.

Subsequently, a harmonised Malay version was sent to another two translators for back-translation into English. The selected translators were native speakers of English and had good command of Malay Language. One of the back-translators was provided by the HPR. The back-translation

versions were reviewed and compared again by the research team and HPR. Comparison was made with the original English version to ensure that the Malay version had maintained semantic and conceptual equivalence. Based on the discussions, the research team agreed on a final Malay version of the HypoSRQ for the cognitive debriefing process.

At the same time, the research team also reviewed the original English version of the HypoSRQ for wordings that may not be familiar in the local setting. Again a detailed report was prepared and any amendments were clarified. The pre-finalised versions were submitted for review by a clinical psychologist and the comments were taken into consideration for modification and finalisation of the final version.

COGNITIVE DEBRIEFING PHASE

The final Malay version (HypoSRQ-My) and the adapted English version (HypoSRQ-EMy) of the HypoSRQ were then prepared for cognitive debriefing to determine their comprehensibility and face validity. This was done by conveniently recruiting a number of patients with Type 2 diabetes mellitus who received their treatment from a teaching primary care clinic, and a couple of patients from a paediatricendocrine clinic. Patients from the paediatric endocrine clinic were adults who were on follow-up for Type 1 diabetes mellitus since young. Care was taken to ensure a variety of patients were selected based on ethnicity, educational status, and type of therapy taken for diabetes mellitus (diet, oral antidiabetic agents or insulin). The patients were invited to participate in a cognitive debriefing process and were given a separate appointment for the process. This was to give ample time for cognitive debriefing. The patients were seen individually by the researchers. Each patient was given a copy of the HypoSRQ-My or HypoSRQ-EMy to be completed. The time taken to complete the questionnaire was documented for each patient. Subsequently, a structured interview was conducted to test their comprehension of the wordings of the questionnaire. Their comments and suggestions were also recorded.

Based on the comments provided by the respondents, the research team reviewed the wordings of the HypoSRQ-My and HypoSRQ-EMy. The reports were reviewed together with HPR and discussions were made to draw on a consensus on the best version for local use. Wordings or phrases that were found difficult to understand by the patients were amended to improve clarity. The final version of the HypoSRQ-My and HypoSRQ-EMy were then agreed upon.

FORMATTING AND PROOFREADING

With the help from HPR, the finalised versions of HypoSRQ-My and HypoSRQ-EMy were proofread to check for errors in spelling and wording. With the help of HPR, tt was then formatted to ensure the layout conformed to the format of the original HypoSRQ.

RESULTS

TRANSLATION AND ADAPTATION PHASE

Two forward translations of HypoSRQ were compared. Comments were obtained from the translators following receipt of the translated work. In general both forward translators found some difficulty in translating certain terms into Malay language. This was because some of the terms were technical and the Malay terms were actually borrowed from the English language. While the borrowed terms existed in the approved Malay language dictionary, they were not commonly used in everyday conversation by Malaysians and thus would be difficult to understand by those with lower educational status. Consensus was achieved after the discussions (Table 1).

COGNITIVE DEBRIEFING PHASE

We recruited a total of 7 participants for cognitive debriefing of the HypoSRQ-My and 5 participants for the HypoSRQ-EMy. The characteristics of the participants were displayed in Tables 2 and 3.

The cognitive debriefing process was fairly straightforward. There were very few terms that required amendment after the cognitive debriefing process. Table 4 showed the terms that were particularly commented on by the participants for the cognitive debriefing of the HypoSRQ-My.

For the cognitive debriefing of the English adaptation, there were no difficulties overall, except for the term 'uncoordinated'. Participants' explanation of their understanding of the term showed that they had difficulty in grasping the concept of 'uncoordinated'. Taking into consideration the findings of the cognitive debriefing of the Malay version, the team decided to drop the term 'uncoordinated' and retain 'unsteady'. An instruction for item no. 20 was also added to standardize both the Malay and English versions.

DISCUSSION

The aim of this project was to produce a cross-culturally valid Malay and English versions of HypoSRQ for local use in Malaysia. The Malay language is the first language of the country and is taught formally in the national education curriculum. Since English is also a widely used in Malaysia, we also aimed to culturally adapt the original English version for local use.

Some words used in the local English version had to be changed for better clarity without altering its original meaning or affecting the constructs being measured. The translation process into Malay and the adaption process for the local English version were generally not problematic except for few, for which obtaining a non-technical Malay term without altering its meaning was difficult. Of all the 19 full statements in HypoSRQ, only 11 terms required some discussions among the panel. In adapting the original version for local use, we had made 3 changes. This included: (i) adding a brief explanatory phrase "(low blood sugar)" after the word "hypoglycaemia"; (ii) adding minor details to increase the clarity of instruction and (iii) changed a phrase "felt sick" to "nauseated".

Table 1: The reconciled terms agreed after the discussion

Original HypoSRQ	BM 1	BM 2	HypoSRQ-My	Comments
Rating	Perkadaran	Penilaian	Penilaian	Although "perkadaran" is a direct translation from rating however, it sounds more technical. "Penilaian" (evaluation) is also acceptable to represent "rating"
Diabetes	Diabetes (Malay)	Kencing Manis	Kencing manis	"Kencingmanis" was more easily understood by lay persons although "diabetes" exists as a Malay term.
Dizzy light-headedness and faints	Pening, goyang atau pitam	Pening, ringan kepala atau hendak pitam	Pening atau hendak pitam	Omitted "light-headed" because the equivalent term in Malay "pening-pening lalat" is similar to the first ("pening"). The difference is only in severity of dizziness.
Passed out / loss of consciousness	Pengsan / hilang sedar	Pengsan / pitam	Pengsan / pitam	The Malay term for 'passed out' and 'lost consciousness' is the same.
Unusually tired weak or lethargic	Luar biasa letih / lemah badan atau tidak bermaya	Letih yang luar biasa lemah dan lesu	Letih yang luar biasa, lemah atau lesu	This translation assumed that "unusually" applies to all three adjectives (tired weak or lethargic) and not just "unusually tired".
Unsteady or uncoordinated	Terhuyung hayang atau tidak terkoordinasi	badan tidak seimbang atau tidak tegap	terhuyung hayang atau tidak seimbang	The term "terkoordinasi" is a borrowed term. Other terms considered included "selaras" however, it did not fit into the context of the sentence.
Unusually emotional	Luar biasa beremosi	Gangguan emosi yang luar biasa	Lebih beremosi daripada biasa	"lebihberemosidaripadabiasa" if directly translated means "more emotional than usual" which is conceptually equivalent to "unusually emotional".
Excessively sleepy	Terlampau mengantuk	Mengantuk yang berlebihan	Lebih mengantuk dari biasa	"lebihmengantukdaribiasa" means more sleepy than usual as mentioned in the translation guidelines.
Slurred speech or difficulty talking	Kelu lidah atau sukar bertutur	Percakapan kurang jelas atau kesukaran bercakap	Pertuturan anda menjadi tidak jelas atau sukar	"Pertuturanandamenjaditidakjelas" means "speech becomes unclear", whereas 'kelu' means 'speechless'
Hypos	Hipo	Keadaan kurang gula	"tahap gula rendah dalam darah" atau "hipo"	Term "hipo" in Malay would sound like hippo as in hippopotamus. If we use "haipo" the pronounciation would be "hypo", but it would not be a valid Malay term. Added explanation for 'hypo' because there is no such locally equivalent word. Not all patients may understand the term 'hypo'.
Consider yourself to be hypo	Menganggap diri anda hipo	Anda anggap sebagai keadaan kurang gula	Anda anggap tahap gula rendah	This is translated as "How much is the level of blood sugar that is considered low sugar levels?" Unable to translate directly from the original English sentence as it would sound strange in local Malay language.
Symptom	Simptom	Gejala	Gejala	Simptom is a borrowed English term and may not be well understood by layperson.

Table 2: Characteristics of the participants for cognitive debriefing of the HypoSRQ-My

	Age	Ethnicity	Sex	Marital status	Education status	Job	Type of DM	Diabetes treatment	Duration of DM (years/ months)	Duration of current treatment (years)
R1	35	Malay	F	Divorced	Secondary	Clinic attendant	2	Tablets	8 years	2 years
R2	56	Malay	M	Married	Tertiary	Retired police officer	2	Tablets	11 years	9 years
R3	66	Indian-Muslim	M	Married	Secondary	Retired technician at coin factory	2	Tablets	6 years	2 years
R4	64	Malay	F	Married	Secondary	Housewife	2	Tablets and insulin	20 years	6 years
R5	45	Malay	M	Married	Secondary	Policeman	2	Tablets	6 years	6 years
R6	62	Indian-Muslim	F	Married	Tertiary	Retired clerk	2	Tablets and insulin	22 years	5 years
R7	23	Malay	F	Single	Tertiary	Student	1	Insulin	>10 y	>10 y

Table 3: Characteristics of the participants for cognitive debriefing of the HypoSRQ-EMy

	Age	Ethnicity	Sex	Marital status	Education status	Job	Type of DM	Diabetes treatment	Duration of DM (years)	Duration of current treatment (years)
R1	66	Indian-Muslim	M	2	Secondary	Retired technician	2	Tablets	6 years	2 years
R2	62	Chinese	M	2	Secondary	Retiree	2	Tablets	18 years	18 years
R3	56	Malay	M	2	Tertiary	Retired police officer	2	Tablets	11y	9y
R4	61	Indian	F	2	Secondary	Telephone operator	2	Insulin and Tablets	14 y	2 y
R5	22	Punjabi	F	1	Tertiary	Student	1	Insulin	>10y	>10y

Cognitive debriefing was fairly straightforward and we managed to test the participants' understanding of the Malay and English versions. There were very minimal amendments following the cognitive debriefing process, which confirmed that the translation process had been carried out well. The participants were able to show understanding of the original intended concepts of the translated and adapted version. This shows that the original HypoSRQ was well constructed with easily understood terms used.

HypoSRQ has been translated into various languages including Turkish (Turkey), Portuguese (Brazil) and Spanish (Peru, Mexico, USA, Columbia), and

Table 4: Participants comments during cognitive debriefing of HypoSRQ-My

Malay term	Participants' comments	Ammendments	Comments
Hipoglisemia; hipo Hypoglycaemia; hypo	Most participants were unfamiliar with this term. However, addition of the explanatory phrase "(tahap gula darah rendah)"	No amendments were made.	The addition of the explanatory phrase was helpful to the participants. Patients who had already received diabetic education from healthcare providers understood the word 'hipo'.
Pening, hendak pitam Dizzy; light-headed and faint	Most participants interpreted 'pening' as feeling dizzy. However, some interpreted it as headache. Participants were able to understand 'hendak pitam' as 'about to faint'	No amendments	The local Malay language used the term 'pening' for 'dizzy', 'vertigo' and 'headache'. There is another item which specifically mentioned 'headache'. Therefore, this would reduce confusion regarding the term.
Terhuyung-hayang, atau tidak seimbang Unsteady or uncoordinated	Participants were able to describe this as being "unsteady and staggering like in a drunken state".	No Malay term equivalent to 'uncoordinated' was included.	The participants were able to understand the concept of being unsteady. However, there was no suitable term for 'uncoordinated' which was readily understood by laypersons. We tested an alternative term 'kekok' which could mean 'clumsy, awkward', but the meaning of the word did not accurately reflect 'uncoordinated'. With further discussion with HPR, the team decided to drop the term 'uncoordinated' and kept the term 'unsteady'.
--	For item no 20; one participant commented on the lack of instructions if their response was "No", whereas if their response was "Yes", they were asked to answer the subsequent section.	We added "Jika tidak, anda telah selesai mengisi soal selidik ini" which meant, "If no, you have completed answering this questionnaire".	Adding the instructions would help to reassure the participants that they do not need to proceed further if their response was "no".

American English (Health Psychology Research Ltd, 2014). So far, none of the translation and cultural validation process have been published. Hence, the ease of translations and validation could not be compared. Also to the best of our knowledge, there has not been any published study regarding the utility of the HypoSRQ as yet. Therefore, although the development of HypoSRQ was rigorous, the clinical application of HypoSRQ and its various translated versions need to be assessed further by looking at its impact on clinical outcomes such as impact of intervention using HypoSRQ on quality of life of patients and metabolic control (Taylor 2012; Taylor et al. 2013). The ease of our translation and adaptation process suggests the positive value of

HypoSRQ in managing patients with diabetes.

STRENGTH AND LIMITATION OF THE STUDY

The main strength of this project was the successful collaboration between the local study team and HPR. The protocol of translation and adaptation was agreed upon and adhered to strictly. Appointment of translators met the criteria set and was agreed by both study teams. Two native Malay speakers proficient in English command undertook the forward translation. One of them has been providing professional translation service and has certification in written English at master degree. The other forward translator has been an academic primary care doctor with certified proficiency by IELTS. Further, the backward translation was undertaken by at least one native English speaker who is proficient in Malay and had resided in Malaysia for few years. The other backward translation service was provided by HPR. We did not require many cycles to discuss and reconcile the final HypoSRQ-My from forward and backward translation cycles. The translated version of HypoSRQ-My was reviewed by a clinical psychologist and four clinicians before cognitive debriefing with patients.

A good spectrum of patients was selected with different treatment regimes, educational, socio-economic background to optimise the face validity of the questionnaire. We only had one cycle of cognitive debriefing as the understanding of terms used were easy by all participants. On the other hand, not all words in the sentences were clarified with the patients. We limited to all words or phrase that were highlighted in bold and had conceptual meaning in 19 statements like, "dizziness", "palpitation" and "lost consciousness". Almost all patients were able to provide examples of situations they experience those symptoms. We only interviewed seven and five patients for HypoSRQ-My and HypoSRQ-EMy respectively. Although small in numbers, we believe further debriefing with more patients would not result in further gain.

CONCLUSION

The original HypoSRQ was successfully adapted to HypoSRQ-EMy and translated to HypoSRQ-My. The next step in validating HypoSRQ would be to undertake psychometric evaluation of the tools in local context, before it is applicable to clinical usage.

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