Examining the Problem Areas In Diabetes scale (MY-PAID-20) among Malay T2DM patients

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***Abstract*—**The Problem Areas in Diabetes Scale (PAID) was translated using forward and backward translations following a predefined set of guidelines. The sample consists of 46 Malay patients from a public hospital in Malaysia. The PAID scale was found to have high internal consistency (Cronbach's Alpha value = 0.921). The patients suffered from mild diabetes distress having an average PAID score of 39.4. The findings gave support of convergent validity with a significant association (Pearson correlation = 0.081; $p<0.05$) between PAID score and HbA_{1c} values. The Malay version of PAID was found to be reliable and valid among Type 2 Diabetes Mellitus patients.

***Keywords*—**PAID, internal consistency, convergent validity, Type 2 Diabetes

I. Introduction

TYPE 2 diabetes mellitus (T2DM) has become a common and burdensome disease. T2DM requires a careful and complex management, such as daily treatment [1]. For patients living with T2DM, daily treatment can lead to a considerable impact on many domains of quality of life [2] – [4]. The measurement of the psychological factors affecting the patient's agreement with treatment can be used as a useful tool to determine their levels of emotional distress [5]. Treatment can have a significant impact on work, social functioning and the physical and emotional well being of the patient [1]. Because of the demanding nature of T2DM treatment, patients are usually largely affected along with their family members who cater for their daily care [6] – [7].

Daily management of diabetes treatment can result in long-term stress [8]. Self-care in diabetes is often perceived as overwhelming and demanding on the patients. Psychosocial factors especially in T2DM patients often lead to poor self-care and treatment management [9]. As a result, patients may not be aware of the consequences of poor DM self-care and may be oblivious to their illness. Poor self-care behaviours may lead to further psychological distress [10] – [11]. The consequences of long-term complications and their severe impact on DM are disturbing and generally lead patients to worry and be preoccupied with such serious complications [12] – [13]. This explains the recent findings by [10] that depression in patients with T2DM is four folds than those of the general population. Patients with T2DM who are depressed, duly suffer from an increased level of diabetes-specific emotional distress [14] – [15]. This in turn affects the lives of patients, and further complicates diabetes management [16] – [17].

Many T2DM patients feel demotivated and hardly comply with the diabetes treatment regimen. Therefore, a myriad of feelings such as emotional distress, anger, guilt, frustration, loneliness and denial have been observed by many studies [7] – [12]. Consequently, the diabetes-specific stressors lead to poor glycemic control and self-care [18] – [19]. The glycemic control is a prime indicator of a T2DM under control and is useful to health care practitioners (The Diabetes Control and Complications Trial Research Group, 1993). This can be used to examine domains related to diabetes. Such domains could include self-care areas and coping with T2DM treatment.

Diabetes distress can impede the self-care behaviors of patients, thereby compromising the blood glucose level [20]. In the study by [20], PAID scores have shown positive associations with HbA_{1c} and they are considered as major predictors to treatment adherence. However, diabetes distress was also found not to be associated with changes in HbA_{1c} values [21] – [22]. A low positive correlation was found between PAID scores and the HbA_{1c} level [8]. Another study by [23] observed that diabetes distress was strongly associated with worse glycemic control.

Moreover, to have a good mastery of the glycemic level, particular attention should be given to diet, blood glucose control, medication and physical activity [24] – [25]. Poorly controlled hyperglycemia in turn leads to diabetes-specific emotional distress thereby increasing the cost of healthcare [26]. Hence, it is of prime importance to develop scales to identify diabetes distress among T2DM patients, which can be very useful to health care practitioners to examine the domains related to diabetes which cause diabetes-specific emotional

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distress. Such domains could be self-care areas, coping with T2DM treatment which may be burdensome for the patients, hence being more able to help them manage their diabetes and at the same keeping diabetes distress at bay.

Problem Areas in Diabetes Scale (PAID) [12] is a short self-report measure of diabetes-specific emotional distress. This instrument consists of 20 items which captures a range of emotional problems relating to diabetes. The questionnaire is used in clinical studies to assess diabetes-related distress and to examine its impact on the psychological adjustment of the patients [1]. PAID was developed at the Joslin Diabetes Clinic. The items were pooled from patients' feedback from 10 healthcare providers, which finally resulted in the 20-item measure [12]. Previous studies have revealed that PAID was a psychometrically sound measure to map emotional distress to diabetes [20], [27].

A Malay PAID version is not yet available and it might be useful for both clinical and research purposes. Therefore, the current study aims to evaluate the reliability and the convergent validity of the PAID (MY-PAID-20) in T2DM patients. A first version of this paper [28] was published in a conference proceedings. Due to the small size of the study, additional analysis included a discussion about the diabetes complications and comorbidities and the convergent validity of MY-PAID-20. This paper also discusses about the translation procedure and the cognitive debriefing process before it was used. Ethical approval for this study was obtained from the Medical Research Ethics Committee (MREC), Malaysia and this study is registered under the National Medical Registry Registration board (NMRR).

This paper is organized as follows: Section 2 provides the methodology employed in the study such as the translation process, the patients, the measure and statistical analysis. The results are presented in Section 3. Section 4 discusses results and Section 5 concludes the paper.

II. Methodology

A. Translation Procedure

The original version of the PAID was translated into Malay language through a series of major steps employed in a linguistic validation process. The translation committee was made up of eight investigators. The linguistic validation process was adapted by the 12 major sets of guidelines [29] for the cultural adaptation process for patient-reported outcome measure. The major steps involved in the translation procedure are (1) preparation; (2) forward translation; (3) reconciliation; (4) back translations; (5) back translation review; (6) harmonization; (7) cognitive debriefing; (8) review of the cognitive debriefing results and finalization; (9) proofreading and (10) final report. Fig.1 depicts the linguistic translation process. The translation coordinator was from the Statistics department and she monitored the translation process. The first forward translator was from the English language department. The second forward translator was a senior lecturer from the Pharmacy department who is acquainted with reported patient outcome questionnaires. The person reconciling the two forward translations was from Pharmacy background and he has been involved in many linguistic validations. The two back translators were experienced researchers from the English department of the University. Two proofreaders whose first language were Malay proofread the final Malay version of PAID.

During the preparation stage, permission to translate and validate the PAID instrument into Malay language was sought from the original developer. The coordinator thereafter recruited the key persons to be involved in the translation process. Native Malay speakers who were proficient in Malay put forward two independent forward translations from the original source. Thereafter, the coordinator reconciled the forward translations into a single one and a report was produced to clarify discrepancies. Backward translations were made by two professional English translators into the English Language. A reconciled version was generated to review the back translation against the source language.

During the cognitive debriefing (CD) process, two researchers from pharmacy background reviewed the reconciled reports and incorporated additional feedbacks. The CD was performed with five patients having T2DM of Malay origin. The sample was recruited by convenient sampling at a public hospital. An in-depth interview was performed with the patients by probing techniques. The patients answered the PAID and any items, which they had difficulty to understand, were noted. Their opinions of how to rephrase the items were also asked. After the CD results were obtained, the final report was finalized and proofread before having the eventual Malay version.

B. Patients

The inclusion criteria for the participants were that the patients were aged above 18 years, diagnosed with T2DM for at least one year, taking T2DM diabetes medications and able to speak, read and write in Malay language. Patients diagnosed with gestational diabetes or mental disorders were excluded from this study. The patients were approached while they were in the waiting area to see the medical practitioner. Before receiving the questionnaire, each patient was debriefed on the study by the investigator on the purpose and procedure of the study. Those who agreed to participate, signed a consent form and had the opportunity to ask clarifying questions.

Each patient answered a demographic questionnaire including questions on age, sex, level of education, monthly income, duration of diabetes, medical conditions and the HbA_{1c}.The medical records of the patients were not reviewed since the patients had a record of their HbA_{1c}.

C. Research Instrument

The PAID scale used comprised of 20 items that identifies diabetes-related emotional distress reported in Type 1 or Type 2 diabetes patients [12]. In this study, the later version of PAID by [27] was used. The PAID is scored between 0 (lower emotional distress) to 100 (greater emotional distress). PAID is rated on a 5-point Likert scale, and the patients rate the

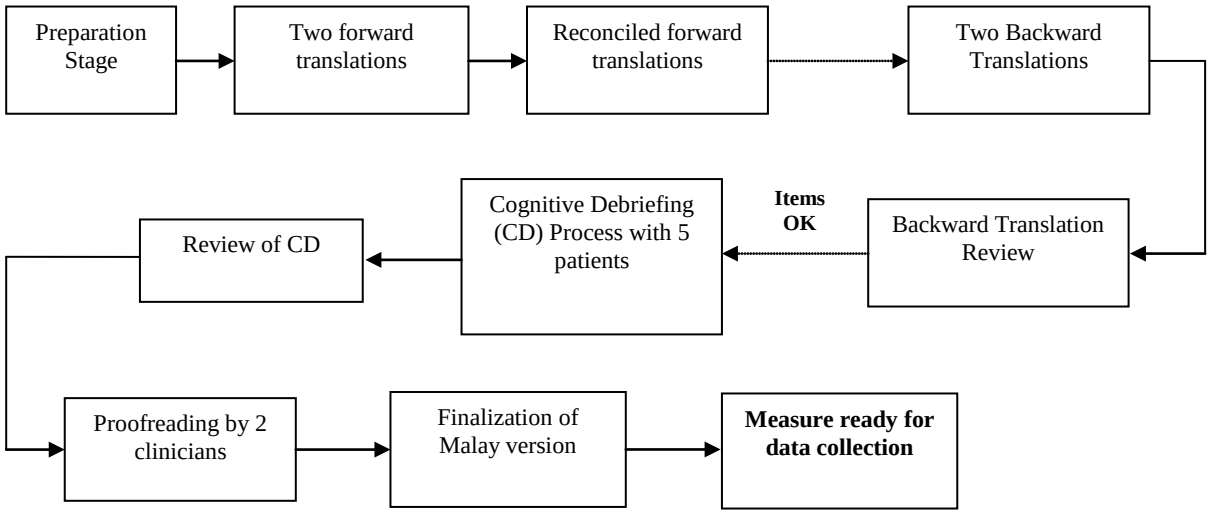

Fig 1. Linguistic Translation Procedure

extent to which each item is problematic for them in the following way; "0 = Not a problem", "1 = Minor problem", "2 = Moderate problem", "3 = Somewhat serious problem", and "4 = Serious problem". The ratings are re-coded into 0 – 100 by summing the 0 – 4 (0 = 0, 1= 25, 2 = 50, 3 = 75 and 4 =100) responses given for the 20 items of PAID after which the sum is then multiplied by 1.25 [27]. The original version of the PAID has been proven to be reliable and valid [1], [12]. The sensitivity of the instrument is subject to change while performing medical and educational interventions [27].

D. Statistical Analysis

Statistical analyses were performed in SPPS 19.0 software package for Windows. Descriptive statistics were used for the demographic and clinical factors in the pilot study. Missing values of the PAID were imputed by the mean as suggested by [29]. An item analysis was conducted to provide information on how well each item was related to other items of the scale. This was to check if any item was inconsistent with the averaged behaviour of other items. Item-total correlations below 0.30 are considered low [30]. The internal consistency of the scale was tested by the Cronbach's Alpha coefficient and a value greater than 0.70 indicates high reliability. Correlations above 0.80 are highly desirable [30]. In order to achieve convergent validity, the Malay version of PAID-20 was compared with the HbA_{1c} indicator. The Convergent validity was determined using Pearson's product-moment correlation. The correlations among measures of the same attribute are expected to fall within the range of $r = 0.40 – 0.80$. A low correlation would indicate that the measure is measuring a different phenomena. We hypothesized that patients with high PAID scores also had high levels of HbA_{1c}.

III. Results

This section presents the Cognitive Debriefing (CD) results, the demographic data, the reliability analysis, the convergent validity analysis and lastly the inter-item correlations.

A. Cognitive Debriefing (CD) Results

After the forward and the backward translations, the reconciled version of the Malay PAID was tested on five Malay-speaking respondents. The mean age was 50 years and they had had diabetes for more than one year. Three of the patients were on tablets while two were on insulin injections.

The respondents took an average of 8 minutes to complete the questionnaire. In general, the respondents did not face much difficulty in answering the Malay version of PAID. Some particular concerns were raised about Item 2, "Feeling discouraged with your diabetes treatment plan?". The word *"rancangan"* was replaced by *"Pelan"* which was found to be more appropriate. In Item 3,"Feeling scared when you think about living with diabetes", only one respondent felt that the word "pengidap"
was less suited to the sentence. *This item was rephrased to* "Rasa takut apabila anda berfikir tentang hidup dengan penyakit kencing manis?". The Item 8: "Feeling overwhelmed by your diabetes" was changed to *"rasa terharu dengan penyakit kencing manis anda?"* to have a clearer meaning of the sentence. Several issues were raised by the respondent for Item 9, "Worrying about low blood sugar reactions", one of the patient suggested to change *"tindakbalas"* to *"keadaan akibat"* since three out of the five respondents had difficulties to understand Item 9. The final version of Item 9 was *"Bimbang tentang komplikasi kandungan gula dalam darah yang rendah"*. In item 13, "Feelings of guilt or anxiety when you get off track with your diabetes management", during the clinician review, it was suggested to change the word "perancangan" to "pelan". For Item 19, "Coping with complications of diabetes", during the proofreading stage, the word *"akibat"* was replaced with *"komplikasi"*. Two respondents proposed to rephrase the question for Item 20, "Feeling "burned out" by the constant effort needed to manage diabetes" since they could not understand the phrase "perlu berterusan berusaha". Hence Item 20 was changed to *"rasa*

kehabisan daya dengan usaha berterusan yang diperlukan untuk menguruskan penyakit kencing manis?"

B. Demographic Characteristics

The PAID instrument was completed by 46 Malay patients who participated in the pilot study. The mean age of patients was 52.2 years and the mean duration of diabetes is 9.3 years. The mean HbA_{1c}value was 7.5 and the mean BMI was 28.3. Out of the 46 Malay patients, 65.2% were male. The majority of the respondents had secondary education (63.0%), 15% had primary background and only 13% went to university. Most (86.7%) of the patients were married. Among the T2DM patients, the most common co-morbidities was heart disease (42.2%) followed by high cholesterol (40.0%). Hypertension was also dominant (37.8%) and only 6.7% had lung complications. Among the diabetic complications, 37.8% of the patients had retinopathy (Eye problems), 31.1% had neuropathy (Nerve problem) and only 8.9% had nephropathy (Kidney problem).

C. Internal consistency reliability and convergent validity

The Cronbach's alpha value of the 20 items of the Malay version of PAID was 0.912 indicating high internal consistency and reliability. The convergent validity was examined by calculating the Pearson's product-moment correlation coefficient between the MY-PAID-20 scores and the HbA_{1c}. A low positive correlation ($r = 0.081$, $p<0.05$) was found. Thus, convergent validity was observed and the hypothesized relationship between MY-PAID-20 and HbA_{1c} was accepted [8].

D. Correlation results

Correlation analysis (results not shown due to space constraint) shows that the majority of the correlations were between 0.30 and 0.70; all statistically significant at 0.01 level.

From the individual item statistics in Table 2, the corrected item total correlation ranged from 0.26 to 0.77. All items had a corrected item-total correlation above 0.30 except for the first item. This particular item "Not having clear and concrete goals for your diabetes care" had a lower corrected item-total correlations ($r = 0.26$), but was not unsatisfactory low.

Two of the 20 items had corrected item-total correlations of less than 0.40: "Feelings of deprivation regarding food and meals"and "Feeling angry when you think about living with diabetes". The highest corrected item-total correlation ($r = 0.77$) is: "Worrying about the future and the possibility of serious complications". The two particular items with inter-item correlation less than threshold indicated that these two items do not correlate well with the scale overall. From these results, it was inferred that the majority of the items provided empirical evidence of good correlation with the chosen scale.

The total score of the MY-PAID for the pilot study ranged from 5 to 80. The mean PAID score was 39.4 with a standard deviation of 19.4. The median PAID score was 41.3. The item "Worrying about the future and the possibility of serious complications" had the highest percentage response of 4 (Serious problem), therefore it was considered as the most serious diabetes-related problem. The item "Uncomfortable social situations related to your diabetes care" was considered as the least serious problem (2.3%). Items such as "Feeling discouraged with your diabetes treatment plan", "Feeling that your friends and family are not supportive of your diabetes management efforts" and "Coping with complications of diabetes" were not considered as minor problem (% response = 4.7) among the respondents.

It is important to note that many feel scared (23.8%), an depressed (19.5%) when they think about living with diabetes (23.8%). Many diabetic patients also worry about low blood sugar reactions (23.3%).

TABLE 1: Demographic and Clinical Data

	%
Demographic factors	
Age (Mean)	52.2
Duration of diabetes (year)	9.3
Clinical parameters (Mean)	
HbA_{1c} (%)	7.5
BMI (kg/m^2)	28.3
Gender (%)	
Male	65.2
Female	34.8
Education (%)	
Primary	15.2
Secondary	63.0
University	13.0
Others	8.7
Marital status (%)	
Single	11.1
Married	86.7
Divorced	0.0
Widowed	2.2
Working status (%)	
Yes	50.0
No	40.9
Retired	9.1
Income (%)	
<RM1000	32.6
RM1000 – 3000	11.6
RM3001 – 5000	37.2
RM5001 – 8000	16.3
Other Medical conditions (%)	
Yes	75.6
No	24.4
Co-morbidities (%)	
Arthritis	24.4
Heart disease	42.2
Hypertension	37.8
High Cholesterol	40.0
Lung problems	6.7
Diabetes Complications (%)	
Neuropathy (Nerve)	31.1
Nephropathy (Kidney)	8.9
Retinopathy (Eye)	37.8

TABLE 2: Individual item analysis of MY-PAID-20

Items	Median MY-PAID-20	Mean	% response option (4 = "Serious Problem")	Corrected item-total correlation
1. Not having clear and concrete goals for your diabetes care.	2.0	1.86	16.3	0.26
2. Feeling discouraged with your diabetes treatment plan.	1.0	1.54	4.7	0.52
3. Feeling scared when you think about living with diabetes.	2.0	2.27	23.8	0.72
4. Uncomfortable social situations related to your diabetes care.	1.0	1.39	2.3	0.50
5. Feelings of deprivation regarding food and meals.	2.0	1.95	16.3	0.34
6. Feeling depressed when you think about living with diabetes.	2.0	1.63	19.5	0.80
7. Not knowing if your mood or feelings are related to your diabetes.	1.0	1.62	9.3	0.68
8. Feeling overwhelmed by your diabetes.	2.0	2.06	12.2	0.61
9. Worrying about low blood sugar reactions.	1.0	1.46	23.3	0.58
10. Feeling angry when you think about living with diabetes.	2.0	1.92	14.3	0.38
11. Feeling constantly concerned about food and eating.	2.0	1.75	7.0	0.64
12. Worrying about the future and the possibility of serious complications.	3.0	2.48	33.3	0.77
13. Feelings of guilt or anxiety when you get off track with your diabetes management.	2.5	2.12	19.0	0.66
14. Not "accepting" your diabetes.	1.0	1.39	11.6	0.52
15. Feeling unsatisfied with your diabetes physician.	0.0	0.88	4.8	0.44
16. Feeling that diabetes is taking up too much of yourmental and physical energy everyday.	1.0	1.58	9.3	0.56
17. Feeling alone with your diabetes.	1.0	0.96	4.8	0.58
18. Feeling that your friends and family are not supportive of your diabetes management efforts.	1.0	0.84	4.7	0.49
19. Coping with complications of diabetes.	1.0	1.24	4.7	0.63
20. Feeling "burned out" by the constant effort needed to manage diabetes.	1.0	1.30	4.8	0.53

IV. Discussion

In this study, the reliability of the Malay translated PAID-20 was evaluated among patients with type 2 diabetes in Malaysia after a thorough cognitive debriefing process with five Malay patients at a local hospital.

The obtained Cronbach's Alpha reliability coefficient of 0.921 is in line with other validation studies [5], [8], [13] in different languages of the original version of the PAID scale. The analysis of the convergent validity reported that PAID was positively associated with HbA_{1c}. This particular finding was similar to the study by [12]. Moreover, the low correlation coefficient of this study was in accordance with [8]. However, few studies [21]-[22] have demonstrated that diabetes-related emotional distress was not associated with HbA_{1c}.

This is the first pilot-study to validate the Malay version of PAID in Malaysia. The most common diabetic complication for this study was retinopathy (Eye Problems) constituting about 37.8% of the T2DM patients. This higher percentage was similar to the study by [8] whereby 56% of patients had retinopathy. Our study revealed that the most serious co-morbidity was heart disease (42.2%) followed by a high cholesterol level (40.0%). Likewise, Huang et al. [3] found that 74% of the patients suffered from heart disease and 19% had retinopathy. Generally, the functional health of the T2DM patients depends largely on the existing co-morbidities and diabetic complications.

Among the PAID-20 items, "Worrying about the future and the possibility of serious complications" was found to be the most serious problem. This finding is similar to previous studies reported by [1], [8], [12], and [20]. Since diabetes is known to be related to many other medical conditions, patients

often fear the possible complications. Since the mean age of patients in this study was 52.2 years, it may be possible that older patients are more at risk to have anxiety concerning the eventual medical conditions, which may arise due to diabetes.

The mean value of the total PAID score ($\overline{X}$ = 39.4) was higher compared to the study for Swedish [8] and Dutch [20] patients. Hermanns et al. [31] suggested a cutoff score of greater or equal to 40 as indication of severe level of diabetes-related distress. In this sample, 36% of the patients scored greater than 40. This percentage was quite considerable and studies will be conducted in more hospitals to get a larger sample of patients to be representative of Type 2 Diabetes Mellitus Malay patients.

V. Conclusion

This study managed to translate the PAID-20 into Malay language using the forward and backward translations. The pilot study results show that MY-PAID-20 is a reliable questionnaire as the items have high internal consistency. The translated items are easy to comprehend by the Malay patients. The MY-PAID-20 can be used to identify diabetes-related distress among diabetes patients in Malaysia. Clinicians can use it to identify problem areas face by T2DM patients and provide better care and attention to those who are suffering from high levels of distress pertaining to their illness. The Malay translated PAID-20 can be obtained from the corresponding author.

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