VALUE IN HEALTH REGIONAL ISSUES 12C (2017) 63–73

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/vhri

Translation, Revision, and Validation of the Diabetes Distress Scale for Indonesian Type 2 Diabetic Outpatients with Various Types of Complications

Bustanul Arifin S. Farm, Apt, MSc, MPH[1,2,3,*], *Dyah Aryani Perwitasari, Apt, PhD*[4], *Jarir At Thobari, MD, PharmD, PhD*[5], *Qi Cao, PhD*[1], *Paul F.M. Krabbe, PhD*[6], *Maarten J. Postma, PhD*[1,3,6]

[1]*Unit of PharmacoTherapy, Epidemiology & Economics (PTE2), Department of Pharmacy, Faculty of Science and Engineering, University of Groningen, Groningen, The Netherlands;* [2]*RSUD Banggai Laut Hospital, Banggai Laut Local Government, Central Sulawesi, Indonesia;* [3]*Institute of Science in Healthy Aging & healthcaRE (SHARE), University Medical Center Groningen (UMCG), University of Groningen, Groningen, The Netherlands;* [4]*Faculty of Pharmacy, University of Ahmad Dahlan, Yogyakarta, Indonesia;* [5]*Department of Pharmacology and Therapy, Medical Faculty, Universitas Gadjah Mada, Yogyakarta, Indonesia;* [6]*Department of Epidemiology, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands*

ABSTRACT

Objectives: To translate, revise, and validate the Diabetes Distress Scale (DDS) instrument for Indonesian type 2 diabetes mellitus (T2DM) outpatients with various complications. **Methods:** Participants were recruited from four hospitals and two primary health care centers. The study was performed with forward and backward translations, an adaptation testing with a small subset of participants, and validation analysis. Factor analysis with maximum likelihood estimation and promax rotation was then used to investigate the instrument structure. Internal consistency among the items was estimated using Cronbach α for each domain of the DDS. **Results:** In total, 324 participants (246 from the hospitals and 78 from the primary health care centers) were involved in this study. To improve participant comprehension of the exact meaning of questions, examples of daily activities for patients with T2DM (e.g., diet, exercise, and adherence to therapy) were added to some questions after the translation and revision procedures. The factor analysis revealed a correlation among the four factors ranging from 0.40 to 0.67. The factor loadings of selected items from the four factors ranged from 0.41 to 0.98. The order of the four factors in the factor analysis was as follows: interpersonal distress, emotional burden, physician distress, and regimen distress. The internal consistency for the four domains ranged from 0.78 to 0.83. The instrument resulting from this study was labeled "DDS17 Bahasa Indonesia." **Conclusions:** The DDS17 Bahasa Indonesia provides an initial psychometric validation study, factor structure, and internal consistency for assessing the distress of Indonesian T2DM outpatients. Use of this instrument in future research and clinical trials is recommended for the Indonesian context.

Keywords: Diabetes Distress Scale, Indonesian type 2 diabetes, psychometric properties, validation.

Introduction

Diabetes mellitus (DM) represents a substantial burden on health care systems with prevalence steadily rising worldwide [1]. In 2015, an estimated 415 million people were suffering from DM [2]; of these, 77% were living in low- and middle-income countries [3]. It is estimated that by 2040, the number of people with DM will rise to nearly 650 million [2], with 90% suffering type 2 diabetes mellitus (T2DM) [4].

In Indonesia, the prevalence of T2DM among people older than 15 years, representing a population of 177 million, mounted significantly from 1.1% in 2007 to 2.1% in 2015 [5]. A report by the Indonesian Ministry of Health [5] shows that a further 1% of the population complained of T2DM symptoms during the most recent month at the time of interview, but could not confirm whether these persons suffered from T2DM itself. In 2007, urban areas accounted for the highest incidence of T2DM, but data from 2013 present a different picture with no significant difference between urban and rural areas [5]. In the analysis of sociodemographic characteristics, the number of persons suffering from T2DM increases with age, with the highest proportion found in people older than 55 years [5]. There was no significant difference by sex [5]. This report also states that in disaggregation by occupation, the highest proportions were identified among the unemployed (7.4%), followed by self-employed and sole proprietors (7.2%), farmers/fisherfolk/manual laborers (6.2%), and active

Conflicts of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

* *Address correspondence to:* Bustanul Arifin, Unit of PharmacoTherapy, Epidemiology & Economics (PTE2), Department of Pharmacy, Faculty of Science and Engineering, University of Groningen, Antonius Deusinglaan 1, Building 3214, Groningen 9713AV, The Netherlands.

E-mail: bustanul.arifin.ury@gmail.com; ury.bustanul.arifin@gmail.com

2212-1099$36.00 – see front matter

http://dx.doi.org/10.1016/j.vhri.2017.03.010

employees (5.8%) [5]. Regarding clinical characteristics, it is reported that 60% of patients with T2DM in Indonesia experience at least one comorbidity caused by T2DM [5,6].

People with T2DM need to follow a strict program of self-management, including a healthy diet, sufficient physical activity, and adherence to their medication [7]. This daily management plan can be especially challenging for patients with cardiovascular and kidney complications, eye disease, nerve damage, and diabetic foot complications [8]. Previous research [9] found that T2DM management plans in themselves are responsible for psychological distress in many patients with T2DM, which may then hinder successful therapeutic outcomes. Because of the prominence of effects from emotional distress, it is imperative that T2DM-specific psychological distress be regularly assessed to identify those individuals who are particularly at risk [7,9]. To ensure that daily management plans are effective, T2DM outpatients should be able to manage their individual concerns and address their essential aspects of diabetes distress. An important contribution to this can come from both patient and caregiver understanding of the distress.

The Diabetes Distress Scale (DDS) was developed by William H. Polonsky from the Problem Areas in Diabetes (PAID) instrument [10,11] and has since become well established and widely recommended for assessing the level of distress in patients with DM [10]. Both the PAID and the DDS have their particular advantages in measuring diabetes distress, but the DDS has a more precise and cross-culturally consistent factor structure compared with PAID as shown in a validation study [12]. The DDS consists of 17 items that measure patients' feelings in four general domains [10,11]. First, the interpersonal distress domain (3 items) reflects the psychological emotions and feelings of patients with DM during their interaction with families, friends, or people around them. Second, the physician distress domain (4 items) portrays the distress that patients with DM experience during interaction with their physician. The third domain, regimen distress (5 items), describes the distress felt by patients with DM because of the need to adhere to a therapy management plan. The last is the emotional burden domain (5 items), which describes the distress related to the personal emotions of the patients suffering from T2DM, including fear of the possibility of DM-related complications.

Although a generic instrument to measure psychological distress can be quite useful for recognizing distressed T2DM outpatients, a more specific DM-related identification of psychological distress may help to choose the appropriate intervention, which will ultimately improve prospects for adequate therapies and better outcomes [10,13]. This instrument, however, has yet to be introduced to the Indonesian population. To this end, our study purposes were to translate, revise, and validate the DDS instrument for Indonesian T2DM outpatients with various types of complications.

Methods

Study Setting

Our study was conducted in four hospitals and two primary care facilities on the island of Java. The revision phase represents the next step after the translation phase. We carried out the revision phase in the first week of February 2015 at only one hospital, the RSUD Kota Yogyakarta Hospital. In the validation phase, we also distributed this instrument to three other hospitals, PKU Muhammadiyah Hospital in Yogyakarta, Moewardi Hospital in Solo, Central Java, and BLUD Sekarwangi in Sukabumi, West Java, while continuing the data collection process at RSUD Kota Yogyakarta Hospital. At the primary care level, the instrument validation process was performed by a family doctor in Wonosari, Yogyakarta, and in a public health center in Pakis, Surabaya, East Java. The overall validation phase lasted from February to July 2015. This study was approved by the Medical Ethics Committee of the Universitas Gadjah Mada Yogyakarta Indonesia in document number KE/FK/1188/EC on November 12, 2014. Permission to develop a version of the DDS for use with Indonesian T2DM outpatients was obtained from the original author (William H. Polonsky, University of California, San Diego, CA) in February 2015.

Sample Selection

The selection process for participants enrolled in this study was carried out in the same manner as in the revision and validation phases. After enrolling in this study, T2DM outpatients aged 18 years or older were informed verbally about the context of the study. After this, they read and signed a statement of willingness to participate, inclusive of informed consent. Some participants with limited reading ability gave their informed consent orally with the approval of their caregiver. All participants were recruited in the locations previously described, thus forming the consecutive sample.

Study Procedure and Data Collection

Translation

The translation phase consisted of the two steps of forward and backward translations, on the basis of the specific recommendation guidelines and international criteria [14,15]. Initially, the original DDS instrument was translated from English to Bahasa Indonesia by two Indonesian professional translators, each working independently. The final version resulting from this step was labeled version 1. In the backward translation, the version 1 document was translated from Bahasa Indonesia to English by three Australian professional translators similarly working independently, all of whom were English native speakers and fluent in Bahasa Indonesia. The final version resulting from the backward translation was labeled version 2. The main purpose of the backward translation was to ensure that the forward translated documents were indeed correct, which we ascertained by comparing the original DDS with the three documents after backward translation. The final product of this process was the initial DDS in Bahasa Indonesia.

Revision

The initial DDS in Bahasa Indonesia was subsequently tested in two groups of participants. The first group consisted of the first 10 T2DM outpatients whom we encountered at random and who satisfied the sample selection criteria. The second group was made up of 10 healthy adults who volunteered to give their opinions on the initial DDS. During this phase, two specific points required attention: 1) whether both groups of participants would have the same difficulties in understanding the DDS questions and 2) the most frequently occurring problems with filling out the DDS. After this, we also asked their opinions about this phase. Some participants agreed to be recorded while stating their opinions, which provided helpful insights in subsequent analyses. At the end of this phase, the DDS was revised as required, on the basis of all comments received and issues observed. The final DDS resulting from this phase was subsequently taken to the validation phase.

Validation

This final form of the DDS was used for the remaining study participants in the validation phase. All participants involved were given information and an opportunity to ask questions.