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Examining diabetes distress, medication adherence, diabetes self-care activities, diabetes-specific quality of life and health-related quality of life among type 2 diabetes mellitus patients



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ABSTRACT

Aims: Health-Related Quality of Life (HRQoL) has been increasing attention in health outcome studies. Factors that individually influence HRQoL, diabetes self-care behaviors, and medication adherence have been widely investigated; however, most previous studies have not tested an integrated association between multiple health outcomes. The purpose of this study was to formulate a hypothetical structural equation model linking HRQoL, diabetes distress, diabetes self-care activities, medication adherence and diabetes-dependent OoL in patients with Type 2 Diabetes Mellitus (T2DM).

Methods: A cross-sectional study design was employed, and 497 patients with T2DM were recruited from outpatient clinics in three public hospitals and one government clinic. The patients completed a series of questionnaires. The hypothetical model was tested using Structural Equation Modeling (SEM) analysis. *Results*: The values of the multiple fit indices indicated that the proposed model provided a good fit to the data. SEM results showed that medication adherence (MMAS) had a significant direct effect on diabetes distress (PAID) (Beta = -0.20). The self-care activities (SDSCA) construct was significantly related to PAID (Beta = -0.24). SDSCA was found to have a significant relationship with HRQoL (SF-36) (Beta = 0.11). Additionally, diabetes distress had a significant effect (Beta = -0.11) on HRQoL of patients. Finally, ADDQoL had a significant effect on HRQoL (Beta = 0.12).

Conclusions: The various health outcome indicators such as self-care behaviors, diabetes distress, medication adherence and diabetes-dependent QoL need to be considered in clinical practice for enhancing HRQoL in those patients.

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Introduction

Diabetes Mellitus (DM) is one of the most important public health concerns. The prevalence of DM has increased dramatically in most countries in the world. Recently, it is estimated that the number of DM patients will increase from 171 million to 366 million between the years 2000 and 2030 [46]. As Malaysia continues its progress as a nation both socially and economically, disease patterns and burdens are changing due to changes in lifestyle and dietary patterns of its population. According to the National Health and Morbidity Survey, the prevalence of DM among Malaysian adults aged older than 30 years had increased from 6.3% in 1986, 8.3% in 1996 and 14.9% in 2006 to finally hitting 15.2% in 2011

[17]. By the year 2030, Malaysia is expected to rank tenth with the highest rate of diabetes worldwide. This increase in the number of people with Type 2 Diabetes Mellitus (T2DM) will be synonymous to huge human burden. T2DM has thus been found to have unfavorable effects on the Heath-Related Quality of Life (HRQoL) of patients [2,28].

To assess HRQoL and diabetes-specific factors, many instruments have been developed over time to obtain the perceived behavior of patients. Some are intended for general use, irrespective of the illness and condition of the patient. The generic instruments are often applicable to even healthy people. Some of the earliest ones were developed initially with population surveys in mind, but later were extended to include clinical trial settings. These instruments are commonly described as QoL scales and they are measures of health status since the focus is mainly physical symptoms. Some generic HRQoL measures, such as the SF-36, contain the essential elements of HRQoL and they are also easily

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cross-culturally validated [8]. The generic scale instruments allow for HRQoL comparisons among different group of patients. On the other hand, the disease-specific instrument attempts to capture only the specific impact of a disease on the patient's functioning and well-being [8,14]. The disease-specific instrument renders it more difficult to assess HRQoL for patients having multiple diseases while the HRQoL instrument is based on the specific health condition of a patient. Therefore, a combination of generic and disease-specific instruments may be more appropriate in measuring the patient's health status [4]. However Herdman et al. [15] proposed for the validation of the diabetes-specific QoL instruments in Asian countries. This is due to the increase in implementation of patient reported outcomes in large clinical trials. Thus, Asia must de facto be included since it is one of the most densely populated continents in the world [43]. Among all the diabetesspecific OoL measures, the Audit of Diabetes Dependent OoL instrument is one of the most widely translated and validated in more than 20 languages as well as the Problem Areas in Diabetes Scale (PAID) [11,13,31,35].

The major objective in the treatment of T2DM is to lower the blood glucose levels in the normal and/or near normal range [29]. A set of indicators for diabetes care has been recommended, such as measuring the control of blood sugar [23]. HRQoL has been posited to be another important health outcome measure. T2DM is a lifelong health condition which can affect the patients' condition significantly. The Quality of Life (QoL) of T2DM patients has been shown to be affected with disease progression and response to medication therapy [2]. Health behaviours are commonly suggested as proximal health outcomes of HRQoL. Self-care in diabetes has been defined as an evolutionary process of development of knowledge or awareness by learning to survive with the complex nature of T2DM in a social context [30]. Since the vast majority of day-to-day care in diabetes is handled by patients and/or families [2], there is an important need for reliable and valid measures for self-management of T2DM [18]. Individuals with diabetes need to perform specific multifaceted activities in their daily lives, such as having an appropriate diet, regular exercising, monitoring their blood glucose levels, foot care and medication self-administration [28]. Patients with low adherence to self-care activities such as exercise and medication were found to have lower HRQoL [28]. On the other hand, diabetes self-care activities are reported to be positively related to HRQoL for adhering patients [16,25].

Psychological factors such as diabetes-related emotional distress were found to be associated with lesser adherence to diet, exercise, frequent blood glucose testing and medication regimens [9,26,27,33]. Previous studies have also found that health-related quality of life were inversely related to diabetes self-care activities and they reported that the EuroQoL-5 dimensions (EQ-5D) index was significantly associated with non-adherence to foot care, exercise duration and smoking [28]. The diabetes-dependent quality of life is also an important indicator of HRQoL. Wee et al. [43] reported that respondents who scored a better EQ-5D index have better Audit of Diabetes Dependent QoL (ADDQoL) Average Weighted Index scores (Spearman correlation = 0.54, *p*value < 0.01). Diabetes distress was also found to be significantly related to medication adherence. Patients who are non-adherent to their daily medication intake had a higher level of diabetesspecific emotional distress [26].

The aim of this study is to test a structural model that links diabetes distress, medication adherence, self-care activities, diabetes-specific QoL and HRQoL using a sample of T2DM patients in Malaysia. This is the first study in Malaysia that extensively investigates the relationships among a number of physiological, psychological, behavioral predictors and adaptive outcomes using psychometrically validated instruments via Structural Equation Modeling (SEM). Literature on diabetes studies has demonstrated

that various factors can individually influence HRQoL, diabetes self-care activities, medication adherence, and diabetes-dependent QoL and diabetes distress. However, most of the previous studies are yet to test a model regarding the multiple associations among these variables. The remainder of this paper is organised as follows: The methodology is explained in Section 2. The SEM results are then presented in Section 3 while Section 4 discusses the findings.

Material and methods

Study design and sample

This study involves a cross-sectional design. The patients were recruited from three hospitals namely Hospital Tuanku Ampuan Rahimah, Hospital Sungai Buloh and Hospital Serdang and a government public health clinic; Klinik Kesihatan Botanic. The three hospitals and the clinic were located in the state of Selangor, Malaysia. The inclusion criteria for the patients who participated was: 1. They were aged above 18 years 2. They were diagnosed with T2DM for at least one year 3. They were taking T2DM diabetes medications and 4. They were able to speak, read and write either in English or Malay language. On the other hand the exclusion criteria was: 1. Participants with gestational diabetes or mental disorders and 2. Those who were not able to read in Malay/English language. Sample size was calculated based on the need to conduct the Structural Equation Modeling (SEM) analysis which means that minimum of 200 subjects was necessary for adequate model specification [7]. The Medical Research Ethics Committee in Kuala Lumpur, Malaysia, through the National Medical Research Register (NMRR) granted the permission for this research.

Instrumentation

For this study, the self-reported questionnaire consisted of socio-demographic questions such as age and duration of diabetes. Participants were also asked to complete five questionnaires: (1) Problem Areas in Diabetes Scale (PAID); (2) Audit of Diabetes-Dependent Quality of Life-19 item (ADDQoL-19); (3) Morisky Medication Adherence Scale (MMAS); (4) Summary of Diabetes Self-Care Activities (SDSCA), and (5) Short-Form 36 (SF-36).

The five instruments used in this paper are either generic or diabetes-specific and were chosen on the basis of the number of items, time taken to complete the questionnaire and their purpose. The ADDQoL and PAID instruments were firstly chosen since they were the most popular and have high internal consistency reliabilities in comparison to the other diabetes-specific instruments [32,44]. Moreover, to study diabetes-related QoL, the ADDQoL was the most suitable since it allows the subject to judge the relevance or importance of each item and to eliminate non-relevant or non-important items from consideration before calculating the final weighted score [6]. This study also aimed at looking into the psychological aspect of diabetes and thus PAID instrument was chosen since it is the most commonly used to measure diabetes-specific emotional distress [26]. Since self-care behaviours are a very important aspect of diabetes, the SDSCA was chosen. The SDSCA takes into consideration various important domains such as diet, exercise, blood sugar testing and foot examination (Toobert, Hampson, & Glasgow, 2000). Lastly to look into the medication aspect, the Morisky Medication Adherence Scale was picked since it is the most concise and easiest to administer among patients [20] in contrast to other diabetes-specific medication instruments. The five chosen instruments are discussed as follows:

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