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Assessment of Reliability and Validity of SF-12v2 among a Diabetic Population

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ABSTRACT

Objectives: To validate the Medical Outcomes Study Short Form version 2 (SF-12v2) in diabetic patients. **Methods:** Adults with self-reported diabetes from the Medical Expenditure Panel Survey (2011–2013) were identified. Reliability (internal consistency and test-retest) and validity (construct, concurrent, criterion, and predictive) of the SF-12v2 were assessed. The SF-12v2 consists of two normalized composite scores: the physical component summary score (PCS12) and the mental component summary score (MCS12). Confirmatory factor analysis was conducted to assess the instrument structure. Concurrent (convergent and discriminant) validity was assessed by a multitrait-multimethod matrix using the Patient Health Questionnaire, the Kessler Scale, and perceived health and mental health questions. The predictive validity was assessed by estimating future limitations. The concurrent validity was tested by comparing the MCS12, PCS12, and utility scores (six-dimensional health state short form) across comorbidity scores. **Results:** The final sample comprised 2214 diabetic patients with mean normalized (population mean 50; range 0–100) PCS12 and MCS12 scores of 40.81 (standard error 0.33) and 49.82 (standard error 0.26), respectively. The PCS12 and MCS12 scores showed good internal consistency (Cronbach α: PCS12 0.85; MCS12 0.83) and acceptable test-retest reliability (intraclass correlation coefficient: PCS12 0.72; MCS12 0.63) and produced acceptable goodness-of-fit indices (normed fit index 0.95; comparative fit index 0.95; root mean square error of approximation 0.11 [95% confidence interval 0.1017–0.1188]). The PCS12 and MCS12 were moderately correlated with perceived health and perceived mental health. The MCS12 was highly correlated with the Patient Health Questionnaire and the Kessler Scale. Both the PCS12 and the MCS12 could predict the future health limitations. The PCS12, MCS12, and utility scores demonstrated sensitivity to the presence of comorbidity scores. **Conclusions:** The SF-12v2 is a valid generic instrument for measuring quality of life in diabetic patients.

Keywords: confirmatory factor analysis, diabetes, SF-6D, SF-12v2, validation.

Introduction

Diabetes mellitus is a chronic illness affecting about 10% of the US population [1]. Diabetic patients are prone to developing other comorbidities, namely, heart diseases, dyslipidemia, depression, and co-complications such as diabetic nephropathy, diabetic retinopathy, glaucoma, diabetic foot ulcers, and amputations [2]. The comorbidity burden and chronic nature of the disease lead to poor health-related quality of life (HRQOL) [3]. In addition to clinical end points, secondary end points such as HRQOL are vitally important in the management of diabetes to measure overall improvements in well-being. Studies assessing the impact of comorbidities and functional impairment associated with diabetes on HRQOL have used generic HRQOL instruments [4,5]. The Medical Outcomes Study Short Form version 2 (SF-12v2) is one such widely used generic HRQOL instrument. The instrument generates two summary scores including the physical component summary score (PCS12) and the mental component summary score (MCS12).

The SF-12v2 has been tested for reliability and validity in a general population during its development stage by Ware et al. [6]. The instrument demonstrated high internal consistency, test-retest reliability, construct validity, and criterion validity, which were consistent with previous findings using the short form 36 health survey (SF-36) [6]. Cheak-Zamora et al. [7] also reported similar results using a nationally representative database. Nevertheless, there were a few disagreements in the results, such as poor concurrence of the MCS12 with mental health measures.

Preliminary results from the study were presented as a podium presentation at Southern Pharmacy Administration Conference, 2016, Oxford, MS. The abstract for the presentation was published in *Research in Social and Administrative Pharmacy* Volume 12, Issue 4, July–August 2016, pages e11–e12, ISSN 1551-7411, http://dx.doi.org/10.1016/j.sapharm.2016.05.027.

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Other studies have evaluated the SF-12v2 in different disease populations [8–11] and found results similar to those reported by Ware et al. [6] and Cheak-Zamora et al. [7]. Effective use of the instrument in specific disease populations requires thorough psychometric evaluation, which the present studies lack.

Despite HRQOL being an important end point in the evaluation of interventions for diabetic patients, the SF-12v2 has not been validated in a nationally representative diabetic population. Therefore, the aim of this study was to assess the reliability (test-retest and internal consistency), structural validity, construct validity, and criterion validity of the SF-12v2 among diabetic patients. On the basis of previous studies by Ware et al. [6] and Cheak-Zamora et al. [7], this study hypothesizes that the SF-12v2 would demonstrate adequate reliability and validity in a diabetic population.

Research Design and Methods

Data Source

This study used a retrospective longitudinal cohort design as well as data from the publicly available survey data, the Medical Expenditure Panel Survey (MEPS). The MEPS is a nationwide representative survey of noninstitutionalized civilians, families, and providers [12,13]. The survey gathers data on the experience, use, and costs of various health care services. The MEPS consists of medical, household, and insurance components. The household component is a subsample of the previous year's National Health Interview Survey population. The survey collects information at the individual and household levels. It involves a panel design, collecting information through interviews over 2 years in five rounds using computer-assisted telephone interviewing, which is administered to one of the interviewing members of the household who records the responses on behalf of all the household members taking part in the survey. An additional self-administered questionnaire (SAQ) is mailed separately in rounds 2 and 4 of the panel for each eligible member of the household to complete individually. The major components of the SAQ include the SF-12v2, the Patient Health Questionnaire (PHQ-2), and the Kessler Scale (K-6) [14,15]. Other important components of the interview included the diabetes-specific survey questionnaire; questions on cognitive limitations, social limitations, perceived health, perceived mental health, and chronic conditions; and demographic information. Longitudinal files of panels 16 and 17 were used for this study, which encompass the years from 2011 to 2013 and include 36,435 study participants.

Study Sample

Only adults 18 years or older and having a self-reported diabetes diagnosis were included in the study. The sample was required to be within the scope for all five rounds and eligible for the SAQ in rounds 2 and 4. It was also required to have nonmissing responses for all the SF-12v2 items in these two rounds. The study sample identification is shown in Figure 1.

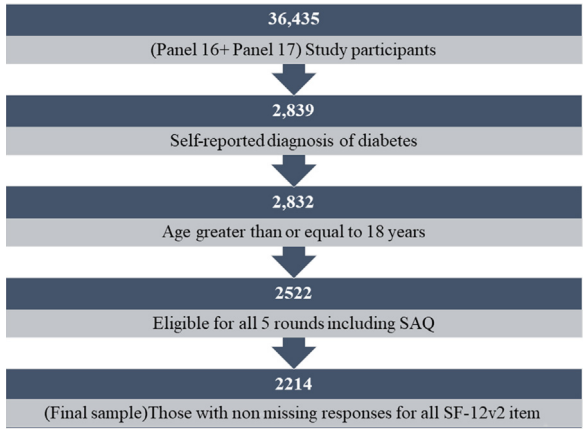

Fig. 1 – Selection process for the final analytical sample. SAQ, self-administered questionnaire; SF-12v2, Medical Outcomes Study Short Form version 2.

Measures

Medical Outcomes Study Short Form version 2

The SF-12v2 is a shortened version of the SF-36 [16,17]. Similar to the SF-36, it consists of items that evaluate eight subscales pertaining to HRQOL, namely, role limitations due to physical restrictions (RP), physical functioning (PF), bodily pain (BP), general health compared with others (GH), vitality (VT), social functioning (SF), role limitations due to emotional issues (RE), and mental health (MH) [17–19]. The responses for questions on GH, BP, and MH were reverse-coded to correspond with the direction of the summary scores. The scores from items on PF, RP, RE, and MH were combined and transformed to a Z score (range of 0–100) to create respective scales using methods from previous studies [6]. The PCS12 was calculated by combining and normalizing RP, GH, BP, and PF scales, whereas the MCS12 was calculated by combining and normalizing RE, MH, RE, SF, and VT scales. Normalized summary scores are generated from the items in each component. The scores range from 0 to 100, where higher scores indicate better health.

Six-dimensional health state short form

The six-dimensional health state short form (SF-6D) score is a preference-based single utility score. The SF-6D utility scores can be estimated using PCS12, MCS12, and age- and sex-specific norms [20]. The SF-6D utility scores calculated as such were used to estimate the disutility associated with diabetes-related comorbidities, namely, diabetes with complications, cardiac diseases, diabetes, and kidney and eye problems caused by diabetes.

Comorbidity Scores

We used the clinical classification codes from the medical condition file in the MEPS and condition-specific weights to calculate the PCS12- and MCS12-specific comorbidity indices [21]. The health-related quality of life comorbidity index (HRQOL-CI) was used for testing the concurrent validity. For estimating concurrent validity, the comorbidity scores were categorized on the basis of the distribution of comorbidity scores obtained for our final sample population. Scores for the PCS12 were grouped into the following score categories: 0, 1 to 2, 3 to 4, 5 to 7, and 8 or more, whereas scores for the MCS12 were grouped into the following score categories: 1, 2, 3, and 4 or more.

Diabetes-Related Comorbidities

The MEPS priority condition questions on cardiac diseases (namely, myocardial infarction, stroke, coronary heart disease, and other heart conditions) and arthritis were used to record the presence of the respective disease. Responses from the diabetes care survey were used to record the presence of diabetes-related kidney and eye problems. Furthermore, the medical conditions file was used to identify patients with diabetes-related complications using Clinical Diagnosis Classification code 50. Binary (yes/no) variables were created for each comorbidity. The diabetes-related comorbidities were used in