Transcultural adaptation of the Malayalam version of the diabetic foot ulcer scale-short form

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ARTICLE INFO

Keywords:
Diabetes mellitus
Diabetic foot ulcer
Quality of life
Validation

ABSTRACT

Introduction: Among Diabetes Mellitus (DM) patients, Diabetic Foot Ulcer (DFU) is the most prevalent complication that affects the patients’ quality of life (QoL). The present study aims to translate, validate, and test the reliability of the Diabetic Foot Ulcer Scale-Short Form (DFS-SF) in the Malayalam language.

Methodology: The DFS-SF questionnaire was translated Malayalam language using the Mapi Research Trust translation guidelines. The content validity index (CVI) and reliability was assessed for the translated DFS-SF Malayalam questionnaire. The construct validity was assessed using the EQ-5D and VAS.

Results: The average CVI score for the DFS-SF Malayalam questionnaire was 1.00. The reliability of the DFS-SF Malayalam version questionnaire has shown an excellent Cronbach’s alpha score. There is a positive correlation between dependence and VAS (r = 0.538, p = 0.014), bothered by ulcer care and VAS (r = 0.494, p = 0.027).

Conclusion: The newly translated DFS-SF Malayalam questionnaire is valid and reliable for assessing the QoL among DFUs in Malayalam patients.

1. Introduction

Diabetes Mellitus (DM) is the most prevalent and oldest metabolic disorder globally. India is the second capital of diabetes, with 77 million diabetic patients in 2019 and estimated to escalate to 134.2 million by 2045. 1 Among DM patients, Diabetic Foot Ulcer (DFU) is the most prevalent complication that affects the patients’ quality of life (QoL). The incidence and prevalence of DFU among DM patients are about 2–3% and 15%, respectively. 2–4

Twenty percent of DM patients with neuropathy will develop ulcers and which progress to amputation due to peripheral vascular disease. The mobility and QoL of the patients were affected due to the presence of complications. 5 Patients with diabetic neuropathy do not experience plantar stiffness; however, patients with ulceration can. Because of this, early stiffness identification could stop the development of later difficulties. 6 DFU is doesn’t merely contribute to the mortality rate but also associated with poor QoL. Several studies have revealed that patients with DFU have significantly reduced QoL by negatively impacting the various domains related to QoL, such as psychological, physical, social and economic functioning. 7–9 Apart from this, DFUs possess an enormous financial burden on the patient and healthcare system. The annual costs of the treatment of DFU patients in the UK in 2018 ($1.32 billion), India ($409), and Nigeria and Sub-Saharan Africa countries ($1200 to $1900). 10–11

The QoL can be measured using a variety of generic and disease-specific instruments. Among them, disease-specific instruments provide the physical, emotional, social functions and other aspects of diseases. Diabetic Foot Ulcer Scale (DFS) and DFS-Short Form (DFS-SF) are the most commonly used tools for assessing the QoL among DFU patients. 2–13 The DFS consists of 58 items and 11 domains, 2,11,13 and DFS-SF is a shortened version of the DFS scale comprising 29 items. 7,9 The DFS-SF is efficient and has good psychometric properties. 12 The DFS-SF questionnaire was previously translated into various languages such as Chinese, Spanish, Turkish, and Polish and showed good validity and
2. Methodology

2.1. Study design and criteria

A prospective observational study was conducted among 20 DFUs patients at tertiary care charitable hospital. Patients from both inpatient and outpatient settings were enrolled in the study. Patients aged above 18 years, who can communicate in the Malayalam language, diagnosed with diabetic foot ulcers were included in the study. The patients with cognitive impairment, terminal illness, psychiatric illnesses and pregnant and lactating women were excluded from the study.

2.2. Data collection

The data was collected by interviewing the patients, and the time taken to administer the questionnaire was about 15–20 minutes. The DFS-SF Malayalam version, Euro Qol-5 Dimension (EQ-5D) and Visual Analog Scale (VAS) questionnaires were administered to patients on day 1 and day 7, respectively. The data such as age, education, domiciliary status, socio-economic status, monthly income, body mass index (BMI), occupation, ulcer grade, co-morbidities, length of diabetes, length and duration of the hospitalization, area of amputation, smoking and alcoholic habits were collected from the patients and patient case files.

2.3. Ethical consideration

Ethical approval was obtained from Nitte (Deemed to be University), Central Ethics Committee (NU/CEC/2020/001). Patients were enrolled in the study after getting their signatures on the informed consent form. Permission was obtained from the MAPI research trust and EuroQol research foundation to use the DFS-SF questionnaire, and EQ-5D and VAS in DFU patients.

2.4. Instruments

2.4.1. DFS-SF

It contains the 29 items, and six domains consist of 1. Leisure, 2. Physical health, 3. Dependence or Daily life, 4. Negative emotions, 5. Worried about ulcers, and 6. Bothered about ulcer care. Domain scores are based on the sum of all items associated with that domain (raw item scores are reverse coded when necessary) and the scores of each domain ranged from 0 (low QoL) to 100 (High QoL).

2.4.2. Euro-Qol 5D (EQ-5D) and VAS

EQ-5D has the five domains represent the health state of patient and VAS represent the health condition scale ranged from 0 (low health) to 100 (maximum health).

2.5. Translation

The DFS-SF questionnaire was translated into Malayalam by forward translation, backward translation, patient testing, and proofreading using the Mapi Research Trust translation guidelines.

2.6. Validation and reliabilitytesting

2.6.1. Content validity

The content validity of the DFS-SF was done by the expert panel consisting of physicians, pharmacists and nurses. The experts were also asked to score the content validity index (CVI) for the questionnaire based on relevance, clarity, simplicity, and explicitly on 4 points likert scale. A CVI score above 0.750 is considered valid.

2.6.2. Construct validity

Construct validity was evaluated by comparing the correlation coefficient of the DFS-SF Malayalam questionnaire with EQ-5D and VAS.

2.6.3. Reliability

The reliability of the Malayalam version of the DFS-SF questionnaire was done by the test-retest method. The internal consistency reliability of the DFS-SF Malayalam questionnaire was assessed by computing cronbach’s-alfa coefficient. A cronbach’s-alfa 0.70 or higher was considered the questionnaire to be reliable.

2.6.4. Floor and ceiling effects

The floor and ceiling effects of the DFS-SF Malayalam questionnaire were performed to capture the changes in QoL of DFU patients. The acceptable values of the floor and ceiling effects should be <20% to capture the full range of the questionnaire.

2.7. Data analysis

Data was presented in mean and SD for quantitative variables, and frequency and % for qualitative variables. The DFS-SF Malayalam questionnaire domains were correlated with EQ-5D and VAS scales using Karl Pearson’s test. Data analysis was carried out by using IBM SPSS v.20.

3. Results

3.1. Sociodemographic details of the DFS-SF Malayalam questionnaire

Out of 20 patients, 15(75%) patients were men, and 5(25%) were women. The study population’s mean age and length of hospital stay (days) were 59.55 ± 10.84 and 28.9 ± 11.11, respectively. Most of the patients had ulcer grade ≥2 (16(80%)), and 11(55%) of them had no amputation. The sociodemographic details are shown in Table 1.

3.2. Content validity

After the linguistic translation, the DFS-SF was validated by the expert panel for content validity. The average f CVI score of the DFS-SF Malayalam questionnaire was 1.00.

3.3. Floor and ceiling effect

In the study, dependence or daily life and negative emotions have shown a floor effect of 5% each, whereas worried about ulcers showed 10% floor and ceiling effects. The floor and ceiling effects are shown in Table 2.

3.4. Reliability scores

The reliability of the Malayalam version of the DFS-SF questionnaire was good (Cronbach’s-alfa value ranged from 0.990 to 0.996). The detailed test-retest and reliability scores of the DFS-SF Malayalam questionnaire are shown in Tables 3 and 4.
3.5. Correlation of the DFS-SF Malayalam questionnaire

The DFS-SF Malayalam questionnaire domains were correlated with EQ-5D and VAS scales. The dependence domain was positively correlated ($r = 0.538$, $p = 0.014$) with VAS. Similarly, bothered by ulcer care domain was also positively correlated ($r = 0.494$, $p = 0.027$) with VAS. The correlation between the domains of the Malayalam version of the DFS-SF马来alam questionnaire domains were correlated with EQ-5D and VAS scales. The dependence domain was positively correlated ($r = 0.538$, $p = 0.014$) with VAS. Similarly, bothered by ulcer care domain was also positively correlated ($r = 0.494$, $p = 0.027$) with VAS. The correlation between the domains of the Malayalam version of the
Table 5
Correlation between the domains of the Malayalam version of the DFS-SF with EQ SD and the VAS scale.

<table>
<thead>
<tr>
<th>Domain</th>
<th>No. of Items</th>
<th>EQ-SD Correlation</th>
<th>p-value</th>
<th>VAS Correlation</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leisure</td>
<td>5</td>
<td>0.205</td>
<td>0.386</td>
<td>0.207</td>
<td>0.382</td>
</tr>
<tr>
<td>Physical Health</td>
<td>5</td>
<td>0.004</td>
<td>0.987</td>
<td>0.098</td>
<td>0.680</td>
</tr>
<tr>
<td>Dependence/ Daily Life</td>
<td>5</td>
<td>0.350</td>
<td>0.157</td>
<td>0.538*</td>
<td>0.014</td>
</tr>
<tr>
<td>Negative Emotions</td>
<td>6</td>
<td>0.377</td>
<td>0.101</td>
<td>0.316</td>
<td>0.175</td>
</tr>
<tr>
<td>Worried about Ulcers</td>
<td>4</td>
<td>0.350</td>
<td>0.130</td>
<td>0.319</td>
<td>0.171</td>
</tr>
<tr>
<td>Bothered by Ulcer Care</td>
<td>4</td>
<td>0.350</td>
<td>0.131</td>
<td>0.494*</td>
<td>0.027</td>
</tr>
</tbody>
</table>

*Significant positive correlation between Dependence and VAS (r = 0.538, p = 0.014), Ulcer care and VAS (r = 0.494, p = 0.027).

5. Conclusion

The Malayalam version of the DFS-SF questionnaire was good and comparable with other similar studies Kontodimopoulos et al., Hui et al., Macioch et al. The DFS-SF Malayalam version questionnaire had good evidence of the cronbach’s alpha reliability value ranging from 0.990 to 0.996. The results were comparable with the other studies, the findings were in line with Kontodimopoulos et al., where the cronbach’s alpha value ranged from 0.79 to 0.94, 0.80–0.92 in the Hui et al., 0.82–0.93 in the Macioch et al., 0.80–0.95 in the Ban et al., 0.96 to 0.99 in the Lee et al. and 0.887–0.983 in the Navarro-Flores et al.

In the study, dependence (r = 0.538, p = 0.014) and bothers by ulcer care (r = 0.494, p = 0.027) domains of DFS-SF were positively correlated with VAS. Different findings were reported in the study by Martinez-Gonzalez et al. In the present study, the domains of the DFS-SF were not correlated with EQ-SD domains. This could be because the EQ-SD is a generic version of the QoL tool, whereas DFS-SF is a disease-specific instrument.

The overall findings for the psychometric aspects of the DFS-SF Malayalam version questionnaire were good and comparable with other similar studies Kontodimopoulos et al., Hui et al., Macioch et al., Bann et al., Lee et al., Toyagare et al., Martinez-Gonzalez et al., de Oliveira et al. 8,12,15

Acknowledgments

We acknowledge all the experts and patients for their support in translating and validating the Malayalam DFS-SF questionnaire. We acknowledge the MAPI research trust and EuroQol Research Foundation for permitting to use of the DFS-SF questionnaire and EQ-5D questionnaires, and VAS scale.

References