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Correlation of SF-36 and SF-12 Component Scores in Patients With Diabetic Foot Disease

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ABSTRACT

The assessment of patient outcomes is becoming increasingly important in all areas of medicine, including foot and ankle surgery. The Medical Outcomes Study Short Form 36-item (SF-36) is widely used as a generic measure of quality of life; however, patients often find answering 36 questions cumbersome. Consequently, the Short Form 12 (SF-12) was developed. We hypothesized that the agreement between the SF-12 and SF-36 component scores would be substantial in patients with diabetic foot disease. We retrospectively reviewed the data from 300 patients with diabetes mellitus (DM) and foot and ankle pathology who completed the SF-36 questionnaire. Of the 300 patients, 155 (51.7%) had problems directly related to complications of DM and 145 (48.3%) had routine foot complaints that were unrelated to complications of DM. The 12 questions of the SF-12 were abstracted from the SF-36. The overall median score for the SF-36 physical component summary was 34.70 compared with the overall SF-12 physical component summary of 36.75 ($p = .04$). The intraclass correlation coefficient was 0.93688. The overall median score for the SF-36 mental component summary was 52.40 compared with the overall SF-12 mental component summary of 51.25 ($p = .34$). The intraclass correlation coefficient was 0.95449. Substantial agreement was observed when comparing the component scores of the SF-12 and the SF-36. From our study results of 300 patients with DM, it appears that the SF-36 and SF-12 are comparable outcome instruments for use with patients with diabetic foot disease.

The assessment of patient outcomes is becoming increasingly important in all areas of medicine, including foot and ankle surgery. Various methods of assessment are available, and self-reported outcome instruments have been used extensively. The Medical Outcomes Study Short Form 36-item questionnaire (SF-36) is widely used as a generic measure of quality of life (QOL) across a wide spectrum of diseases, including diabetic foot disease. This self-reported outcome measure calculates 8 subscales and 2 overall summary scores according to the patient responses to 36 questions. Some patients have complained that completing 36 questions is cumbersome. Consequently, the originators of the SF-36 developed the SF-12 (1). Using regression analysis, Ware et al (1) were able to select 12 questions from the SF-36 that reliably produced scores that mirrored those from the SF-36. Recently, the SF-36 has been combined with the Foot and Ankle Ability Measure (FAAM) to assess overall health and region-specific (lower extremity) function in patients with amputations, Charcot neuroarthropathy, diabetic foot infections, and diabetic foot ulcers. However, combining these 2 outcome instruments requires the patient to answer 67 questions, a task that is often considered burdensome to patients. Consequently, we have explored the possibility of substituting the SF-12 for the SF-36 to reduce the time spent by patients in completing outcome instruments. The aim of the present study, therefore, was to determine whether agreement exists between the physical component summary (PCS) and mental component summary (MCS) scores of the SF-12 and SF-36 when completed by patients with diabetic foot disease. To the best of our knowledge, agreement of the SF-12 and SF-36 scores has not been previously reported for patients with diabetic foot disease. Our hypothesis, based on other areas of medicine, was that substantial agreement would be found between the 2 scores.

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Conflict of Interest: Dane K. Wukich is a consultant for Stryker and receives royalties from Arthrex.

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Patients and Methods

The institutional review board approved the present study. The research registry of our academic foot and ankle center was retrospectively reviewed for patients with diabetes mellitus (DM) who had completed both the SF-36 and the FAAM. These self-reported outcome instruments were prospectively recorded in the registry; however, we retrospectively abstracted the data from the registry. The period for review was January 2011 through December 2014. Scoring of the 36 questions of the SF-36 allowed for calculation of 8 subscales. These subscales were then combined to form the PCS and MCS scores. The SF-12 uses only 12 of the 36 questions from the SF-36, and the 12 questions can be abstracted from the answers provided in the SF-36. This method of calculating the SF-12 scores has been found to be similar when the SF-36 and SF-12 are processed independently (2,3). The component scores for the SF-12 and SF-36 are norm-based, with a mean score of 50 and standard deviation of ± 10. A higher score is associated with better QOL and a lower score, poorer QOL. The FAAM is a region-specific instrument assessing lower extremity function. It uses 21 questions that constitute a general and activity of daily living subscale and 8 questions that constitute a sports subscale. A total of 300 patients with a diversity of the foot problems were included. The selection process was not random and was designed to represent a wide spectrum of foot and ankle problems encountered by diabetic foot surgeons. The patients selected were not from a consecutive series of registry patients, because we attempted to have representation of various pathologies. The 300 patients included those with below-the-knee amputations (group 1, 31 patients), Charcot neuroarthropathy (group 2, 47 patients), diabetic foot ulcers (group 3, 29 patients), diabetic foot infections (group 4, 48 patients), routine foot problems such as flatfeet, tendinitis, and ligament injuries (group 5, 67 patients), and diabetic foot screening (group 6, 78 patients). Thus, 155 patients (51.7%) had problems directly related to complications of DM and 145 patients (48.3%) had routine foot complaints unrelated to complications of DM. Age, DM duration in years, type of diabetes (type 1 or 2), and the use of insulin was recorded for all patients and abstracted from the medical records.

The senior author (D.K.W.) selected the 300 patients included in the present study. Abstraction of the SF-12 responses from the SF-36 questions was performed by 2 of us (T.L.S., N.M.M.), who also calculated the SF-12 scores. Statistical evaluation was performed by 2 experienced biostatisticians (N.C.S., B.L.R.). The data were summarized as the mean ± standard deviation for normally distributed continuous data and as the median and interquartile range for non-normally distributed continuous data. The intraclass correlation coefficient (ICC), using a 2-way mixed effects model for absolute agreement, was used to determine the degree of agreement between SF-12 and SF-36, SF-12 PCS and FAAM, and SF-36 PCS and FAAM measures (4). The ICC score ranges from 0 to 1. The ICC score reflects the level of agreement as follows: virtually none, 0.00 to 0.10; slight, 0.11 to 0.40; fair, 0.41 to 0.60; moderate, 0.61 to 0.80; and substantial, 0.81 to 1.00 (5). Confidence intervals (CIs) were also calculated for each ICC score. All analyses were completed using SPSS statistical software, version 22 (SPSS Inc., Chicago, IL).

Results

The mean age of our patients was 57.6 ± 10.3 years, and 178 of 300 patients (59.3%) were male (Table). Type 2 DM was present in 263 of 300 patients (87.7%), and the median duration of DM was 10 years (25th to 75th interquartile range, 5.5 to 19.0). Insulin use was reported for 176 of 300 patients (58.7%). The overall median SF-36 PCS score was 34.70 compared with an overall median SF-12 PCS score of 36.75 ($p = .04$). The ICC between the SF-12 PCS and SF 36 PCS scores was 0.937 (95% CI 0.874 to 0.964), indicative of substantial agreement. The overall median SF-36 MCS score was 52.40 compared with an overall median SF-12 MCS score of 51.25 ($p = .34$). The single-measure ICC between the SF-12 MCS and SF-36 MCS was 0.955 (95% CI 0.940 to 0.965), indicative of substantial agreement. All 6 subgroups demonstrated substantial agreement between the SF-12 (PCS and MCS) and SF-36 (PCS and MCS) scores. Figs. 1 and 2 demonstrate the linear relationship (correlation) and agreement between the component scores of the SF-12 and SF-36.

In contrast, only slight agreement was found when comparing the SF-12 PCS and FAAM general score (ICC 0.369, 95% CI 0.233 to 0.486) and the SF-36 PCS and FAAM general score (ICC 0.353, 95% CI 0.238 to 0.456). No agreement was found when comparing the SF-12 PCS and FAAM sports score (ICC 0.069, 95% CI 0.033 to 0 .173) and the SF-36 PCS and FAAM sports score (ICC 0.060, 95% CI 0.036 to 0.160).

Discussion

The SF-12 has been used as an outcome instrument across a wide spectrum of orthopedic subspecialties, including the ankle (6), foot (7), cervical and lumbar spine (2,8), hip and knee reconstruction (9–12), orthopedic trauma (13,14), upper extremity (14,15), and workers' compensation (15). The SF-12 has also been used as a generic outcome instrument to assess the QOL of patients with type 2 DM in an effort to study the differences across gender and treatment groups (16–19). Schunk et al (19) evaluated many variables, such as age, gender, duration of DM, use of insulin, and body mass index using the SF-12 as a measure of QOL. Several other studies have used the SF-12 as an outcome instrument for patients with diabetic foot ulcers (16,18,20). Many other studies of QOL in diabetic foot disease have used the SF-36 as an outcome instrument (3,21–27). To the best of our knowledge, the ICC of the SF-36 and SF-12 component scores in diabetic foot disease has not been previously established. A study of patients with cervical spondylosis demonstrated a good correlation between the 2 components scores (PCS and MCS) of the SF-12 and SF-36 (2). This correlation followed a near linear correlation; however, the internal consistency and reliability were greater for the SF-36 scoring (2). The investigators believed that the inferior reliability of the SF-12 was because only 33% of the questions from the SF-36 were included. Despite this shortcoming, the SF-12 appears to capture health-related QOL in a comparable manner to the SF-36 (2).

Table
Results of intraclass correlation

Variable	Single-Measures ICC (95% CI)	SF-12 Score*	SF-36 Score*	*p* Value
Physical component summary				
Overall SF-12 and SF-36	0.937 (0.874 to 0 .964)	36.7 (28.4 to 44.4)	34.7 (26.4 to 44.4)	.04
Group 1 (n = 31)	0.890 (0.756 to 0.949)	36.5 (33.3 to 42.3)	34.2 (28.6 to 43.8)	.40
Group 2 (n = 47)	0.930 (0.690 to 0.974)	30.3 (24.9 to 42.6)	30.1 (22.2 to 36.6)	.24
Group 3 (n = 29)	0.903 (0.734 to 0.959)	32.6 (27.2 to 43.5)	33.8 (24.8 to 40.6)	.52
Group 4 (n = 48)	0.912 (0.699 to 0.964)	29.2 (24.0 to 37.3)	26.3 (21.2 to 35.3)	.16
Group 5 (n = 67)	0.890 (0.758 to 0.943)	31.5 (26.4 to 37.3)	32.7 (27.3 to 40.2)	.24
Group 6 (n = 78)	0.918 (0.872 to 0.948)	48.8 (41.6 to 53.8)	47.8 (38.8 to 53.5)	.56
Mental component summary				
Overall SF-12 and SF-36 MCS	0.955 (0.940 to 0.965)	51.2 (40.2 to 57.9)	52.4 (40.4 to 59.5)	.34
Group 1 (n = 31)	0.977 (0.914 to 0.991)	54.1 (36.9 to 57.9)	55.1 (38.7 to 59.7)	.55
Group 2 (n = 47)	0.933 (0.877 to 0.964)	51.1 (38.1 to 58.1)	52.4 (39.6 to 59.5)	.49
Group 3 (n = 29)	0.966 (0.915 to 0.985)	51.1 (42.4 to 61.6)	50.2 (46.7 to 61.7)	.63
Group 4 (n = 48)	0.964 (0.937 to 0.980)	42.8 (31.7 to 54.7)	41.6 (31.7 to 57.3)	.76
Group 5 (n = 67)	0.944 (0.902 to 0.967)	50.0 (41.5 to 59.4)	53.0 (42.0 to 60.5)	.38
Group 6 (n = 78)	0.949 (0.920 to 0.967)	53.4 (45.8 to 57.8)	53.9 (44.2 to 57.6)	.85

Abbreviations: CI, confidence interval; Group 1, below-the-knee amputation; Group 2, Charcot neuroarthropathy; Group 3, diabetic foot ulcer; Group 4, diabetic foot infection; Group 5, routine foot problems; Group 6, diabetic foot screening; ICC, intraclass correlation.

* Data presented as median (25th to 75th interquartile range).