Health-related Quality of Life in Patients with Diabetic Foot Problems in Malaysia

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SUMMARY

This study aimed to evaluate the impact of foot problems on health-related quality of life (HRQoL) in patients with diabetes in Malaysia. Short-Form 36 (SF-36) questionnaire was used to assess the HRQoL of 140 diabetic patients with foot problems attending outpatient diabetic foot clinic in a tertiary hospital, University Malaya Medical Centre. Their HRQoL were compared with 134 diabetic patients without foot problems attending the same clinic. The median score of all the eight SF-36 domains differed significantly between the two groups, where patients with foot problems having statistically significant lower scores. The two domains that were most severely compromised were components of the physical health: Physical Functioning and Role Physical domains. The SF-36 scale scores in diabetic patients with foot problems were also lower than those of the SF-36 norms for the Malaysian population. In conclusion, the results showed that diabetic foot problems negatively affect the patients' HRQoL in both physical and mental health aspects based on the SF-36.

KEY WORDS:
Diabetes mellitus, Diabetic foot, Health-related quality of life, Short form 36

INTRODUCTION

The economic consequences of diabetic foot problems are major, both to society as well as to the patients and their families [1]. Diabetic foot complications have been found to account for 12% of all diabetic hospital admissions in Malaysia [2]. The resulting cost to society can be measured in direct costs attributed to treatment such as dressings or surgical procedures, as well as indirect costs in lost of productivity, social services, home care and quality of life [1]. The authors believe that diabetic patients in Malaysia who develop foot complications may suffer more than experts previously realised.

Foot problems encountered in the clinical setting ranges from benign skin and nail changes to the more severe debilitating ulcerations and infections. Previous health-related quality of life (HRQoL) studies have shown markedly poor quality of life in diabetic patients with foot problems. One of the most frequently studied diabetic foot problems is diabetic foot ulcers. Patients with diabetic foot ulcers experience severe restrictions on daily life as a result of the ulcer. They face social isolation from reduced mobility, require frequent clinical treatment and constant caution to ensure that effective care is taken of the feet [3]. This has also had a negative psychological impact on patients. Patients with diabetic foot ulcers frequently experienced higher levels of depression, fear for the future, greater dissatisfaction with their personal lives and poorer psychosocial adjustment to illness [4,5].

Studies on patients with other foot problems also provided some information about the impact of foot complications on everyday life. Patients who had lower extremity amputation perceive their quality of life to be as equally impaired as those with diabetic foot ulcers [6,7]. Diabetic peripheral neuropathy has been found to be significantly associated with reduced physical aspects of diabetic patients' quality of life, while patients with Charcot arthropathy reported poor physical and mental health [8-10]. The findings suggest the need to have a better understanding of diabetic foot problems consequences on patients' quality of life.

To the author's best knowledge, until now, there is no data currently available on the HRQoL of Malaysian population with diabetic foot problems. This study was undertaken to analyse HRQoL amongst diabetic patients with foot problems attending a diabetic foot clinic in University Malaysia Medical Centre (UMMC) in comparison to diabetic patients without foot problems.

MATERIALS AND METHODS

This was an unmatched comparative cross sectional study conducted in UMMC in 2007. All patients included in this study attended a specialized diabetic foot clinic in UMMC. This clinic caters for all diabetic patients, with or without foot problems and accepts referrals from various outpatient clinics in UMMC. Patients with diabetic foot problems may have a more frequent follow-up consultation, depending on the nature and severity of the foot problems, whilst those without foot problem come for six monthly or annual consultations.

Data was collected from diabetic patients who attended the foot clinic over a period of four months and the patients were sampled using a convenient sampling method. Patients were included in the study if they had at least one of these foot complications: i) current foot ulcer, ii) symptomatic peripheral neuropathy, iii) symptomatic peripheral arterial disease and iv) active Charcot arthropathy. These patients were grouped together as "patients with foot problems" due to the similarity in their impairment. All patients experienced some problems with mobility caused by their foot problems as compared to those who did not have any foot problems.

The patients were excluded if they were either less than 18 years old, illiterate in English or Bahasa Malaysia, had serious medical problems or co-morbidities that would affect the quality of life, had major amputation (level Syme's and above) in one or both lower limbs or had recent hospitalization in the past three months. Patients without any of the diabetic foot problems mentioned earlier were selected as the comparative group. As this is an unmatched comparative cross sectional study, the sample group and the control group were not matched for any specifics.

All patients who agreed to participate were asked to complete two sets of questionnaires before consulting the health provider at the clinic. This is to prevent any bias to their reported quality of life. The first set of questionnaire includes data for socio-demographic characteristics, co-morbidities and diabetic treatment, while the second set was SF-36 questionnaire.

SF-36 self-reported questionnaire was used in two languages, English and Malay. The Malay version of SF-36 used in this study has previously been translated and validated in the Malaysian population [11,12]. Patients were allowed to choose the language that they were comfortable with. SF-36 covers eight domains/subscales of quality of life, comprising of physical aspects (physical health components) and psychosocial aspects (mental health components) of quality of life. The physical health components are made up of Physical Functioning, Role Physical, Bodily Pain and General Health perception, while the mental health components are made up of Role Emotional, Vitality, Mental Health and Social Functioning.

All eight domains were scored on a scale of 0 – 100 (100 being the best possible health state). Two summary scores can be derived: i) physical component summary (PCS) and ii) mental component summary (MCS). The two summary components were computed following a standardized three-step procedure. The details of the study instrument and scoring algorithm are explained in the SF-36 version 2.0 manual guide [13].

Once the questionnaires were completed, physical assessments were performed by the main researcher and two trained medical personnel for the purpose of this research. The diabetic foot was categorised into four main groups based on the most prominent clinical findings; foot ulcer, peripheral neuropathy, peripheral arterial disease and Charcot arthropathy.

Physical assessments performed on the foot include assessments using monofilament and ankle brachial pressure index to determine presence of peripheral neuropathy and peripheral arterial disease. Presence of foot ulcers were documented based on Wagner's classification system [14]: grade 1 (localized superficial or partial thickness ulcer), grade 2 (deep ulcer extending to tendon, joint or bone), grade 3 (deep ulcer with osteitis), grade 4 (ulcer involving gangrene of forefoot), and grade 5 (whole foot gangrene). Active Charcot arthropathy was determined based on clinical and X-Ray findings.

Statistical analyses of all data collected were made using the SPSS version 15.0 software. The demographic and clinical characteristics of the study sample were analysed using descriptive and analytical statistical functions of the software. To determine inter-group differences, independent t-test using a two-tailed test was used to compare mean values of continuous data and χ^2 test was used to compare categorical data. The median score for each SF-36 domain and the summary scores were compared between the two groups using the Mann Whitney-U test as the data was not normally distributed. This study has been approved by UMMC ethical committee and the permission to use the SF-36v2TM Health Surveys, was obtained from the Quality Metric Incorporated (license number F1-020606-25352).

RESULTS

A total of 164 patients with foot problems were eligible for this study from 203 patients initially assessed during the study period. However, only 140 patients with foot complications agreed to be in the study and were recruited (85.4% response rate). One hundred and thirty-four patients without foot problems were selected as the control group.

The demographic characteristics of the 274 patients are presented in Table I and the clinical characteristics are presented in Table II. Both groups were statistically comparable in the demographic characteristics except for household income. For clinical characteristics, differences were seen in the diabetes duration and the types of diabetes treatment taken between respondents in the two groups. More than half of patients with foot problems have had diabetes longer than ten years compared to only about one third in the comparison group. Insulin therapy either on its own or in combination with oral hypoglycaemic agents was more frequently prescribed for patients with foot problems (47.2%) when compared to those without foot problems (17.2%) translating to a ratio of 2.7:1.

The number of medical co-morbidities did not differ significantly between the two groups of patients. The co-morbidities reported were hypertension, dyslipidemia, ischemic heart disease, gouty arthritis and renal disease. We only reported the number of co-morbidities present at the time of assessment. However, all the co-morbidities were well controlled, not severe enough to affect HRQoL (subjective opinion from patients) or required hospitalization within the past three months. If the co-morbidities are badly affecting the patients, we exclude the patients from participating in this study, as mentioned in our exclusion criteria.

Sixty-six patients (47.1%) had foot ulcer, 62 patients (44.3%) had symptomatic foot neuropathy, seven patients (5%) had symptomatic peripheral arterial disease and five patients (3.6%) had active Charcot arthropathy. From the total of 66 patients with foot ulcer, 23 patients (34.9%) had grade 1 foot ulcers, 40 patients (60.6%) with grade 2 foot ulcers, two patients (3.0%) with grade 3 foot ulcers and one patient (1.5%) with grade 4 foot ulcer based on the Wagner's classification system [14].

Table I: Socio-demographic characteristics of the respondents

Variable	Diabetics with foot problems (n = 140)	Diabetics without foot problems (n = 134)	χ2	p-value
Age in years				
Mean age ± SD [a]	57.60 ± 10.05	59.80 ± 10.06	NA	0.071
35- 44	12 (8.6%)	11 (8.2%)		
45- 54	52 (37.1%)	31 (23.1%)		
55- 64	40 (28.6%)	47 (35.1%)		
65 and above	36 (25.7%)	45 (33.6%)		
Gender [b]				
Male	77 (55.0%)	68 (50.7%)	0.50	0.481
Female	63 (45.0%)	66 (49.3%)		
Ethnic group [b]				
Malay	46 (32.9%)	49 (36.6%)	4.44	0.217
Chinese	15 (10.7%)	24 (17.9%)		
Indian	70 (50.0%)	55 (41.0%)		
Others	9 (6.4%)	6 (4.5%)		
Marital status [b]				
Single	10 (7.1%)	4 (3.0%)	4.47	0.107
Married	113 (80.8%)	120 (89.6%)		
Divorced/ widowed	17 (12.1%)	10 (7.5%)		
Educational level [b]				
Primary education	49 (35.0%)	36 (26.9%)	7.72	0.052
Secondary education	65 (46.4%)	66 (49.2%)		
Tertiary education	26 (18.6%)	32 (23.9%)		
Employment status [b]				
Employed	46 (32.9%)	45 (33.6%)	0.02	0.899
Unemployed	94 (67.1%)	89 (66.4%)		
Household income/month [b]				
< RM 1000	67 (47.9%)	40 (29.9%)	22.24	< 0.001*
RM 1000 – 3000	59 (42.1%)	71 (53.0%)		
RM 3001- 5000	4 (2.9%)	20 (14.9%)		
> RM 5000	10 (7.1%)	3 (2.2%)		

NA : non-applicable
SD : standard deviation
a   : Differences tested with independent t-test
b   : Differences tested with Pearson Chi-square
*   : p <0.05

Table II: Clinical parameters of the respondents

Variable	Diabetics with foot problems (n = 140)	Diabetics without foot problems (n = 134)	p-value
Diabetes duration (years) [a]			
Mean ± SD	14.14 ± 8.54	8.73 ± 6.10	<0.001*
1-<6	29 (20.7%)	51 (38.1%)	
6-<10	28 (20.0%)	41 (30.6%)	
≥ 10	83 (59.3%)	42 (31.3%)	
BMI (kg/m²) [a]			
Mean ± SD	26.25 ± 4.71	26.61 ± 4.44	0.513
Up to 24.9	58 (41.4%)	52 (38.8%)	
25.0 to 29.9	56 (40.0%)	54 (40.3%)	
≥ 30.0	26 (18.6%)	28 (20.9%)	
Types of diabetes treatment [b]			
Diet control	2 (1.4%)	5 (3.7 %)	<0.001*
Oral hypoglycemic agents	72 (51.4%)	106 (79.1%)	
Insulin therapy	29 (20.7%)	5 (3.7 %)	
Both insulin and OHA	37 (26.5%)	18 (13.5%)	
Number of other medical co- morbidities besides diabetes, present at the time of study [b]			
0	32 (22.9%)	19 (14.2%)	0.139
1	55 (39.2%)	52 (38.8%)	
2	39 (27.8%)	52 (38.8%)	
≥ 3	14 (10.0%)	11 (8.2%)	

SD : standard deviation
a   : Differences tested with independent t-test
b   : Differences tested with Pearson Chi-square
*   : p <0.05

Table III: The scores for eight SF-36 domains/subscales and two SF-36 summary components in the two groups of patients

SF-36 domains and summary scales	Diabetics with foot problems (n = 140) Median (IQR)	Diabetics without foot problems (n = 134) Median (IQR)	p value (Mann-Whitney U test)
Physical Functioning	55.0 (40.0-75.0, 0.0-100.0)	80.0 (58.75-95.0 , 10.0-100.0)	<0.001*
Role Physical	68.75 (43.75-100.0, 2.50-100.0)	93.75 (62.50-100.0 , 12.50-100.0)	<0.001*
Bodily Pain	54.0 (41.0-80.0, 0.0-100.0)	72.0 (52.00-84.0 , 22.0-100.0)	<0.001*
Vitality	53.12 (43.75-67.19, .0-100.0)	68.75 (50.0-81.25 , 18.75- 100.0)	<0.001*
General Health	55.0 (40.0-74.25, 0.0-97.0)	67.0 (52.0-82.75 , 10.0-100.0)	<0.001*
Social Functioning	68.75 (50.0- 87.50, 0.0-100.0)	87.50 (62.50-100.0 , 25.0-100.0)	<0.001*
Role Emotional	83.33 (50.0- 100.0, 16.67-100.0)	100.0 (66.67-100.0, 16.67-100.0)	0.002*
Mental Health	65.0 (50.0-80.0, 0.0-100.0)	77.50 (60.0-90.0 , 30.0-100.0)	<0.001*
Physical Component Summary	41.05 (35.24-47.97, 19.31-62.34)	48.16 (42.03-54.06, 24.08-67.70)	<0.001*
Mental Component Summary	63.48 (55.42-77.78, 37.74 -120.09)	55.05 (52.30-61.75, 52.30-61.75)	<0.001*

Footnote: Values are expressed as Median (25th – 75th percentiles, min-max) with 0 as poorest health and 100 as the best health
SF: Short Form
*: p <0.05

Table III shows the median scores of the eight domains and the two summary scales in the SF-36. In general, diabetic patients with foot problems had significantly lower median scores in all eight SF-36 domains, which mean that diabetic patients with foot problems have substantially poorer HRQoL than patients without foot problems. The summary scores showed a significantly lower PCS among patients with diabetic foot problems than those without foot problems. This is however, not seen in the MCS score which revealed an opposite result with lower score among patients without foot problems than in patients with diabetic foot problems.

DISCUSSION
Diabetic complications have the potential to greatly impact the quality of life of patients with diabetes [15]. One of the most frequently studied complications has been the effect of foot problems to the HRQoL using self-reported SF-36 questionnaire. In this study, when analyzing the effect of foot problems on diabetic patients' HRQoL, we found that the scores of all eight domains and the two summary scales in the SF-36 were significantly different between patients who had foot problems and those without foot problems. Based on the domain scores, patients with foot problems had significantly lower quality of life in both physical and mental health aspects. The score differences between the two groups were greater than ten points in all the eight domains. It has been suggested that a difference of five points should be considered to represent the minimal clinically important difference for SF-36 scores [16].

The two domains that were most severely compromised were components of the physical health: Physical Functioning and Role Physical domain. These two domains showed the greatest score differences between diabetic patients with foot problems and without foot problems. Other studies using SF-36 have also reported the greatest impact on physical health in diabetic patients with foot problems when compared to the diabetic control. Valensi et al.[17] compared the HRQoL between 239 patients with foot ulcers and 116 patients without ulcers and found the largest difference between the two groups were for the Role Physical domain and the smallest difference in the Mental Health. Similarly, Meijer et al.[18] found a striking difference in the Role Physical domain with diabetic foot ulcer patients having a 30-point lower mean score when compared to patients without foot ulcers. The smallest difference was also found to be in the Mental Health domain.

The Physical Functioning domain deals with all physical activities including walking, bending, stretching and climbing stairs without limitation while the Role Physical domain deals with problems of work or other daily activities resulting from the physical health. The low scores noted in the two domains of physical health in patients with foot problems in this study indicate severe limitations with mobility. This is probably due to the loss of mobility caused by a non-weight-bearing regimen from foot ulcers and Charcot arthropathy and the impact of symptomatic painful peripheral neuropathy and peripheral arterial disease on mobility. Patients with symptomatic diabetic peripheral neuropathy were shown to have greater impairment in physical mobility and emotional reactions when compared to diabetic and non-diabetic controls [19].

Mental health was also significantly affected although not as severely compromised as some of the components in physical health. Mental health component assesses the psychological distress, degree of happiness, limitations that emotional problems place on the extent of activities one is able to perform and general well being. A possible explanation of the significantly poorer mental health components in patients with foot problems compared to patients without foot problems in this study is that patients with foot problems often experienced emotional uncertainty as to when or whether the foot problems will heal. They may also experienced living restrictions and have poorer psychosocial adjustments as noted in previous studies [4,5].

The summary scores in the SF-36 questionnaire, PCS and MCS, also showed a statistically significant difference between the two groups of patients. However, the significantly lower MCS score is not consistent with the higher scores found in all the SF-36 mental health component domains. As explained by Ware JE et al.[20], summary scores are derived from weighted aggregation of scores for the eight SF-36 domains, thus a thorough comparison with results based on the eight SF-36 domains is encouraged when trying to explain the different conclusion based on summary scores. One of the methods to compare the eight domains with PCS and MCS is to transform the SF-36 domain scores to have the same mean and standard deviation (50 and 10, respectively) as PCS and MCS using a certain recommended scoring processes. This was not done in this study and therefore, our main findings are discussed largely on the domain scores.

The availability of the norms of the SF-36 scores for Malaysian population makes it possible to compare HRQoL of patients with and without foot problems in this study with that of general population. Population sample within the same range as the study sample were used (ages 30 and above) and excluding those aged between 18-29 to obtain the general population mean score appropriate for the present study. The mean score of all the SF-36 domains for the general Malaysian population were[11]: Physical Functioning (84.46), Role Physical (81.20), Bodily Pain (69.33), General Health perception (65.68), Vitality (66.86), Role Emotional (80.59), Social Functioning (83.84) and Mental Health (75.31). PCS and MCS scores were not available for the general Malaysian population norm; therefore comparisons were made only for the eight SF-36 domains.

Among the three populations, patients with diabetic foot problems had the lowest scores in all the eight scales of SF-36, except for Role Emotional domain. However, the score difference in Role Emotional domain between the group with foot problems and Malaysian population was too small (less than three points) to be considered clinically different. Overall, the result showed that diabetic patients with foot problems in Malaysia have significantly poorer quality of life compared to the general population. Diabetic patients without foot problems on the other hand, fared better than the general Malaysian population in almost all SF-36 domains except in the Physical Functioning. These findings are not consistent with other studies comparing diabetic patients with the general population. For example, Ribu et al.[21] found that the overall HRQoL in the general population was significantly higher than the diabetes population (with or without foot problems).

The finding that diabetic patients without foot problems in this study scored somewhat higher than general population needs to be cautiously interpreted. First, this study sample was taken in a selected diabetic population from a specialized diabetic foot clinic in one centre, which is situated in the urban area. Therefore, they did not truly represent the general diabetes population in Malaysia. Second, there was also no Malaysian norm for diabetes population to further confirm that diabetes patients in Malaysia perceive their health better than the general population.

There are several limitations in this study. The sample size is modest and all the confounders were not addressed with linear regression analysis in this study due to the non-normality of the SF-36 data. Apart from that, there are differences in diabetes duration and insulin treatment between the two groups of patients in this study. Matching for diabetes duration and types of treatment is difficult due to the fact that usually more chronic diabetic patients would have diabetic foot problems.

In conclusion, the results of this study demonstrated that having diabetic foot problems is associated with severely impaired HRQoL in both physical and mental health aspects based on the SF-36. The findings also imply that domains of the physical health have the greatest impact from foot problems when compared to diabetic controls. These are consistent with evidences reported in other developed countries. In addition, diabetic patients with foot problems in

this study also had lower HRQoL scores than the general Malaysian population, scoring the lowest in almost all the scales. In the clinical setting, this knowledge can be used to encourage medical professionals to actively identify patients with foot problems during routine diabetic follow-up consultations. This practice could assist in early detection of any reduced HRQoL. Both the physical and mental aspects of HRQoL should be looked into and interventions are planned accordingly. Since physical health is greatly affected, attempts to improve the patients' physical function and mobility via an individualized program may alleviate the overall HRQoL.

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