

# Comparison of demographic and clinical characteristics influencing health-related quality of life in patients with diabetic foot ulcers and those without foot ulcers

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**Background:** A number of studies have demonstrated that health-related quality of life (HRQoL) is negatively affected by diabetic foot ulcers. The aim of this study was to compare HRQoL in diabetic patients with and without foot ulcers and to determine demographic and clinical factors influencing HRQoL.

**Methods:** There were no variables affecting HRQoL except for gender in diabetic patients without foot ulcers. Demographic and clinical variables were recorded and HRQoL was evaluated using the Short Form 36 (SF-36) survey for all participants. The summary physical component score (PCS) and mental component score (MCS) and eight domains of HRQoL were compared in the two groups. Linear regression analysis was also used to investigate sociodemographic and clinical characteristics as predictors of quality of life as measured by SF-36.

**Results:** The overall score, PCS, and MCS, were significantly higher in patients without diabetic foot ulcers. Except for gender, none of the variables affected HRQoL in diabetic patients without foot ulcers. Male gender had a higher score in all domains of quality of life than female gender in diabetic patients without foot ulcers. Living alone, a low educational level, and having at least one complication were all associated with a lower HRQoL score in patients with foot ulcers. High-grade ulcers determined by Wagner's classification and poor glycemic control as measured by HbA<sub>1c</sub> predicted HRQoL impairment in patients with diabetic foot ulcers.

**Conclusion:** Because Wagner's grade was one of the strongest variables associated with HRQoL, this scale is recommended for monitoring of patients with diabetic foot ulcers in order to prevent continuing deterioration of HRQoL by treatment of foot ulcers at an earlier stage.

**Keywords:** quality of life, diabetics, foot ulcer

## Introduction

Research has shown that people with diabetes have a worse health-related quality of life (HRQoL) compared with people without chronic disease. Diabetic patients report lower HRQoL, especially with regard to physical functioning. Furthermore, it has been shown that individuals with more symptomatic and disabling conditions have the lowest Short Form 36 survey (SF-36) physical component scores (PCS).<sup>1</sup> Foot problems often persist for a long period of time and may result in amputation.<sup>2</sup> The presence of diabetic foot ulcers may have a major impact on patient HRQoL.<sup>3</sup>

International epidemiologic studies suggest that 2.5% of diabetic patients develop foot ulcers each year, and 15% of all diabetic patients develop foot ulcers during their lifetime.<sup>3</sup> Currently, the prevalence of diabetes is 7.7%, which is equivalent to

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3 million cases when extrapolated to the Iranian population aged 25–64 years. The prevalence of foot ulcers is estimated to be 3% in diabetic patients in our region.<sup>4</sup> This figure is expected to rise considerably by 2025.<sup>4</sup> Several factors influencing the impact of diabetes on HRQoL include sociodemographic and clinical characteristics, such as age, level of education, comorbid conditions, and complications.<sup>1</sup> Older age, presence of type 2 diabetes mellitus, increased severity of Wagner grade, longer duration of foot ulcer, and the presence of more ulcers were also found to be significant predictors of lower HRQoL in other report.<sup>5</sup> HRQoL is often described in patients with diabetic foot ulcers, but comparisons have rarely been made with HRQoL in diabetic patients without foot ulcers. Such a comparison would give us a broader picture of HRQoL in our region by considering the way in which clinical and demographic characteristics affect HRQoL in diabetic patients with and without foot ulcers. The aim of this study was to compare HRQoL between diabetic patients with and without foot ulcers and to examine the differences between the two groups according to sociodemographic and clinical characteristics. The results of this study may provide a useful guide for the interpretation of HRQoL scores, and may assist in identifying patient problems when setting treatment goals.

## Materials and methods

Two groups of adult patients were recruited for this study. Subjects were allocated to Group 1 if they had suffered from diabetes without current or previous foot ulcers and any other complications of diabetes. Subjects were allocated to Group 2 if they had diabetes mellitus with at least one foot ulcer, defined according to Wagner's classification, and were admitted to hospital. Some individuals in this group also had other diabetic complications. The aim of the study was explained to all subjects with and without diabetic foot ulcers, and all participants signed a formal consent form. All responses were anonymous. Permission to conduct this research was approved by the ethics committee of Urmia University of Medical Sciences.

## Subjects without diabetic foot ulcers

This cross-sectional prospective study was conducted from September 2009 to December 2010 in the urban area of Urmia city using two-stage cluster random sampling to obtain data from diabetic patients. Based on a power analysis using a moderate effect size (0.5), at the 0.05 significant level and power 90%, and considering the design effect of cluster sampling, a sample size of 160

was estimated. First, eight of 30 health care centers were selected as clusters. Twenty diabetic patients who met the inclusion criteria were then chosen from each center. Currently diagnosed type 2 diabetic patients aged older than 30 years were enrolled into the study. Patients with complications or conditions that would potentially affect quality of life were excluded.

## Subjects with diabetic foot ulcers

All subjects with diabetic foot ulcers admitted to one of two medical training hospitals (Taleghani or Emam-Khomaini) from September 2009 to December 2010 were enrolled in the study. A total of 90 subjects diagnosed with type 2 diabetes, having diabetic foot ulcers, and aged more than 30 years completed the study.

## Sociodemographic and behavioral variables

Demographic data were collected about age, gender, educational level, and cohabitation. Age was categorized into two groups, ie,  $\geq 50$  years and  $< 50$  years, and a low education level was defined as illiterate/primary school. The sociodemographic variable "cohabitation" was categorized as living with others or living alone. All sociodemographic variables were self-reported. Behavioral factors, including current smoking (daily and occasional smokers), and body mass index were also obtained. Body mass index was divided into two categories, ie, normal (body mass index  $< 25$ ) or overweight (body mass index  $\geq 25$ ).

## Clinical characteristics

A questionnaire was used to collect data about general clinical status, duration of diabetes, treatment intensity (classified as insulin therapy, or other therapy such as oral agents and diet), and baseline laboratory data, including glycosylated hemoglobin ( $HbA_{1c}$ ) and blood sugar.  $HbA_{1c} > 8.5$  was considered to indicate poor glycemic control.<sup>6</sup>

Additional information on diabetic subjects with foot ulcers included diabetes complications according to medical records or drug history (at least one complication), grade of foot ulcer, and amputation as an adverse outcome during hospitalization. Wounds were classified into Wagner grade  $\leq 2$  (low-grade) or grade  $\geq 3$  (high-grade) foot ulcers. Using Wagner's classification, diabetic foot ulcers are classified as Grade 0, high risk foot; Grade 1, superficial ulcer; Grade 2, deep ulcer penetrating to tendon, bone or joint; Grade 3, deep ulcer with abscess or osteomyelitis; Grade 4, localized gangrene; or Grade 5, extensive gangrene requiring a major amputation. Amputation was

defined as complete loss in the transverse anatomical plane of any part of the lower limb.

## Health-related quality of life

HRQoL was measured using the SF-36 health survey, a geometric instrument that allows results to be compared across studies and between populations.<sup>1</sup> The SF-36 consists of 36 questions, and measures eight conceptual domains, ie, physical functioning, role limitations due to physical health, bodily pain, general health perceptions, vitality, social functioning, role limitation due to emotional problems, and mental health. The scores in each domain are transformed into measurements on scales of 0 to 100, and a high score indicates good HRQoL. The SF-36 has satisfactory reliability and validity, and is the most thoroughly tested and accepted measure for assessing psychometric properties in many countries.<sup>3</sup> The validity and reliability of the Persian translation of the SF-36 are also acceptable for assessing health perceptions in the population.<sup>7</sup> The SF-36 has also been developed into a two-factored model with PCS and MCS scales.<sup>1</sup>

Because most participants were not able to complete the questionnaire, two medical students were trained to complete the SF-36 and gathered the demographic and clinical data. Although earlier research has shown that in-person interviews tend to elicit more socially desirable responses than do self-administered questionnaires, the use of *t*-tests indicated no significant differences in HRQoL between the two groups.<sup>3</sup> Patients in the two groups were therefore interviewed to complete the SF-36 questionnaire.

## Statistical analysis

All analyses were conducted using SPSS version 17 (SPSS Inc, Chicago, IL). Descriptive analyses were used to present the demographic and clinical characteristics of the two groups. Chi-square and *t*-test analyses were used to evaluate differences in the distribution of sociodemographic and clinical characteristics between the diabetic patient groups with and without foot ulcers for categorical and continuous variables. The relationships between sociodemographic and clinical variables and HRQoL data were analyzed using Spearman's correlation coefficients. Linear regression analysis was used to investigate the sociodemographic and clinical characteristics as predictors of HRQoL measured by the SF-36.

## Results

With regard to demographic and clinical characteristics and HRQoL in the presence and absence of diabetic foot ulcers, of 250 diabetic subjects, 90 had foot ulcers and 160 had no

foot ulcers. The mean age of patients with and without diabetic foot ulcers was  $60.73 \pm 11.3$  years and  $50.36 \pm 7.1$  years, respectively ( $P = 0.000$ ). There were significantly more patients older than 50 years in the group with diabetic foot ulcers than in the group without foot ulcers (84.4% versus 56.2%). There was also a significant difference in the gender distribution between the two study groups. Most patients with diabetic foot ulcers were male (63.3% versus 24.4%). More than half (57.4%) of the participants with diabetic foot ulcers had a low education level (elementary school and/or illiterate). However, 86% of diabetic patients without foot ulcers were in the low education category ( $P = 0.000$ ). The mean body mass index in patients with diabetic foot ulcers was significantly lower than in those without foot ulcers, and 63.3% of patients with diabetic foot ulcers were overweight (body mass index  $\geq 25$  kg/m<sup>2</sup>) versus 88.1% in diabetic patients ( $P = 0.000$ ). The smoking habit was significantly more frequent in patients with diabetic foot ulcers compared with the other group (53.3% versus 8.8%,  $P = 0.000$ ).

Treatment intensity in the group with diabetic foot ulcers showed that 86.2% of participants were managed with oral agents/diet, only 13.8% were on insulin alone or in combination, and 10.9% of diabetic patients with no foot ulcers were treated by insulin. There was no significant difference in duration of diabetes between the two groups. A higher proportion of participants with diabetic foot ulcers were living alone than those in diabetic patients (32.7% versus 28.4%). However, this difference was not statistically significant.

Eighty-four percent of subjects with diabetic foot ulcers reported having at least one complication of diabetes, eg, cardiovascular disease, nephropathy, or retinopathy. Almost three quarters (71.3%) of participants had a previous history of diabetic foot ulcers. Eighty-three percent of wounds were classified as high-grade ulcer (Grade  $\geq 3$ ). Thirty-four percent of diabetic foot ulcers met clinical criteria for amputation during hospitalization.

Baseline laboratory data including HbA<sub>1c</sub> and blood sugar at the time of admission were significantly higher among respondents with diabetic foot ulcers. The frequency of poor diabetes control in the participants was 31.2% in the patients without diabetic foot ulcers group versus 57.8% in the patients with diabetic foot ulcers group ( $P = 0.000$ ). Table 1 shows demographic and clinical characteristics in diabetic subjects with and without foot ulcers.

A comparison of eight domains of HRQoL in the two groups showed higher scores in four domains in patients without foot ulcer. There was no significant difference in bodily pain, general health perceptions, mental health, and vitality domains. Patients with diabetic foot ulcers had significantly poorer HRQoL, as

**Table 1** Baseline characteristics of study population

Variables	DFU subjects	Diabetic subjects	P value
Gender, male/female, (n)	57/33	39/121	0.000
Age, mean (SD) years	60.73 (11.3)	50.36 (7)	0.000
Low educational level (%)	57.8	63.2	0.21
Living alone (%)	32.7	28.4	0.36
Overweight (%)	63.3	88.1	0.000
Current smoker (%)	53.3	8.8	0.000
Duration of diabetes, mean (SD) years	8.21 (3.1)	7.42 (4.5)	0.55
Complications of diabetes, 1+ (%)	84.2	–	
Treatment intensity, insulin therapy (%)	13.8	10.9	0.41
HbA <sub>1c</sub> , mean (SD) years	9.76 (2.5)	7.93 (2)	0.000
Blood sugar, mean (SD) years	326.94 (96.8)	267.78 (62.9)	0.000
Wagner classification $\geq 3$ (%)	68.9	–	

**Abbreviations:** DFU, diabetic foot ulcers; SD, standard deviation.

indicated by lower mean scores in four domains including physical functioning, role limitations due to physical health, role limitation due to emotional problems, and social functioning than did the other group. The largest differences between the groups was found for the social functioning domain. Similarly, the physical and mental summary scores on the SF-36 showed poorer HRQoL in diabetic patients with foot ulcers than in those without foot ulcers ( $P = 0.000$ ), with differences of around seven points for physical and eight points for the mental summary scores. All these differences remained significant after adjustment for variables including age, gender, and duration of diabetes. Table 2 shows HRQoL in the two study groups.

## Variables associated with HRQoL in subjects with and without diabetic foot ulcers

The total HRQoL score was  $53.03 \pm 13$ . The scores, including total, PCS, and MCS scores, did not differentiate between gender and age in diabetic patients with foot ulcers. Differences in total, PCS, and MCS scores were also found according to

cohabitation and level of education as demographic variables. HRQoL in patients having diabetic foot ulcers with a lower level of education, obesity, and living alone was significantly poor. A high-risk wound, as defined by Grade  $\geq 3$  Wagner classification, having complications, and poor glycemic control as measured by HbA<sub>1c</sub> were all clinical variables associated with HRQoL impairment. The risk of amputation was strongly associated with lower HRQoL. Table 3 shows the demographic and clinical variables associated with HRQoL. The risk of amputation was strongly associated with lower score of HRQoL. In regression analysis, after adjusting for demographic and behavioral variables, poor diabetic control (HbA<sub>1c</sub>  $> 8.5$ ) and a high-grade ulcer were significant variables in the final model, which predicted a lower total, and PCS and MCS scores of HRQoL. In diabetic subjects without foot ulcers, female gender was the only factor associated with poor HRQoL.

## Discussion

Foot ulcers are a common, serious, and costly complication of diabetes, preceding 84% of lower extremity amputations

**Table 2** Comparison of health-related quality of life domains between subjects with and without diabetic foot ulcers

Variables, mean (SD)	DFU subjects	Diabetic subjects	P value
Physical functioning	60.38 (24.1)	72.56 (26.4)	0.000
Role limitation due to physical health	50.10 (16.7)	61.41 (24.4)	0.000
Bodily pain	52.80 (20.0)	57.82 (29.0)	0.147
Role limitation due to emotional problems	51.57 (13.9)	60.31 (20.8)	0.000
General health perception	49.44 (16.1)	50.36 (21.8)	0.72
Vitality	52.61 (9.1)	56.74 (22.1)	0.91
Social functioning	54.86 (15.9)	72.18 (25.1)	0.000
Mental health	53.84 (21.8)	52.61 (9.1)	0.61
Physical summary score	53.18 (17.1)	60.54 (21.8)	0.006
Mental summary score	52.91 (10.3)	60.78 (18.8)	0.000
Total score	53.03 (13.2)	60.66 (19.3)	0.000

**Abbreviations:** DFU, diabetic foot ulcers; SD, standard deviation.

**Table 3** Demographic and clinical variables associated with health-related quality of life in subjects with diabetic foot ulcers

Variables	Total score		PCS		MCS	
	Mean (SD)	P value	Mean (SD)	P value	Mean (SD)	P value
Gender						
Males	54.13 (12.8)	0.31	54.82 (16.2)	0.22	53.45 (10.4)	0.51
Females	51.15 (13.5)		50.28 (18.5)		51.96 (10.1)	
Age						
<49 years	57.06 (11.5)	0.22	58.83 (14.5)	0.17	55.28 (9.1)	0.35
>50 years	52.28 (13.5)		52.11 (17.4)		52.46 (10.5)	
Educational level						
Low	50.39 (13.4)	0.02	49.69 (17.5)	0.02	51.09 (9.9)	0.05
High	56.64 (12.4)		57.9 (15.6)		55.38 (10.4)	
Cohabitation						
Living alone	47.54 (11.1)	0.01	45.4 (15.1)	0.05	49.69 (8.0)	0.01
Living with family	55.14 (13.5)		56.14 (17.0)		54.13 (10.8)	
Complications of diabetes						
Yes	51.11 (13.2)	0.01	50.58 (17.05)	0.01	51.64 (10.3)	0.000
No	63.44 (7.8)		67.15 (9.1)		59.733 (7.6)	
Diabetes control						
HbA <sub>1c</sub> < 8.5	62.82 (8.1)	0.000	65.85 (10.5)	0.000	59.79 (6.9)	0.000
HbA <sub>1c</sub> ≥ 8.5	45.87 (11.5)		43.88 (14.9)		47.87 (9.5)	
Body mass index						
<24 kg/m <sup>2</sup>	56.65 (14.2)	0.04	57.05 (17.9)	0.10	56.26 (11.9)	0.01
>25 kg/m <sup>2</sup>	50.93 (17.9)		50.90 (16.4)		50.95 (8.8)	
Severity of wounds						
Wagner's grade ≥ 3	44.78 (10.5)	0.000	45.67 (13.1)	0.000	48.67 (8.9)	0.000
Wagner's grade < 3	63.91 (7.2)		66.81 (10.9)		60.71 (7.2)	

**Abbreviations:** SD, standard deviation; PCS, physical component score; MCS, mental component score.

in diabetic patients and increasing the risk of death by 2–4-fold compared with diabetic patients without ulcers. HRQoL is worse in individuals with diabetes than in those without diabetes, and complications of diabetes, including diabetic foot ulcers, have a major negative effect on HRQoL. Qualitative research has confirmed the clinical observation that diabetic foot ulcers have a huge negative psychologic and social effect.<sup>8</sup> Armstrong et al suggested that patients with diabetic foot ulcers have severely impaired physical and mental functioning, which is comparable with those with other serious medical conditions.<sup>9</sup> Nabuurs-Franssen et al revealed that HRQoL of patients with chronic neuropathic and neuroischemic foot ulcers, without critical limb ischemia, is poor and comparable with, for instance, the HRQoL of patients with relapsed breast cancer.<sup>10</sup>

This cross-sectional prospective study demonstrated that HRQoL was severely impaired by diabetic foot ulcers and described an important correlation between HRQoL scores and severity of foot ulcers. The most important sociodemographic characteristics that differ between patients with and without diabetic foot ulcers are male gender, living alone, and obesity. One study demonstrated that most diabetic foot patients were men and nearly twice as many of those with foot ulcers were living alone.<sup>1</sup> This finding indicates that

men living alone are an especially vulnerable group among the diabetic population.<sup>1</sup> Interestingly, Hjelm et al found that different beliefs about health and illness between male and female foot subjects may affect self-care. They found that women are usually more active in self-care and preventive care, whereas men show a more passive attitude.<sup>11</sup>

Our findings showed that HRQoL in four areas (bodily pain, general health perceptions, mental health, and vitality domains) was lower in diabetic patients with foot ulcers compared with those without foot ulcers. This may be due to differences in sociodemographic and clinical characteristics in the two groups, eg, patients with foot ulcers were slightly older, overweight, and smokers. However, differences in total, PCS, and MCS HRQoL scores between the two groups remained significant after adjusting for confounders. Similar findings have been reported by several other studies, which found that HRQoL scores were significantly lower for patients with diabetic foot ulcers.<sup>5,12–15</sup> Tennvall and Apelqvist compared health status in diabetes with current foot ulcers, and those who underwent minor or major lower extremity amputations. The results of their study showed that subjects with current ulcers had lower health status than did patients who had healed primarily without any amputation and those who had undergone a minor amputation.

Patients who had undergone a major amputation had poorer health status than patients who healed primarily and those who had undergone a minor amputation.<sup>14</sup>

Jelsness-Jorgensen et al reported that a diabetic foot had a major negative impact on 7/8 subscales of the SF-36 compared with a diabetic outpatient group.<sup>16</sup> Another study revealed that the most striking differences were in role limitations due to physical health and physical functioning.<sup>1</sup> In our study, the lower physical function scores in patients with foot ulcers are in accordance with other studies, in which the physical functioning scale changed the most among those with diabetes complications.<sup>1,17</sup>

In diabetic patients with no foot ulcers, HRQoL scores in men were significantly higher than those in women; however, scores in patients with diabetic foot ulcers were similar in men and women. Age had no significant impact on HRQoL in both groups. A low educational level and living alone were other variables which decreased total, PCS, and MCS scores in the diabetic foot ulcer group in our study. In accordance with our findings, Ribu et al showed that women reported poorer health than did men. They found no significant association between self-assessed health and age in patients with diabetic foot ulcers. The reason may be that ulcers cause poor physical functioning regardless of age.<sup>3</sup> Another study indicated that female gender and macrovascular complications are related to worse physical and psychologic well being as detected by the SF-36 questionnaire. Increasing age showed a strong correlation with decreased physical functioning but a positive association with the MCS of the SF-36.<sup>6</sup> Quah et al reported that higher quality of life in diabetic patients is associated with younger age, male gender, and a higher educational level.<sup>18</sup> Another study in Turkey reported that quality of life was higher in diabetic patients who were less than 40 years of age, male, married, had less than 8 years of education, lived with their family, and had no complications or prior hospitalization.<sup>19</sup>

Obesity was a much more common problem in diabetic patients with diabetic foot ulcers in our study than those without foot ulcers, indicating a sedentary lifestyle, as reported in some studies,<sup>1,17</sup> although it was not associated with HRQoL in patients without foot ulcers. Obesity had a negative effect on HRQoL scores in our study. In agreement with our finding, Redekop et al suggested that obesity was correlated with lower HRQoL independent of gender and age.<sup>20</sup> In contrast, another study showed that patients with a body mass index  $<25$  kg/m<sup>2</sup> scored lower on general health perceptions, vitality, and mental health, and notably on general health perceptions.<sup>3</sup>

As expected, there was a significant relationship between the presence of complications and lower HRQoL in total, PCS and MCS scores, as demonstrated by several studies.<sup>3,19,20</sup> Quah et al reported that lower quality of life is associated with comorbidities and diabetic complications.<sup>18</sup> In contrast, factors linked to the development of late complications, such as cardiovascular comorbidity and neuropathy, were not detected in the study by Jelsness-Jorgensen et al.<sup>16</sup> Another study showed that neuropathy also proved to be a variable that reduced HRQoL. Paradoxically, peripheral vascular disease did not prove to have a negative impact on quality of life.<sup>15</sup>

Short-term glycemic control as measured by HbA<sub>1c</sub> was variable in regression models among patients with diabetic foot ulcers in our study; however, the association between poor glycemic control and lower HRQoL was not identified in the diabetic patient group. One study reported that higher fasting blood glucose and HbA<sub>1c</sub> levels were negatively associated with HRQoL, but these factors were not significant after adjustment for other factors using multivariate analysis.<sup>14</sup> Quah et al indicated that HbA<sub>1c</sub> did not correlate with quality of life. They suggested that the diabetic patient might not appreciate the impact of good diabetic control immediately on his or her HRQoL. More effort should be invested in patient education concerning the importance of glycemic control to prevent these long-term complications.<sup>18</sup> Another study revealed that diabetic patients with poor metabolic control reported more retinopathy and vascular and nervous problems than did patients with acceptable metabolic control. Furthermore, patients with poor metabolic control also had a lower level of education.<sup>21</sup>

A high-grade ulcer, as determined by Wagner's classification, was another variable which was found to be a significant and independent predictor of HRQoL impairment in patients with diabetic foot ulcers in our study. We also found that the risk of amputation was significantly higher in patients with lower HRQoL. One study showed that individuals with diabetic foot ulcers experienced profound compromise of physical quality of life, which was worse in those with unhealed ulcers.<sup>22</sup> Ragnarson et al reported that patients with current foot ulcers rated their HRQoL significantly lower than patients who had healed primarily without amputation.<sup>14</sup> Severity of foot ulcer as an independent predictor on HRQoL impairment was also demonstrated in a study by Valensi et al.<sup>5</sup>

In conclusion, these findings have implications for clinical and policy decisions, as well as for the design for future studies with larger sample sizes. In particular, our findings underscore the importance of HRQoL in the

management of diabetic patients with or at risk of foot disease. Wagner's grade was one of the strongest variables associated with HRQoL, which may suggest a role for this scale in the monitoring of patients with diabetic foot ulcers in order to prevent continuing deterioration of their HRQoL by treatment of foot ulcers at an earlier stage.

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## Disclosure

The authors report no conflicts of interest in this work.

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