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Research Article

**HEALTH RELATED QUALITY OF LIFE AND SELF-CARE
MANAGEMENT AMONG PEOPLE SUFFERING DIABETIC
FOOT ULCERS**

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Abstract:

To evaluate the Health-Related Quality of Life (HRQL) of diabetic patients along with and without foot ulcers and then to figure out elements influencing disease-specific HRQL for all those with foot ulcers. 355 diabetic patients, incorporating 239 along with foot ulcers (as considered group 1) and 116 without having foot ulcers (as considered group 2) have been examined over a cross-sectional setting. Socio-demographic as well as clinical factors had been documented and HRQL was examined through generic HRQL set of questions (SF-36) for most subjects. Concerning group 1, the degree of foot ulcers had been evaluated based upon Wagner's classification, and disease-specific HRQL considered making use of the Diabetes Foot Ulcer Scale (DFS).

HRQL had been found to be considerably lowered ($P = 0.0001$) in group 1 than in group 2 for all domains of the SF-36. Independent reverse relationships had been discovered between effective HRQL in the DFS domain of Leisure and Wagner grade ($OR = 0.136 [0.029-0.467]$) and the number of foot ulcers ($OR = 0.365 [0.191-0.678]$). Age had been considerably related to a number of DFS domains including Daily Activities, Physical Health and Dependence.

Our investigations encourage about the number and intensity of foot ulcers are connected with patient HRQL, specifically in terms of leisure activity disruption and restrictions due to treatment. These discoveries have ramifications for the evaluation, planning and management of patient care in diabetic foot disease.

Keywords: Foot Ulcers; Diabetes; HRQL; Life Quality

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INTRODUCTION:

Foot ulcers often herald the onset of more serious complications such as gangrene, requiring limb amputation. Up to 5.3% of diabetic patients may have a current or have had past foot ulcer(s). Over a 4year study period, Moss *et al.* found that 9.5% of younger-onset and 10.5% of older-onset patients developed chronic foot sores or ulcers. Diabetic foot lesions are a significant source of hospitalization. They have been shown to account for 20% of all diabetic admissions and 50% of all non-traumatic amputations. Furthermore, 4 to 6% of the diabetic population is subjected to lower extremity amputation due to foot ulcers. Foot ulcers are also an important factor in the excess mortality rates of those found in the diabetes population.

Factors influencing the impact of diabetes on Health-Related Quality of Life (HRQL) may include socio-demographic and clinical characteristics such as: age, level of education, co-morbid conditions and complications. A number of publications have addressed the impact of severe complications of diabetes on patient HRQL, some with particular respect to the presence of diabetic foot ulcers. However, no data is currently available in the form of literature on the HRQL of French persons with diabetes. It is of great importance to assess the impact of chronic illnesses, such as diabetes, and their treatment with regards to their influence on HRQL. There are two strategies for HRQL evaluation: using disease specific instruments and/or generic instrument. Regardless of the condition under study, a combination of both types of instruments is the recommended approach.

The aims of the present work are:

- To compare HRQL in persons suffering from diabetes with and without foot ulcers using a well validated generic HRQL measure.
- To explore the relationships between clinical characteristics related to diabetic foot ulcers, diabetes and HRQL using a disease-specific HRQL measure.

MATERIAL AND METHODS:

The study, which was performed in France, involved patients recruited over a period of two and a half months. It was a cross-sectional, observational study conducted among general practitioners (GPs), diabetologists-endocrinologists, dermatologists, surgeons (general, orthopedic and vascular),

geriatricians, angiologists and internists. The patients were enrolled in the study by 98 clinicians randomly selected from a national database of health professionals, who had accepted telephone invitations to participate in this study. Patients were recruited to the study consecutively by the clinicians as they presented in the clinician's office.

Patients:

Two groups of adult patients were recruited to the study. Patients were included in group 1 if they had diabetes mellitus with at least one diabetic foot ulcer, defined according to Wagner's classification treated for more than one month or in the process of healing. Some patients in this group also had other degenerative complications. Patients were included in group 2 if they had suffered from diabetes for at least 5 years without current or previous foot ulcers; a few of these patients had other degenerative complications. Information on patient socio-demographic and clinical characteristics was collected by the clinicians using case report forms especially designed for the study. All patients gave their informed consent to participate in the study and all appropriate regulatory and ethics approvals were obtained.

Clinical Analysis:

Clinical history was obtained on all subjects for current risk factors (tobacco and alcohol ingestion), type of diabetes, year of diabetes diagnosis, presence of diabetic complications other than foot disease (e.g. hypertension, retinopathy, nephropathy, neuropathy), and treatment (insulin or oral hypoglycemic agents). Physical examination included measurement of height, weight and blood pressure. A record was also made of the presence of other diseases.

Information was obtained on the previous history of patients with foot ulcer(s), the number of current ulcers and the characteristics of the principal current foot ulcer(s) (onset, initial presentation, triggering factors, location, etiology, initial and present size, initial and current clinical severity according to Wagner's classification), any change in diabetes therapy since the appearance of the foot ulcer(s), and amputation history. A record was also made of the time interval between the appearance of the principal foot lesion and the beginning of treatment, the appearance of the principal foot lesion and the beginning of treatment, the person who discovered the lesion, and the person who referred the patient to the clinician.

HRQL Analysis

All patients filled out an HRQL questionnaire comprising a generic measure, the Short-Form 36 Health Survey (SF-36). Subjects with diabetic foot lesions also completed a specific measure, the Diabetic Foot Ulcer Scale (DFS).

The SF-36 is a generic HRQL instrument developed in US English and translated into more than 40 languages. The English version of the SF-36 is widely used in Pakistan and has been validated in several disease conditions; norms are available for diabetic patients. The SF-36 consists of 36 items grouped into 8 domains: **Physical Functioning, Role Physical, Bodily Pain, Social Functioning, Role Emotional, Mental Health, General Health and Vitality**. The scores were calculated for each domain. Two summary scores ranging from 0 (poor HRQL) to 100 (good HRQL) were calculated: one Mental Component Summary score (MCS-36) and one Physical Component Summary score (PCS-36). These two scores were determined by weighting responses to each item by coefficients calculated for the general American population.

The DFS questionnaire, developed by Johnson and Johnson (ICOM Health Economics, US), is a specific questionnaire for assessing HRQL domains of importance for diabetic patients with foot ulcers. Two studies have shown that the DFS can discriminate between diabetic patients with healed foot ulcers and

no healed foot ulcers and that it is sensitive to changes in wound status.

RESULTS:

Clinicians

Ninety-eight clinicians recruited 355 diabetic patients; 29.6% of clinicians were GPs, 31.6% were diabetologist-endocrinologists, 7.4% were surgeons and the remainder were dermatologists, geriatricians, angiologists and internists. These professionals practiced in public clinics (63.1% of the sample), private clinics (15.5%), nursing homes (12.6%), rehabilitation centres (3.1%) and other health related centres. Ten of these clinicians were members of a clinical network specialized in foot care. These 10 investigators were diabetologists or endocrinologists based in different regions of France and recruited 12% of the patients with foot ulcers. Among the 98 clinicians, 80 recruited diabetic patients with foot ulcers and 18 recruited diabetic patients without foot ulcer(s).

Patients

Of the 355 diabetic subjects, 239 had foot ulcers (group 1) and 116 had no foot ulcers (group 2). The majority of patients were under the care of GPs and diabetologists-endocrinologists (28% and 29% respectively in group 1; 39% and 44% respectively in group 2). Socio-demographic and clinical characteristics of the 355 patients are shown in below mentioned Table 1:

Table I
Socio-demographic and clinical parameters by patient group.

	Group 1(n = 239)	Group 2(n = 116)	P-value
Sex Male/Female	159/79	57/57	0.002
Age (yrs), mean (SD)	65.5 (± 11.2)	62.3 (± 12.7)	0.03
Type of diabetes 1 / 2	62/174	21/95	0.09
Diabetes duration (years), mean (SD)	17.3 (± 11.1)	12.6 (± 8.6)	0.0001
Smoking habits (%)	61 (25.5%)	11 (9.5%)	0.001
Alcohol consumption (%)	73 (30.5%)	28 (24.1%)	0.210
BMI (kg/m ²), mean (SD)	27.7 (± 5.0)	28.8 (± 4.9)	0.056
Systolic blood pressure/diastolic blood pressure (mmHg), mean	139.4 / 78.8	140.7 / 80.9	NA
Fasting blood glucose (mmol/l) mean (SD)	8.51 (± 4.6)	7.51 (± 3.8)	0.016
Insulin therapy	154 (64.4%)	27 (23.3%)	0.001
Duration of the insulin therapy (yrs), mean (SD)	10.1 (± 12.6)	7.0 (± 9.0)	0.199
Oral hypoglycemic agents	96 (40.2%)	95 (81.9%)	0.001
Duration of the oral therapy (yrs), mean (SD)	15.3 (± 9.7)	11.3 (± 8.9)	0.0001
Diabetic complications			
Background retinopathy	89 (37.2%)	11 (9.5%)	0.001
Proliferative retinopathy	47 (19.7%)	5 (4.3%)	0.001
Nephropathy (microalbuminuria > 30 mg/l)	87 (36.4%)	10 (8.6%)	10 ⁻⁹
Renal insufficiency	26 (10.9%)	5 (4.3%)	10 ⁻⁹
Neuropathy with objective sensory symptoms	112 (46.9%)	12 (10.3%)	NA
Neuropathy with subjective sensory symptoms	62 (25.9%)	5 (4.3%)	NA
Autonomic Neuropathy	24 (10.0%)	3 (2.6%)	NA
Peripheral arterial disease/coronary disease	81 (33.9%)	10 (8.6%)	NA
Aetiology for diabetic foot ulcer			
Multiple aetiologies	161 (67.4%)	NA	NA
Single aetiology	78 (32.6%)	NA	NA
Peripheral neuropathy	27 (34.6%)	NA	NA
Arteriopathy	34 (43.6%)	NA	NA
Infection	10 (12.8%)	NA	NA
Others	7 (8.9%)	NA	NA
Hypertension	148 (61.9%)	71 (61.2%)	0.709
Other chronic illnesses	146 (61.1%)	64 (55.2%)	0.43

Group 1: diabetics with foot ulcers; Group 2: diabetics without foot ulcer. NA: Not Available.

HRQL in Patients with and without Foot Ulcers

Group 1 patients had significantly poorer HRQL, as indicated by lower mean scores in all SF-36 domains ($P = 0.0001$), than Group 2 patients, as below mentioned Figure 1. The largest differences between groups were found for the domains of: Physical Functioning, Role Physical and Role Emotional respectively 30-point, 47-point and 36-point

difference). Similarly, the physical and mental summary scores of the SF-36 (PCS-36 and MCS-36) showed poorer HRQL in group 1 than in group 2 ($P = 0.0001$), with differences around 12 points for the PCS-36 score and 5 points for the MCS-36. All these differences remained significant after adjustment on clinical parameters (i.e. age, gender, duration and type of diabetes).

► Figure 1

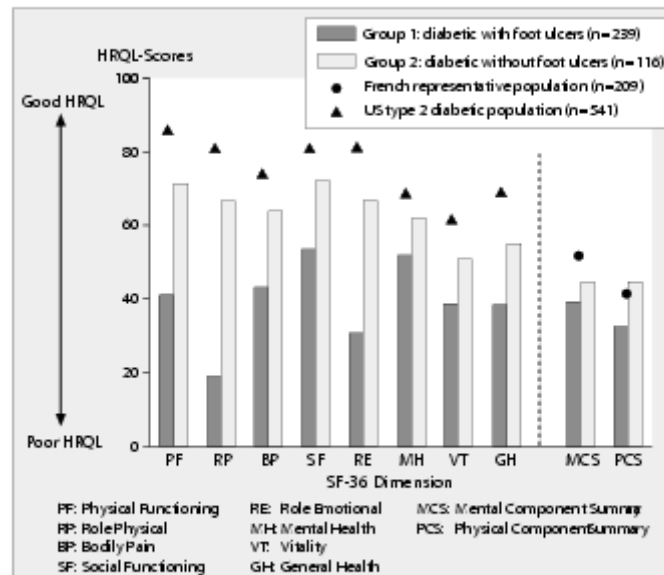


Figure 1. SF-36 domain scores in the two groups of patients.

Clinical Data on Foot Ulcers

The foot ulcer was discovered in 63% of the cases by the patients themselves or by: the clinician (17%), the caregiver (5%) or another healthcare professional (2%). In 13% of cases, we did not have this information. Discovery of an ulcer led to an initial consultation with a GP (58%), a diabetologist-endocrinologist (13%) or a nurse (10%). Two-thirds of the patients (146 patients) had at least one chronic condition other than diabetes. One hundred forty one patients (59%) had experienced foot ulcers in the past. Among the 239 patients with foot ulcer(s), 79 patients (33%) had experienced two or more ulcers at the time of this study.

The principal ulcer was located on the toe or sole of the foot in 76% of the patients. At the time of diagnosis, 41% of the patients initially had a superficial ulcer (Wagner grade 1), 31% of the patients had an ulcer with an extension to deeper layers (grade 2), 11% had tendonitis or osteomyelitis (grade 3) and 17% had gangrene (grade 4/5).

The ulcer had been present for at least 5 months in 50% of the patients (first quartile = 2 months; third

quartile = 12 months). The time between the discovery of the foot ulcer and the beginning of treatment was less than 10 days for 50% of the patients and greater than 30 days for 25% of the patients.

DFS in Diabetes Patients

Scores for DFS domains ranged from 41.2 ± 28.0 for Daily Activities to 79.7 ± 21.1 for Family Life, as mentioned in Table 2 below. 50.7% of subjects reported the maximum possible score in the Medical Compliance domain, suggesting a substantial ceiling effect, while 21.3% of subjects reported the lowest possible score for the Positive Relationship domain (the greatest floor effect).

DFS scores did not differentiate between the HRQL of subjects by gender except in the domain of Family Life with women reporting fewer difficulties in family relationships than men ($P = 0.0282$). DFS scores were slightly but significantly correlated with age for the domains of Dependence ($r = -0.29$; $P = 0.0001$), Daily Activities ($r = 0.16$; $P = 0.0172$) and Diet Compliance ($r = 0.18$; $P = 0.0068$).

Differences in scores were also found between subjects depending on the clinician's specialty, with subjects consulting diabetologist-endocrinologists reporting less deterioration in physical health ($P = 0.0116$), less irritation due to the appearance and duration of foot ulcer care ($P = 0.022$), greater closeness with their partners and friends, and greater satisfaction with medical care ($P = 0.0001$), compared to those cared for by GPs and other medical specialists.

DISCUSSION:

This cross-sectional, observational study demonstrated that HRQL is severely impaired by diabetic foot ulcers and describes an important correlation between HRQL scores and foot ulcer characteristics. Our findings show that HRQL evaluated by the SF-36 questionnaire, in particular in the areas of physical health and well-being, is lower in diabetic patients with foot ulcers compared to diabetic patients without foot ulcers.

It should be noted that group 1 (diabetics with foot ulcers) were slightly older, had a longer duration of diabetes, and that a higher percentage of this group were male, lived alone and were on insulin therapy than those in group 2. However, differences in HRQL scores between groups remained significant for all SF-36 domains after adjusting for cofounders. It has been suggested that a difference of 3-5 points should be considered to represent the minimal clinically important difference for SF-36 scores; the difference between groups 1 and 2 in this study was greater than 10 points for all domains and greater than 5 points for both component summary scores.

Similar findings have been reported in the literature. Carrington *et al.* found that psycho-social adjustments to illness were worse in diabetic patients with chronic foot ulcer(s) or amputation than gender and age-matched diabetic controls. Furthermore, patients with ulcers were more depressed and less satisfied with life than persons with diabetes but no ulcers.

Diabetic patients with chronic foot ulceration had a significantly more negative attitude towards their feet than diabetic unilateral lower limb amputees and diabetic patients with no history of foot ulceration. In a study conducted in the Netherlands, Meijer *et al.*, used the SF-36 to compare the HRQL of diabetic patients with and without foot ulcers; scores were significantly lower on the physical functioning, social functioning, physical role and health experience scales for those patients with diabetic foot ulcers.

Assessment of health utilities associated with diabetes and its treatments, complications and co morbidities in a study of more than 2,000 Americans also confirmed that foot ulceration was associated with a substantial reduction in HRQL.

CONCLUSION:

These findings have implications for clinical and policy decisions as well as for the design of future studies, and especially for clinical trials in diabetes foot disease. In particular, they underline the importance of patient HRQL in the management of diabetic patients with or at-risk of foot disease. Since Wagner's staging was the clinical variable with the strongest association with disease-specific HRQL, this may suggest a role for the routine use of this scale for early detection and monitoring of patients with diabetic foot disease in order to prevent continuing deterioration of their HRQL. Although it is possible that other factors in the recruitment process might have affected the health status of patients recruited by different types of clinicians, the association found between HRQL scores and type of practitioner also has implications for policy and planning of shared care in diabetes.

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