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COVER PAGE

Project Title: Mental Health Issues Associated with Foot Complications of Diabetes Mellitus

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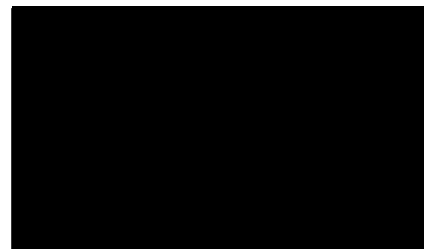
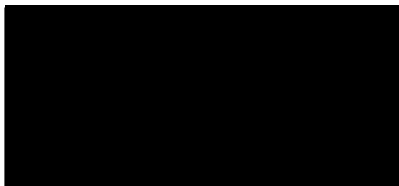
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Summary: Diabetes mellitus (DM) is a chronic disease associated with severe multi-system complications including, but not exclusive to, peripheral neuropathy, peripheral vascular disease, renal and cardiovascular disease. Diabetic peripheral vascular disease and neuropathy often result in foot ulcers and Charcot arthropathy that can be complicated by infection, amputation and increased morbidity and mortality. Diabetic patients, especially those with severe functional impairment, have more frequent symptoms of psychological depression than the general population, which is further increased if the patient concurrently has a diabetic foot ulcer. Currently, there is limited information available on the effect of diabetic foot complications on other mental health issues, including the sphere and extent of anxiety disorders, co-morbid alcohol and substance abuse disorders, suicidality, and perceived need for mental health treatment. There is also a gap in the knowledge on the physical, emotional, and psychological stress that is placed on the caregiver, frequently being spouses and extended family members, for a patient with DM and DM foot problems. Therefore, the goal of this research was to evaluate diabetic patients with and without diabetic foot problems, and caregivers of patients with diabetic foot problems. The student will use patient interviews, and a series of psychological outcomes surveys to explore the impact that this disease has on the population and their caregivers. The objectives for the student would be gain knowledge of evidenced based medicine, biostatistics and epidemiological skills to evaluate the impact this disease has on select patient populations.

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BODY OF PAPER

ABSTRACT

Aims: To evaluate the effect of diabetic foot problems on mental health in diabetic patients and caregivers.

Methods: Diabetic patients with and without diabetic foot problems, and caregivers of patients with diabetic foot problems, were evaluated. Outcomes surveys were completed, including Diabetes Symptom Checklist-2 (DSC-2), Hospital Anxiety and Depression Scale (HADS), Medical Outcome Study Short Form 36 (SF-36), Short-Form McGill Pain Questionnaire (SF-MPQ), Suicidal Behaviors Questionnaire-Revised (SBQ-R), Alcohol Use Disorder Identification Test (AUDIT), and Montgomery Caregiver Burden Assessment (MCBA).

Results: In contrast with diabetic patients having no foot problems, diabetic patients with foot problems had, on average, significantly greater diabetic symptoms (DSC-2 score), greater depression symptoms (HADS Depression score), worse health related quality of life (SF-36 Physical Component Summary score and 6 of the 8 SF-36 subscales), greater pain (all 4 SF-MPQ scales), and greater suicidal behavior (SBQ-R score). There was no significant difference in alcohol use (mean AUDIT score), anxiety (HADS Anxiety score), or SF-36 Mental Component Summary score between patients with or without foot problems. Caregivers had marked caregiver burden (average MCBA score) and high average levels of anxiety and depression (HADS total score), with probable anxiety in almost one-third of caregivers (Mental Health Outcome).

Conclusions: Diabetic foot problems are significantly associated with mental health symptoms in patients and caregivers.

INTRODUCTION

Diabetes mellitus is a chronic disease associated with severe multisystem complications including peripheral neuropathy, peripheral vascular disease, retinopathy, renal failure, cardiovascular disease, stroke, erectile dysfunction, and premature death. Peripheral neuropathy and vascular disease result in the development of foot ulcers and Charcot arthropathy that may be complicated by infection and lower extremity amputation [1, 2]. Diabetic foot ulcers represent a large economic burden and significantly decrease quality of life [2, 3]. Furthermore, diabetic patients with foot pathology have two-fold greater mortality than diabetic patients without foot ulcer [2, 4, 5], and five-year mortality after lower extremity amputation is between 39% and 68% [6].

Diabetic patients, especially those with severe functional impairment, have more frequent symptoms of psychological depression than the general population [7-10]. One-third of all patients who develop their first diabetic foot ulcer concurrently suffer from clinical depression, and diabetic patients with minor and major depressive disorders have a three-fold hazard risk for mortality [9]. Depression is associated with decreased compliance with medication, decreased glycemic control, decreased health-related quality of life, and increased social isolation, morbidity, and mortality [5, 11]. Furthermore, depression is associated with suboptimal healing of diabetic foot ulcers [12]. Several studies have shown an increased prevalence of anxiety in patients with diabetic foot ulcers compared with the general population or diabetic patients without foot problems [13-17]. However, another study showed that patients with diabetic foot

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ulcers had a lower frequency of diagnosis of anxiety disorders than patients without foot ulcers [18]. Furthermore, limited information is available about the effect of diabetic foot problems on other mental health problems, including the sphere and extent of anxiety disorders (panic disorders, post-traumatic stress disorder (PTSD), general anxiety disorder (GAD), agoraphobia, and social phobia), co-morbid alcohol and substance use disorders, suicide, and perceived need for mental health treatment.

Caregivers of a patient with diabetes and diabetic foot problems may experience major associated physical and emotional stress. These caregivers frequently are the spouses and extended family members of patients. The severity of caregiver stress associated with diabetes is second to that associated with dementia and cancer [19]. Daily assistance provided by caregivers of diabetic patients may include glucose monitoring, dietary management, and giving medication such as insulin, dressing changes, and transportation assistance for physiotherapy, outpatient clinic appointments, and pharmacy. Caring for the elderly patient with diabetes also may cause major burden on the caregivers, increased with greater amount of caregiver time [20-22]. Caregivers to patients with type 1 diabetes, especially fathers, may experience clinical depressive symptoms and heightened individual, cultural, family, and environmental stress. [23-25]. However, limited information is available about the effect of diabetic foot problems on mental health of caregivers.

We hypothesized that diabetic foot problems may increase mental health problems in diabetic patients and their caregivers. The purpose of this study was to evaluate the effect of diabetic foot problems on mental health in patients and caregivers.

MATERIALS AND METHODS

Subjects

From 2008-2009, 105 diabetic patients at a tertiary care outpatient facility (Health Sciences Centre, Winnipeg, Manitoba, Canada) were approached and registered to participate in the current study. The study was completed by 47 of 50 patients with foot pathology (diabetic foot ulcers or Charcot arthropathy) from the Diabetic Foot and Complicated Wound Clinic and 49 of 55 patients without foot problems from the Endocrinology Clinic; 3 patients with foot pathology and 5 patients without foot problems did not complete the questionnaire, and 1 patient without foot problems was excluded because of initiation of hemodialysis. Furthermore, 21 caregivers (defined as non-paid individuals who had regular contact with the patient and were responsible for, or assisted with, activities of daily living) of the patients with foot pathology received and completed the caregiver assessment survey. Written informed consent was obtained from all participants. Upon completion of the questionnaire, participants received a per diem payment. The study protocol was approved by the Bannatyne Campus Research Ethics Board at the University of Manitoba in Winnipeg, Manitoba.

Evaluation

Patients and caregivers completed self-report forms to document demographic information, history of lower extremity problems, diabetes treatment, medical co-morbidities, and mental health history; missing information after completion of the forms was obtained with a

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follow-up telephone call. Furthermore, the following standardized and validated health surveys were completed.

The Hospital Anxiety and Depression Scale (HADS), previously developed for use with physical illness and validated to adequately establish the severity of anxiety and depression in both primary care patients and the general population [13,14,26]. It consisted of two independent subscales (one subscale each for anxiety and depression); each subscale had seven items using a four-point Linkert scale that recorded the severity of anxiety and depression symptoms [26,27]. A total anxiety or depression subscale score of 8 or more indicated depression or anxiety (total range of each HADS subscale: minimum, 0; maximum, 21); anxiety and depression were rated as normal (HADS subscale, 0 to 7), mild (8 to 10), moderate (11 to 15), and severe (15 to 21) [13,26-27]. Probable anxiety or depression was defined by HADS subscale in the moderate or severe range (HADS subscale, 11 to 21).

The Medical Outcome Study Short Form 36 (SF-36), reliable and valid for numerous conditions including diabetes, consisted of 36 questions to determine two summary scores (Physical Component Summary and Mental Component Summary) and eight subscales: Physical Functioning, Role Limitations due to Physical Health, Bodily Pain, General Health, Vitality (Energy/Fatigue), Social Functioning, Role Limitations due to Emotional Problems, and Mental Health (Emotional Wellbeing) [27-30]. Subscale scores ranged from 0 to 100, with higher scores representing a better health-related quality of life [31], and each of the 8 subscales may be relevant to diabetic patients with or without foot problems [32]. The Summary scales and subscales were transformed to have a mean of 50 ± 10 points (possible range, 0-100 points) in the general United States population [33]. Differences of the average PCS and MCS scores of greater than 10 points between the two treatment groups, or between a treatment group and the mean value of 50 points in the general United States population, were considered clinically meaningful [34].

The Short-Form McGill Pain Questionnaire (SF-MPQ), used to grade pain intensity, consisted of four scales: Sensory Pain Dimension (11 sensory descriptors, each rated from minimum [0] to maximum [3] pain intensity; total Sensory Pain Dimension range: minimum, 0; maximum, 33); Affective Pain Dimension (4 affective descriptors, each rated from minimum [0], to maximum [3] pain intensity; total Affective Pain Dimension range: minimum, 0; maximum, 12); Visual Analogue Scale (range: minimum pain, 0; maximum pain, 10); and Present Pain Intensity (range: minimum, 0; maximum, 5) [35]. The Present Pain Intensity and Visual Analogue Scale are also included to provide overall intensity scores, but not included in the total SF-MPQ score.

The Suicidal Behaviors Questionnaire-Revised (SBQ-R) score was a four-item measure of suicidal tendency; the total score was obtained by adding scores from all four items (total range of SBQ-R: minimum, 3; maximum, 18). Higher scores indicated a greater current suicidal risk [22], and a score of 7 or higher had 93% sensitivity and 95% specificity in identifying individuals in the general adult population at-risk for suicide [35,36].

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The Alcohol Use Disorder Identification Test (AUDIT) was used as a screening tool for alcohol dependence. Higher scores in this measure indicated likely hazardous and harmful alcohol use (total range of AUDIT: minimum, 0; maximum, 40). Alcohol dependence was defined by an AUDIT score of ≥ 10 to provide greater specificity than the previously used threshold score of 8 [16], and probable alcohol dependence was defined by AUDIT score 8 to 9.

The Diabetes Symptom Checklist-2 (DSC-2), a reliable and validated checklist developed for the use in clinical and epidemiological research, is a 34-item checklist of symptoms associated with hyperglycemic, hypoglycemic, cardiac, neuropathic, psychological, and vision-related problems. The DSC-2 may demonstrate differences in symptom severity between patients and changes in symptoms for an individual patient over time (total range of DSC-2: minimum, 0; maximum, 34) [37].

The Montgomery Caregiver Burden Assessment (MCBA) Scale was used to measure objective burden, demand, and stress in non-paid caregivers assisting patients with activities of daily living. The 14 inventory questions assessed the level of change in a caregiver's life and relationship to the patient, and the reply to each question was rated using a Linkert Scale (minimum, 0; maximum, 5). The reply to all 14 questions were added together to give the total MCBA score (total range of MCBA: minimum, 14; maximum, 70) [38-41].

Mental health outcome scores and factors were recorded and analyzed using the SF-36, MCBA, HADS, and AUDIT questionnaires. Patients with or without foot problems completed the HADS, SF-36, SF-MPQ, SBQ-R, AUDIT, and DSC-2 surveys. Caregivers completed the HADS, SF-36, AUDIT, and MCBA surveys.

Data analysis

Data analysis was done with statistical software (SPSS Inc., Chicago, Illinois). Chi-square test was used to evaluate socio-demographic enumeration data. Linear regression analysis was done to compare survey data for the two patient populations (with or without foot problems), controlling for variables such as gender, which was different for the two patient groups. Logistic regression analysis was used to evaluate the relation between foot pathology and the dependent dichotomous outcome variables, i.e. variables with only two possible outcomes. Correlation analysis between caregivers and patients with diabetic foot problems was done with Pearson correlation coefficients. Statistical significance was defined by $P < 0.05$.

RESULTS

The patients with foot problems were significantly younger at the time of diabetes diagnosis, and more frequently male and unemployed or on pension, than patients without foot problems (Table 1). There were no significant differences in body mass index, ethnicity, marital status, education level completed, annual income, residence, or diabetes type between patients with or without foot problems (Table 1). Of the 21 caregivers for patients with diabetic foot problems, 21 (100%) caregivers were women, 18 (86%) were Caucasian, 16 (76%) were spouses of the patient, 14 (67%) were married, and 13 (62%) resided in an urban locale. The most common foot problems were ulcers, osteomyelitis, and Charcot arthropathy (Table 1).

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In contrast with patients having no foot problems, patients with diabetic foot problems had, on average, significantly greater diabetic symptoms (DSC-2 score), greater depression symptoms (HADS Depression score), worse health related quality of life (SF-36 Physical Component Summary score and 6 of the 8 SF-36 subscales), greater pain (all 4 SF-MPQ scales), and greater suicidal behavior (SBQ-R score) (Table 2). Patients with diabetic foot problems had lower average SF-36 Physical Component Summary score than the general population (Table 2). There was no significant difference in alcohol use (mean AUDIT score), anxiety (HADS Anxiety score), or SF-36 Mental Component Summary score between patients with or without foot problems (Table 2). In the 96 patients in the study, 44 patients (46%) had neuropathy: painful neuropathy in 29 patients (30% of all study patients; 66% of patients who had neuropathy) and non-painful neuropathy in 15 patients (16% of all study patients; 34% of patients who had neuropathy).

Patients with foot problems more frequently had eye disease than patients without foot problems, but this difference was not significant upon controlling for gender (Table 3). There were no differences between patients with or without foot problems in frequency of diabetes treatment factors, emotional problems or mental illness, cardiovascular disease, renal disease, or alcohol dependence (Table 3).

Caregivers of patients with diabetic foot problems had overall health-related quality of life (SF-36 Physical and Mental Component Summary scores) similar to that of the general population (general population scores, 50 [38, 39]) (Table 4). However, caregivers scored, on average, higher than the general population in seven of the eight SF-36 subscales (Table 4). Caregivers had marked caregiver burden (average MCBA score) and high average levels of anxiety and depression (HADS total score), with probable anxiety in almost one-third of caregivers (Mental Health Outcome) (Table 4). There was a significant weak positive correlation between alcohol dependence in caregivers (AUDIT score) and SF-36 Mental Component Summary score for patients with diabetic foot problems (Table 5).

DISCUSSION

The data support the hypothesis that diabetic foot problems are associated with worse mental health in diabetic patients, including greater average depression, pain, and suicidal behavior scores (Table 2). Furthermore, caregivers of patients with diabetic foot problems frequently had mild to moderate depression and anxiety (Table 4)

Previous work showed decreased health-related quality of life in diabetic patients with foot ulcers (Short Form-12 [SF-12] Health Survey) and Charcot arthropathy (SF-36 Health Survey) for the Physical Component Summary score, but not the Mental Component Summary score, than the general population [1,42,43]. In patients with diabetic foot problems, the average SF-36 Physical Component Summary score in the present study (Table 2) was similar to the average SF-12 and SF-36 Physical Component Summary scores in previous studies from the same foot clinic, confirming reproducibility of this survey score [42,43].

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The average SF-36 Mental Component Summary scores in the present study (Table 2) also were similar to those in previous studies of patients with diabetic foot ulcers and Charcot arthropathy [42,43] and published scores for the general population [44,45]. This is consistent with the previous finding that the SF-12 and SF-36 surveys are not sensitive to the mental effects of diabetic foot problems [42,43, 46]. In contrast with the SF-36 Mental Component Summary score, the HADS, SF-MPQ, and SBQ-R showed significantly greater depression, pain, and suicidal behavior in patients with diabetic foot problems (Table 2), suggesting that these surveys were more sensitive to the mental and emotional effects of diabetic foot problems than the SF-36 Mental Component Summary score.

In the present study, diabetic foot problems were associated with increased frequency of unemployment or pension (Table 1). This finding is consistent with previous research that demonstrated marked physical limitations associated with diabetic foot ulcers that may decrease patient mobility and independence, precluding work activity [3,7], and a high prevalence of unemployment, early retirement, or inability to work in the majority (50% to 79%) of patients with diabetic foot ulcers [1,3,6].

The observed association between diabetic foot problems and depression (Tables 2 and 3) is consistent with findings of previous studies [9-13, 32] that had demonstrated a two- to three-fold greater frequency of depression in diabetic patients with foot complications [9, 47]. There is limited previous information about anxiety in patients with diabetic foot problems; the similarity of average anxiety scores in patients with and without diabetic foot problems (Table 2) was surprising because of the association of diabetic foot problems with risk of amputation, vascular complications, other diabetic complications, increased pain scores (Table 2), increased unemployment or pension status (Table 1), and necessity of additional appointments and procedures for treatment of the diabetic foot problems.

The findings of depression and anxiety in caregivers of patients with diabetic foot problems (Table 4) may be expected, in part because the majority of caregivers were spouses of the patients and had close exposure to the physical and emotional difficulties of the patients. Previous work demonstrated that caregivers of diabetic patients may experience heightened stress [25] and caregiver burden [20,21], further increased with the amount of caregiver time with the patient [20, 22]. Nevertheless, the present results showed no significant difference between caregivers and the general population in SF-36 Physical and Mental Component Summary scores (Table 4) [33,38,39].

The only significant correlation between caregiver and patient scores was the positive association between caregiver alcohol use (AUDIT) and patient mental health quality of life (SF-36 Mental Component Summary (Table 5). Although statistically significant, it is doubtful that this finding is clinically relevant because of the limited sensitivity of the SF-36 Mental Component Summary score for mental health problems associated with diabetic foot problems compared with the general population (Table 2) [42,43]. Absence of significant correlation between the other caregiver and patient scores may be attributed to limitations of score sensitivity or limited statistical power (sample size) of the study.

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Limitations of the present study include potential bias and subjectivity associated with the use of self-answered questionnaires, albeit previously validated. This may have contributed to the large variation in scores between patients in the same group, resulting in large standard deviations (Table 2). Selection bias in favor of more functional patients may have occurred by including only patients from hospital outpatient clinics; potentially more debilitated, depressed, and anxious patients who were housebound, institutionalized, or otherwise unable to attend a hospital clinic for treatment were excluded by the design of the study. In addition, caregivers of patients with diabetic foot problems were not compared with a control group of caregivers of patients without foot problems, and population data generated from previous research were used to validate the epidemiological screening tools. Furthermore, evaluation of patients at a single time point precluded a longitudinal assessment of the effects of treatment or development of new diabetic foot problems.

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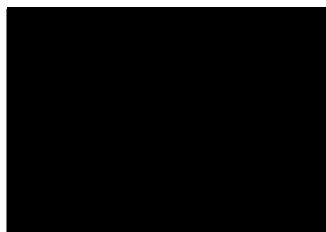
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Student's Signature



Supervisor's Signature

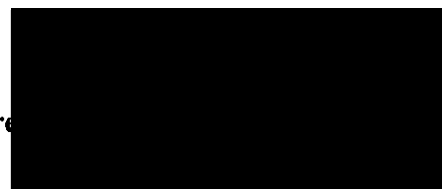


Table 1. Relation between diabetic foot problems and patient profile in diabetic patients *

| Parameter | Number (percent) patients | | χ^2 (df) † | P < ‡ |
|--|---------------------------|----------|-----------------|-------|
| | Yes | No | | |
| Foot problems present * | | | | |
| Total number of patients | 47 (100) | 49 (100) | | |
| Age at diagnosis of diabetes (yr) § | 37 ± 11 | 45 ± 15 | | 0.003 |
| Length of time with diabetes (yr) | 16.6 ± 9.69** | | | |
| Body Mass Index (kg/m ²) § | 31 ± 7 | 31 ± 6 | | NS |
| Gender | | | | |
| Male | 37 (79) | 27 (55) | 6.02 (1) | 0.05 |
| Female | 10 (21) | 22 (45) | | |
| Ethnicity | | | | |
| Caucasian | 30 (64) | 34 (69) | | |
| Aboriginal/Metis | 15 (32) | 9 (18) | 4.04(4) | NS |
| Asian | 1 (2) | 3 (6) | | |
| Hispanic | 0 (0) | 1 (2) | | |
| Other | 1 (2) | 2 (4) | | |
| Marital status | | | | |
| Married | 23 (49) | 35 (71) | | |
| Separated | 10 (21) | 6 (12) | 7.62(4) | NS |
| Common law | 6 (13) | 4 (8) | | |
| Single (never married) | 6 (13) | 1 (2) | | |
| Widowed | 2 (4) | 3 (6) | | |
| Education level completed | | | | |
| High School | 20 (43) | 11 (22) | | |
| Less than High School | 10 (21) | 13 (27) | 6.14(4) | NS |
| Trade school/technical colleg | 9 (19) | 14 (29) | | |
| Graduate Degree | 6 (13) | 5 (10) | | |
| Bachelor's Degree | 2 (4) | 6 (12) | | |
| Annual income (Canadian dollars) | | | | |
| \$0-\$19,999 | 9 (19) | 8 (16) | | |
| \$20,000-\$34,999 | 13 (28) | 13 (27) | 1.90(4) | NS |
| \$35,000-\$59,999 | 12 (26) | 12 (24) | | |
| \$60,000+ | 13 (28) | 16 (33) | | |
| Residence | | | | |
| Urban | 27 (57) | 36 (73) | | |
| Rural | 15 (32) | 10 (20) | 2.75(2) | NS |
| Reserve | 5 (11) | 3 (6) | | |
| Employment | | | | |
| Unemployed/Pension | 21 (45) | 4 (8) | | |
| Retired | 12 (26) | 20 (41) | | |
| Sedentary Worker | 5 (11) | 12 (24) | 19.08(5) | 0.01 |
| Indoor Laborer | 5 (11) | 10 (20) | | |
| Outdoor Laborer | 3 (6) | 3 (6) | | |
| Student | 1 (2) | 0 (0) | | |
| Diabetes type | | | | |
| Type 2 | 38 (81) | 41 (84) | 0.13(1) | NS |
| Type 1 | 9 (19) | 8 (16) | | |

*Excluding information about caregivers. Patients with foot problems were from the Diabetic Foot Clinic; patients without foot problems were from the Endocrinology Clinic

** Range: minimum=1, maximum=39

† df = degrees of freedom

‡ NS = not significant, P ≥ 0.05

§ Reported as mean ± standard deviation

Table 2. Relation between diabetic foot problems and outcome measure in diabetic patients *

| Outcome measure | Score * | | P < ‡ |
|---|---------|-----------|-------|
| | Yes | No | |
| Foot problems present † | | | |
| Alcohol Use Disorder Inventory Test (AUDIT) total score | 4 ± 5 | 3 ± 4 | NS |
| Diabetes Symptom Checklist Total Score | 15 ± 10 | 8 ± 8 | 0.001 |
| Hospital Anxiety and Depression Scale (HADS) | | | |
| HADS Anxiety Total Score | 5 ± 3 | 5 ± 4 | NS |
| HADS Depression Total Score | 6 ± 4 | 3 ± 3 | 0.001 |
| Short-Form 36 Health Survey (SF-36) | | | |
| SF-36 Component Summary scores | | | |
| SF-36 Physical Component Summary | 34 ± 10 | 48 ± 11 | 0.001 |
| SF-36 Mental Component Summary | 52 ± 11 | 53 ± 9 | NS |
| SF-36 subscales | | | |
| SF-36 Mental Health (Emotional Wellbeing) | 74 ± 17 | 79 ± 18 | NS |
| SF-36 Role Limitations due to Emotional Problems | 71 ± 42 | 82 ± 30 | NS |
| SF-36 Social Functioning | 66 ± 28 | 83 ± 23 | 0.001 |
| SF-36 Bodily Pain | 59 ± 26 | 78 ± 23 | 0.001 |
| SF-36 Vitality (Energy/Fatigue) | 54 ± 24 | 66 ± 19 | 0.003 |
| SF-36 General Health | 46 ± 22 | 60 ± 19 | 0.001 |
| SF-36 Physical Functioning | 42 ± 28 | 74 ± 30 | 0.001 |
| SF-36 Role Limitations due to Physical Health | 28 ± 38 | 73 ± 37 | 0.001 |
| Short-Form McGill Pain Questionnaire (SF-MPQ) | | | |
| SF-MPQ Sensory Pain Dimension | 8 ± 6 | 3 ± 5 | 0.001 |
| SF-MPQ Affective Pain Dimension | 2 ± 2 | 1 ± 2 | 0.001 |
| SF-MPQ Visual Analogue Scale | 2 ± 2 | 1 ± 2 | 0.001 |
| SF-MPQ Present Pain Intensity | 1 ± 1 | 0.6 ± 0.8 | 0.001 |
| Suicidal Behaviors Questionnaire-Revised (SBQ-R) score | 4 ± 2 | 3 ± 0.8 | 0.022 |

* Linear Regression Analysis, controlling for gender; reported as mean ± standard deviation

† Patients with foot problems were from the Diabetic Foot Clinic (N=47 patients); patients without foot problems were from the Endocrinology Clinic (N=49 patients)

‡ NS = not significant, P ≥ 0.05

Table 3. Relation between diabetic foot problems and clinical factors

| Clinical factor | Number (percent) patients [†] | | P < ‡ | OR (95% CI) § | AOR (95% CI) § |
|--------------------------------------|--|---------|-------|---------------------|----------------------|
| | Yes | No | | | |
| Foot problems present † | | | | | |
| Diabetes | | | | | |
| Diabetic medication | 46 (98) | 42 (86) | NS | 7.67 (0.91 - 64.94) | 9.34 (1.07 - 81.58) |
| Diabetic diet | 30 (64) | 36 (73) | NS | 0.64 (0.27 - 1.52) | 0.69 (0.28 - 1.69) |
| Insulin | 28 (60) | 27 (55) | NS | 1.20 (0.53 - 2.70) | 1.32 (0.57 - 3.06) |
| Emotional problems or mental illness | | | | | |
| Suicide ideation or attempt | 15 (32) | 11 (22) | NS | 1.62 (0.65 - 4.02) | 1.83 (0.71 - 4.75) |
| Depression | 10 (21) | 0 (0) | NS | - | - |
| Professional treatment | 9 (19) | 5 (10) | NS | 2.08 (0.64 - 6.76) | 2.90 (0.815 - 10.33) |
| Suicide risk (current) | 4 (9) | 0 (0) | NS | - | - |
| Anxiety | 3 (6) | 4 (8) | NS | - | - |
| Hospitalization | 3 (6) | 0 (0) | NS | - | - |
| Medical comorbidities | | | | | |
| Eye disease | 26 (55) | 17 (35) | 0.05 | 2.33 (1.02 - 5.31) | 2.31 (0.99 - 5.40) |
| Cardiovascular disease | 16 (34) | 14 (29) | NS | 1.29 (0.54 - 3.06) | 1.48 (0.59 - 3.66) |
| Renal disease | 6 (13) | 5 (10) | NS | 1.29 (0.37 - 4.54) | 1.08 (0.30 - 3.95) |
| Alcohol dependence | 5 (11) | 2 (4) | NS | - | - |

[†] Patients with foot problems were from the Diabetic Foot Clinic (N=47 patients); patients without foot problems were from the Endocrinology Clinic (N=49 patients)

[‡] NS = not significant, P ≥ 0.05

[§] OR = odds ratio; AOR = adjusted odds ratio (controlled for gender); CI = confidence interval

^{||} "Suicide ideation or attempt" (current or previous) was defined as present when the respondent answered "yes" to the question, "Had you ever thought about or attempted killing yourself?"

"Suicide risk (current)," a measure of current risk for suicide, was defined as present for total SBQ-R score ≥ 7

Table 4. Outcome scores and mental health factors for caregivers of patients with diabetic foot problems (N= 21 caregivers)

A. Outcome scores for caregivers

| Outcome measure | Score * |
|--|---------|
| Age (yr) | 51 ± 14 |
| Short-Form 36 Health Survey (SF-36) | |
| SF-36 Component Summary scores | |
| SF-36 Physical Component Summary | 47 ± 12 |
| SF-36 Mental Component Summary | 46 ± 14 |
| SF-36 subscales | |
| SF-36 Physical Functioning | 72 ± 29 |
| SF-36 Social Functioning | 70 ± 26 |
| SF-36 Role Limitations due to Physical Health | 68 ± 42 |
| SF-36 Role Limitations due to Emotional Problems | 68 ± 44 |
| SF-36 Emotional Wellbeing | 68 ± 17 |
| SF-36 Pain | 63 ± 25 |
| SF-36 General Health | 63 ± 25 |
| SF-36 Energy/Fatigue | 55 ± 25 |
| Caregiver Burden Assessment | 36 ± 8 |

* Reported as mean ± standard deviation

B. Frequency of anxiety, depression, and alcohol abuse in caregivers

| Mental Health Factors | Number (percent) caregivers |
|---|-----------------------------|
| Anxiety (HADS anxiety subscale)* | |
| Normal (HADS anxiety, 0 to 7) | 8 (38) |
| Mild (HADS anxiety, 8 to 10) | 7 (33) |
| Moderate (HADS anxiety subscale, 11 to 14) | 4 (19) |
| Severe (HADS anxiety subscale, 15 to 21) | 2 (10) |
| Probable Anxiety (HADS anxiety, 11 to 21) † | 6 (29) |
| Dimension (HADS depression subscale)* | |
| Normal (HADS depression, 0 to 7) | 14 (67) |
| Mild (HADS depression, 8 to 10) | 4 (19) |
| Moderate (HADS depression, 11 to 14) | 3 (14) |
| Severe (HADS depression, 15 to 21) | 0 (0) |
| Probable Depression (HADS depression, 11 to 21) † | 3 (14) |
| Alcohol Use | |
| Hazardous Alcohol Use (AUDIT ≥ 10) ‡ | 1 (5) |
| Probable Alcohol Dependence (AUDIT 8 to 9) ‡ | 1 (5) |

* HADS (anxiety or depression): Hospital Anxiety and Depression Scale (anxiety or depression subscales)

† Individuals with probable anxiety or depression had moderate or severe HADS anxiety or depression subscale scores (11 to 21)

‡ AUDIT (Alcohol Use Disorder Identification Test)

Table 5. Relation between outcome scores for caregivers and patients with diabetic

| Caregiver : Patient scores | r * | P < ‡ |
|--|--------|-------|
| Caregiver burden | | |
| SF-36 Physical Component | -0.287 | NS |
| SF-36 Mental Component | 0.058 | NS |
| Diabetes Symptom Checklist Total | 0.193 | NS |
| Hospital Anxiety and Depression Scale (HADS) | | |
| SF-36 Physical Component | 0.038 | NS |
| SF-36 Mental Component | -0.074 | NS |
| Diabetes Symptom Checklist Total | 0.189 | NS |
| Alcohol Use Disorder Inventory Test (AUDIT) | | |
| SF-36 Physical Component Summary | 0.109 | NS |
| SF-36 Mental Component Summary | 0.468 | 0.032 |
| Diabetes Symptom Checklist Total | -0.034 | NS |

* r = Pearson correlation coefficient (caregivers matched to their respective patients)

‡ NS = not significant, P ≥ 0.05