The diabetic foot syndrome, diagnosis and consequences
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Chapter 3

Quality of life in patients with diabetic foot ulcers


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Abstract

Aim To compare Quality of Life (QoL) between diabetic patients with (former or present) and without foot ulcers.

Methods Two patient groups of comparable age, sex distribution, type distribution and duration of diabetes were studied. Fourteen patients with former or present, but clinically stable diabetic foot ulcers (DFUs) were examined. The control group were 24 patients not known to have DFUs. None of the participants had other diabetic complications or conditions that would potentially affect QoL. A diabetic foot risk score and QoL were assessed. QoL was scored with the RAND-36, the Barthel Score (ADL) and the Walking and Walking Stairs Questionnaire (WSQ).

Results Marked and significant differences were found in physical functioning (p<.001), social functioning (p<.05), physical role (p<.001) and health experience (p<.05) between the two groups with the RAND-36 and the four sub-scales of the WSQ (all p<.001). On all these scales, QoL was significantly poorer in the study group. A correlation was found between the risk score and QoL (physical functioning and physical role Spearman's r: -.66, -.56 and WSQ -.63, -.64, -.67 and -.71, respectively).

Discussion Presence or history of DFUs has a large impact on physical role, physical functioning and mobility. Physical impairments especially influenced QoL. Probably, QoL can be increased by providing attention that will enhance mobility and by giving advice about adaptations and special equipment.
3.1 Introduction

A disabling long-term complication of diabetes mellitus (DM) is the diabetic foot ulcer (DFU), caused by the presence of neuropathy, angiopathy and/or foot deformity. DFUs are common and it is estimated that they affect 15% of all individuals with DM during their lifetime.

Recently, three studies have been published on Quality of Life (QoL) in patients with DFUs. Rijken et al. studied the association of foot pain with several other parameters in the field of impairments, disabilities and quality of life in 29 patients, without controls. There were no patients with ulcers included. Several clinical variables and four unvalidated functional variables were assessed on fatigue, functional ability, walking distance and quality of life. In this study foot pain was related to fatigue, disability in walking and a lower level of quality of life.

Carrington et al. examined 13 diabetic patients with ulcers, 13 diabetic patients with a unilateral amputation and 26 controls. They assessed psychological adjustment to illness (PAIS), anxiety and depression (HAD) and life satisfaction (QoL ladder) and concluded that the psychological status of mobile amputees is better than that of the diabetic foot ulcer patients, but not as good as diabetic controls. They did not assess mobility.

Brod studied quality of life in diabetic patients with foot ulcers and their caregivers, by semi-structured discussions on the domains of social, psychological, physical and economic impact. Two groups participated, consisting of 14 patients and 11 caregivers without a control group. A negative impact on all domains of QoL was experienced because of the limitations in mobility caused by the ulcer. The conclusions were group findings and not based on individual assessments.

In conclusion, QoL in diabetic patients with foot ulcers is greatly influenced by physical (especially mobility), social and psychological impairments and disabilities. However, it is not clear which specific domains of QoL are most affected by DFUs.

The aim of this study was to evaluate the QoL of individual patients with present or former DFUs by comparing them to DM patients not known to have DFUs. QoL was defined as "the physical, social and psychological functioning of the patients as being influenced by disease or therapy", and was investigated using the sub-items mobility, activities of daily living and general QoL.
3.2 Patients and Methods

Patients
A cross-sectional patient-control study was performed on patients who were admitted to the Diabetes Department of the Rehabilitation Centre Beatrixoord between 1993 and 1997. Two groups were composed, a study group with patients with DM who had been hospitalised because of DFUs and a control group with patients without any foot problems, who had a diabetes duration of at least 1 year and had been admitted because of diabetic dysregulation. Patients were included if they were ambulatory at the time of the study. Exclusion criteria were: not diabetes related diseases (neurological or orthopaedic problems, cardiac or pulmonary problems), diabetes related problems (severe retinopathy, nephropathy, amputation above the level of the toes, unstable ulcers on the feet and symptomatic diabetic polyneuropathy) and cognitive or psychological problems.

During the period studied, 410 patients had been admitted to the department for various reasons (dysregulation, amputation, instruction and prevention, ulcers etc). To select patients and controls, the records were read by JT and checked by JWGM. Referring to the in- and exclusion criteria mentioned, 31 patients were initially selected for the study group and 53 for the control group. To get informed about the actual state of the patients, their general practitioners were contacted to check in- and exclusion criteria just before starting the study. This led to the exclusion of 12 patients of the study group and 20 of the control group, the reasons are described in Table 1.

Unfortunately 5 patients of the study group and 9 of the controls refused to take part in the study, resulting in 14 participants of the study group and 24 of the control group, as shown in Table 1.

Table 1: Patient selection

<table>
<thead>
<tr>
<th></th>
<th>Study group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>initially selected</td>
<td>31</td>
<td>53</td>
</tr>
<tr>
<td>check general practitioner</td>
<td>-12</td>
<td>-20</td>
</tr>
<tr>
<td>-5 died</td>
<td>5 comorbidity</td>
<td>15 comorbidity</td>
</tr>
<tr>
<td>-2 moved house</td>
<td></td>
<td>2 moved house</td>
</tr>
<tr>
<td>selected</td>
<td>19</td>
<td>33</td>
</tr>
<tr>
<td>-5 refused</td>
<td>-9</td>
<td>refused</td>
</tr>
<tr>
<td>participated</td>
<td>14</td>
<td>24</td>
</tr>
</tbody>
</table>
**Methods**

Risk profiles for diabetic foot complications were determined and QoL was assessed. The same observer examined all the patients (JT).

1 **Risk Profile**

The risk profile test from the Dutch consensus report on the diabetic foot was used to assess the risk of developing foot complications. This profile employs the known risk factors neuropathy, angiopathy, foot deformity and ulceration. Risk is graded from 0 (no risk) to 3 (highest risk). In grade 0, none of the 4 risk factors are present. In grade 1 the only risk factor present is neuropathy; in grade 2 neuropathy is present combined with angiopathy or foot deformity, while in grade 3 there is an existing or previous ulcer.

Neuropathy was diagnosed with Semmes Weinstein Monofilaments. Inability to feel the 10-gram filament at 4 plantar locations on the foot was defined as the presence of neuropathy. Angiopathy was defined as symptomatic arterial disease (Fontaine class 2 or higher) and/or absence of arterial foot pulsations. Foot deformity was defined as the presence of hallux valgus/rigidus, prominent bony parts or pressure areas. Ulceration was present when there were Wagner stage 1 to 5 abnormalities.

2 **Quality of Life**

QoL was assessed with the RAND-36, the Barthel Index and the Walking and Walking Stairs Questionnaire (WSQ).

2.1 RAND-36

The RAND-36 is a general questionnaire for measuring the influence of health on QoL (physical, psychological and social aspects). It has proven to be valid and reliable. There are 8 domains: physical and social functioning, emotional and physical impairment of role, mental health, vitality, pain and experienced health. For each domain there is a minimum score of 0 and a maximum score of 100. The higher the score, the better the quality of life.

2.2 Barthel Index

The Barthel index is a questionnaire on skills/disabilities of activities of daily living (ADL), which consists of 10 questions ranging from bowel and bladder control items to mobility and personal care items. The maximum score is 20 points (normal); less than 10 points means severely impaired ADL.

2.3 Walking and Walking Stairs Questionnaire

A reliable and valid preliminary version of the Walking and Walking Stairs Questionnaire (WSQ) was used to evaluate mobility. This questionnaire consists of 62 items, divided into 4 hierarchical scales: using stairs (16 items),
walking indoors (18 items), walking outdoors (20 items) and walking velocity (8 items). Each scale has a maximum of 100 points; the higher the score, the better the mobility.

**Statistics**

The statistical package SPSS-PC was used to compute descriptive statistics, Spearman's correlation coefficient and the Mann Whitney test. Significance level: $p < .05$.

Differences on item level were computed by calculating the Effect Size (EF) (t-tests for means), defined as $^{18}$:

$$
\frac{\text{Mean}_A - \text{Mean}_B}{\text{Sp}}
$$

where $\text{Sp} = \sqrt{\frac{SS_A + SS_B}{(N_A - 1) + (N_B - 1)}}$

$\text{Mean}_A$ = mean of group A, $\text{Mean}_B$ = mean of group B, $\text{Sp}$ = Pooled standard deviation, $SS_A$ = sum of squares of group A, $SS_B$ = sum of squares of group B, $N_A$ = total of group A, $N_B$ = total of group B

*Interpretation of the ES: no or trivial effect < 0.20; small effect = 0.20 – 0.49; medium effect = 0.50 – 0.79; large effect = > 0.79.$

### 3.3 Results

Patient characteristics are shown in Table 2. The two groups were found to be comparable regarding age, sex distribution, known duration and type of DM (no significant differences).

The patients selected initially for the study (n=31) and control (n=53) groups were compared to the patients who actually participated in the two groups on the items sex distribution, age, known duration and type of diabetes. In the participating control group, the mean duration of diabetes was significantly longer than that in the excluded group. In the study group with foot ulcers there were significantly more men than in the group of excluded patients. No other significant differences were found between the subjects selected initially and those who actually participated.
Table 2: Patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>study group</th>
<th>control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>14</td>
<td>24</td>
</tr>
<tr>
<td>Sex (male : female)</td>
<td>10 : 4</td>
<td>13 : 11</td>
</tr>
<tr>
<td>Age (years) (mean (SD))</td>
<td>62.8 (13.8)</td>
<td>58.7 (13.8)</td>
</tr>
<tr>
<td>Duration DM (years) (mean (SD))</td>
<td>11.3 (10.8)</td>
<td>12.8 (12.0)</td>
</tr>
<tr>
<td>Type of DM (1 : 2)</td>
<td>3 : 11</td>
<td>10 : 14</td>
</tr>
</tbody>
</table>

1 Risk Profile

A significant difference was found in the risk profile between the two groups (p-value < .0001). The study group had a higher risk of developing foot complications (mean score of 3.00; SD 0.0) than the control group (mean score 0.58; SD 1.10).

2 Quality of Life

2.1 RAND-36

Patients in the study group scored both relevantly and significantly lower (experienced a lower QoL) than the controls on the domains physical functioning, social functioning, physical role and health experience, as shown in Table 3.

On an item level, the most relevant and significant differences (Effect Size) were present for producing moderate (1.4) and heavy physical effort (1.8), walking distances of more than 500 metres (1.2) and using stairs (1.4). The patients also experienced problems with working, especially a lower productivity (1.1). There were no differences in complaints about pain.
Table 3: RAND-36

<table>
<thead>
<tr>
<th></th>
<th>study group mean ± SD</th>
<th>control group mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical functioning</td>
<td>52.1 ± 31.7 **</td>
<td>90.0 ± 15.9</td>
</tr>
<tr>
<td>Social functioning</td>
<td>80.4 ± 27.6 *</td>
<td>96.4 ± 7.8</td>
</tr>
<tr>
<td>Physical role</td>
<td>42.9 ± 34.6 **</td>
<td>83.3 ± 29.2</td>
</tr>
<tr>
<td>Emotional role</td>
<td>92.3 ± 14.6 ns</td>
<td>84.7 ± 31.1</td>
</tr>
<tr>
<td>Mental health</td>
<td>75.7 ± 19.5 ns</td>
<td>77.2 ± 15.6</td>
</tr>
<tr>
<td>Vitality</td>
<td>71.2 ± 16.0 ns</td>
<td>72.3 ± 15.9</td>
</tr>
<tr>
<td>Pain</td>
<td>68.7 ± 28.4 ns</td>
<td>76.2 ± 14.3</td>
</tr>
<tr>
<td>Health experience</td>
<td>51.1 ± 23.1 *</td>
<td>66.4 ± 14.9</td>
</tr>
</tbody>
</table>

* p < .05, ** p < .001, ns not significant

2.2 Barthel Index

The study group scored 19.2 points (SD 1.5), and the control group scored 19.8 points (SD 0.5) (not significant).

2.3 WSQ

In all four categories, the study group had significantly lower scores than the control group, which means that the patients with foot ulceration experienced more disabilities on mobility than the controls. The study group scored 80.0 points for using stairs versus 96.7 points in the controls (p<.001); for walking indoors the scores were 54.8 and 90.3 (p<.001), respectively. For walking outdoors, the study group scored 54.5 points versus 87.0 in the controls (p<.001), while for walking velocity, these scores were 51.8 and 89.1 points (p<.001) respectively. On the level of individual items, the most relevant and significant differences (Effect Size) between the two groups were observed for using stairs both up and down (more effort (1.4), more time (1.1)) and for walking small distances in (1.1) and outdoors (1.5).
3 Relation between Risk Profile and Quality of Life

In Table 4 the significant correlations between risk profile and QoL are shown for the entire study population. The severity of the risk profile was significantly related to QoL on all the scales of the WSQ and on the physical functioning and impairment of physical role domains of the RAND-36. There was no significant correlation between risk profile and social functioning, self-perceived health and the other domains of the RAND-36 or the Barthel Index.

Table 4: Relation between Risk Profile and Quality of Life (Spearman's r)

<table>
<thead>
<tr>
<th>RAND-36</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical functioning</td>
<td>-.66*</td>
</tr>
<tr>
<td>Physical role</td>
<td>-.56*</td>
</tr>
<tr>
<td>WSQ</td>
<td></td>
</tr>
<tr>
<td>Using stairs</td>
<td>-.64*</td>
</tr>
<tr>
<td>Walking indoors</td>
<td>-.67*</td>
</tr>
<tr>
<td>Walking outdoors</td>
<td>-.71*</td>
</tr>
<tr>
<td>Walking velocity</td>
<td>-.63*</td>
</tr>
</tbody>
</table>

Only the significant correlations are shown, *p < .001

3.4 Discussion

This study addressed the interrelations between physical, social and psychological dimensions of QoL in DM patients. The obvious physical limitations of patients with DFUs, reflected by the WSQ and by the physical functioning domain of the RAND-36, greatly affected QoL, and were probably causing limitations in social functioning. On an individual level, there were highly relevant and significant differences for producing moderate and heavy physical effort, walking in and outdoors, using the stairs both up and down (more effort, more time) and working (lower production). In contrast with the results reported by Rijken³, we did not find a relation between having a DFU and complaints of pain. Whereas other studies found more psychological complaints in patients with foot
disease, this was not found in our study for the item psychological functioning. Very few of our patients had an acute phase of foot disease. Perhaps they had learnt to accept their disabilities and had found a new psychological balance.

In conclusion, an existing or previous ulcer has an obvious negative influence on the physical and social aspects of quality of life in patients with diabetes mellitus. This is in line with the findings of earlier studies.

In a general population of patients with diabetes, psychological and social aspects contributed to the overall QoL, while physical complaints had less influence. This suggests that having a diabetic foot changes the spectrum of factors that influence QoL, with an increase in the impact of limitations related to physical functioning and mobility.

The population studied is not very large and selected at a specific institution. Therefore generalisation might be limited. However, the influence of physical disabilities on quality of life, by decreasing mobility of patients, is very significant and relevant for workers in the field of rehabilitation.

Despite the fact that the clinical situation was stable in all the patients with DFUs at the time of the study, their mobility and physical functioning were limited. The significant correlation between risk profile and QoL suggests that the decrease in physical functioning and mobility in the patients with foot disease was caused by physical restrictions due to the DFU itself, or due to signs and symptoms of risk factors, such as neuropathy or angiopathy. This decrease might have been further strengthened by restrictions imposed by preventive patient education (for example patients are advised to walk only short distances). Our data emphasize the necessity to pay attention to mobility in patients with clinical stable foot ulcers.

In conclusion, diabetic foot ulcers have a large impact on quality of life, especially on physical functioning, social functioning and mobility. Physical disabilities, due to the presence of risk factors or ulcers, are responsible for this decrease in quality of life.

In our opinion, combining diabetic foot prevention programmes with a rehabilitation programme for patients with DFUs can increase quality of life. Such a programme might provide physical training for these patients (to enhance their condition and decrease disabilities), increase awareness about adaptations and equipment to enhance mobility (prescription of special footwear, walking aids or electric trikes and stair-lifts) and offer vocational therapy.

This study was sponsored by a grant from the Vereniging Beatrixoord, Haren, the Netherlands

32 - The diabetic foot syndrome
3.5 References


34 - The diabetic foot syndrome