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Prevalence and correlates of pain in fatigued patients with type 1 diabetes

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ABSTRACT

Objective: To investigate the prevalence, location and severity of pain, as well as its association with psychosocial and clinical variables and its impact on functional impairment in fatigued patients with type 1 diabetes.
Methods: 120 severely fatigued patients with type 1 diabetes completed questionnaires on pain (McGill Pain Questionnaire, MPQ; Short Form Health Survey subscale bodily pain, SF-36), fatigue severity (Checklist Individual Strength subscale fatigue severity, CIS), depressive symptoms (Beck Depression Inventory Primary Care, BDI-PC) and functional impairment (Sickness Impact Profile-8, SIP-8). HbA1c and diabetes-related complications were assessed, and physical activity was measured using actigraphy.
Results: 72% of patients reported pain. Muscle, joint and back pain, and headache were most common. Patients with pain were more often female (69 vs. 44%, $p = 0.013$), reported more complications (mean number: 0.7 vs. 0.3, $p = 0.009$) and scored higher on the BDI-PC measuring depressive symptoms (mean score: 3.8 vs. 2.3, $p = 0.002$), compared to patients without pain. Pain was associated with diabetes duration, the number of complications, fatigue severity, depressive symptoms and functional impairment, but not with HbA1c or physical activity. Of patients with pain, 26% reported a high impact of pain. Both pain ($\beta = -0.31$, $t(117) = -3.39$, $p = 0.001$) and fatigue severity ($\beta = 0.18$, $t(117) = 2.04$, $p = 0.044$) contributed to functional impairment.
Conclusion: Pain was highly prevalent in fatigued patients with type 1 diabetes, although pain impact and severity were relatively low, and the location of some pain symptoms was similar to the location of those in the general population. As pain is related to fatigue and contributes independently to functional impairment, fatigue interventions should address pain.

1. Introduction

Numerous complications and conditions associated with diabetes mellitus are known to cause pain. For example, painful peripheral neuropathy is a microvascular complication affecting 16% of patients with type 1 and type 2 diabetes [1]. Painful co-morbidities such as entrapment neuropathy e.g. carpal tunnel syndrome and trigger fingers [2,3], or less frequently described rheumatic manifestations in diabetes such as cheiroarthropathy, are common and associated with pain [4]. Pain in diabetes is not only present in relation to the complications of the disease. A recently published study investigating the prevalence of pain in a sample of 11,689 patients with primarily type 2 diabetes found that approximately 58% of all participants reported moderate or severe pain [5], demonstrating that pain in diabetes is highly prevalent. The impact of pain in diabetes is substantial as patients with diabetes and co-morbid chronic pain report a lower quality of life [6] and poorer diabetes self-management [7].

Recent research has shown that pain is associated with severe and chronic fatigue, both in type 1 [8,9] and type 2 diabetes [10]. Chronic fatigue has been found to be a highly prevalent and disturbing symptom in patients with type 1 diabetes [8]. One study examining persistently fatigued patients with type 1 diabetes demonstrated that pain is a predictor of severe fatigue [9], which suggests the importance of addressing pain in the management of fatigue in patients with type 1 diabetes. Recently, a treatment protocol for fatigue in type 1 diabetes has been developed that addresses pain as a perpetuating factor of fatigue [11]. Although a relationship between pain and fatigue has been demonstrated, and pain has been shown to have an adverse impact on patients' health, we have not yet identified the scope of the problem; specifically,

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the prevalence and severity of pain, and its associations with psychosocial and clinical variables in fatigued patients with type 1 diabetes.

The present study investigated (1) the prevalence, location and severity of pain in fatigued patients with type 1 diabetes, as well as (2) the differences between patients with and without pain in this group. As review of the literature has shown that pain is associated with lower levels of physical activity [12], more depressive symptoms [13], and fatigue [8], we (3) investigated the relationship between pain and these variables. We also studied the relationship between pain and glycemic control (i.e. HbA1c = glycated hemoglobin) and diabetes complications. To determine if pain and fatigue contribute independently to functional impairment, we (4) analyzed the extent to which functional impairment was predicted by pain and fatigue severity.

2. Method

2.1. Participants and procedure

The present study relied on the baseline data collected for a randomized controlled trial testing the efficacy of a cognitive behavioral therapy for chronic fatigue in type 1 diabetes. Details of this study have been published [11]. Briefly, the objectives of this trial were to investigate whether cognitive behavioral therapy aimed at changing behaviors and beliefs thought to maintain fatigue reduces fatigue severity in chronically fatigued patients with type 1 diabetes, compared to a waitlist control condition. Patients were recruited between February 2014 and March 2016 from hospitals in the south-east of the Netherlands, and via social media. Out of 1816 patients who were screened for the study, 120 patients between 18 and 70 years old who were diagnosed with type 1 diabetes of at least one year duration, participated in the study. Type 1 diabetes diagnoses were based on clinical criteria; symptoms and signs documenting absolute insulin deficiency, often combined with C-peptide negativity and anti-GAD antibody positivity. At the time of the study, all patients were receiving treatment consisting of multiple daily insulin injections or insulin pump therapy. All patients were severely fatigued - as defined by a score of ≥35 on the Checklist Individual Strength (CIS), subscale fatigue severity [14] - and fatigue had been present for at least six months. Exclusion criteria were (1) moderate to severe renal failure, (2) blindness or severe visual impairment, (3) medical history of congestive heart failure, (4) medical history of a stroke in the past five years, (5) body mass index of 40 or higher, (6) wheelchair-dependent, and (7) other concurrent psychiatric or medical co-morbidity that could explain the fatigue. All patients gave written consent for participation, and the study was approved by each hospital's local ethics committee.

2.2. Measures

2.2.1. Pain – prevalence, severity, location and impact

The prevalence and location of pain were assessed using the McGill Pain Questionnaire (MPQ) [15]. The first question of the MPQ, "Do you experience pain?," measures the presence of pain. Patients who answered "yes" on this question completed the other two parts of the MPQ questionnaire: a figure to indicate the location of the pain, and the visual analogue scale (VAS) to measure the magnitude of pain at the current moment. The VAS scale ranges from 0 cm (no pain) to 10 cm (the most severe pain). The MPQ is a reliable instrument [16].

The Short Form Health Survey (SF-36), subscale bodily pain was used to assess pain severity and impact over the last four weeks [17]. The scale ranges from 0 to 100, with higher scores indicating less severe, lower impact pain. A dichotomous variable, "low and high impact of pain," was defined with a cut-off of 54 on the SF-36, subscale bodily pain, i.e. the mean minus one standard deviation of the general population. Scores of >54 indicated low impact of pain, and scores of ≤54 indicated high impact [18].

Participants used a paper diary to assess daily observed pain (DOP) over twelve consecutive days. Four times a day, patients reported the severity of pain on a scale of 0 (no pain) to 4 (severe pain). The twelve DOP scores were averaged into one score ranging from 0 to 16 [19]. Using the same diary, patients reported the presence of any headache, muscle pain, sore throat, joint pain, stomach ache and or back pain, four times per day (0 = not present, 1 = present). Parts of the diary that have been used to assess daily observed fatigue in other studies have demonstrated good reliability and validity [20,21]. We investigated the reliability and validity of the DOP in our sample, and found a good split-half reliability measured by the correlation between scores of week one and week two of the diary ($r = 0.87$, $p < 0.001$) and a good convergent validity measured by the correlation between the DOP and other pain measures, i.e. the VAS current pain ($r = 0.703$ $p < 0.001$) and the SF-36 subscale bodily pain ($r = -0.653$ $p < 0.001$). A previous study has shown that the DOP is sensitive to change and can detect the effects of behavioral interventions [19]. To increase compliance, patients received a detailed explanation of how to use the diary, and the 12-day period was linked to the assessment of an actigraphy system to measure the level of physical activity.

2.2.2. Fatigue severity

Fatigue severity was assessed with the Checklist Individual Strength (CIS), subscale fatigue severity [14]. The CIS consists of four subscales; the subscale fatigue severity contains eight items with scores ranging from 8 to 56. Higher scores indicate higher levels of fatigue. The items are scored on a Likert scale from (1) "Yes, that is true" to (7) "No, that is not true". The CIS has excellent psychometric properties with a Cronbach's alpha coefficient of 0.90 and a split-half reliability coefficient of 0.92 [14].

2.2.3. Physical activity

The level of physical activity was assessed with an actigraphy system using the actometer (©Actilog V3.0); a small, light motion-sensing device manufactured by the Department of Electronics and Instrumental Services of the Radboud University Nijmegen (43x29x16mm; 41 g) [22]. The actometer detects accelerations by a piezoelectric sensor, storing those that meet a predefined threshold for physical activity into an internal memory. Each second, a microcontroller reads and resets the actometer's counter. The integration counter is set to produce a physical activity score every 5 min [22,23]. Patients wore the actometer around their ankle for twelve consecutive days, after which the data was uploaded into a computer software program. Mean scores from the five minute intervals were used to determine the level of physical activity, and a mean activity score over the 12 consecutive days was calculated.

Additionally, we differentiated between three types of physical activity: (1) pervasively passive activity levels, (2) relatively active activity levels and (3) pervasively active activity levels. Patients whose average daily physical activity score remained below a mean reference value of 66 [23] at 11 or 12 days were defined as pervasively passive. Patients who scored above the reference value at two to ten days were defined as relatively active and patients who scored above the reference value at 11 or 12 days were defined as pervasively active.

2.2.4. Depressive symptoms

The Beck Depression Inventory Primary Care (BDI-PC) was used to assess depressive symptoms [24]. The BDI-PC consists of seven items scored on a four-point Likert Scale. Scores range from 0 to 21, with higher scores indicating more depressive symptoms.

2.2.5. Clinical variables

HbA1c was measured by high-performance liquid chromatography (Menarini Diagnostics, Neuss, Germany). HbA1c values were obtained from medical records whenever possible. Patients reported the presence of seven common *diabetes-related complications*: retinopathy,