PAIN® 155 (2014) 629–634

PAIN®

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Health-related quality of life in 975 patients with complex regional pain syndrome type 1

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article

ARTICLE INFO

Article history:
Received 29 October 2013
Received in revised form 5 December 2013
Accepted 10 December 2013

Keywords:
Quality of life (QoL)
Complex regional pain syndrome (CRPS)
Physical functioning
Pain

ABSTRACT

There are limited data available on health-related quality of life (QoL) in patients with complex regional pain syndrome (CRPS). In the present study we examined QoL in 975 CRPS patients attending 6 different clinics in the Netherlands. QoL was assessed using the MOS 36-Item Short-Form Health Survey (SF-36) with the Mental Health Summary Score (MHS) and the Physical Health Summary Score (PHS) as dependent variables. The influences of gender, type of affected limb, disease duration, pain scores, CRPS severity and set of diagnostic criteria used were investigated. We found the lowest scores of QoL in the physical domains of the SF-36, with lower-limb CRPS patients reporting poorer results than patients with an affected upper limb. Influence of gender on QoL was not observed, and correlations of QoL with disease duration and the CRPS severity score were weak. Pain correlated moderately with QoL. In addition, patients fulfilling stricter diagnostic criteria (ie, the Budapest criteria) had lower QoL scores than patients fulfilling less strict criteria (ie, the Orlando criteria). We conclude that loss of QoL in CRPS patients is due mainly to reduced physical health. A comparison with data available from the literature shows that CRPS patients generally report poorer QoL than patients with other chronic pain conditions, particularly in the physical domains. Pain correlated moderately with QoL and therefore deserves ongoing attention by physicians. Finally, patients meeting the diagnostic Budapest criteria have lower QoL scores than patients meeting the Orlando criteria, highlighting the impact of different sets of criteria on population characteristics.

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1. Introduction

Complex regional pain syndrome (CRPS) is a condition that may have a profound effect on daily life, often rendering patients invalids for many years [7,8]. Typically, CRPS develops after a trauma to 1 of the limbs, but occasionally it progresses to other limbs [17,30,40]. In the acute phase, patients report intense pains accompanied by autonomic, trophic, and motor disturbances of the affected limb [18]. A considerable number of patients develop a chronic course in which autonomic signs are usually less pronounced, and pain, along with sensory and motor disturbances, predominates [34]. The incidence ranges from 5.5 to 26.2 per 100,000 person-years [22,33], with the highest incidence rates occurring between 61 and 70 years and with women being affected 3 to 4 times more often than men [22].

Although, in recent years, considerable progress has been made in the understanding of the pathophysiology of CRPS [18], this has not translated into an effective therapy from which all patients benefit; a large group of patients experience incomplete recovery and are confronted with long-term disability and partial or complete inability to resume their former jobs [4,28].

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http://dx.doi.org/10.1016/j.pain.2013.12.017

It is self-evident that such disease consequences may have a grave impact on the lives of CRPS patients. Indeed, previous studies on quality of life (QoL) in CRPS patients reported high levels of disability and continuing pain and motor disturbances. However, these studies were usually performed in small samples [6,14,34,39] or involved patients in trials who had to meet certain eligibility criteria, which affected the generalizability of the findings [29,39]. In the present study, we therefore analysed the QoL data of almost 1000 Dutch patients collected over the past 10 years in 5 major CRPS clinics. Specifically, we studied the influence of gender, type of involved extremity (upper or lower), disease duration, and pain on perceived QoL.

In addition, we studied the influence of diagnostic criteria on QoL, as the profile of signs and symptoms differs according to the diagnostic criteria that the patient fulfils [25], whereas QoL may vary with perceived complaints. Finally, we included the CRPS Severity Score, a recently developed severity index that counts the number of the patient's signs and symptoms, to study the relationship between the number of occurring signs and symptoms and perceived QoL [10].

2. Methods

2.1. Participants

Patients were recruited from 5 pain clinics and 1 department of neurology of university hospitals participating in Trauma RElated Neuronal Dysfunction (TREND) a Dutch knowledge consortium that integrates research on CRPS (www.trendconsortium.nl). All patients were 18 years or older; fulfilled the diagnostic criteria for CRPS adopted at the 1993 consensus conference ('Orlando criteria') [21], the Budapest clinical criteria (Bdp-c), or the Budapest research criteria (Bdp-r) [11]; and did not have any other conditions that could account for the signs and symptoms encountered. Exclusion was made based on the presence of dementia, cognitive impairment, or any other factor resulting in an inability to understand and to complete self-assessment questionnaires.

2.2. Assessment methods and measurement instruments

Methods of examining patients were standardised across centres by the use of a universally applied measurement protocol and 3-monthly plenary training sessions. Signs and symptoms were recorded on a standard score sheet. Patients also completed a set of questionnaires. All data were stored in a NEN-7511 certified, central, Web-based data management system (ProMISe). Written informed consent was obtained from all participants; procedures were performed in accordance with the Declaration of Helsinki; and the protocol was approved by the medical ethical committees of all participating centres.

We classified patients into 3 groups to examine the influence of the involved limb on QoL; 1 upper limb affected, 1 lower limb affected, and more than 1 limb affected. To evaluate the influence of diagnostic criteria on perceived QoL, we allocated patients to the most strict criterion that they met (Orlando < Bdp-c < Bdp-r).

The Dutch version of the MOS 36-Item Short-Form Health Survey (SF-36) was used as outcome measure of QoL in this study [43]. This generic questionnaire consists of 8 health domains: 1) limitations in Physical Functioning; 2) limitations in usual role activities because of physical problems (Role-Physical); 3) Bodily Pain; 4) General Health perceptions; 5) Vitality; 6) limitations in Social Functioning because of physical problems; 7) limitations in usual role activities because of emotional problems (Role-Emotional); and 8) general Mental Health. For the main analysis, the Physical Health sum Score (PHS) (mean of domains 1–4) and the Mental Health sum Score (MHS) (mean of domains 5–8) were used. Scores are presented as percentages (0–100), with higher scores indicating better QoL.

Pain was quantified using the pain rating index of the McGill Pain Questionnaire [20] and the Numeric Rating Scale. The McGill Pain Questionnaire consists of 20 categories of 3 or 4 rank-ordered words that evaluate different aspects of pain (range, 0–63, with higher scores indicating more pain). For the Numeric Rating Scale score, we asked patients to rate the average pain intensity of the previous week on a scale from 0 to 10, with 10 reflecting the worst pain imaginable.

As an indicator of severity of CRPS, we used the CRPS Severity Score, a checklist consisting of 17 CRPS-associated signs and symptoms [10].

The following questionnaires were not used in the primary analyses of this study, but were included to provide a broader perspective on the mental and physical health of patients: The Hospital Anxiety and Depression Scale [44]; the Radboud Skills Questionnaire [24]; and the Questionnaires on Walking and Rising [31,32]. The Hospital Anxiety and Depression Scale measures the presence and severity of mood disorders (range 0–42, with higher scores indicating more severe anxiety or depression); in the present study, the mean Anxiety and Depression scores of this questionnaire were used. The Radboud Skills Questionnaire measures the difficulty that patients with an affected upper limb perceive when performing manual activities of daily life (range, 1–5, with higher scores indicating worse functioning). The Questionnaires on Walking and Rising measures limitations in walking and rising in patients with an affected lower limb (range, 0–30; summary score of 'walking inside', 'walking outside', and 'rising', with higher scores indicating worse functioning; because of the different number of items in these 3 scales, all scores were first transformed to a scale of 0 to 10 and then summed).

2.3. Statistical analyses

All statistical analyses were performed with IBM SPSS Statistics version 20 (IBM Corporation).

Normality of the data was checked by inspecting histograms of frequency distributions, normal probability plots, residual scatter plots, and the Kolmogorov–Smirnov test. Data were considered statistical significant when P values were less than .05 and corrected for multiple comparisons (Bonferroni) when multiple analyses were performed within the same research question.

For the difference in QoL scores between sexes, the independent t test was used, and an analysis of variance (ANOVA) was carried out to examine the influence of type of limb or CRPS criteria on QoL. The Pearson correlation coefficient was calculated to examine the correlation between QoL and age, disease duration, symptom severity, or pain. Coefficients of 0.70 or higher were classified as strong, those 0.30 to 0.69 as moderate, and those less than 0.30 as weak [15]. Data are presented as mean scores ± standard deviations (SD).

3. Results

3.1. Study participants

A total of 975 patients (age, 46.8 ± 14.3 years; 817 female) were included in the analysis, of whom 374 (38.4%) had an affected upper limb and 408 (41.8%) had an affected lower limb (Table 1). In 193 patients (19.8%), more than 1 limb was affected: 28 patients (2.8%) had 2 affected upper limbs, 25 (2.6%) had 2 affected lower limbs, and the remaining 140 (14.4%) had a combination of an affected upper and lower limb ($n = 53$; 5.4%) or more than 2 affected

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