

Clinical Study

Pain and Its Consequences in Quality of Life: A Study with WHOQOL-Bref in Leprosy Patients with Neuropathic Pain

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Chronic neuropathic pain emerges as a challenge in the treatment of leprosy patients after multidrug therapy discharge. The aim of this study was to determine the quality of life and its repercussions in leprosy patients with chronic pain. We studied male and female patients with chronic neuropathic pain in the last year. Neuropathic pain was confirmed using *Douleur Neuropathique en 4* (DN4) and its intensity evaluated by visual analogue scale (VAS). A general questionnaire was applied to evaluate quality of life (WHOQOL-bref). Statistical analyses were composed by descriptive and central tendency. Spearman correlation was used to identify the relation between pain intensity, quality of life domains, and facets. Multiple linear regressions were performed to verify the influence of pain intensity on each facet. Neuropathic pain patients scored worst in physical and environment domains. The low facets were related to pain and discomfort, thinking and concentration, sexual activity, and recreation opportunities. Pain intensity has a high negative influence on psychological domain and recreation opportunities. These findings should contribute to the development of rehabilitation programs considering patients needs to improve their quality of life and true social reintegration.

1. Introduction

Leprosy is a chronic granulomatous infection, principally affecting the skin and peripheral nerves, caused by *Mycobacterium leprae* [1]. Neuropathic pain is a common complaint due to leprosy-induced neuritis, whether spontaneous or upon palpation of a nerve trunk (silent neuritis), which may be associated with impairment of function [1–6]. In addition to not knowing the precise number of patients who develop disabilities after multidrug therapy (MDT), chronic pain arises as a new disabling condition during or after bacteriological treatment [7–12].

The International Association for the Study of Pain (IASP) defined pain as an “unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.” Neuropathic pain

is defined as “pain arising as a direct consequence of a lesion or disease affecting the somatosensory system [13, 14]. According to new theories, pain is a subjective experience influenced by a combination of cortical mechanisms [15].

It is widely believed that pain has a profound effect on a person’s quality of life (QoL). Considering that leprosy causes sensory loss, it was expected that patients do not experience pain, and it has not been well studied in leprosy [10]. Therefore, a lack of knowledge persists regarding chronic pain in leprosy [12]. The aim of this study was to examine the repercussions of chronic pain in leprosy patients’ QoL.

2. Methods

The study was approved by the Research Ethics Committee of the Hospital Clementino Fraga Filho of the Federal University

of Rio de Janeiro (HUCFF/UFRJ). Informed, written consent was obtained from the participants in the study before inclusion, using a standard consent form. No financial incentives were given.

This cross-sectional study was carried out in a referral hospital in Rio de Janeiro, Brazil, between July 2011 and August 2012. Patients were invited after discharge of MDT, over 18 years of age, with pain at the time of the interview that had persisted for at least six months. Patients with a cognitive deficit, doubtful diagnosis, leprosy reactions, diabetic neuropathy, traumatic nerve injury, renal or cardiac insufficiency, plantar ulcer, or drop foot were excluded.

Subjects' disability was classified in accordance with World Health Organization (WHO) disability criteria as 0, 1, or 2: Grade 0 for no problem related to leprosy, Grade 1 for loss of sensitivity, and Grade 2 for deficiencies such as lagophthalmos and/or ectropion, trichiasis, central corneal opacity, visual acuity (the patient is unable to count fingers at a distance of 6 metres), trophic lesions and/or traumatic lesions, mobile claw hand, clawed toes, reabsorption, wrist drop, foot drop, and contracture of the ankle [1, 3].

Neuropathic pain was confirmed by neuroanatomical pain distribution and neurological examination demonstrating positive or negative sensory or motor loss in the innervated areas of the affected peripheral nerves [10]. After clinical examination, patients completed the "Douleur neuropathique en 4 questions" (DN4) which serves to identify patients with neuropathic pain and consists of 7 items related to symptoms and 3 related to clinical examination. The DN4 is easy to score, and a total score of 4 out of 10 or higher suggests neuropathic pain [16, 17]. The DN4 has been used in large epidemiological studies to estimate the prevalence of neuropathic pain.

Pain intensity was assessed using a visual analogic scale (VAS) ruler. On the front side of the ruler one end was labelled "no pain" and the other "worst pain possible." On the back of the instrument there was a 10.0-cm-long horizontal line. Patients were asked to mark their average pain intensity during the previous month [18].

Quality of life information was collected using the instrument WHOQOL-bref, developed under the coordination of the World Health Organization Quality of Life Group (WHO-QOL Group) from the World Health Organization (WHO). This is a self-administered generic questionnaire, composed of 26 questions, where two are general questions and the remaining 24 encompass four domains: physical, psychological, and social relations and environment. It emphasizes subjective responses rather than objective life conditions, with assessments made based on the preceding two weeks. The response options range from 1 (very dissatisfied/very poor) to 5 (very satisfied/very good). Three questions (pain and discomfort, dependence on medicinal substances, and medical treatment and negative feelings) are scored in an inverse manner [19, 20].

The final scores of overall QoL and of each domain are calculated by a syntax that considers the answers for each question that composes the domain, resulting in final scores on a scale from 4 to 20 [19, 20]. The average score for each facet was calculated and subsequently the average

TABLE 1: Sociodemographic and clinical profile characteristics of participants.

Variables	<i>n</i> (21)	% (100)
<i>Sociodemographic</i>		
Gender		
Male	13	61.9
Female	8	38.1
Level of education		
Elementary	15	71.4
Secondary	6	28.6
Personal income		
≤minimum wage	14	66.7
>minimum wage	7	33.3
<i>Clinical</i>		
Operational classification		
Paucibacillary	4	19.0
Multibacillary	17	81.0
WHO disability grade		
1	8	38.1
2	13	61.9

score for each of the 4 domains, as well as the overall QoL. Both descriptive statistics and evaluations of central tendency were employed. Spearman's correlation coefficient was used to identify relationships between pain intensity, QoL domains, and facets. Afterwards, multiple linear regressions were performed to verify the influence of pain intensity in each facet. The internal consistency of the WHOQOL-bref for questions and domains was evaluated using Cronbach's reliability coefficient. Data analyses were performed using the Statistical Package for Social Science (SPSS) version 13.0 with significance level set at $P \leq 0.05$.

3. Results

3.1. Sample Profile. Over the time period of the study, we identified 33 leprosy patients with pain. Twenty-one had neuropathic pain (66.3%) according to the clinical definition and DN4 questionnaire. This sample size was adequate because we estimated that we should detect 20 patients with neuropathic pain.

The sample consisted of 13 men and 8 women, with a mean age of 47.7 years (SD = 9.4). Fifteen (71.4%) subjects had fundamental and 8 (28.6%) had a secondary level of education. Considering personal income, 14 (66.7%) receive less than one salary and 7 (33.3%) receive more than one salary per month. With respect to clinical profile, 17 (81%) patients were classified as multibacillary and 4 (19%) as paucibacillary. The mean period of MDT discharge was 7.6 years (SD = 5.6). All patients had disabilities: eight (38.1%) with grade 1 and 13 with grade 2 (61.9%) (Table 1).

The visual analogue scale (VAS) ranges from 0 = no pain to 10 = worst possible pain. The results of VAS indicated that pain intensity ranged from 4.0 cm to 10.0 cm with mean 7.1 cm (SD = 2.9). Differences in pain intensity with respect

TABLE 2: Mean scores and 95% confidence interval of the facets of WHOQOL-bref.

Domain	Facet	Mean	95% CI
Physical	Activities of daily living	2.8	2.3–3.2
	Dependence on medicinal substances	3.4	2.8–4.0
	Energy and fatigue	2.7	2.3–3.1
	Mobility	3.1	2.4–3.8
	Pain and discomfort	3.5	2.9–4.1
	Sleep and rest	2.3	1.7–3.0
	Work capacity	2.4	1.7–3.1
Psychological	Bodily image and appearance	3.1	2.5–3.7
	Negative feelings	2.9	2.2–3.6
	Positive feelings	3.1	2.5–3.7
	Self-esteem	3.3	2.7–3.9
	Spirituality/religion	4.0	3.5–4.4
	Thinking, learning	3.1	2.6–3.6
	Bodily image and appearance	3.6	3.0–4.2
Social relationships	Personal relationships	3.6	2.9–4.2
	Social support	4.0	3.5–4.6
	Sexual activity	3.0	2.4–3.7
Environment	Financial resources	2.2	1.7–2.8
	Freedom and physical safety	2.7	2.0–3.4
	Health and social care: accessibility	3.8	3.2–4.4
	Home environment	3.4	2.6–4.1
	New information and skills	3.1	2.6–3.6
	Recreation/leisure activities	2.7	2.0–3.4
	Physical environment	3.4	2.9–3.9
	Transport	3.0	2.4–3.6

to gender were minimal, 6.9 cm (SD = 3.2) in male versus 7.0 cm (SD = 2.6) in female patients. With respect to level of education, subjects with fundamental schooling scored 7.0 cm (SD = 2.7) and those with elementary schooling scored 7.3 cm (SD = 3.8). Patients with less than 1 wage per month had a mean pain intensity of 7.0 cm (SD = 3.3); with more than 1 wage the mean was 7.3 cm (SD = 2.1). In terms of clinical profile, patients classified as multibacillary had a mean pain intensity of 6.8 cm (SD = 3.2) and paucibacillary had a mean of 8.2 cm (SD = 1.3). Disability grade 1 subjects scored 7.1 cm (SD = 2.0) and grade 2, 7.1 cm (SD = 3.4). The comparisons of mean VAS between sociodemographic and clinical profiles were not statistically significant.

3.2. The Contribution of Pain to QoL. The QoL domains that showed the lowest mean scores were physical, with a mean of 10.8 (SD = 3.3) and environment, with 12.2 (SD = 3.1). The highest domain was social relations, with an average score of 14.6 (SD = 3.7), followed by psychological with a mean of 13.7 (SD = 3.3). The mean overall QoL was 12 (SD = 4.1).

Considering the sociodemographic profile, although it was not statistically significant, women were more satisfied in all domains: physical (11.3, SD = 4.0), psychological (13.8, SD = 2.8), and overall QoL (13.5, SD = 3.5). The exceptions were in social relations (15.3, SD = 3.6) and environment (12.5, SD = 2.7), domains in which males had high scores.

With regard to the general questions assessing QoL, the results representing the patients' satisfaction with their QoL showed that 3 (14.3%) were very dissatisfied, 9 (42.9%) moderately satisfied, 7 (33.3%) satisfied, and 2 (9.5%) very satisfied. With respect to the results of patients' satisfaction with their health, 11 (52.4%) were dissatisfied, 3 (14.3%) were moderately satisfied, and 7 (33.3%) were satisfied or very satisfied.

The average score and 95% confidence interval for each facet in all four domains are represented in Table 2.

The physical domain, involving questions related to disability, showed that pain and discomfort, dependence on medicinal substances, sleep and rest, and work capacity were facets that scored low. Patients were more satisfied with their mobility.

In the psychological domain, bodily image and appearance, thinking, learning, memory and concentration, negative feelings, and positive feelings were the lowest facets. Spirituality, religion and beliefs were the highest scoring facets in this domain.

With respect to the social relations domain, patients were more dissatisfied with their sexual activity. Social support was the best-scored facet in this domain.

Financial resources, freedom and physical safety, and participation in and opportunities for recreation or leisure activities were more affected in the environment domain.

TABLE 3: Spearman correlation coefficient between VAS and WHOQOL-bref domains.

Variable	WHOQOL-bref domains				
	Physical	Psychological	Social relations	Environment	Overall QoL
r_s (Spearman)	-0.26	-0.48	-0.30	-0.32	-0.13
P	0.25	0.03	0.18	0.15	0.56

Patients were more satisfied with the facets corresponding to health and social care: accessibility and quality.

3.3. Which Components of QoL Are Influenced by Pain? Analysis of the correlation of each domain on the WHOQOL-bref questionnaire with pain intensity showed a significant negative association with all domains. The highest coefficient occurred in the psychological domain (-0.48), followed by environment (-0.32), social relations (-0.30), physical (-0.26), and overall QoL (-0.13). Statistical significance was particularly high in the psychological domain. However, we failed to demonstrate any significant correlations with other QoL domains or VAS (Table 3).

The Spearman's rank correlation coefficient ranged from -0.01 to -0.58. All domains, 5 facets out of 24, had higher correlation with the VAS, reaching statistical significance in 3. Between domains, higher levels of correlation were observed in mobility (-0.58) (physical), memory and concentration (-0.37) (psychological), sexual activity (-0.29) (social relations), and recreation and leisure opportunity (-0.58) (environment). Seven facets showed no significant correlation, the lowest correlation coefficients being for sleep and rest (-0.001) and energy and fatigue (-0.008). Table 4 summarizes the results, including Spearman's rank correlation coefficients and the linear regression, of the facets that were statistically correlated with pain intensity.

4. Discussion

The success of MDT in the treatment of leprosy patients was associated with the inexorable concept of cure. However, bacteriological cure was not followed by advances in disability prevention after a full course of MDT. The WHO makes efforts to identify the precise number of patients with disabilities in the world. Control programs have been concerned with case finding and MDT treatment, management of reactions, and prevention of disability [21, 22]. Besides physical impairments, neuropathic pain has emerged as a disabling condition and a challenge in the treatment of post-MDT leprosy patients [7–12].

In the last 10 years, more attention has been given to chronic neuropathic pain after the completion of MDT treatment. Hietaharju et al. [23] described the clinical findings from 16 multibacillary patients who had chronic pain despite finishing their treatment, but there was no reference to pain intensity. Lund et al. [24] studied histological and clinical findings in 17 leprosy patients with chronic neuropathic pain who had completed MDT.

TABLE 4: Spearman correlation coefficient and multiple linear regression between VAS and the highest correlated WHOQOL-bref facets.

Facets	Pain intensity			
	Spearman (r_s)	P	R^2	P
Recreation	-0.58	0.003	0.41	0.002
Mobility	-0.51	0.008	0.26	0.01
Thinking, learning	-0.46	0.04	0.21	0.03
Self-esteem	-0.42	0.06	0.18	0.06
Bodily image and appearance	-0.38	0.09	0.15	0.09

Despite the known prevalence of neuropathic pain there remains a lack of knowledge. In the 19th World Congress of Neurology, Hietaharju et al. [25] in a study with 101 patients reported the presence of neuropathic pain in 22 (21.8%) patients confirmed by DN4 and physical examination. Stump et al. [8] reported that 201 of 358 leprosy patients had experienced pain but only 53 had complained at the time of the study. Saunderson et al. [11] in a study of 96 patients, who had been discharged for more than 10 years, found 28 with symptoms of neuropathic pain, reported as severe in 12 (43%), moderate in 14 (50%), and mild in two (7%). Pucci et al. [26] in a retrospective study with 732 leprosy patients found that 65.9% had loss of tactile, thermal, or painful sensitivity but only 4.31% had severe pain at palpation, especially on the tibial (50%) and ulnar (43.8%) nerves. Haroun et al. [27] assessed the prevalence of neuropathic pain and depression in 80 Ethiopian leprosy patients, and 48 patients (60%) reported pain, with purely neuropathic pain in 9 (11%).

More recently, Chen et al. [28] studied neuropathic pain in leprosy villages in China. In a sample of 275 patients, they found 126 (45.8%) that reported symptoms suggestive of neuropathic pain. However, only 9 (3.3%) complained of pain at the time of interview.

Chronic neuropathic pain can be disabling and cause deterioration of functional capacity and QoL [15]. To the best of our knowledge, this study is the first to evaluate QoL using the WHOQOL-bref in a sample of leprosy patients with neuropathic pain. The study of Mankar et al. [29] used WHOQOL-bref to evaluate QoL in leprosy patients as compared to normal community members in India and found that leprosy patients had lower scores in physical and psychological domains than those of the control group, but no significant difference was found in the social relationships and environment domain.

In our sample, physical and environment domains were the most distressed domains of the QoL. Comparing our results with Mankar et al. [29] we found that patients scored

low in physical, psychological, and environment domains but not in social relations. Besides those findings in the physical domain that would reflect the disabling characteristic of pain, the low scores could also be explained by the sensory or motor loss present in disability grades 1 or 2.

Pain showed a moderate but significant negative correlation with the psychological domain. These findings were in accordance with Lasry-Levy et al. [30] who evaluated the association of chronic neuropathic pain and psychological morbidity in 101 leprosy patients in India; psychological morbidity was detected in 41% of the patients with neuropathic pain.

Accordingly, within each domain the facets that consistently had high scores were mobility (physical), spirituality (psychological), social support (social relations), and health and social care (environment). These findings may be due to the absence of cases with drop foot in our sample that would affect mobility. The high scores in spirituality could be explained by its role as an emotional support. Mellagi and Monteiro [31] consider that religion is an escape to alleviate the physical consequences of the disease and the social stigma. Joseph and Sundar Rao [32], when comparing leprosy patients after MDT with controls, found higher QoL in the healthy group except in spirituality. We believe that the high scores in the other two facets can be explained by the fact that the patients had been treated in a referral centre by a multidisciplinary health team with a family approach.

The more affected facets were pain and discomfort (physical), positive feelings (psychological), sexual activity (social relations), and financial resources (environment). Chen et al. [28] also reported that 94% of their sample of leprosy patients with neuropathic pain had their sleep disrupted. The low scores on positive feelings may be due to the lack of expectations with respect to their lives. Sexual activity may be affected by pain or by the impact of the disease in the family. Low scores in financial resources may be related to the low schooling of the sample or the low scores observed in work capacity in the physical domain.

The average pain intensity measured by VAS was 7.1. Pain intensity in leprosy patients seems to be high. Our results are in accordance with Chen et al. [28], who found an average score of 7.7, ranging from 3 to 10 in the Likert scale. However, the present study did not find higher pain intensity in male patients as observed by those authors.

It is becoming clear that neuropathic pain is a common condition in leprosy. However, there is no consensus about pathophysiological mechanisms or treatment of neuropathic pain. Different pathogenetic mechanisms have been suggested to explain neuropathic pain in leprosy, including entrapment of nerves, firing of the *nervi nervorum*, sensitization of nociceptors, axonal damage, and lowered activation thresholds [7–9, 12]. Several approaches have also been proposed in the literature to treat chronic neuropathic pain with agents such as tricyclic antidepressants, carbamazepine, tramadol, gabapentin, and corticosteroids, as well as by immobilization and surgical nerve decompression [10]. Physical therapy using a method called neural mobilization has shown good results with regard to pain intensity in leprosy patients with neuropathic pain [33].

Chronic pain does not seem to have a single well-defined mechanism. Therefore, in the assessment of chronic pain patients it is important to point out that the Cartesian model does not fit; that is, it is difficult to establish a biological aspect of pain. Unfortunately, medical interventions such as different drugs or surgery would therefore not be expected to have the desired effect [34, 35]. We suggest that pain is influenced by different aspects as defined by the *neuromatrix* theory and should be treated as a multimodal condition [15, 36, 37].

According to this *neuromatrix* theory, chronic pain is a combination of cortical mechanisms that, when activated, produce pain. A critical component of the current theory is that pain is experienced in the body image that is held by the brain [15, 36, 37]. We believe that not only nerve damage but also social exclusion, stigma, deformities, psychological disturbance, low level of quality life, and participation could contribute to chronicity. These are explained by nonnociceptive (cognitive-evaluative) mechanisms [15].

The current study did not aim to identify risk factors for neuropathic pain as related in previous researches in the literature. On the other hand, the strength of our study lies in its examination of repercussions of chronic neuropathic pain in QoL. However, the findings could be influenced by several variables due to the multidimensional aspects of QoL, involving cultural, socioeconomic, and regional factors. Therefore, the findings in our study should be interpreted respecting this particularity.

The use of scales as tools to measure different aspects in leprosy patients was recently pointed out by Lockwood [38]. Not only QoL questionnaires but also daily living and participation instruments would be useful to elucidate risk factors and especially to contribute to the development of new treatment interventions, rehabilitation, and social reintegration of leprosy patients with chronic pain.

5. Conclusion

Neuropathic pain in leprosy patients emerges as a new disabling condition that affects QoL. We found high average pain intensity in chronic neuropathic pain patients, as also observed in other studies in the literature. Chronic neuropathic pain in leprosy patients showed high average levels of pain intensity that affected both the physical and environment domains. Pain was also shown to have a negative influence on the psychological domain. The most affected facets were pain and discomfort, positive feelings, sexual activity, and financial resources. Lack of knowledge remains about pain in leprosy, but identifying patients' needs could contribute toward the development of new approaches. In accordance with the results of this study, we suggest that treatment may best focus on the physical and psychological domains in neuropathic pain treatment in leprosy. Modifications in the environment domain may be achieved if an efficient public policy allows full social reintegration of leprosy patients, by providing conditions to have the same opportunities in society such as recreational and financial resources.

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