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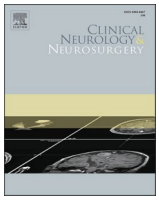

Impact of social-functioning and sleep on quality of life in chronic inflammatory demyelinating polyneuropathy

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ABSTRACT

Introduction/Aims: The impact of impairment of social functioning and sleep on health-related quality of life (HR-QoL), is unknown in chronic inflammatory demyelinating polyneuropathy (CIDP). The value of the Chronic Acquired Polyneuropathy Patient-Reported Index (CAP-PRI) to identify potential social functioning and sleep issues is equally unknown.

Methods: We performed a cross-sectional evaluation of social functioning and sleep using the "Scales for Outcomes in Parkinson's Disease" (SCOPA) in 40 subjects with clinically-stable CIDP through a structured questionnaire. We assessed HR-QoL through the CAP-PRI. Disability was evaluated through the Overall Neuropathy Limitation Score (ONLS).

Results: SCOPA social functioning scores were impaired at least "a little" per averaged item in > 50 % of subjects, and at least "quite a bit" per averaged item in > 20 %. Most affected items were (i) difficulty with work/household/other chores (ii) difficulties with hobbies/sport/leisure activities. SCOPA sleep sub-scores indicated at least "a little concern" for night-time sleep in nearly 50 % of subjects. Abnormal sleep timing was rare. Associations were found between both SCOPA social-functioning and SCOPA sleep scores and the CAP-PRI. Linear regression demonstrated the SCOPA social-functioning score was independently associated with the CAP-PRI. The CAP-PRI showed high association with disability scores, good internal consistency, absence of ceiling effect, absence of significant floor-effect, and good criteria-related as well as construct-related validity.

Discussion: Social functioning and night-time sleep are frequently affected in CIDP and impact on HR-QoL. In contrast to traditional disability scales, the CAP-PRI additionally allows adequately capturing these impairments and may represent an adequate holistic outcome measure.

1. Introduction

Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) is the commonest chronic inflammatory neuropathy. CIDP causes functional neurological deficits as a result of motor weakness and impairment of large fibre sensory function. CIDP may not only impact on physical ability, but also on the capability for social interaction as well as on mental well-being, leading to adverse effects on quality of life (QoL) [1,2].

Besides neuropathy-related physical impairment, factors such as mood and fatigue may contribute to overall disability in CIDP. Similarly, it is possible that poor psychosocial status and sleep difficulties may similarly negatively impact upon the individual's health-related QoL (HR-QoL) [3]. Validated scales or outcome measures are available and commonly used in patients with CIDP for monitoring of neuropathy-related physical disability, treatment response, and change in clinical status [4]. The motor and sensory-related disability is the exclusive focus of such scales. Consideration of overall HR-QoL although the aim of few recent studies [5,6], has not become routinely used in clinical practice and has not to date, been utilised as primary outcome measure in research studies in CIDP.

The Chronic Acquired Polyneuropathy Patient-Reported Index (CAP-PRI) is a 15-item disease specific patient-reported scale constructed and validated in a multi-centre study in the United States in 2016 [6]. The CAP-PRI allows evaluation of the physical, social, and emotional well-being of patients with CIDP. Few recent studies have brought support to the practicality and validity of this scale to assess and longitudinally monitor HR-QoL in patients with CIDP [7,8].

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Disease specific and patient reported scales of non-physical disability and HR-QoL are well-stablished in other neurological diseases such as Parkinson's Disease (PD). In PD, the "Scales for Outcomes in Parkinson's Disease" (SCOPA), have been specifically developed to assess commonly encountered non-motor symptoms impacting HR-QoL, including psychosocial or emotional impairment [9] and sleep disturbances [10] amongst others.

In the current study, we used, in absence of availability of disease-specific measures, the SCOPA for psychosocial functioning and sleep to assess these areas, in a cohort of patients with CIDP, in whom we concurrently evaluated HR-QoL using the CAP-PRI.

The primary aim of our study was to evaluate our patients' psychosocial functioning and sleep. We concurrently proposed to evaluate the overall HR-QoL in this cohort using the CAP-PRI scale, and current disability through the ONLS. We attempted to ascertain the most affected psycho-social and sleep items in our cohort and to determine if these additional assessments may be useful to capture, and eventually attempt to usefully treat, these impairments affecting patients with CIDP in routine practice. We also planned to establish the associations of social-functioning and sleep disturbances with overall HR-QoL measures as determined by the CAP-PRI scale as well as with traditional CIDP disability and strength scales, with the aim of establishing their respective value in identifying non-neuropathic features in patients with CIDP.

2. Methods

Patients attending the Inflammatory Neuropathy Clinic at University Hospitals Birmingham, United Kingdom, were identified, and their electronic records were screened. We enrolled consecutive patients meeting the 2010 European Federation of Neurological Societies/Peripheral Nerve Society (EFNS/PNS) Guidelines criteria for "definite" or "probable" CIDP, who were clinically stable with or without on-going immunomodulatory therapy.

Demographic and clinical data were collected, including age of onset, disease duration, disease subtype, and current or previous immunomodulatory treatment. The most recently recorded I-RODS, within 6 months of questionnaire administration (Inflammatory Rasch-built Overall Disability Scale) score [11] and Medical Research Council (MRC) sum score from 8 paired muscle groups [12], were in addition, retrieved from electronic records. Two investigators (C.E. and K.K.N.) practised implementing the telephone questionnaire in order to ensure consistency in the method of questioning and to avoid investigator-related bias and discrepancy.

The first section of the questionnaire consisted of the overall neuropathy limitation score (ONLS) [13], routinely administered at each clinical visit in our practice. The second section of the questionnaire required answering the 11 items of the SCOPA-PS [9]. The score (best 0/33, worst 33/33) was recorded, rating to what extent each situation described posed a problem in the past month (0=not at all, 1=a little, 2=quite a bit, 3=very much). The third section of the questionnaire required the patients to answer the 15-item scale CAP-PRI [6]. The score (best 0/30, worst 30/30) was calculated based on the patients' rating of each item of this scale (0=not at all, 1=a little bit, 2=a lot). Finally, the last section of this questionnaire involved answering of the 14 items of the SCOPA sleep score [10]. Each patient was initially (i) asked to report the use of sleeping tablets (0=not at all, 1= less than once a week, 2= once/twice a week, 3=more than 3 times a week; best score 0/3, worst score 3/3), and (ii) to provide the name, amount, and dosage of sleeping tablet they might be using. Subsequently, the patients were asked to answer to what extent a described situation posed a problem in the past month. 5 items of the scale assessed quality of sleep at night (possible answers: 0=not at all, 1= a little, 2= quite a bit, 3= very much; best score 0/15, worst 15/15), and 6 items of the scale assessed sleeping during the day and evening (possible answers: 0=never, 1=sometimes, 2=regularly, 3=often; best score 0/18, worst 18/18). The global evaluation of sleeping at night was recorded by asking the patient to rate how well they slept at night (0=very well, 1=well, 2=rather well, 3=not well but not badly, 4=rather badly, 5=badly, 6=very badly; best score 0/6, worst 6/6). The overall score of the SCOPA sleep was then calculated (best 0/42, worst 42/42).

Permission was granted from the International Parkinson and Movement Disorder Society (MDS) for the use of the SCOPA, to assess psychosocial functioning and sleep quality/daytime sleepiness. This study was registered, reviewed, and approved as a Clinical Audit by our relevant institutional body (CARMS no. 17735, 06th January 2022, University Hospitals Birmingham). All participants provided informed consent.

Statistical analysis was performed using SPSS 28.0 software (IBM, Armonk, New York). Correlations were performed with Spearman's rank correlation with 2-tailed analysis. Independent associations were determined by logistic regression analysis. Internal consistency was analysed using Cronbach's alpha. The proportion of subjects obtaining the highest achievable score (ceiling effect) and lowest possible score (floor effect) were calculated. Construct-related validity due to demographic factors and criterion-related validity due to disease sub-type variations, were evaluated through Spearman's correlation. Significance was set at p values < 0.05.

3. Results

We identified 89 subjects with "definite" or "probable" CIDP, meeting our eligibility criteria. Of those, 9 declined to participate and 40 could not be contacted by telephone after 2 attempts. Hence, 40 subjects participated in this study. The main demographic and clinical characteristics of this cohort are provided in Table 1. The atypical CIDP group in the cohort included multifocal CIDP in 5 (12.5 %), motor CIDP in 2 (5 %) and sensory CIDP in 2 (5 %). All were clinically stable for > 6 months on current or previous immunomodulatory therapy.

The mean ONLS on the day of questionnaire administration, was 3.4 (range: 0–7; S.D.: 2.32). Mean upper limb ONLS was 1.53 (S.D.: 1.22) and mean lower limb ONLS was 1.83 (S.D.: 1.3). Twenty-three subjects (57.5 %) scored ≥ 2 on the upper limb score, implying difficulties with functionality whereas 10 subjects (25 %) scored ≥ 3 on the lower limb score, implying requirement of a walking aid.

The mean total SCOPA social functioning score was 12.25 (range: 0–28; S.D.: 9.02). Twenty-two subjects (55 %) scored ≥ 11, corresponding to a mean response score of 1, i.e., of at least "a little" concern, per item. Nine subjects (22.5 %) scored ≥ 22, corresponding to a mean response score of 2, i.e., of at least "quite a bit" of concern per item. The items with the highest mean scores in the cohort, suggesting greatest concern were, in descending order, (i) difficulty with work, household and other chores (ii) difficulties with hobbies, sport or leisure activities (iii) feeling more housebound than one would wish (iv) feeling of having ask others for help too often (v) having concerns about the future. Those

Table 1
Demographic and clinical characteristics of 40 interviewed patients with chronic inflammatory demyelinating polyneuropathy from Birmingham, U.K.

Number	40
Gender	13 females, 27 males
Typical CIDP	31
Atypical CIDP	9
Age at time of interview	Mean: 61.1 years (S.D.: 16.8),
Disease duration	Mean: 96.4 months (S.D.: 76.4)
ONLS	Mean: 3.4 (S.D.: 2.32)
Upper Limb ONLS	Mean: 1.53 (S.D.: 1.22)
Lower Limb ONLS	Mean: 1.83 (S.D.: 1.3)
I-RODS (raw score)	Mean: 33.6 (S.D.: 10.5)
MRCSS	Mean: 70.5 (S.D. 10.8)
SCOPA Social Functioning Score	Mean: 12.25 (S.D.: 9.02)
SCOPA Sleep Score	Mean: 10.35 (S.D.: 6.85)
CAP-PRI Score	Mean: 14.78 (S.D.: 8.55)

with the lowest mean scores, of therefore rare relevance, were in ascending order (i) difficulty having a conversation (ii) uncertainty in contact with others, and (iii) feeling ashamed of one's disease.

In the first section ("A") of the SCOPA sleep questionnaire, 4/40 (10 %) of participants reported using sleeping tablets in the past months, of whom 2 (5 %) had done so more than 3 times a week. Section "B" of the questionnaire, relating to night sleep quality showed a mean cohort score of 5.2 (range: 0–15; S.D.: 4.4), corresponding to an average score of > 1 per item, suggestive of at least "a little concern". Nineteen subjects (47.5 %) scored ≥ 5 on this section, indicating at least "a little" concern, averaged per item. Nine subjects (22.5 %) scored ≥ 10, indicating at least "quite a bit" of concern, averaged per item. In decreasing order, (i) getting too little sleep, (ii) waking up too often and (iii) trouble falling asleep, were the commonest problems identified. Section "C", consisting of a single question and single answer about how well individuals had slept, produced a mean cohort score of 2.35, in between "rather well" to "not well but not badly". Ten subjects (25 %) responded "rather badly", "badly" or "very badly" to this question. Section "D" relating to sleep during the day and evening, showed a mean cohort score of 3.03 (range: 0–14; S.D.: 2.65). Three subjects (7.5 %) had a "D" score of ≥ 6, corresponding to occurrence of abnormal sleep onset timings at least "sometimes", on average, whereas one subject (2.5 %) had a score of ≥ 12, corresponding to this occurring at least "regularly", on average. Mean SCOPA total sleep score was 10.35 (S.D.: 6.85). Fifteen subjects (37.5 %) scored ≥ 13, corresponding to an average score of 1 averaged per item, indicating at least an issue with sleep occurring at least "sometimes".

The mean total CAP-PRI score was 14.78 (S.D.: 8.55). Mean item score was 0.97 and mean inter-item correlation was 0.51 (range: 0.104–0.914). High correlations, corresponding to Spearman's rho $\geq$ 0.80, were observed, in descending order, for items 6 (work limitations) and 15 (difficulties with activities around the house), items 1 (frustration) and 12 (inability to perform all leisure activities one wants), items 8 (dependency on others) and 15 (difficulties with activities around the house), and items 12 (inability to perform all leisure activities one wants) and 15 (difficulties with activities around the house). Twenty-three subjects (57.5 %) had a total score ≥ 15, corresponding to a mean response ≥ 1, i.e., indicating at least "a little bit" of concern, averaged per item. The items with the highest mean scores in the cohort, of > 1, were, in descending order, (i) inability to perform all leisure activities one wants (ii) being off balance when walking (iii) frustration (iv) trouble doing activities around the house (v) being worn out (vi) limitations performing work, and (vii) dependency on others. Those with the lowest mean scores were, in ascending order, (i) trouble eating (ii) falling, and (iii) trouble sleeping. Internal consistency evaluation for the CAP-PRI found a Cronbach's Alpha of 0.94. In relation to construct- and criterion-related validity, no association of the CAP-PRI score was found with age ($p = 0.78$), gender ($p = 0.35$), disease duration ($p = 0.97$), or disease sub-type ($p = 0.40$). No ceiling effect was observed, with only a minor floor effect of 10 %.

Results of inter-scale correlations are shown in Table 2. Analysis of traditional measures showed high inter-correlation of ONLS, I-RODS and MRCSS. ONLS correlated with age and disease duration. The I-RODS inversely correlated with age. The MRCSS inversely correlated with both age and disease duration. A significant association was found between the SCOPA social-functioning score and the CAP-PRI score, the ONLS, as well as both its upper limb and lower limb components, and with the I-RODS. The SCOPA sleep score correlated significantly with the CAP-PRI, the I-RODS, but not with the ONLS, although, and of note, correlated exclusively with its upper limb component. In addition, the SCOPA sleep score also correlated inversely with disease duration and with female gender. SCOPA social-functioning and SCOPA sleep scores were inter-correlated. The CAP-PRI score correlated with both the ONLS and the I-RODS, which were both highly negatively inter-correlated.

Linear regression analysis demonstrated the SCOPA social-functioning score was independently associated with the CAP-PRI score only ($p < 0.001$). The SCOPA sleep score was independently associated with disease duration ($p < 0.001$), female gender ($p = 0.005$), and I-RODS ($p = 0.015$). The CAP-PRI score was independently associated with the SCOPA social-functioning score ($p < 0.001$) and the I-RODS ($p < 0.001$), only.

Table 2
Inter-scale Spearman's Correlations in 40 interviewed subjects with chronic inflammatory demyelinating polyneuropathy.

	ONLS	I-RODS	MRCSS	SCOPA-SF	SCOPA-Sleep	CAP-PRI
ONLS		r = −0.803; ***P < 0.001***	r = −0.754; ***P < 0.001***	r = 0.631; ***P < 0.001***	NS	r = 0.65; ***P < 0.001***
I-RODS	r = −0.803; ***P < 0.001***		r = 0.601; ***P < 0.001***	r = 0.514; ***P < 0.001***	r = 0.409; ***P = 0.009***	r = 0.649 ***P < 0.001***
MRCSS	r = −0.754; ***P < 0.001***	r = 0.601; ***P < 0.001***		r = 0.374; ***P = 0.017***	NS	r = −0.373; ***P = 0.018***
SCOPA-SF	r = 0.631; ***P < 0.001***	r = 0.514; ***P < 0.001***	r = 0.374; ***P = 0.017***		r = 0.438; ***P = 0.005***	r = 0.878; ***P < 0.001***
SCOPA-Sleep	r = 0.438; ***P = 0.005***	r = 0.409; ***P = 0.009***	NS	r = 0.438; ***P = 0.005***		r = 0.45; ***P = 0.004***
CAP-PRI	r = 0.65; ***P < 0.001***	r = 0.649 ***P < 0.001***	r = −0.373; ***P = 0.018***	r = 0.878; ***P < 0.001***	r = 0.45; ***P = 0.004***	

4. Discussion

Social functioning and sleep were frequently affected in our evaluated patients with CIDP and found to impact on HR-QoL. Fatigue and mood were not evaluated in the current analysis, and it is possible such factors may represent other determinants of these impairments [14].

Of interest, we found that difficulties with work, household chores, leisure activities and dependency were the commonest social functioning problems, as expected, highly associated with disability. Also, sleep issues were independently associated with female gender, and inversely with both disease duration and disability. This may suggest that sleep disturbances need to be considered in female subjects with CIDP in the earlier disease stages and with severe disability. These findings are consistent with previous reports of more severe sleep problems in subjects with greater illness severity [15], and in general, in females in both healthy [16] and diseased [17] populations. The increased severity of sleep problems early in the disease may otherwise, interestingly reflect maladaptation to stress due to the condition, in the initial stages, which may often be more severe, as compared to later in the course of the illness. This is supported by the inverse association of the "B" SCOPA sleep sub-score, i.e., night-time sleep, with disease duration, which was on the other hand not associated with the "D" sub-score, i.e., day-time and evening sleep, itself more likely impacted by fatigue.

Administration of the CAP-PRI showed greatest impact on leisure activities and performing household chores, in contrast to work. This may illustrate a possible cultural and wealth-status-related patient concern which may be highly variable from one population to another. Interestingly in this regard, our cohort had a higher mean CAP-PRI score than a previous study of CIDP subjects from Serbia [7] (14.78; S.D.: 8.55 vs. 10.3; S.D.: 8.3; $p = 0.004$). Reasons for this difference may include, amongst many other potential factors, the socio-cultural differences in these 2 populations, particularly given the contrasting higher mean

MRCSS in our cohort compared to that from Serbia (70.5; S.D.: 10.3 vs. 54.3; S.D.: 10.3, $p < 0.001$).

The CAP-PRI HR-QoL scale, designed for chronic inflammatory neuropathy demonstrated significant correlations with strength and disability scores and with social-functioning and sleep scores, with an independent association with the former. This demonstrates its value as HR-QoL scale in capturing both neuropathic and non-neuropathic effects in CIDP. On the other hand, the limitations of the I-RODS scale, particularly with regards to patient perceptions, were shown in another recent study [18]. We otherwise found comparable favourable results to those of a previous study of the CAP-PRI scale with regards Cronbach's alpha, floor, and ceiling effects as well inter-item correlations [7]. In contrast, the ONLS and MRCSS were both impacted upon by age and disease duration and the I-RODS, by age.

Our study has a number of limitations. Firstly, the sample size studied was small. The cohort was clinically heterogeneous, as patients were recruited on the basis of the 2010 EFNS/PNS diagnostic criteria, including both typical and atypical disease sub-types. This study was planned before the new updated guidelines for CIDP [19], were published. However, it appears unlikely from validation studies since performed that this would have impacted on our results [20,21]. The analysis we performed in the current study was cross-sectional. In addition, other potential aspects, including mood, anxiety and fatigue were not evaluated.

We believe these results, however, demonstrate the important impact of the studied non-neuropathic features in CIDP, and may bring support for consideration of use of the CAP-PRI scale, as adequate disease-specific measure of HR-QoL in the disorder. Further research, including longitudinal, is desirable to explore all disease aspects including those non-directly due to sensory and motor deficits, in subjects with CIDP.

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All authors contributed to this manuscript significantly and approve submission. Christina ENGLEZOU:-Data collection, Data analysis, Writing of first draft. Kabir Khan NAZEER:-Data Collection, Revising manuscript for scientific content. Yusuf A. RAJABALLY:-Concept, Supervision, Data Analysis, Writing of first draft, Revising second version.

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