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Clinical Trial

Spasticity in multiple sclerosis: Associations with impairments and overall quality of life

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ABSTRACT

Objectives:
(1) To determine the association between spasticity and quality of life (QOL) in multiple sclerosis (MS).
(2) To investigate the associations between spasticity and impairments of function and activity limitations.
Design: Cross-sectional survey.
Setting: A convenience sample of people with MS routinely attending an appointment with their local MS service.
Participants: 701 patients with clinically definite MS.
Main outcome measures: Demographic details were obtained and patients completed a battery of measures including spasticity (Multiple Sclerosis Spasticity Scale – 88), fatigue (Neurological Fatigue Index – MS), urinary dysfunction (Qualiveen-SF), pain (Neuropathic Pain Scale), mood disorder (Hospital Anxiety and Depression Scale), disability (World Health Organisation Disability Assessment Schedule) and QOL (Leeds Multiple Sclerosis QOL Scale).
Results: 85.7% of patients reported spasticity. Patients with higher levels of spasticity were more likely to be disabled, suffer from depression and anxiety, have higher levels of fatigue and report more pain and bladder problems ($p < 0.01$). Spasticity remained as a significant direct effect upon QOL in a multivariate model adjusted for other impairments, activity limitation and depression.
Conclusions: There is a strong association between spasticity and fatigue, depression, anxiety, pain and bladder problems. The retention of a significant direct relationship with QOL in a multivariate model emphasises its influence upon the everyday lives of people with MS.

1. Introduction

Spasticity affects the majority of patients with multiple sclerosis (MS) and is rated as one of the most disabling symptoms (Rizzo et al., 2004; Paisley et al., 2002). It can cause pain, reduces ability to move and interferes with personal hygiene (Stevenson, 2010; Thompson et al., 2005). Spasticity has also been shown to be the main contributing factor to disability in the lower limbs (Barnes et al., 2003). As a result of such significant disabilities associated with spasticity, it could be expected that spasticity may adversely impact upon Quality of Life (QOL). The World Health Organisation (WHO) defines QOL as 'the individual's perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns' (WHO, 1995). The term health-related QOL (HRQOL) or health status, refers to health aspects of QOL such as activities and participation (Schipper and Clinch, 1996).

Despite spasticity being one of the most common impairments associated with MS, little is known regarding its relationship with QOL. In contrast, several studies have previously reported that spasticity is associated with worse health status. Two large American studies totalling over 22,000 people with MS found that patients with spasticity had significantly lower scores on the physical components of SF-36 and SF-12 (Rizzo et al., 2004; Wu et al., 2007). Similar findings were reported in two European studies. Arroyo et al. found significant negative correlations between spasticity (measured by patient rated Numerical Rating Scale (NRS) and the Ashworth scale) and the SF-12 (Arroyo et al., 2013). Another study by Flachenecker et al. (2014) reported that patients with moderate (NRS 4–6) and severe (NRS 7–10)

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spasticity scored significantly worse on the Multiple Sclerosis QOL −54 (MSQOL-54) scale and EuroQoL-5D.

Although the above studies suggest that spasticity is associated with worse health status, its relationship with QOL is unclear. Despite the studies concluding that spasticity affects QOL, all studies employed health status measures, measuring functioning, rather than overall QOL instruments which are designed to obtain the patients' perception of their QOL. Literature regarding this distinction suggests that HRQOL and QOL are unique constructs and should be assessed individually (Smith et al., 1999; Ferrans et al., 2005). Secondly, QOL in MS is known to be affected by factors other than spasticity, such as depression, pain, fatigue and bladder dysfunction etc. (Lobentanz et al., 2004; Hemmett et al., 2004; Amato et al., 2001; Goksel Karatepe et al., 2011). Since there is evidence to suggest that spasticity may be related to other impairments of MS for which the previous studies did not account, it could not be concluded that spasticity is an independent determinant of QOL (Oreja-Guevara et al., 2011).

The aim of this study is to investigate the relationship between spasticity and overall QOL using a disease specific measure, the Leeds Multiple Sclerosis QOL (MSQOL) (Ford et al., 2001). The study will also explore, the relationships between spasticity and other impairments. Finally, the study aims to examine socio-demographic (age, sex, marital status, duration, and type of MS) and impairment and activity limitation variables (anxiety, fatigue, pain, bladder, and disability), together with depression, using multivariable logistic regression analysis, to explore the association between spasticity and Quality of Life within a multivariate context.

2. Methods

2.1. Study participants

One thousand one hundred thirty-seven patients with clinically definite MS were recruited to the TONiC (Trajectories of Outcomes in Neurological Conditions) study by five MS services in the UK (Liverpool, Preston, Manchester, Leeds, Sussex). All patients with MS capable of informed consent who did not have a second diagnosis believed to influence their quality of life, such as malignancy, were eligible irrespective of age, disability level, duration or type of MS. Each participant gave written, informed consent. Sociodemographic (age, sex, employment and marital status) and clinical details (type of MS, duration, Extended Disability Status Scale (EDSS) score, disease modifying therapy) were obtained upon enrolment into the study by a clinician or researcher. Questionnaire packs containing the measures described below were given to the participants for completion. Reminder telephone calls were made in cases when participants did not return the questionnaire pack within a 4-week period or the questionnaire was incomplete. Demographic characteristics of the non-responders were compared to those of responders. The study received full ethical approval from the local research committee (11/NW/0743).

2.2. Measurement instruments

2.2.1. Spasticity

Spasticity was assessed using the 'stiffness' subscale of the Multiple Sclerosis Spasticity Scale-88 (MSSS-88), a self report measure (Hobart et al., 2006). Two other subscales were not included in the regression model due to high inter-correlation (r=0.86-0.9), which would adversely affect multicollinearity in the multiple regression. In addition, there were no differences in correlation between MSSS-88 subscales and LMSQOL.

2.2.2. Quality of life

The LMSQOL is an 8-item instrument developed specifically to measure overall QOL in MS (Ford et al., 2001). A total score is calculated by adding up all the items. Higher score indicates worse QOL.

2.2.3. Disability

WHO Disability Assessment Schedule (WHODAS) 2.0 consists of 36 items covering 7 domains (Üstün, 2010). The total score was calculated by adding the item responses and transforming to 0-100 scale using the SPSS syntax obtained from the WHO website.

2.2.4. Impairments and mood disorder

Fatigue was assessed using the Neurological Fatigue Index – MS (NFI-MS), which has been shown to have robust psychometric properties for measuring fatigue in MS populations (Mills et al., 2010). The 10-item subscale of overall fatigue was used in the analysis.

The Neuropathic Pain Scale (NPS) consists of 11 items addressing different types and qualities of pain (Galer and Jensen, 1997). Although originally developed for evaluation of pain in peripheral nerve disorders, NPS has been shown to be valid in conditions characterised by central causes of pain, such as MS (Rog et al., 2007). A total pain score is calculated by adding up 10 items of the NPS (1 item on temporality of pain is excluded).

SF-Qualiveen provides a brief assessment of bladder dysfunction and its impact on the patient's life (Bonniaud et al., 2008). The 8-item scale has been previously validated in MS (Bonniaud et al., 2008).

Mood disorder assessment was carried out using Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983). HADS consists of anxiety and depression subscales, each containing 7 items and has been previously validated in MS (Honarmand and Feinstein, 2009).

2.3. Statistical analysis

Socio-demographic characteristics were analysed using descriptive statistics. All ordinal Patient Reported Outcome measures (PROM's) were converted into categorical values based upon their inter-quartile ranges. Where clinical cut points were available (e.g. anxiety), these cut points were used to categorise patients. Thus these categorical variables were then entered into a logistic regression analysis with the LMSQoL split at the median as the dependent variable. Initially unadjusted univariate odds ratios for each quartile (lowest as reference) were determined for each predictor variable. Significant variables were then entered into a multivariate model.

3. Results

3.1. Characteristics of the study sample

Data were available from 701 participants (61.7% response). Socio-demographic and disease characteristics are summarised in Table 1. Mean age was 48.8 years (SD 11.7, range 18–82) and 505 (72%) were female. The sample was representative of a wide range of disabilities, types of MS and disease durations. No significant differences in demographic characteristics were detected when the sample was compared with non-responders.

3.2. Spasticity characteristics

Most of the patients reported some degree of spasticity (599,