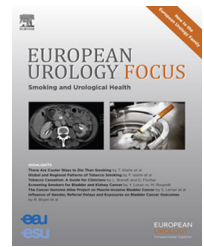


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Review – Neuro-urology

A Quality Assessment of Patient-Reported Outcome Measures for Sexual Function in Neurologic Patients Using the Consensus-based Standards for the Selection of Health Measurement Instruments Checklist: A Systematic Review

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Abstract

Context: Impaired sexual function has a significant effect on quality of life. Various patient-reported outcome measures (PROMs) are available to evaluate sexual function. The quality of the PROMs to be used for neurologic patients remains unknown.

Objective: To systematically review which validated PROMs are available to evaluate sexual function in neurologic patients and to critically assess the quality of the validation studies and measurement properties for each identified PROM.

Evidence acquisition: A systematic review was performed according to the Preferred Reporting Items for Systematic Review and Meta-analysis statement. The included publications were assessed according to the Consensus-Based Standards for the Selection of Health Measurement Instruments checklist.

Evidence synthesis: Twenty-one studies for PROMs regarding sexual function were identified for the following patient groups: spinal cord injury (11 studies), multiple sclerosis (MS; 6 studies), Parkinson's disease (2 studies), traumatic brain injury (1 study), and epilepsy (1 study). The evidence for the quality of PROMs was found to be variable, and overall evaluation of measurement properties was lacking in 71% of the studies. The measurement error and responsiveness were not studied in any of the publications.

Conclusions: Several PROMs have been identified to evaluate sexual function in neurologic patients. Strong evidence was found only for the Multiple Sclerosis Intimacy and Sexuality Questionnaire-15 and Multiple Sclerosis Intimacy and Sexuality Questionnaire-19 for patients with MS, although evidence was lacking for certain measurement properties as well. Future research should focus on identifying relevant PROMs and establishing adequate quality for all measurement properties in studies with high methodological quality.

Patient summary: A quality assessment of patient-reported outcome measures (PROMs) for sexual function in neurologic patients was made. The evidence found for good PROMs was limited. Studies with high methodological quality are needed to improve the quality of PROMs to evaluate sexual function in neurologic patients.

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1. Introduction

The presence of a neurologic disease might have significant consequences for sexual function in patients [1]. Sexual function has been identified as one of the highest priorities of functional recovery in paraplegic and quadriplegic patients [2]. Prevalence of sexual dysfunction ranges from 30% to 90% depending on the underlying neurologic disorder [3–5]. Neurologic patients are confronted with changes in interpersonal relationships, change in sexual arousal, and physical challenges during sexual activity [1,6,7]. Problems in sexual function can be identified at three levels in neurologic patients. Symptoms that result from neuronal damage and directly influence sexual function, such as decreased vaginal lubrication or ejaculatory dysfunction, are categorized as the primary level. The secondary level includes symptoms that arise from the neurologic disease and indirectly influence sexual function, such as fecal or urinary incontinence. The final tertiary level results from psychosocial and emotional issues that influence sexual function [8]. The factors influencing sexual function also differ between neurologic patients. Patients with spinal cord injury (SCI) and multiple sclerosis (MS) can be confronted with decreased erectile function or lubrication [9,10], whereas patients with Parkinson's disease (PD) can experience hypersexuality [11]. Patients with spina bifida are confronted with sexual functioning during their adolescence and could require counseling [12]. When assessing sexual function, it is important to consider that sexual dysfunction on one level does not necessarily result in an overall sexual dysfunction. When evaluating sexual function in neurologic patients, this multifactorial nature should be taken into account. Patient-reported outcome measures (PROMs), usually in the form of a questionnaire, can be used in the assessment of sexual function and to evaluate change over time. In recent years, the availability of studies on questionnaires to assess sexual function for the general population has increased steadily [13–15]. However, given the multifactorial nature of sexual function in neurologic patients [6,7,16,17], it has been recommended that questionnaires are validated in this specific patient group [18]. A critical review of the methodological quality of studies and the measurement properties of the actual questionnaires is essential.

We had two important aims regarding the evaluation of sexual function in neurologic patients with this systematic review: (1) to determine which validated questionnaires are used to evaluate sexual function in neurologic patients and (2) to determine which validated questionnaires demonstrate the most adequate measurement properties for use in neurologic patients [19].

2. Evidence acquisition

This review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement [20]. The protocol was registered and is available on PROSPERO (CRD42014015287; <http://www.crd.york.ac.uk/PROSPERO>).

2.1. Search strategy

The Medline, Embase, and Cochrane controlled trial databases and ClinicalTrials.gov were searched for all relevant publications from January 1, 1946, to January 27, 2015. Patients had to have a neurologic disease and be aged >18 yr. The terms *neurological patient*, *sexual dysfunction*, and *questionnaire*, and derivatives of these terms were used. The complete search string is shown in Supplement 1. The reference lists of all relevant review articles were also searched.

2.2. Eligibility criteria

All publications using a validated PROM to assess sexual function in adult neurologic patients were eligible for full text retrieval. Publications involving only non-neurologic patients, children, or animals were excluded. No limitation was placed on type, date, sample size, or language of publication. PROMs in which sexual function was a subscale were not considered eligible, unless the subscale could be used separately. PROMs were considered validated if at least one measurement property had been evaluated. The actual validation of these PROMs was determined through validation papers in neurologic patients. Finally, for the quality assessment of the PROMs, only the publications regarding validation or development of PROMs to evaluate sexual function in neurologic patients were eligible.

2.3. Selection of studies

After deduplication, three reviewers (B.F.M.B., J.G., and L.H.) independently screened the titles and abstracts of the relevant publications for eligibility. All potentially eligible records were retrieved as full text and, using a standardized form, independently screened by two authors (J.G. and L.H.). Any disagreements were resolved by the third reviewer (B.F.M.B.).

2.4. Data extraction

The full-text publications were again independently assessed by two reviewers (J.G. and L.H.) and predefined data were extracted using a standardized form. General study characteristics included PROM used, country and language, underlying neurologic disease, number of patients, age, and sex. PROM-specific data included response options, range of scores, lower or higher scores indicating good or impaired sexual function, measurement properties used to assess validity, and the corresponding values.

2.5. Measurement properties

The psychometric performance of a PROM was determined by evaluating the quality of standard measurement properties [18]. The different measurement properties are part of three overall domains: reliability, validity, and responsiveness [21].

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