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Psychometric properties of the Neck OutcOme Score, Neck Disability Index, and Short Form–36 were evaluated in patients with neck pain

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Abstract

Objective: To assess reliability, construct validity, responsiveness, and interpretability for Neck OutcOme Score (NOOS), Neck Disability Index (NDI), and Short Form–36 (SF-36) in neck pain patients.

Study Design and Setting: Internal consistency was assessed by Cronbach alpha. Test-retest reliability was evaluated by intraclass correlation coefficient (ICC), and measurement error was estimated from the standard error of measurement. Responsiveness was assessed as standardized response mean (SRM) and interpretability from the minimal important difference (MID). Construct validity was tested correlating subscale scores from NOOS and SF-36 and NDI items.

Results: At baseline, 196 neck pain patients were included. Cronbach α was adequate for most NOOS subscales, NDI, and SF-36 with few exceptions. Good to excellent reliability was found for NOOS subscales (ICC 0.88–0.95), for NDI, and for SF-36 with few exceptions. For NOOS, minimal detectable changes varied between 1.1 and 1.9, and construct validity was supported. SRMs were higher for NOOS subscales (0.19–0.42), compared to SF-36 and NDI. MID values varied between 15.0 and 24.1 for NOOS subscales.

Conclusions: In conclusion, the NOOS is a reliable, valid, and responsive measure of self-reported disability in neck pain patients, performing at least as well or better than the commonly used SF-36 and NDI. © 2016 Elsevier Inc. All rights reserved.

Keywords: Patient-reported outcome; Questionnaire; Measurement instrument; Neck pain; Reliability; Construct validity; Responsiveness; Interpretability

1. Introduction

When evaluating treatment effects in patients with neck pain, different patient-reported outcome (PRO) instruments such as the disease-specific Neck Disability Index (NDI) [1] and the generic Short Form–36 (SF-36) [2] are most commonly used. However, despite their frequent use, their psychometric properties are considered inadequate [3], and there is an urgent need for PROs with sound psychometric foundation for the evaluation of treatments in people with neck pain. As a result, we developed a new PRO instrument named the Neck OutcOme Score (NOOS) for patients experiencing neck pain. The NOOS questionnaire was founded on a reflective model (classic test theory) [4], and the International Classification of Functioning, Disability and Health framework [5] was used as the conceptual model for the development of the NOOS questionnaire; thus, the goal was to be able to evaluate neck disability related to impairment (body functions and structure), activity limitations (activity), and participation restrictions (participation) [5]. The NOOS was developed in accordance with state of the art guidelines for development and evaluation of PRO instrument [6–8]. It includes 34 items divided into five subscales: "Mobility" (7), "Symptoms" (5), "Sleep disturbance" (4), "Every day activity and pain" (8), and "Participation in everyday life" (10). A normalized score (100 indicating "no symptoms" and 0 indicating "extreme problems") is calculated for each subscale, which displayed together creates an outcome profile. A detailed description of the development and validation of NOOS including selection and formulation of items, item reduction, and assessment of structural validity was previously reported [8].

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What is new?

Key findings

- NOOS is a reliable, valid, and responsive outcome measure for patients with neck pain.
- NOOS includes items related to both impairment, activity limitations, and participation restrictions.
- NOOS performs better than SF-36 and NDI.

What this adds to what was known?

- NOOS contains new items and constructs not previously explored in patients with neck pain.
- A globale measure of change may not be the best way to capture change over time.
- There is a need for new methods to assess construct validity

What is the implication and what should change now?

- The NOOS covers all three ICF domains, including participation, which should be addressed in order to ensure a patient-centered evaluation of a given intervention.
- Outcome measures, like the NOOS, which covers all three ICF domains, should be considers as the gold standard when evaluating the treatment effect of a given intervention.

The present article presents the evaluation of (test–retest reliability, measurement error, and internal consistency), evaluation of floor and ceiling effects, construct validity, responsiveness, and interpretability of the NOOS. To provide context for the reliability and responsiveness of the NOOS, we include these data for the NDI and SF-36.

2. Materials and methods

The Regional Scientific Ethical Committee for Southern Denmark, Denmark and the Danish Data Protection Agency approved the study (reference number 30513). All participants gave informed consent, and all rights of the participants were protected.

2.1. Study sample

People with neck pain were eligible for participation if they were aged over 18 years, were able to communicate in written and spoken Danish, had neck pain (with/without cervical radiculopathy) indicated on a body diagram [9] and who sought treatment for their neck pain. Participants were excluded if they were being investigated for cancer; had a neurological disorder (e.g., Multiple Sclerosis); lacked the ability to communicate (e.g, due to a psychotic episode); or had a history of drug or alcohol abuse, which might affect the participant's memory or ratings.

2.2. Data collection

The data collection took place at 15 private physiotherapist clinics and 1 spine center from May 2012 to March 2013. The clinics were located in or near Copenhagen, Aarhus, Odense, and Aalborg, Denmark. For data collection, a survey production tool (SurveyXact, Rambøll, Copenhagen, Denmark) was used. The questionnaire was completed three times—once in the clinic using a tablet—and twice by e-mail after 1 week and 3 months, respectively. The participants received the NOOS [8], NDI [1], SF-36 [2] (Acute version 1.1, Health Assessment Laboratory, Hillerod, Denmark, 1993) [10], and a Global Perceived Effect (GPE) scale, asking participants to rate their condition on a five-point scale. Participants were asked the following question: "How do you experience your neck problems today compared to 1 week (or 3 months) ago, when you completed the questionnaire the first time" with the following response options "much better" (+2), "better" (+1), "unchanged" (0), "worse" (−1), or "much worse" (−2).

SF-36 is a globally used self-administered generic measure of health status [2]. It includes 36 items divided into eight subscales: Physical Functioning (PF), Role-Physical (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role-Emotional (RE), and Mental Health (MH). Each scale is transformed into a 0–100 worst to best scale. SF-36 is a reliable measurement, which has been validated in the Danish population [10,11].

The NDI measures disability in activities of daily living in patients with neck pain. It includes 10 items and each item has six response categories (range 0–5, total score range 0–50). The higher the score, the more the disability [1]. The NDI was chosen despite the fact that the psychometric properties are considered inadequate [12,13] because it is the most frequently applied questionnaire for patients with neck pain. Furthermore, some studies have found the NDI to be reliable and demonstrated construct validity, showing positive correlations ($r \geq 0.53$) when compared with instruments measuring pain and/or physical functioning in patients with chronic neck pain, cervical radiculopathy, and whiplash-associated disorder [3,14].

2.3. Methodological evaluation of measurement properties

2.3.1. Floor and ceiling effect

Floor and or ceiling effects reflect issues with content validity and may limit the detection of change over time

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