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Outcome Measures of Functionality, Social Interaction, and Pain in Patients with Cervical Spondylotic Myelopathy: A Validation Study for the Iranian Version of the Copenhagen Neck Functional Disability Scale

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Study Design: Cross-sectional.
Purpose: To translate and validate the Iranian version of the Copenhagen Neck Functional Disability Scale (CNFDS).
Overview of Literature: Instruments measuring patient-reported outcomes should satisfy certain psychometric properties.
Methods: Ninety-three cases of cervical spondylotic myelopathy were entered into the study and completed the CNFDS pre and postoperatively at the 6 month follow-up. The modified Japanese Orthopedic Association Score was also completed. The internal consistency, test-retest, convergent validity, construct validity (item scale correlation), and responsiveness to change were assessed.
Results: Mean age of the patients was 54.3 years (standard deviation, 8.9). The Cronbach α coefficient was satisfactory (α=0.84). Test-retest reliability as assessed by the intraclass correlation coefficient analysis was 0.95 (95% confidence interval, 0.92–0.98). The modified Japanese Orthopedic Association score correlated strongly with the CNFDS score, lending support to its good convergent validity (r=–0.80; p<0.001). Additionally, the correlation of each item with its hypothesized domain on the CNFDS was acceptable, suggesting that the items had a substantial relationship with their own domains. These results also indicate that the instrument was responsive to change (p<0.0001).
Conclusions: The findings suggest that the Iranian version of the CNFDS is a valid measure to assess functionality, social interaction, and pain among patients with cervical spondylotic myelopathy.

Keywords: Validity; Copenhagen Neck Functional Disability Scale; Cervical spondylotic myelopathy; Iran

Introduction

Cervical spondylotic myelopathy (CSM) includes cervical herniated disc (CHD) and cervical spinal stenosis and is a progressive spine disease. It is the most common cause of spinal cord dysfunction. The symptoms of CSM depend on

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the level(s) of spinal cord involvement and its pattern [1-3].

A variety of measures are available to evaluate CSM and disability, such as the Neck Disability Index [4], the Northwick Park Neck Pain Questionnaire [5], the Copenhagen Neck Functional Disability Scale (CNFDS) [6], the Neck Pain and Disability Scale [7], the Bournemouth Questionnaire for Neck Pain [8], the Patient-Specific Functional Scale [9], the modified Japanese Orthopedic Association (mJOA) [10,11], the JOA Cervical Myelopathy Evaluation Questionnaire [12]. The Nurick score [13,14], and the JOA score [15], the Cooper-myelopathy scale [16], the Prolo score [17] and the European-myelopathy score [18]. However, it has been argued that none of these instruments are the gold standard [19].

The CNFDS was designed to assess disability related to neck dysfunction. It is a self-administered questionnaire, originally developed in Denmark [6], and is easily understood by patients [8]. It has been translated into Polish, Turkish, and French [19-21] and the entire questionnaire can be completed in <10 minutes [6]. Psychometric studies could help clinicians and researchers worldwide to carry out similar studies and compare the results. The aim of this study was to translate the CNFDS into Persian (Iranian language), validate and use the questionnaire to study health-related outcomes in Iranian patients with CSM.

Materials and Methods

1. Questionnaire

The CNFDS is designed to evaluate the disability experienced by patients with CSM. It consists of three sections including 15 items that evaluate: the impact of neck pain including the patient's perception of the future impact of neck pain (items 1, 5, and 15), disability during everyday activities (items 2, 3, 4, 5, 7, 8, 9, 10, and 12), and social interactions and recreation (items 6, 9, 11, 13, and 14) [6,21]. Each item has three possible response categories (yes=0, occasionally=1, and no=2) for the first five items and the remaining items are scored in reverse (yes=2, occasionally=1, and no=0). The total score is 0–30. A higher score indicates greater disability (Appendix 1).

2. Translation

We asked for permission to translate the CNFDS into Persian. Then, the "forward-backward" procedure was applied to translate the CNFDS from English into Persian. Two general practitioners translated the questionnaire into Persian, and these were back translated into English by a health professional and a professional translator. A few changes were made after a careful review, and the provisional Persian version of the questionnaire was pilot tested to establish that it could be understood and that the questions measured what they were intended to measure [22-24].

3. Patients and data collection

The final draft of the Iranian version was administered to a sample of patients newly diagnosed with CSM who were attending a neurosurgery clinic of a Shahid Beheshti University of Medical Sciences (Tehran, Iran) during April 2007 to June 2013. No restrictions were put on patient selection with regard to type of CSM, age, or other characteristics. The exclusion criteria were prior cervical spine surgery and spinal anomalies. The stenotic level(s) were localized on magnetic resonance or computed tomography images. All patients had typical symptoms of CSM and were surgical candidates. Two neurosurgical health professionals independently scored the questionnaires of patients admitted for surgery. Both independent observers assessed the patients on the same day. Scoring was performed on the day before surgery. The observers were unaware of the purpose of the study. Patients were assessed pre and postoperatively at the 6 months follow-up.

4. Surgical procedure

The key to treating CSM is to remove pressure from the spinal cord. Surgical methods to decompress the spinal cord include three approaches: (1) anterior cervical corpectomy from the front of the neck, as with anterior cervical discectomy and fusion and (2) cervical laminectomy and fusion and cervical laminoplasty from the back of the neck, and (3) combined procedure [25].

5. Additional measure

In addition to the CNFDS, the Iranian version of the mJOA was administered simultaneously to patients. The mJOA is a self-administered, disease-specific tool that originated from JOA score [10,11]. It consists of four sections including 22 items: Motor dysfunction of the upper

extremities (six items), motor dysfunction of the lower extremities (eight items), sensation (four items), and sphincter dysfunction (four items). The scores for each section are 0–5, 0–7, 0–3, and 0–3, respectively, giving a total score of 0–18. Higher score indicate less disability. In this study, the total mJOA score was used for the assessment.

6. Statistical analysis

The psychometric properties of the CNFDS were evaluated for reliability, validity, and responsiveness to change. (1) Reliability: Cronbach α coefficient was used to test reliability and internal consistency of the questionnaire, and α≥0.70 was considered satisfactory. In addition, we assessed test-retest reliability using the intraclass correlation coefficient (ICC) analysis. ICC values >0.80 were considered excellent stability [26]. (2) Validity: Construct validity was assessed with the item-scale correlations. Correlations were calculated using Pearson correlation coefficient (*r*) analysis. We expected that item scores would correlate higher with the hypothesized scale than the other scales. Correlation values ≥0.40 were considered satisfactory (*r*≥0.81–1.0, excellent; 0.61–0.80, very good; 0.41–0.60, good; 0.21–0.40, fair; and 0–0.20, poor) [19]. In addition the correlation between CNFDS and mJOA scores was assessed using Pearson correlation coefficient analysis to assess convergent validity (criterion validity). This type of validity is useful for showing that the construct of an instrument is meaningful. Values ≥0.40 were considered satisfactory (*r*≥0.81–1.0, excellent; 0.61–0.80, very good; 0.41–0.60, good; 0.21–0.40, fair; and 0–0.20, poor) [26]. (3) Responsiveness to change: Responsiveness was evaluated as a psychometric property of the questionnaire. As such, the patient's pre and postoperative scores were compared using the paired *t*-test to examine whether the CNFDS could capture the changes after surgery

7. Ethics

The Ethics Committee of Shahid Beheshti University of Medical Sciences (Tehran, Iran) approved this study.

Results

1. Study sample

Ninety-three patients with CSM were studied. The mean age of the patients was 54.3 (standard deviation [SD], 8.9) years, most were married (72%), and had completed primary or secondary education (61.3%). The patient's characteristics and their mJOA scores are shown in Table 1. Most patients with CSM had a developmentally narrow spinal canal, and the decompressive laminae were distributed from the C2 to T1 levels. The number of decompressed lamina was 3.1 (SD, 1.0). Most patients with CHD had a one- or two level discectomy distributed from the C2 to C7 levels. Significant differences were observed between the pre and postoperative assessments, indicating improvements on the outcomes and functionality on all subscales (p<0.001). However, no differences were detected between patients with cervical spinal stenosis and CHD (p≥0.05).

Table 1. The characteristics of the study sample (n=93)

Variable	No. (%)
Age (yr), mean±SD (range)	54.3±8.9 (20–79)
Sex	
Male	42 (45.2)
Female	51 (54.8)
Educational status	
Illiterate	19 (20.4)
Primary	34 (36.6)
Secondary	23 (24.7)
College/university	17 (18.3)
Marital status	
Single	14 (15.1)
Married	67 (72.0)
Divorced/widowed	12 (12.9)
Type of disease	
Cervical herniated disc	50 (53.8)
Cervical spinal stenosis	43 (46.2)
The modified JOA score	
Preoperative	
Total mean±SD	7.1±1.2

SD, standard deviation; JOA, Japanese Orthopedic Association score.

2. Reliability

(1) The internal consistency for the CNFDS and its three sections as calculated by the Cronbach α coefficient is shown in Table 2. All sections exceeded the minimum reliability standard of 0.70 at the preoperative assess-

Table 2. Descriptive statistics for the three Copenhagen neck Neck Functional Disability Scale subscales (n=93)

Variable	No. of items	Mean±SD	Cronbach alpha coefficient[a]	Kappa statistics[b]
Pain severity	3	4.4±1.5	0.82	-
Disability	9	11.3±4.5	0.84	-
Social interaction	5	5.2±1.9	0.85	-
Total	15	20.9±8.1	0.84	0.81

SD, standard deviation.
[a]A value of 0.70 or above indicates adequate reliability; [b]This was calculated for inter-observer rating of the questionnaire.

Table 3. Test-retest reliability for the Copenhagen Neck Functional Disability Scale (n=78)

Variable	No. of items	Test	Retest	Test-retest reliability (ICC[a], 95% CI)
Pain severity	3	4.2±1.5	4.2±1.5	-
Disability	9	11.1±4.5	10.9±4.5	-
Social interaction	5	5.3±1.9	5.0±1.9	-
Total	15	20.7±8.1	20.1±8.0	0.95 (0.92–0.98)

Values are presented as mean± standard deviation.
ICC, intraclass correlation coefficient; CI, confidence interval.
[a]A value of ICC above 0.80 was considered as evidence of excellent reliability.

ment. The Cronbach α for the scale was 0.84, indicating satisfactory results. The results are shown in Table 2. (2) Test-retest reliability: The ICC was excellent (0.95) for the CNFDS (95% confidence interval, 0.92–0.98) (Table 3).

3. Construct validity

Construct validity of the CNFDS was examined using item-scale correlations and criterion validity. The item scale correlation matrix between each item and the three CNFDS subscales are shown in Table 4. All correlations between items and the hypothesized scale were satisfactory, suggesting that the items had a substantial association with their own subscale. Pearson correlation coefficient exceeded 0.40 (range, 0.57 [Q10]–0.71 [Q4]).

4. Convergent validity

Total score on the CNFDS was correlated strongly with total score on the mJOA, supporting the good convergent validity (r= −0.80, p<0.001)

5. Responsiveness to change

Responsiveness to change was evaluated using the paired t-test. In all instances, the CNFDS detected changes after the intervention (surgery), indicating improvements in all subscales as expected. The outcomes are shown in Table 5.

Discussion

This study is the first to report on translating and validating an Iranian version of the CNFDS. The results indicate that the Persian version of the CNFDS is a valid and reliable instrument for measuring disability in patients with CSM. The measurements were consistent and reproducible, with good discriminative properties, and was comparable with versions in other languages [6,19-21].

This Persian version of CNFDS is the only condition-specific outcome measure for patients with CSM that has undergone a psychometric evaluation in Iran. The Cronbach α for the Persian CNFDS exceeded the recommended threshold, suggesting that the Persian version of the questionnaire has satisfactory internal consistency. The results were similar to those reported by other authors who have used this measure in patients with degenerative and discopathic disorders of the cervical spine and chronic neck pain [6,19,21]. Test-retest reliability was examined using ICCs. ICCs of the tool were >0.80, demonstrating good test-retest reliability for the scale, which is similar

Table 4. Item-scale correlation matrix for the three Copenhagen Neck Functional Disability Scale subscales[a] (n=93)

Items (item no.)	Pain severity	Disability	Social interaction
Can you sleep at night without neck pain interfering? (Q1)	0.67	0.17	0.21
Can you manage daily activities without neck pain reducing activity levels? (Q2)	0.23	0.64	0.17
Can you manage daily activities without help from others? (Q3)	0.18	0.58	0.22
Can you manage putting on your clothes in the morning without taking more time than usual? (Q4)	0.26	0.71	0.18
Can you bend over the washing basin in order to brush your teeth without getting neck pain? (Q5)	0.71	0.69	0.28
Do you spend more time than usual at home because of neck pain? (Q6)	0.14	0.26	0.61
Are you prevented from lifting objects weighing from 2-4 kilograms due to neck pain? (Q7)	0.22	0.64	0.18
Have you reduced your reading activity due to neck pain? (Q8)	0.26	0.77	0.27
Have you been bothered by headaches during the time that you have had neck pain? (Q9)	0.20	0.63	0.71
Do you feel your ability to concentrate is reduced due to neck pain? (Q10)	0.22	0.57	0.17
Are you prevented from participating in your usual leisure time activities due to neck pain? (Q11)	0.31	0.16	0.67
Do you remain in bed longer than usual due to neck pain? (Q12)	0.19	0.69	0.28
Do you feel that neck pain has influenced your emotional relationship with your nearest family? (Q13)	0.12	0.19	0.59
Have you had to give up social contact with other people during the past two weeks due to neck pain? (Q14)	0.11	0.26	0.76
Do you feel that neck pain will influence your future? (Q15)	0.68	0.23	0.24

[a]Pearson correlation (r) equal to or greater than 0.40 was considered satisfactory (correlation ≥0.81–1.0 as excellent, 0.61–0.80 very good, 0.41–0.60 good, 0.21–0.40 fair, and 0.0–0.20 poor) [14].

Table 5. Responsiveness to change as measured by the Copenhagen Neck Functional Disability Scale (n=93)

Variable	Preoperative	Postoperative	*p*-value[a]
Pain severity	4.4±1.5	1.8±1.2	<0.0001
Disability	11.3±4.5	4.8±2.1	<0.0001
Social interaction	5.2±1.9	2.1±1.4	<0.0001
Total	20.9±8.1	8.7±4.6	<0.0001

Values are presented as mean±standard diviation.
[a]Derived from paired samples *t*-test.

to other studies reporting psychometric properties of the CNFDS [6,20]. Our results show that the CNFDS has acceptable interobserver reliability; however, it was not investigated in other studies.

We evaluated convergent validity, which contributes to a psychometric evaluation of the instrument. Correlations between the CNFDS and the visual analog scale [6,21], or the Neck Pain and Disability Scale (NPDS) have been reported by other studies [6,20,21]. Furthermore, the CNFDS showed excellent item-scale correlation. These results match the good construct validity reported by similar studies in other languages, and could be regarded as a valid measure.

This study had some limitations. Sample size was small, and a larger study would help establish stronger psychometric properties for the questionnaire. We performed

a number of limited tests for the validation. It may be necessary to perform other tests, such as a factor analysis, to indicate the factor structure. In addition, we were unable to include other types of neck pain disease in this study for the psychometric assessment due to a variety of disease- and treatment-related variables in patients with neck pain. Lastly, for a complete validation of the scale, other criteria, such as interpretability, by means of minimum clinically important difference, or responsiveness, using minimum detectable change, should also be tested. It is unclear that the difference in pre- and postoperative scores is the proper approach to validate responsiveness in the absence of a comparison against a known gold standard.

Conclusions

The findings from this preliminary validation study indicate that the Iranian version of the CNFDS is a reliable and valid instrument to test functionality, social interactions, and pain among patients with CSM.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Appendix 1. The Copenhagen Neck Functional Disability Scale.

The Copenhagen Neck Functional Disability Scale			
	Yes	**Occasionally**	**No**
(1) Can you sleep at night without neck pain interfering?			
(2) Can you manage daily activities without neck pain reducing activity levels?			
(3) Can you manage daily activities without help from others?			
(4) Can you manage putting on your clothes in the morning without taking more time than usual?			
(5) Can you bend over the washing basin in order to brush your teeth without getting neck pain?			
(6) Do you spend more time than usual at home because of neck pain?			
(7) Are you prevented from lifting objects weighing from 2-4 kilograms due to neck pain?			
(8) Have you reduced your reading activity due to neck pain?			
(9) Have you been bothered by headaches during the time that you have had neck pain?			
(10) Do you feel your ability to concentrate is reduced due to neck pain?			
(11) Are you prevented from participating in your usual leisure time activities due to neck pain?			
(12) Do you remain in bed longer than usual due to neck pain?			
(13) Do you feel that neck pain has influenced your emotional relationship with your nearest family?			
(14) Have you had to give up social contact with other people during the past two weeks due to neck pain?			
(15) Do you feel that neck pain will influence your future?			