Original Article

The Responsiveness of the Persian Version of Neck Disability Index and Functional Rating Index Following Physiotherapy Intervention in People with Chronic Neck Pain

Reza Salehi[1,2], PhD; Hossein Negahban[3,4], PhD; Najmeh Saghayezhian[1], MSc; Maryam Saadat[1], PhD

[1]Musculoskeletal Rehabilitation Research Center, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran;
[2]Rehabilitation Research Center, Department of Rehabilitation Management, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran;
[3]Department of Physical Therapy, School of Paramedical Sciences, Mashhad University of Medical Sciences, Mashhad, Iran;
[4]Orthopedic Research Center, Mashhad University of Medical Sciences, Mashhad, Iran

Correspondence:
Najmeh Saghayezhian, MSc;
Musculoskeletal Rehabilitation Research Center, Ahvaz Jundishapur University of Medical Sciences, Postal code: 61357-33133, Ahvaz, Iran
Tel: +98 61 33743101
Fax: +98 61 33743506
Email: nszh90@gmail.com
Received: 17 November 2017
Revised: 8 January 2018
Accepted: 4 February 2018

Abstract

Background: Clinicians and researchers commonly use responsive outcome measures to interpret changes in a patient's condition as a result of an intervention. This study was conducted to assess the ability of the Persian version of Neck Disability Index and Functional Rating Index to detect responsiveness in the patients with neck pain.

Methods: A diagnostic accuracy study was done in Ahvaz, Iran, 2016. A convenience sample of 57 Persian-speaking patients with non-specific chronic neck pain completed the Neck Disability Index and the Functional Rating Index at the beginning and after physiotherapy intervention. The responsiveness was investigated by the receiver operating characteristics method and the correlation analysis. Statistical analysis was done using SPSS (version 21), with a P<0.05 as the level of significance.

Results: The Functional Rating Index showed that the area under the curve was greater than 0.70 (range=0.651-0.942). The optimal cutoff points for the Functional Rating Index and the Neck Disability Index were 9.5 and 7.5, respectively. Gamma correlation between change scores of the Functional Rating Index and the Neck Disability Index and the Global Rating of Change Scores was 0.53 and 0.33, respectively.

Conclusion: The results indicated that the Persian version of the Functional Rating Index could detect clinical changes following physiotherapy intervention in a group of patients with chronic non-specific neck pain. Therefore, we recommend that this instrument be used as a responsive measure of neck pain disability in patients with neck pain.

What's Known

• Persian version of the Neck Disability Index and Functional Rating Index are valid and reliable.

What's New

• Persian version of the Functional Rating Index in Iranian patients with chronic neck pain has an acceptable level of responsiveness.
• The best cutoff point for the Functional Rating Index was 9.5 out of 40 points.

Introduction

Chronic Neck Pain (CNP) is a common musculoskeletal problem in the general population and its incidence is estimated to be nearly 19%.[1] CNP is characterized by pain and functional limitation in daily activities,[2] and health outcome measures are commonly used to determine such functional limitation and disability.[3] Since the disability as the result of an interaction between the person and his environment, there is no gold standard for assessment

of neck pain disability. Therefore, questionnaires with good psychometric qualities could be used for evaluation of the functional limitation and disability.[3, 4]

To assess the effects of neck pain in daily activities, Vernon and Mior developed the Neck Disability Index (NDI).[4] NDI is the most commonly used questionnaire for evaluating functional limitation in neck pain clinical research.[2, 5]

Functional Rating Index (FRI) was developed by Feise and Menke to evaluate the perspective on pain and functional status in patients with neck pain.[6, 7] They combined concepts of the Oswestry Disability Index in low back pain and the NDI to improve the clinical utility in FRI.[7] Psychometric and clinical properties of the original and cross-cultural adaptation of NDI and FRI have been previously reported.[2, 6] Persian versions of NDI and FRI are found to have acceptable measurement properties in patients with neck pain[8-10] and the outcome questionnaires are commonly used to measure treatment efficacy in clinical research.[2] NDI and FRI are expected to measure the effect of treatment on pain and functional limitation.[11] To evaluate the effects of treatment programs, it is necessary that instruments be responsive.[2, 11] In the other words, measurement tools or questionnaires must be able to detect minimum changes in scores relevant to the patients, clinicians or socioeconomic perspectives.[11] One of the concepts that have been used to determine the responsiveness of measurement tools is the anchor-based approach. In this approach, researchers compare changes in the instruments with a second, external measure of change, as an external criterion (anchor).[2, 12-14]

The most common method in this approach is the calculation of minimal clinically important difference (MCID) that was determined by the Receiver Operating Characteristic (ROC) curve cut-off point.[3, 11, 13, 15]

Having an acceptable reliability and validity is also essential for establishing the responsiveness of measurements. Some studies have reported on the responsiveness and ability of the NDI to detect the changes in the other language versions, but limited reports exist about the responsiveness of the FRI.[7, 11, 12] To the best of our knowledge, no study has yet compared the responsiveness ability of this two outcome measures in patients with non-specific chronic neck pain. Although the validity and reliability of the Persian version of the NDI and the FRI in Iranian patients with CNP have been already confirmed,[8, 9] the responsiveness of these Persian version outcome measures is unknown. Therefore, the aim of this study was to assess the responsiveness of the NDI and FRI questionnaires according to the anchor-based approach in Persian-speaking patients with CNP following physiotherapy intervention.

Participants and Methods

Participants

Patients with CNP were enrolled from outpatient physiotherapy clinics located at territory university centers in Ahvaz. Fifty-seven native Persian-speaking patients with CNP were selected for this study. All patients were diagnosed by orthopedic surgeon based on the history, physical examination, and imaging findings. The sample size was calculated based on the comparison of two independent diagnostic tasks with $AUC_1 - AUC_2 = 0.2$, 95% confidence level and 80% power.[16]

Inclusion criteria for this study were non-specific CNP, neck pain with or without referral pain to upper limbs, neck pain more than 3 months, the age range between 18 and 50 years old, and also the ability to read or understand the items of the patient-reported questionnaires. Non-specific neck pain involves neck pain with no specific underlying pathology.[17] Patients were excluded if they had specific neck pathology, e.g. disk herniation, canal stenosis, history of neck surgery, pregnancy, shoulder pathology, trauma, or post whiplash symptoms.

This study was approved by the local Research Ethics Board and all subjects signed an informed consent form for being part of this study.

Procedure

The design of this study was a diagnostic accuracy. Persian versions of the NDI and FRI were completed by all subjects at the beginning of the study (at the first visit) and also after physiotherapy intervention (12 sessions physiotherapy). At the final visit session, each patient rated changes in the Global Rating Change (GRC) of neck function compared to his/her baseline status in 7-point ordinal scale. The GRC was composed of seven responses, including 1=very much better, 2=much better, 3=slightly better, 4=no change, 5=slightly worse, 6=much worse, 7=very much worse. This scale was used as the external criterion of clinically important changes in the patient`s neck functions.[18] In effect, the patients were considered improved patients if they scored "very much better" or "much better", and were classified as unimproved patients if they scored "slightly better", "no change", "slightly worse", "much worse" or "very much worse".[19, 20]

The physiotherapy treatment program consisted of Transcutaneous Electrical Nerve Stimulation (TENS), cervical mobilization technique, stretching exercises for the scalenes, upper trapezius, levator scapulae, pectoralis minor and major, strengthening exercises for deep cervical flexor, extensor, and shoulder muscles. Participants received three treatment sessions in a week over a 4-week period and each treatment session lasted between 45 and 60 minutes. Data were collected during a period of 8 months between March 2016 and October 2016.

Outcome Measures

The NDI is a 10-item instrument and each item has a six-point response scale ranging from 0 (no pain or limitation) to 5 (as much pain as possible or maximal limitation) in the activities. The NDI total score ranges from 0 to 50, as higher score indicates greater disability.[4] The Persian version of NDI has been further validated for use in Iran.[8] In this study, the raw score of the NDI was converted to a percentage.

The FRI consists of 10 items created to improve response scales of the Oswestry Disability Index and NDI. Each item of this instrument has a 5-point response scale (scored from 0 to 4) and the original score is converted to a scale of 100. The total range of scores is 0% (no disability) to 100% (severe disability).[6, 7] The Persian version of FRI has been also validated for use in Iran.[9]

Statistical Analysis

Statistical analysis was performed with SPSS version 21.0 for Windows (SPSS Inc., Chicago, IL). The level of statistical significance was set at $P<0.05$.

To examine the responsiveness, the difference scores between baseline and final visits were calculated for NDI and FRI.

In this study, the responsiveness was evaluated using the receiver operating characteristics (ROC, 95% confidence interval [CI]) and the correlation analysis.[3, 11-15, 19, 20] The ROC curve is constructed by plotting the true positive rate against the false positive rate at various threshold settings as an external criterion.[11]

We divided the patients into two groups based on their GRC scores (improved-unimproved). In the ROC method, the patient's GRC score was used as an external criterion. The ROC curve is constructed by plotting the sensitivity on the y-axis against the 1-specificity on the x-axis for each cutoff point in change scores of the instrument.[18, 19] The area under curve (AUC)

and 95% confidence interval and the optimal cutoff point (MCID) were useful statistics extracted from the ROC curve.[21] In effect, the AUC is used to show the responsiveness of an instrument. In other words, the AUC is the instrument's ability to differentiate between two groups of improved and unimproved patients based on the Global Rating Change.[3, 15, 21] The AUC closer to 1 indicates better accuracy in discrimination power of the instrument.[22] The AUC equal to or greater than 0.70 is considered as an acceptable level of responsiveness.[15, 19, 20] The MCID has been used to represent the magnitude of the change score that is a clinically meaningful change. In effect, the MCID denotes the smallest difference in the domain of the patient's or clinician's perspectives, and it might also represent the responsiveness ability of an instrument.[14, 15] The optimal cutoff point was determined using a minimum distance from the left-upper corner of the unit square of the ROC curve.[3, 23]

The responsiveness was also assessed by the correlation analysis between the change scores of the NDI and FRI with the raw scores of GRC using the Gamma correlation coefficient. In fact, in this method, the strength of the correlation was interpreted as the indication of the responsiveness in such a way that the correlation coefficients less than 0.25, 0.25-0.5, 0.5-0.75 and >0.75 were considered as little, fair, moderate to good, and good to excellent relationships, respectively.[15]

Table 1: Demographic and clinical characteristics of the patients with chronic neck pain completing the questionnaires (n=57)

	N (%)
Demogaraphic data	
Age(year), mean±SD	38.40±10.8
Height(cm), mean±SD	163.80±10
Weight(kg), mean±SD	72.70±17.20
Gender	
Men	13(22.80)
Women	44(77.20)
Year of education	
9-12	28(49.10)
>12	29(50.90)
Marital status	
Single	13(22.80)
Married	44(77.20)
Clinical data	
Pain duration(year), mean±SD	2.80±3.4
Affected side	
Right hand	12(21.20)
Left hand	11(19.30)
Two	25(43.90)
None	9(15.80)

Results

Demographic and clinical characteristics of the patients participated in this study are listed in table 1. Descriptive statistics for the NDI and FRI scores, including the mean scores and standard deviations of pre-intervention, post-intervention, and change scores are also summarized in table 2.

The mean change scores for the improved and unimproved patients were 21.54% and 11.93% for the NDI, and 28.59% and 10.29% for FRI, respectively. Based on the Global Rating Scale, 41 patients were classified as improved patients.

The results of the AUC (95% CI) and Gamma correlation coefficient for each instrument according to the GRC as an external criterion, (classified as improved versus unimproved) are shown in table 3.

Figures 1 and 2 show Roc curves of corresponding NDI and FRI questionnaires, respectively.

The FRI showed the AUC greater than

Table 2: Mean scores and standard deviation of pre-intervention, post-intervention, and change scores for Neck Disability Index and Functional Rating Index questionnaires

Questionnaires	Pre-intervention mean±SD	Post-intervention mean±SD	Change mean±SD
NDI			
Total (n=57)	41.38±14.77	22.53±15.25	18.84±13.46
Improved (n=41)	40.59±15.62	19.04±15.59	21.54±12.90
Unimproved (n=16)	43.41±12.58	31.48±10.07	11.93±12.70
FRI			
Total (n=57)	51.48±14.28	28.02±15.80	23.45±17.04
Improved (n=41)	52.50±13.93	23.90±14.64	28.59±12.69
Unimproved (n=16)	48.88±15.32	38.59±13.96	10.29±19.93

NDI: Neck disability index; FRI: Functional rating index

Table 3: Gamma correlation coefficient area under the receiver operating characteristics curve for each questionnaire according to the external, classified measures of global rating scale (improved versus unimproved; n=57)

Questionnaires	Gamma coefficient (P value)	AUC (95%CI)	Optimal cut-off value	Sensivity (95%CI)	Specificity (95%CI)
NDI	0.33 (0.001)	0.677 (0.531-0.823)	7.50	0.70 (0.54-0.83)	0.75 (0.47-0.91)
FRI	0.53 (<0.001)	0.796 (0.651-0.942)	9.50	0.68 (0.51-0.81)	0.75 (0.47-0.91)

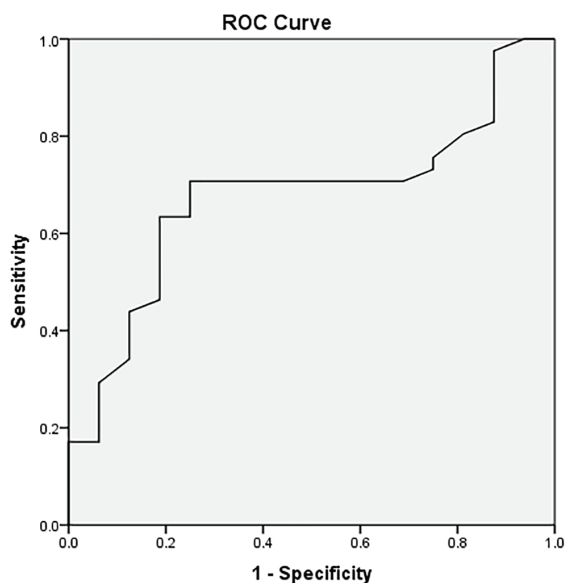NDI: Neck Disability index; FRI: Functional rating index; AUC: Area under curve

Figure 1: The figure shows receiver operation charactristic cure for the Neck Disability Index.
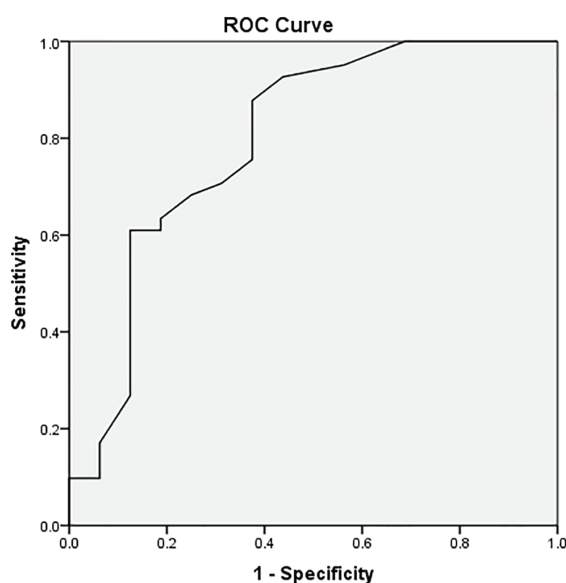

Figure 2: The figure shows receiver operation charactristic cure for the Functional Rating Index.

0.70 (AUC range=0.651-0.942), indicating an acceptable discrimination power between the two groups of improved and unimproved patients.

The best cutoff points with the best combination of sensitivity and specificity for the FRI and NDI were 23.75% (with sensitivity=0.68, specificity=0.75), 15% (with sensitivity=0.70, specificity=0.75), respectively.

The correlation coefficient between changes in the FRI / NDI and changes in the Global Rating Scale was found to be 0.53 and 0.33, respectively. That just says that the FRI showed moderate to good relationship with GRC.

Discussion

In this study, we evaluated the ability of FRI and NDI to identify meaningful clinical changes in the cervical function following physiotherapy intervention.

The results showed that the Persian version of the FRI has an adequate responsiveness, as indicated by the two methods of evaluating responsiveness. Although both the FRI and the NDI exhibited a significant reduction in disability of patients with CNP, our study showed that the FRI was a responsive instrument for the change in neck health status when true change occurred (AUC FRI=0.796). However, NDI did not show such responsiveness (AUC NDI=0.677). This implies that the constructs of the FRI are more sensitive to the true change expected by physiotherapy in patients with chronic non-specific neck pain than the constructs of the NDI. The AUC was used as an indicator of the probability to discriminate the improved patients from those unimproved. In this study, the FRI had an AUC greater than 0.7 which was consistent with the results reported in other studies. For instance, Lee and others evaluated the responsiveness of the FRI and the NDI in patients with non-specific neck pain. Their results showed the AUC values of 0.75 for the Korean versions of the NDI and FRI.[24]

The AUC of NDI in this study was slightly lower (0.677) than that reported by Jorritsma and others [11] and Young and others.[25] Johansen and others reported AUC=0.70 for the Norwegian version of the NDI.[26] These differences may be explained by the different cutoff points in the GRC score and the long time (2 years) follow-up in the Norwegian version. Cleland and others also reported the AUC=0.57 of the NDI in patients with cervical radiculopathy.[27] These findings indicated that the responsiveness of instruments would be context-related or condition specific. Our findings could be supported by the findings of the study by Pereira and others, in which Portuguese Version of the NDI demonstrated moderate responsiveness (AUC=0.59).[28]

Results obtained from the correlation analysis are in agreement with the ROC method. The change score of the FRI showed a higher correlation coefficient with the raw global rating change score compared with the change score of the NDI (0.53 vs. 0.33, respectively). The FRI showed moderate to good correlation with GRC.

To determine a clinically important change, the optimal cutoff point was achieved through the ROC curve. The results obtained in this study showed that a change of 7.5 out of 50 points (15%) for the NDI and 9.5 out of 40 points (23.75%) for the FRI was the MCID in patients with chronic non-specific neck pain. The MCID has been also reported in other studies. For example, Jorritsma and others reported a minimal important change of 3.5 out of 50 points for the NDI.[11] Likewise, Cleland and others reported an MCID of 10 out of 50 points in a sample of cervical radiculopathy patients.[27] Young and others also determined an MCID of 7.5 out of 50 points in the patients with primary mechanical neck pain.[25] The variability reported in the responsiveness values of a patient outcome measure can be rationalized due to the different cut offs selected in the global rating scale and different patient populations, different external criteria, or a different formula for the MCID calculation.[11, 25]

This study has, in turn, some limitations that may limit the generalizability of the results. First, the findings of this study can only be generalized to Persian-speaking patients with chronic non-specific neck pain who underwent a physiotherapy intervention. Second, recall bias associated with the global rating change score as an external criterion is probably compromised in this study. Third, although the sample size in this study is based on the formula, the small sample size threats the balance between the subgroups (improved/ unimproved), thus decreasing the reliability of the optimal cutoff point. We recommended a large sample size to give greater power to detect differences in future studies.

Conclusion

The results indicated that the Persian version of the FRI could detect clinical changes following physiotherapy intervention in a group of patients with chronic non-specific neck pain. Therefore, we recommend that this instrument be used as a responsive measure of neck pain disability in patients with neck pain.

Acknowledgment

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