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Title: Psychometric properties of the Norwich Patellar Instability Score in people with recurrent patellar dislocation.

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ABSTRACT

Background: Patellar dislocations account for 2% of all knee injuries with a 17% chance of re-dislocation. There are few validated scores specific to instability. One of these is the Norwich Patellar Instability Score. There has been limited assessment of the validity, floor-ceiling effect and responsiveness of the Norwich Patellar Instability (NPI) Score from an independent centre. The purpose of this paper is to address this limitation.

Methods: Data from 90 patients referred to a tertiary referral patellofemoral clinic were analysed. All routinely completed data including NPI Score, Kujala Patellofemoral Disorder Score, and demographic outcomes during appointments, up to 36 months following initial clinical assessment was analysed. Convergent validity was assessed by correlating outcomes of the Kujala Patellofemoral Disorder Score to the NPI Score. Effect size (ES) was determined between baseline to 12-month and 12 to 36-month assessments to determine responsiveness. Floor-ceiling effect was evaluated at baseline, 12-month and 12 to 36-month follow-up.

Results: NPI Score demonstrated good convergent validity to the Kujala Patellofemoral Disorder Score (p<0.001; 95% confidence interval (CI): -0.71 to -0.52). NPI Score demonstrated good responsiveness to change both between baseline to 12 months (ES: 0.43; 95% CI: 0.42 to 0.10) and 12 to 36 months (ES: 0.67; 95% CI: 0.60 to 0.15). Whilst the NPI Score did not demonstrate a ceiling effect, there was moderate risk of a floor-effect where 13% of the cohort reported the lowest levels of NPI scores.

Conclusions: The NPI Score is a valid and responsive outcome for people with recurrent patellar dislocation.

Keywords: Patellar dislocation; subluxation; patient-reported outcome measure; validity; responsiveness; floor-ceiling

1.0   INTRODUCTION

Patellar instability is a disabling musculoskeletal condition associated with patellar dislocation, subluxation or a perception of either occurring.[1] People with patellar instability report a spectrum of functional disability, ranging from dressing to shopping to higher-level, multidirectional activities.[1] The Norwich Patellar Instability (NPI) Score was designed to assess patellar instability in this population.[2] It is a disease-specific, self-reported, patient-reported outcome measure (PROM) that consists of 19-items, where respondents report the severity of their perceived patellar instability symptoms to activities previously reported as potentially symptomatic.[1] The NPI Score has been adopted in a number of clinical trials, both surgical [3,4] and non-surgical.[5]

There has been limited evidence reporting the validity and responsiveness of this tool. This early data has indicated that the NPI Score is valid to assess patellar instability for individuals following patellar dislocation.[2,6] This has largely been conducted in the NPI Score's developing team's clinical centre. Accordingly, there remains uncertainty as to whether the psychometric properties associated with this PROM are associated with the patient population seen in that centre and whether there are institutional effects in the administration of the tool for their reported cohorts.

To examine these, the purpose of this study is to report data on the psychometric properties of the NPI Score from an independent centre. We specifically wanted to answer the following questions from this cohort: (1) does the NPI Score correlate to previously validated outcome measures (Kujala Patellofemoral Disorder Score) used to evaluate people with recurrent patellar instability; (2) is the NPI score responsive to change over the first 24 months following injury for people with recurrent patellar instability; and (3) does the NPI Score demonstrate a floor-ceiling effect for people with recurrent patellar instability?

2.0   METHODS

2.1   Participants

Data from a routinely collected database of 90 consecutive patients who had experienced recurrent patellar dislocation and attended the senior author's patellar instability specialist clinic were analysed. This is a tertiary referral centre in London, United Kingdom (UK).

Data routinely collected during hospital appointments in this clinic include: age, gender, ethnicity, family history of patellar instability, number of previous patellar dislocation and date of last dislocation, Body Mass Index (BMI), hypermobility assessed using the Beighton criteria,[7] Apprehension test and J-Sign test,[8] pain numerical rating score, knee flexion-extension range of motion and observable lateral tracking. The surgical or non-surgical interventions participants underwent was reported. Participants were also asked to complete a NPI score[2] and Kujala Patellofemoral Disorders Score.[9] Data were collected at baseline (pre-intervention), three, six, 12 and up to 36 months post-intervention. Only patients who presented with full NPI Score data at follow-up were included in the analyses.

2.2   Data Analysis

Descriptive statistical tests including the mean and standard deviations (SD) were calculated to assess the participant's demographic characteristics including: age, gender and surgical procedure. The Shapiro Wilk W test confirmed the dataset was normally distributed.

Validity was assessed in accordance with the Medical Outcomes Trust health instrument assessment criteria.[10] Convergent validity was assessed by correlating the NPI Score to the Kujala Patellofemoral Disorder Score using a Pearson Correlation Coefficient statistical test. This was appropriate since the Kujala Patellofemoral Disorder Score is a patellofemoral-specific tool which includes questions on key aspects of patient's with instability lived experiences, namely instability, pain and functional deficit.[9]

Responsiveness was determined for the NPI Score by calculating the mean difference (MD) in NPI Score between each follow-up period. The effect size (ES) of the NPI Score between the different follow-up periods was determined through the pooled SD for all data. Through these two analyses, the responsiveness of the NPI Score for individuals following intervention was made for the follow-up periods.

The frequency of respondents with the highest (ceiling) and lowest (floor) scores for total NPI Score was determined for the NPI score dataset. A ceiling-effect assessed the proportion of respondents who report the highest possible response option.[11] Conversely a floor-effect indicated the proportion of respondents which reported the lowest possible response option.[11] Based on previous studies of musculoskeletal populations, a 15% threshold was adopted to indicate high floor or ceiling-effects.[12,13]

All analyses were undertaken using SPSS (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp).

3.0 RESULTS

3.1 Cohort

A summary of the cohort characteristics is presented in **Table 1**. Data from 90 patients were included. This consisted of 72 females (80%) and 18 males (20%) with a mean age of 29 years (SD: 9.8). Thirty-six participants (40%) underwent non-operative management. Mean Beighton score was 2.46 (SD: 2.62).

3.2 NPI Score convergent validity

There was a linear association with higher Kujala Patellofemoral Disorder scores and lower NPI scores (p<0.001; R=-0.629; 95% confidence interval (CI): -0.71 to -0.52). As illustrated in **Figure 1**, this was a negative (inverse) linear relationship. Therefore there was strong convergent validity between the NPI Score and Kujala Patellofemoral Disorder Score.

3.3 NPI Score responsiveness

There was sufficient data to report the responsiveness of the NPI Score and Kujala Patellofemoral Disorders Score at two time-points: baseline to 12 months and 12-36 months. The baseline and follow-up mean and SD values for these are presented in **Table 1**. Both demonstrate responsiveness to change. The NPI Score demonstrated greater responsiveness, with an effect size estimate from baseline to 12 months of 0.43 (95% CI: 0.42 to 0.10). The 12 to 36 month effect size estimate for the NPI Score was 0.67 (95% CI: 0.60 to 0.15). In contrast, the Kujala Patellofemoral Disorder Score demonstrated an effect size estimate from baseline to 12 months of 0.14 (95% CI: 0.14 to 0.47). The 12 to 36 month effect size estimate was 0.59 (95% CI: 0.55 to 1.02).

3.4 Floor-ceiling effect

A summary of the floor-ceiling analysis is presented in **Table 2**. As this illustrates, there was limited evidence of a ceiling effect across the NPI Score data irrespective of follow-up interval. There was limited evidence of a floor-effect at the baseline to 12-36 month follow-up interval. There was moderate evidence of a floor-effect at the 12-month follow-up interval where 13% of participants reporting the lowest response option.

4.0   DISCUSSION

This analysis from an independent centre indicates that the NPI Score is a valid and responsive PROM for people who attend hospital following recurrent patellar dislocation. Whilst the NPI Score demonstrates convergent validity to the Kujala Patellofemoral Disorder Score, it demonstrates superior responsiveness to change at 12-months and 12-36 months post-baseline measure. Although there is no evidence of a ceiling effect, the NPI Score demonstrated a moderate floor-effect for 13% of patients. This suggests that the instrument may be more appropriate at initial assessment for those with moderate symptoms or greater, rather than those who present with mild symptoms at baseline.

The NPI Score has demonstrated convergent validity. This was assessed against a previously validated outcome measure in the Kujala Patellofemoral Disorders Score.[9] Whilst the Kujala Patellofemoral Disorder Score assesses some of the same domains as the NPI Score, it also assesses additional, non-instability specific domains including: pain, function, muscle weakness and range of motion. Whilst similarities may be expected to this, complete agreement would not be expected. The data indicates that this to be the case. Whilst the NPI Score may be recommended to assess instability, it is acknowledged that other important domains such as health-related quality of life and pain could not be determined using the NPI Score. Using a number of PROMS to assess the individual's global status has been previously recommended for this population.[14] These results suggest that the NPI Score would be an appropriate instrument to use for the patellar instability domain.

An outcome measure should capture a change in status when one occurs.[15] The results from this analysis indicate that the NPI Score is responsive to change for people with recurrent dislocation who are surgically or non-surgically managed. Based on this, clinicians and researchers have greater confidence that if a change in status occurs, this can be measured. However, the results also demonstrate a floor-effect. Through this, the NPI Score may be less capable of detecting change for people with the lowest levels of instability symptoms. Whilst this may be the minority of cases in conventional hospital-based clinical practice, this should be considered when assessing individuals who present with more subtle instability symptoms or those where symptoms are only manifested on higher-level, multidirectional activities, requiring greater provocation.

There is limited evidence from independent centres on the validity and responsiveness of patellar instability scores. Both the NPI Score[2] and Banff Score,[16] the two PROMS designed to assess patellar instability, have been largely evaluated from their host institutions in Norwich[2,6] and Banff.[14,17,18,19] This study augments that of Arebola et al's [20] work to present findings from an independent centre. In both instances, the NPI Score has demonstrated strengths and provides further support for its adoption in clinical practice.

The minimimally important clinical change (MICC) and minimilaly clinically important difference (MCID) has yet to be determined for the NPI score. This would aid the interpretation of the NPI score and provide the basis of future clinical trial sample size calculation when the NPI score is used as a primary outcome. This remains a future research priority given that this analysis has re-enforced the validity of the NPI score.

This study presents with three key limitations. Firstly, this cohort presented with a number of missing data. Whilst complete NPI scores at baseline were an eligibility criterion, there were missing data on the Kujala Patellofemoral Disorders Score and other outcome measures. As a result, the initial cohort of 90 reduced over time. This is not uncommon given previous literature has demonstrated the high lost-to follow-up.[5] Secondly, as there were limited data on radiological outcomes from the routinely collected database; findings were associated with clinical and not radiological outcomes. Given that

radiological measurements are a key part of pre-operatively surgical decision-making pre-operatively,[21] examining the relationship between the NPI Score and radiological markers would be valuable to understand how these may relate. Finally, whilst the cohort presented with a spectrum of physical outcomes, they were all based on one region (London). Continued analyses to assess the psychometric properties of the NPI score with other populations would be valuable. This will build on Arreola et al's[20] work of cultural adoption of the NPI Score, but would be valuable to maximise its adoption to measure patellar instability worldwide for both adult and paediatric cohorts.

5.0 CONCLUSIONS

This study provides further evidence from an independent centre that the NPI Score is a valid PROM to measure instability for people who attend hospital clinic with recurrent patellar dislocation. Further exploration on the psychometric properties of this measure would be valuable in adolescent populations and further cross-cultural adaption to develop the research and implementation of this measure in other UK and non-UK centres.

FIGURE AND TABLE LEGENDS

Table 1: Summary of demographic characteristics of analysed patellar instability cohort.

Table 2: Summary of floor-ceiling analysis of the NPI score at baseline, 12 month and 12-36 month follow-up intervals.

Figure 1: Scatter-graph illustrating the relationship between the Kujala Patellofemoral Disorder Score and the NPI Score across the time-points

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Table 1: Summary of demographic characteristics of analysed patellar instability cohort.

Characteristics	
Mean Age (SD)	29.4 (9.8)
Gender (M/F)	18/72
Side (R/L/Bilateral)	45/55/10
Treatment interventions	
Physiotherapy (non-surgical)	36
MPFL Reconstruction	26
Trochleoplasty	10
Trochleoplasty and lateral release	9
Trocheloplasty and MPFL reconstruction	4
Trocheloplasty and MPFL and lateral release	1
Arthroscopy and osteochondral fragment removal	3
Tibial tubercle osteotomy and MPFL reconstruction	1
Ethnicity	
White	38
Asian	5
Black	5
Mixed	4
Not reported	38
Family History	
Yes	21
No	29
Not reported	40
Mean BMI (SD; N=45)	26.3 (4.96)
Mean Weight in Kg (SD; N=45)	77.0 (21.12)
Mean Height in cm (SD; N=45)	167.5 (11.52)
Mean Beighton Score (SD; N=65)	2.46 (2.62)
Apprehension Test	
Positive	41

|	
Negative	29
Not reported	20
Mean Range of motion (SD)	
Flexion	-1.6 (6.0)
Extension	109.4 (20.5)
Not reported	18
J-Sign	
Positive	10
Negative	80
NPI scores	
Mean baseline score (SD; N=90)	40.1 (26.0)
Mean 12 month score (SD; N=70)	29.3 (25.0)
Mean 12-36 month score (SD; N=24)	25.2 (17.9)
Kujala Patellofemoral Disorder Score	
Mean baseline score (N=75)	61.8 (20.9)
Mean 12 month score (SD; N=68)	65.0 (23.6)
Mean 12-36 month score (SD; N=24)	72.8 (15.8)

BMI – body mass index; F – female; Kg – kilogram; L – left; M - male MPFL – medial patellofemoral ligament; N - number of participants; NPI – Norwich Patellar Instability Score; R – right; SD – standard deviation

Table 2: Summary of floor-ceiling analysis of the Norwich Patellofemoral Instability (NPI) score at baseline, 12 month and 12-36 month follow-up intervals.

NPI Score	N	Frequency of Highest Response Option (%)	Frequency of Lowest Response Option (%)
Baseline	90	4 (4.5)	3 (3.4)
12 months	70	1 (1.4)	9 (12.9)
12-36 months	24	0 (0.0)	1 (4.2)

N – Number; NPI – Norwich Patellar Instability Score

Figure 1: Scatter-graph illustrating the relationship between the Kujala Patellofemoral Disorder Score and the NPI Score across the time-points
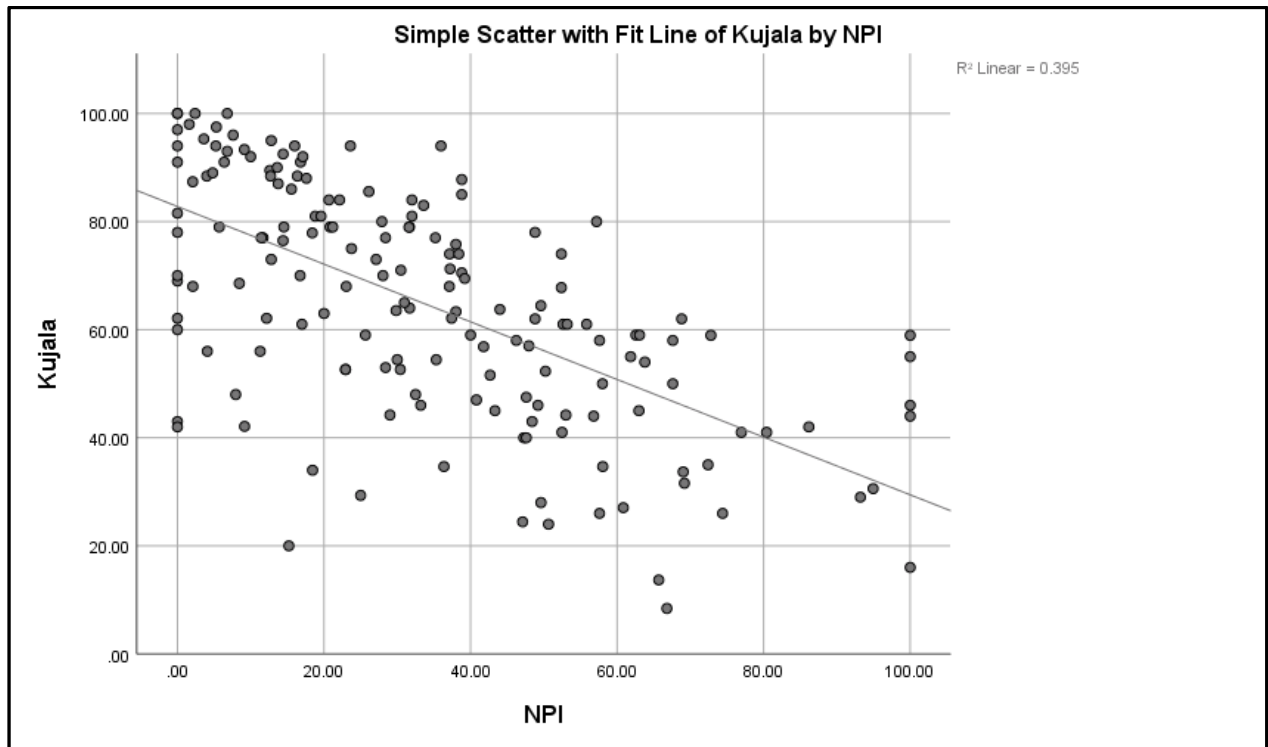
NPI – Norwich Patellofemoral Score