Neonatal brachial plexus palsy : impact throughout the lifespan

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CHAPTER FOUR

Translation and adaptation of the Pediatric Outcome Data Collecting Instrument (PODCI) into the Dutch language and preliminary validation in children with neonatal brachial plexus palsy

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ABSTRACT

Objective

This study aimed to translate and cross-culturally adapt the Pediatric Outcome Data Collecting Instrument (PODCI) into the Dutch language and evaluate its measurement properties among children (age 3–10) with Neonatal Brachial Plexus Palsy (NBPP).

Patients and methods

The PODCI was translated and adapted according to international guidelines and administered to 10 children with NBPP before and after surgery and thereafter twice again. Subsequently, the Mallet-score, Assisting Hand Assessment and active Range of Motion (aROM) were recorded. Cronbach's-α and correlations between the PODCI and other outcome measures were determined, as well as Intraclass Correlation Coefficients (ICC). In addition, effect sizes (ES), Standard Response Means (SRM) and change scores with the 95% Confidence Interval (95% CI) were calculated.

Results

The final Dutch PODCI 'Upper Extremity and Physical Function' subscale and total score 'Global Functioning' showed good internal consistency (Cronbach's-α 0.695/0.781) and reliability (ICC 0.97/0.80) and were significantly associated with aROM and the Mallet-score. After surgery, a significant change of the total score (ES 0.57, SRM 1.23, change 4.22 points, 95% CI 1.04–7.4) was seen.

Conclusions

The final Dutch PODCI had good measurement properties and appears useful in evaluating quality of life and functioning in children with NBPP.

INTRODUCTION

Neonatal Brachial Plexus Palsy (NBPP) occurs in about 0.38–5.10/1000 live born children[1-3] of which 20–30% remain with some functional deficits.[3] Treatment is directed at improving daily activities and participation and Health-related quality of life (HRQoL) instruments are considered useful in the assessment of these treatment outcomes.[4,5] The number of HRQoL instruments for children with musculoskeletal disorders, taking into account normal neurological maturation, is limited.[4,5] Therefore, the Pediatric Outcome Data Collecting Instrument (PODCI) was developed by the American Academy of Orthopedic Surgeons (AAOS).[4] The PODCI consists of 5 subscales: 'Upper Extremity and Physical Function', 'Transfer and Basic Mobility', 'Sports and Physical Function', 'Pain and Comfort', 'Happiness' and one total score: 'Global Functioning' (summary of all subscales, excluding 'Happiness'). It is available in three versions (2–10 year parent-reported, 11– 18 year parent- and self-reported).

During the development of the PODCI multiple musculoskeletal disorders were tested including Scoliosis, Myelodysplasia, Cerebral Palsy (CP), Juvenile Rheumatoid Arthritis, Legg-Calve-Perthes, Congenital Talipes Equino-varus, Congenital Leg-length Discrepancies, Osteogenesis Imperfecta, Developmental Delay and Abnormal Gait.[4] The PODCI was shown to be reliable, valid and sensitive to change.[4] After its initial development, the PODCI was used in studies evaluating children with NBPP[6-9], CP[10], Unilateral Upper Extremity Deficiencies[11], Scoliosis[12], Arthrogryposis[13], Duchenne Muscular Dystrophy[14,15] and Acute Hand and Wrist Injuries.[16]

So far, the PODCI has been translated into multiple languages (Hebrew/Spanish/Korean/Brazilian) but no Dutch version was available. Only the Korean and Brazilian translations are published.[10,17]

The aim of the present study was to develop a Dutch version of the PODCI, translated and adapted according to international guidelines[18-20], and preliminary examine its reliability, validity and responsiveness in children with NBPP.

PATIENTS AND METHODS

Translation and adaptation

The PODCI consists of 83 to 86 questions depending on the version (11–18 self-reported; 83 questions, 2–10 and 11–18 parent-reported; 86 questions). An Excel (Microsoft, Redmond, Washington/USA) scoring form, downloadable for free from the AAOS website, calculates the standardized and normative sub-scores and total score.[21] Standardized scores range from 0–100, with "0" poor outcome/worse health and "100" best possible outcome/best health. Normative scores are calculated so that a higher score indicates better functioning. All scores are referenced to the American based general/healthy population mean normative score of 50. This normative score does not hold for the Dutch general/healthy population. According to international cross-cultural adaptation guidelines, all PODCI versions were translated and adapted.[18-20]

Stage I: Initial translation
Three bilingual native Dutch-speaking translators, two medically educated and one layperson, translated all PODCI versions from the original language (English) into the target language (Dutch). All items and instructions were translated without discussion among translators. Challenging phrases or uncertainties were highlighted.

Stage II: Synthesis of translations
The three translations were subsequently compared and any discrepancies were resolved by discussion between the translators and the principal investigator (MH). A synthesis of the 3 translations was produced, resulting in one common version in the Dutch language.

Stage III: Back-translation
The common translated versions were back translated into the original language by three bilingual native English-speaking translators, one medically educated and two laypersons, who did not have access to the original versions.

Stage IV: Expert committee
An expert committee comprising a physical therapist (HV), a pediatric physical therapist (JE) and the principal investigator (MH), who is also a pediatric physiotherapist, reviewed all back-translations and the common Dutch translations. During a face-to-face meeting, consensus was reached on final wording, grammatical issues, formatting, cultural relevance and content validity resulting in the final Dutch PODCI versions.

Stage V: Test of the translated and adapted version
The final 2–10 year parent-reported version was field-tested among parents of 10 patients with NBPP who attended the Orthopaedic (outpatient) clinic of the Leiden University Medical Center. These 10 participants were asked to write down any comments on addressed issues, wording or lay out.

Validation
Study design
This study had a prospective cross-sectional design. It was executed between May 2008 and October 2013 in the Leiden University Medical Center, which is a specialized NBPP center in the Netherlands. Ethical approval was obtained from the Institutional Review Board, (addendum) P08.008. All parents gave written informed consent.

Patients
All children with NBPP who were scheduled to undergo shoulder surgery (Internal contracture release and mm. Latissimus Dorsi/Teres Major tendon transfers) were eligible for this study. Additional inclusion criteria were: Age: 3–10 years, Involvement of C5, C6 and/or C7 (“shoulder affected”) and unilateral impairment.

Assessments

Of all children, sociodemographic and disease characteristics (age, gender, involved nerve roots, affected side and previous treatments) were obtained from the medical record pre-operatively.

The translated and adapted Dutch PODCI was self-administered pre-operatively and 12 months thereafter in a clinical setting. Additionally the following assessments were done pre-operatively: Active Range of Motion (aROM): Abduction and External rotation[22], Mallet score measuring often used arm movements, including overhead movements (1: no function – 5: normal function)[7,23,24] and the Assisting Hand Assessment (AHA), a semi-structured, video-recorded, play-session for children (1.5-12 years) in which toys are used that encourage bimanual handling. Scoring is done by reviewing the video with respect to 22 items, subdivided in 6 categories: 'General Use', 'Arm Use', 'Grasp/Release', 'Fine Motor Adjustment', 'Coordination' and 'Pace' using a 4-point criterion referenced rating scale (4: Effective – 1: Does not do).[25-28]

To examine the test-retest reliability the translated and adapted Dutch PODCI was self-administered twice after the initial 12 months follow up, by regular mail, to all parents of the children, with an interval of 2 weeks.

Statistical analysis

Statistical analyses were executed using SPSS 20.0 (IBM, Armonk, New York/USA).[29] All continuous variables were expressed as means and standard deviations (SD), or as medians and Inter Quartile Ranges (IQR), according to their distributions.

Internal consistency

Internal consistency of the final Dutch PODCI (the extent to which the different items are correlated) was determined by calculating Cronbach's alpha. The internal consistency is considered to be good when Cronbach's alpha is between 0.70 and 0.95.[30]

Floor and ceiling effects

Mean final Dutch PODCI scores were determined and floor and ceiling effects were counted. Floor or ceiling effects are present if > 15% of the population scores either the minimum or the maximum.[31]

Construct validity

Spearman's rho was determined between the final Dutch PODCI and all clinical variables (aROM, Mallet score, AHA) to determine the construct validity. Correlations > 0.5 are considered to be moderate to good correlations and correlations > 0.75 are considered to be good to excellent correlations.[32] Significance for all correlations was computed as well with a p value smaller than 0.05 being considered significant.

Responsiveness to change

Cohen's effect size (ES = (pre-treatment mean – post-treatment mean)/pre-treatment SD) and the Standardized Response Mean (SRM = (pre-treatment mean – post-treatment mean)/

change score SD) were computed between pre-operative and 12 months post-operative final Dutch PODCI measurements. An ES/ SRM >0.2 is considered to be a small effect, > 0.5 a moderate effect and > 0.8 a large effect.[33-35] In addition, a paired sample t-test was performed to detect significant changes over time ($p < 0.05$ for statistically significant difference).

Test-retest reliability

Systematic differences between the test and retest were calculated for all final Dutch PODCI scores by means of Wilcoxon's signed rank tests. In addition, intra-class correlation coefficients (ICC) were computed between the test and retest scores, with a value of > 0.70 being considered the minimum acceptable value.[30,36]

RESULTS

Translation and adaptation of the PODCI

During the translation process, a few PODCI items were discussed for adaptation. Question 2 is about pouring milk from a half-gallon container. In The Netherlands, these kind of half-gallon containers are seldom used. One litre and 1.5 litre milk cartons are commonly available. Finally, the 1.5 litre carton was included in question 2 because the weight of this carton is closest to the original half-gallon container. Questions 23 and 24 refer to being able to walk 1 (q24) or 3 blocks (q23). Since there is no definition of the exact length of 1 block, the translation of 'block' into the Dutch word 'straat' (street) was chosen. Question 44 poses a few examples of sport and play activities including touch football. Since touch football is not commonly played in The Netherlands it was removed. The final translated and adapted version (final Dutch PODCI) was used in the field test.

Field test

The final Dutch PODCI was field tested among parents of 10 patients with NBPP. They were asked to state all inconsistencies, wording and lay out problems they found. None were declared and therefore the field-tested version was adopted as the final version.

Validation study

Disease characteristics

Ten patients participated in this study. There were five girls and five boys with a mean age of 5.3 years (SD 2.4). Four had C5/C6 lesions and six had C5/C6/C7 lesions, three were right-side affected and seven left-side. Six were treated neurosurgically (1 neurolysis, 5 Brachial Plexus reconstructions) and four were treated conservatively. The disease characteristics are reported in Table I as well.

All patients completed the pre-operative and post-operative assessments, including the parent reported final Dutch PODCI, whereas nine patients completed the parent reported final Dutch PODCI thereafter twice again to determine the reliability.

Table I Sociodemographic and disease characteristics of 10 children with Neonatal Brachial Plexus Palsy undergoing a combined internal contracture release and muscle tendon transfer participating in the Dutch PODCI validation study.

	Total group (n=10)
Gender (m/f); no.	5/5
Age, years; mean (Standard Deviation)	5.3 (2.4)
Lesion topography; no.	
C5/C6	4
C5/C6/C7	6
Affected side; no.	
Left	3
Right	7
Previous treatment(s); no.	
Neurolysis	1
Nerve reconstruction	5
Conservative	4

Internal consistency, floor and ceiling effects and responsiveness to change

Table II shows the internal consistency of the final Dutch PODCI, the mean pre- and post-operative final Dutch PODCI scores including floor/ceiling and responsiveness to change scores between baseline and 12 months follow-up.

Cronbach's alpha for internal consistency varied between 0.161 and 0.928. It was low for the 'Pain and Comfort' subscale, moderate for the 'Transfer and Basic Mobility' and 'Sports and Physical Function' subscales, and good for the 'Upper Extremity and Physical Function', 'Happiness' subscales and the total score 'Global Functioning'.

No floor scores were seen in the final Dutch PODCI. Ceiling effects, however, were seen for 'Transfer and Basic Mobility', 'Sports and Physical Function' 'Pain and Comfort' and 'Happiness' subscales but not for the 'Upper Extremity and Physical Function' subscale and the total score 'Global Functioning'.

The responsiveness to change (pre-operative - 12 months follow-up) is shown by means of ES, SRM and the paired sample t-test with 95% confidence intervals. ES were small (0.05–0.46) except for the total score 'Global Functioning' it was moderate (0.57). SRM was moderate for the 'Upper Extremity and Physical Function', 'Transfer and Basic Mobility', 'Sports and Physical Function' subscales (0.53–0.67) and small for the 'Happiness' and 'Pain and Comfort' subscales (0.07–0.46). For the total score 'Global Functioning' a large change was found (SRM 1.23). A significant improvement was seen only for the total score 'Global Functioning' (mean change 4.22 points, 95% CI: 1.04–7.41, p = 0.016). The 'Transfer and Basic Mobility' and 'Sports and Physical Function' subscales reached a near significant change over time (p = 0.06).

Table II Measurement properties of the Pediatric Outcome Data Collecting Instrument (PODCI).

PODCI N=10	Mean T1 (min-max)	Mean T2 (min-max)	Mean change (95%CI)	Cronbach's α	Ceiling score T1/T2 No. of patients (%)	Floor score T1/T2 No. of patients (%)	T1-T2 ES Cohen's d	T1-T2 SRM
Upper Extremity scale	67.80 (33-94)	72.20 (38-90)	2.56 (- 3.98 - 9.09)	0.695	0 (0%) / 0 (0%)	0 (0%) / 0 (0%)	+0.22	+0.53
Transfer and Basic Mobility scale	95.10 (78-100)	97.90 (88-100)	2.80 (- 0.27 - 5.87)	0.667	3 (30%) / 7 (70%)	0 (0%) / 0 (0%)	+0.42	+0.65
Sports and Physical Functioning scale	85.80 (57-100)	91.90 (69-100)	6.10 (- 0.42 - 12.62)	0.597	2 (20%) / 1 (10%)	0 (0%) / 0 (0%)	+0.46	+0.67
Pain and Comfort scale	90.90 (67-100)	94.10 (67-100)	3.20 (-1.80 - 8.20)	0.161	6 (60%) / 8 (80%)	0 (0%) / 0 (0%)	+0.24	+0.46
Happiness Scale	93.57 (80-100)	94.00 (60-100)	4.29 (- 1.33 - 9.90)	0.928	4 (40%) / 6 (60%)	0 (0%) / 0 (0%)	+0.05	+0.07
Global Functioning scale	84.00 (69-96)	89.20 (79-98)	4.22 (1.035 - 7.410)*	0.781	0 (0%) / 0 (0%)	0 (0%) / 0 (0%)	+0.57	+1.23

* Significant difference $p<0.05$. Responsiveness to change; Effect size (ES) and Standardized Response Mean (SRM): 0.2 (small effect), 0.5 (moderate effect), 0.8 (large effect). T1 = Baseline. T2 = 12 month follow up. Cronbach's α for internal consistency using raw scores on separate items.

Construct validity

Table III shows the associations between the final Dutch PODCI scores and all other variables. The 'Upper Extremity and Physical Function' subscale correlated moderate to strongly with aROM abduction, Mallet 'External rotation', 'Hand to Head' and 'Hand to Back' items, the total Mallet score and the AHA 'Arm use' items as well as the AHA total score ($r = 0.505–0.915$). All were significant ($p < 0.05$) except for the Mallet 'Hand to Head' item, the AHA 'Arm use' items and the AHA total score. The total score 'Global Functioning' shows high correlations with aROM abduction, Mallet 'External rotation', 'Hand to Head', 'Hand to Back' and 'Hand to Mouth' items as well as the total Mallet score ($r = 0.520–0.901$). All were statistically significant ($p < 0.05$) except for the aROM Abduction and Mallet 'Hand to Back' and 'Hand to Mouth' items. Furthermore the 'Happiness' and 'Pain and Comfort' subscales showed high correlations with Mallet 'External rotation', 'Hand to Head' and 'Hand to Back' items ($r = 0.523–0.667$) of which only the Mallet 'Hand to Head' item correlation to the 'Happiness' subscale is significant ($p < 0.05$).

Test-retest reliability

Table IV shows the mean test and retest scores and ICC for test-retest reliability. None of the differences reached statistical significance. The largest absolute difference was seen in the 'Pain and Comfort' subscale (Test: 90.67, SD 13.98 and Retest: 98.78, SD 3.67). This difference was found to be mainly the result from a large discrepancy between scores provided by one parent (Test: 56 and Retest: 100). The 'Upper Extremity and Physical Function', 'Transfer and Basic Mobility', 'Sports and Physical Function', 'Happiness' subscales and the total score 'Global Functioning' showed a good to moderate test-retest reliability (ICC 0.636–0.972, $p < 0.025$). The 'Pain and Comfort' subscale had a very low ICC (0.022, $p = 0.476$).

Table III Pediatric Outcome Data Collecting Instrument (PODCI) subscales associations with outcome measures.

PODCI N=10	aROM Exo 90°	aROM Abd	Mallet Abd	Mallet Exo	Mallet Hand to Head	Mallet Hand to Back	Mallet Hand to Mouth	Mallet total score	AHA arm use items	AHA total score
Upper Extremity scale	0.202	0.740*	0.411	0.725*	0.538	0.725*	0.414	0.915*	0.505	0.627
Transfer and Basic Mobility scale	0.285	0.145	0.425	-0.227	0.290	0.357	0.000	0.265	0.336	0.450
Sports and Physical Functioning scale	0.479	0.062	-0.291	0.218	0.188	-0.457	0.393	-0.025	0.007	-0.435
Pain and Comfort scale	0.420	0.031	-0.261	0.049	0.667*	-0.128	0.392	0.264	0.111	-0.031
Happiness scale	0.308	-0.10	-0.338	0.523	-0.147	-0.338	0.523	0.245	-0.128	-0.225
Global Functioning scale	0.287	0.591	0.138	0.728*	0.665*	0.520	0.572	0.901*	0.405	0.374

* Significant difference $p<0.05$. Correlations; Spearman's rho (r)
aROM= actiev range of motion
Exo = External rotation
Abd= Abduction
AHA= Assisting Hand Assessment

Table IV Pediatric Outcome Data Collecting Instrument (PODCI) test-retest reliability.

PODCI N=9	T1 Mean (SD)	T2 Mean (SD)	T1-T2 Cronbach's α	T1-T2 ICC
Upper Extremity scale	83.33 (18.13)	83.44 (17.85)*	0.986	0.972**
Transfer and Basic Mobility scale	99.67 (1.00)	99.33 (1.32)*	0.778	0.636**
Sports and Physical Functioning scale	92.56 (5.15)	93.56 (5.59)*	0.973	0.948**
Pain and Comfort scale	90.67 (13.98)	98.78 (3.67)*	0.043	0.022
Happiness scale	88.89 (17.09)	90.56 (13.57)*	0.980	0.96**
Global Functioning scale	91.56 (7.02)	93.56 (6.41)*	0.891	0.803**

* Differences between test and retest did not reach statistical significance (All P>0.05, Wilcoxon Signed Rank test). ** Significance p<0.05. Means with Standard Deviations (SD). Intra Class Correlation (ICC)

DISCUSSION

This study aimed to translate and adapt the PODCI into the Dutch language and validate the 2–10 years parent-reported version for use in children with NBPP. The final Dutch PODCI was found to be a useful tool to evaluate QoL and functioning in children with NBPP. The final Dutch PODCI's internal consistency, responsiveness to change, construct validity and test-retest reliability was overall found to be good.

These findings are generally in line with the literature concerning the development of the PODCI[4] and the usability in children with musculoskeletal disorders including NBPP.[6-13,16] In these reports the validity and reliability was also found to be good. The internal consistency in the present study was lower than reported in the development study of the PODCI[4] and the Brazilian cross cultural adaptation.[17] The 'Pain and Comfort' scale showed a low Cronbach's alpha (0.16, Table II). This could be due to the fact that the study population was rather small. The Korean cross cultural adaptation and validation study however also reported a low internal consistency for this sub-scale.[10]

Floor and ceiling effects were explicitly reported by few other studies.[8,16,37] A ceiling score was observed in all subscales of which the most in the 'Transfer and Basic Mobility', 'Pain and Comfort' and the 'Happiness' subscales (Table II). This corresponds with the findings in the present study, however no ceiling effects were found for the 'Upper Extremity and Physical Function' subscale and the total score 'Global Functioning'. From other publications concerning NBPP patients, floor and ceiling effects can only be concluded from the score ranges observed.[6,7]

The final Dutch PODCI showed to be responsive to change (Table II). Moderate to large ES and SRM were seen especially for the total score 'Global Functioning'. This total score showed a significant difference between baseline and 12 months follow up. This is in line with previous studies in children with musculoskeletal disorders, including NBPP.[9,10,13,16]

The results in regard to the relationships between the final Dutch PODCI scores and Mallet scores (Table III) are in line with previous studies. Bae et al. found significant correlations between the aggregated Mallet scores and the total score 'Global Functioning'.[7] However, Dedini et al. found no significant correlations between ROM and PODCI scores[8] whereas the current study found a significant correlation between the abduction aROM and the 'Upper Extremity and Physical Function' subscale (Table III).

Correlations between the AHA and the final Dutch PODCI have not been investigated before and the present study shows a moderate to good correlation between the 'Upper Extremity and Physical Function' subscale and the AHA 'arm use' items and total score although not significant (Table III).

ICC were found to be good even though the study group was small (Table IV). This is in line with previous studies.[4,10,17,38] The 'Transfer and Basic Mobility' subscale has an ICC value just below the minimal acceptable value of 0.70. This is explained by the fact that one parent reported that putting on a coat was easy at time point 1 and a little hard at time point 2. Due to the relative small study group, the effect of this one different answer is rather large. One could argue though whether the item putting on a coat should be in the 'Transfer and Basic Mobility' scale or in the 'Upper Extremity and Physical Function' scale since putting on a coat is also related to arm function. The 'Pain and Comfort' subscale scores very low because 4 parents reported differently at different time points. The 3 items within this subscale refer to pain in the previous week. Since the test-retest was done in a 2-week period a change in answering is possible. A study within a larger group should be conducted to see whether the test-retest reliability of this subscale is really low.

This study had a number of limitations. First, a relative small, diverse group was used. Secondly, no other questionnaire was used for reference and to measure validity. Thirdly, the patient group used was bound to report problems on the 'Upper Extremity and Physical Function' subscale because of their diagnose. Children with NBPP however mostly don't have problems with other parts of their body and therefor other subscales of the final Dutch PODCI show ceiling effects and no correlations with other measures were seen, as was expected.

To further investigate the psychometric properties of the final Dutch PODCI for general use in children with musculoskeletal disorders, including NBPP, a cross sectional study in a larger group of children should be done.

CONCLUSION

The PODCI is a well-established tool to evaluate QoL and physical functioning in children with musculoskeletal disorders including NBPP as shown in previous studies.[6-13,16] This study showed the final Dutch PODCI version to be reliable and useful to assess QoL and physical functioning in children with NBPP.

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