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Review Article

Outcome measures used in clinical studies on neonatal brachial plexus palsy: A systematic literature review using the International Classification of Functioning, Disability and Health

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Abstract.

BACKGROUND: Symptoms of a neonatal brachial plexus palsy (NBPP) can vary widely among individuals and numerous clinical studies have been performed to identify the natural history and to improve treatment. The aim of this study was to identify and describe all outcome measures used in clinical studies on patients with an NBPP and categorize these outcome measures according to the International Classification of Functioning, Disability and Health (ICF).

METHOD: Electronic searches of different databases were carried out. All clinical studies describing one or more outcomes of NBPP were selected. Data on outcome measures was systematically extracted and the contents were analyzed and linked to the ICF.

RESULTS: A total of 217 full texts were selected and 59 different outcome measures were identified. The 5 most frequently used outcome measures included range of motion of the shoulder ($n = 166$ studies, 76%), range of motion of the elbow ($n = 87$ studies, 40%), the Mallet scale ($n = 66$ studies, 30%), Magnetic Resonance Imaging ($n = 37$ studies, 17%) and the Medical Research Council motor grading scale ($n = 31$ studies, 14%). Assessments related to Body functions and Structures were most frequent, whereas assessments associated with Activities and Participation and Environmental Factors were relatively uncommon.

CONCLUSION: There was a high variability among the outcome measures used, with measures within the ICF component Body Functions being most common. These results underscore the need for the development and usage of outcome measures representing all domains of health status in patients with NBPP.

Keywords: Brachial plexus neuropathies, obstetric paralysis, international classification, treatment outcome, outcome assessment

Level of evidence: Level IV

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1. Introduction

Neonatal brachial plexus palsy (NBPP) is caused by traction on the brachial plexus during delivery and can result in severe impairments in arm function. The incidence varies between 0.4 and 4.6 per 1000 live births [1,2]. The upper brachial plexus, comprising of the spinal nerves C5-C6 and the superior trunk, is most commonly affected, resulting in weakness or paralysis of the shoulder and elbow flexion muscles. The severity of the injury of the brachial plexus may vary from neurapraxia and axonotmesis to neurotmesis and avulsion of rootlets from the spinal cord. Elbow extension, wrist and hand function are additionally impaired when the C7, C8, Th1, medial trunk and inferior trunk are involved. An isolated injury of the lower brachial plexus (C8-Th1) is rare. The majority of NBPP is mild and spontaneous functional recovery will be present in about 70% of patients within 4–6 months of age [3,4]. The remaining group is left with functional deficit [5].

Symptoms of NBPP can vary widely among individuals and numerous clinical studies have been performed to identify the natural history and to improve treatment [3–12]. A large variety of outcome measures is used to evaluate the natural history and the effect of treatment, however there is no consensus on which outcome measures are the most appropriate [14,15]. The International Classification of Functioning, Disability and Health (ICF) is a valuable and validated tool to identify and compare the areas of functioning and disability of persons in several domains. The ICF includes the components Body Structures, Body Functions, Activities and Participation as well as Environmental Factors [16]. Recently, a systematic review on evaluation methods for NNBP was published, which also describes the use of many different outcome measures [17]. In that review, outcome measures were categorized using the ICF, however this was not done according to published ICF linkage rules [18], in which each item of a measurement instrument has to be linked separately to the ICF on the most detailed level as possible.

So far, the ICF has not been applied to studies concerning the burden of NBPP.

The objectives of this systematic review are (1) to identify outcome measures cited in published clinical studies focusing on individuals with NBPP and (2) to identify the concepts contained in these measures, using the ICF as a reference tool.

2. Method

This systematic literature review was performed according to the PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) statement for developing a study protocol and reporting of systematic reviews [19].

The selection of papers, data extraction, scoring of the methodological quality and linking of the contents of outcome measures to the ICF was done by two of the authors (CS and AW). In case of discrepancies a decision was made by consensus. If consensus was not achieved, a third author (TVV) made the final decision.

2.1. Search strategy

In cooperation with a trained librarian (JWS) a search strategy was composed. The search strategy consisted of variations on the condition “obstetrical brachial plexus injuries”.

All relevant keyword variations were used, not only keyword variations in the controlled vocabularies of the various databases, but the free text word variations of these concepts as well. The following databases were searched from January 2000 until August 2011: Pubmed, Web of Science, EMBASE, PsycINFO, CINAHL, PEDro and the Cochrane Library. The search strategy was optimized for all consulted databases, taking into account the differences of the various controlled vocabularies as well as the differences of database-specific technical variations (Appendix A).

In addition to the electronic search, the reference lists of the selected articles were checked for additional, potentially eligible articles. Review articles and meta-analyses were not included in this review. However, the reference lists of relevant review articles included in the results from the electronic search were checked for additional eligible articles.

All retrieved references were exported to a Reference Manager Version 12 data file.

Due to time restrictions, the authors of abstracts were not contacted in case no full text article related to the abstract and/or title could be identified in any of the databases used (e.g. if the abstract and/or title concerned a conference).

2.2. Selection of studies

In a first step the titles and abstracts of the retrieved papers from the electronic search were reviewed and

included applying the following criteria: (1) Studies presenting clinical data on at least 10 patients with persistent functional deficits due to NBPP. We decided to only include studies with at least ten patients because studies with very small patient groups (case reports and case series) are more likely to be descriptive and qualitative, and less likely to use standardized outcome measures. All study designs, including randomized controlled clinical trials, controlled clinical trials, case control studies, observational studies, multiple case series and qualitative studies were permitted; (2) Full text paper in English language available. Excluded were titles and abstracts concerning (1) Veterinary and cadaver studies; (2) Comments; (3) Editorials; (4) Reviews; (5) Meta-analyses; (6) Law suits; (7) Traumatic brachial plexus lesions. We set no restrictions regarding the age of the NBPP patients. In case the title and/or the abstract met the above-mentioned criteria, it was unclear or if an abstract was not available, the full study text was retrieved.

In a second step, the above-mentioned inclusion and exclusion criteria were again applied to the retrieved full-text papers to check eligibility. In case of multiple publications by the same group of authors and a lack of clarity on potential overlap of study populations, papers were considered as individual studies. If the same study was described in more than one paper it was considered as one study and information from all these papers was used.

2.3. Data extraction

2.3.1. Study characteristics

The first author, publication year and country, characteristics of the studied population (primary diagnosis, number of patients and duration of follow-up in months), study design (randomized controlled trial, controlled clinical trial, cohort, case-control or cross-sectional study or case series) and intervention (evaluation of a specific surgical or conservative treatment or a diagnostic tool or observational studies with no specific outcome) were recorded.

2.3.2. Outcome measures

All outcome measures employed, irrespective of whether they were standardized and/or validated in this patient group and/or self-developed or not, were identified and recorded.

Outcome variables included clinical parameters, such as imaging and physical examination as well as composite indices and questionnaires focusing on daily

activities, participation in social life, and disability due to the plexus injury, pain and functional outcome of the arm.

2.3.3. Methodological quality

According to the PRISMA guideline a description of methods used for assessing risk of bias of individual studies is necessary [19].

The methodological quality of all included studies was assessed using the Newcastle Ottawa Scale (NOS) [20]. The NOS was developed to assess the quality of non-randomized studies by judging a study from three broad perspectives: the selection of the study group(s); the comparability of the groups (if applicable); and the ascertainment of either the exposure or outcome of interest for case-control or cohort studies, respectively. The NOS addresses 8 items. A study can be awarded stars for each numbered item within the subscales selection (4 items) and outcome (3 items). In addition, a maximum of 2 stars can be awarded for the subscale comparability of study groups (1 item). A maximum number of 8 stars can be awarded per study. Due to lack of control groups in many of the included studies, we modified the tool and did not score the subscale comparability of the groups, yielding a 7-item instrument with a score range from 0 to 7 stars. The reviewers resolved disagreements by discussion to achieve consensus. For a detailed description of the quality assessment according to the NOS refer to the supplementary material (Appendix C). For the purpose of this study we considered high-quality studies as those with a total quality score of at least 6 out of 7 stars, moderate-quality as those with a total quality score of 4 or 5 out of 7 stars and low-quality as those with a total quality score of < 4 out of 7. If possible, the rates of use of outcome measures in studies with a high and moderate/low methodological quality would be compared.

2.4. Analysis

Descriptive statistics were used to report frequencies of outcome measures, ICF components, chapters or categories and the methodological quality scores.

To analyze the contents of the outcome measures used, all information contained in an outcome measure was divided into "meaning units". A meaning unit is defined as a specific unit of text, a few words or a few sentences with a common theme. In a following step the theme that dominates a meaning unit was identified, the so-called "meaningful concept" One meaning

unit can contain more than one meaningful concept. These meaningful concepts were linked independently by two researchers (CS, AW), who are experts in the ICF and in the application of the linkage rules, to the most specific ICF category possible, according to linking rules developed for this purpose [18,21]. The categories of the ICF are arranged in a hierarchical nested structure represented by an alphanumeric code. The letter stands for the component (Body Functions, B; Body Structures, S; Activities and Participation, D; and Environmental Factors, E). These letters are followed by a numeric code that starts with the chapter number (one digit), followed by the second (another digit) third and fourth levels—one extra digit for each level [18,21]. Therefore, the items within outcome measures and assessment tools can be linked to the ICF by selecting the appropriate category code or codes at the different levels. If an item was not found in the ICF, it was assigned as *nc* (not classified). If the individual items of questionnaires or other, complex outcome measures were not specified in the publication, the instruments were obtained by checking the references or by conducting database and Internet searches.

The degree of agreement between the 2 investigators regarding the selection of papers was calculated by means of the kappa statistic [22]. As a high prevalence of data extraction errors (errors in 20 out of 34 reviews) has been observed it is strongly recommended that more than one person extracts data from every report to minimize errors and reduce potential biases being introduced by review authors [23–25]. To ensure that data extraction is indeed valid, the consistency of the results of multiple authors needs to be determined. For that purpose, the use of Kappa statistics is advocated. Therefore, standardized electronic forms were used for the selection (using a nominal scale, selected yes or no, based on the recorded presence of all inclusion and exclusion criteria), which were completed by two authors independently. Then Kappa statistics (IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp, released 2011) was applied to determine the agreement between authors regarding both the selection of abstracts and of full text papers.

Kappa coefficients > 0.61 were considered as moderate to good [26].

3. Results

3.1. Study selection

The database search yielded 1321 titles and abstracts and 113 additional references were identified through

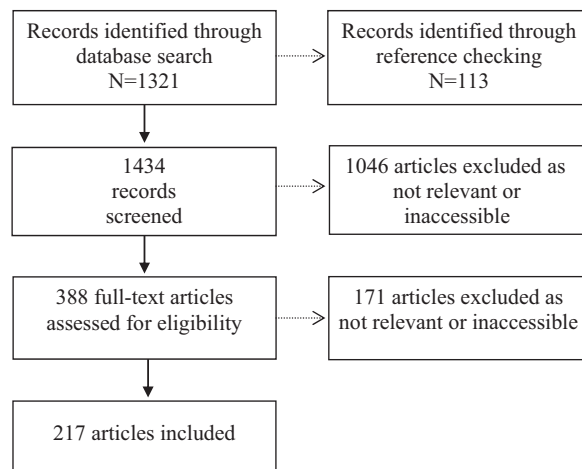


Fig. 1. Selection of the full text articles. The first step is the identification of the records (titles and abstracts) through the databases and through reference checking, the second step is the screening of the records, the third step is the assessment for eligibility of the full-text articles and the final step is the number of included articles for analysis.

reference checking. The inclusion and exclusion criteria were applied to the 1434 titles and abstracts of which 388 titles were considered potentially suitable. After reading the 388 full text papers a total of 217 papers, reporting on 217 studies, were finally selected for inclusion in the review (Fig. 1). A full list of the studies is included as Appendix B (see supplementary material).

The kappa statistic for agreement (which were yes or no answers) regarding the selection of full text papers to be retrieved from the titles and abstracts and the final selection of studies to be included from the full-text papers were 0.83 and 0.82 respectively, indicating good agreement.

3.2. Study characteristics

In Table 1 the characteristics of the 217 included studies are reported. Length of follow up and number of patients varied greatly among the studies. The majority of the studies were observational studies describing the outcome of specific interventions such as neurosurgical repair surgery or soft tissue procedures. In observational studies, which were not related to a specific intervention a lack of information regarding the follow-up period, type of lesion or information on prior surgical treatments was relatively common.

3.3. Methodological quality

The NOS scale for cohort studies was applied to the 204 papers concerning cohort studies, cross-sectional

Table 1

Characteristics of 217 included studies included in a systematic review on outcome measures in obstetric brachial plexus lesions

Study characteristics	Sum of all 217 studies (%)
No. of patients	
Total number of patients	11587
No. of patients per study (mean, sd)	54 (SD: 57.1)
Follow up in months (mean per study (SD))	46 (SD: 50.3)*
Type of lesion	
All lesions mixed (C5-T1)	115 (53%)
Other/not specified	59 (27%)
C5-C7	18 (8%)
C5-Th1	18 (8%)
C5-C6	7 (3%)
Study design	
Cohort study	131 (60%)
Case series	57 (26%)
Cross-sectional study	12 (6%)
Case-control study	12 (6%)
Randomized controlled trial	1 (0.5%)
Other/Not specified	4 (2%)
Study Intervention	
Nerve repair surgery	50 (23%)
Soft tissue procedure	49 (23%)
Osteotomy	16 (7%)
Elbow and/or hand surgery	9 (4%)
Botox injection	4 (2%)
Casting/Splinting	1 (0.5%)
Physical therapy	1 (0.5%)
Observational study	
No specific outcome intervention	83 (38%)
Diagnostic tool	4 (2%)

*Follow up was described in 130 articles.

studies or case-series, whereas for the remaining 12 case-control studies the NOS scale for case-control studies was used. One study described a randomized controlled trial [27] and therefore the methodological quality was not assessed using the NOS scale.

For the cohort studies the median methodological score was 4 stars (range: 2–7).

9% (18/204) of the studies had a score of 6 stars and 0.5% of 7 stars (1/204), indicating a high-quality score. 31% (64/204) of the studies had a score of 4 stars and 30% (61/204) of 5 stars, indicating a moderate-quality score. 24% (48/204) of the studies had a score of 3 stars and 6% (12/204) of 2 stars, indicating a low-quality score. For the case-control studies the median methodological score was 4 stars (range: 2–7). Two studies had a score of 6 or 7 indicating high quality; six studies had a score of four and five stars, indicating moderate-quality and the remaining four studies had a score of 2 and 3 stars, indicating low-quality. Regarding the overall methodological quality of the studies, the distribution of the total score of the NOS is presented in Appendix C. Methodological flaws most often identified

included the absence of a healthy control group and selection bias (Appendix C). As the overall methodological quality of the studies was moderate/low, with only 9% high quality studies, no comparison of the use of outcome measures in high and low/moderate quality could be made.

3.4. Outcome measures used

Tables 2A to 2D show the outcome measures identified in the included studies, categorized according to the components of the ICF. In total 59 different outcome measures were identified in 217 studies. The most frequently used outcome measures included range of motion of the shoulder ($n = 166$ studies, 76%), range of motion of the elbow ($n = 87$ studies, 40%), the Mallet scale ($n = 66$ studies, 30%), Magnetic Resonance Imaging (MRI) ($n = 37$ studies, 17%) and the British Medical Research Council motor grading scale ($n = 31$ studies, 14%). Two studies comprised an outcome measure of which the content was not described in the paper and could not be found by using references or searching the Internet (the modified Ansula questionnaire and the Internet usage questionnaire) [28,29]. The authors of these papers were contacted, but due to lack of response the content of these outcome measures could not be analyzed. Furthermore, one study described complications after microsurgical reconstruction of the brachial plexus and no outcome measure was used [30], leaving 57 outcome measures in 214 studies, for further analysis.

3.5. Linking of contents of outcome measures to the ICF

Eighty-three percent (178/214) of the studies covered the ICF component Body Functions, 37% (79/214) covered Body Structures, 6% (12/214) Activities and Participation and 3% (7/214) Environmental Factors.

From the 57 different outcome measures identified, 1094 meaningful concepts were derived and were linked to a total of 189 unique ICF categories; 56% (32/57) of the outcome measures covered one ICF category, 12% (7/57) two categories, 12% (7/57) three to five categories and 19% (11/57) more than 5 categories (Tables 2A–2D).

Regarding the ICF component Body Functions, the most frequently used instruments, shoulder and elbow range of motion, were linked to one unique ICF category in the Body Functions component: B7100 (mobility of a single joint). The Mallet scale was linked

Table 2

Outcome measures cited in 217 selected articles, categorized according to different ICF components or a combination of components and corresponding ICF classification

Outcome measures	Sum of all studies % (n)	ICF classification
(A) Body Structures		
Imaging		
MRI (deformity yes/no; PHHA; Birch score; Waters score; Pearls score; GDS;GSA)	17% (37/217)	S7200/S7201/S7202 S73000/S73001
CT (PHHA; GDS; deformity; SHEAR; Myelography)	8% (17/217)	S7200/S7201/S7202 S7300/ S73001
Conventional radiograph (deformity)	6% (12/217)	S7200
Ultrasound (deformity)	1% (2/217)	S7202
Dual-energy X ray bone densitometry	0.5% (1/217)	S7200
Biopsy		
Histopathological evaluation	2% (5/217)	S198
Questionnaire		
Self developed questionnaire assessing difference in limb length	0.5% (1/217)	S730
Body functions		
Range of motion physical examination (active and/or passive; expressed as degrees with goniometer; degrees by estimation; unvalitaded rating scale)		
Shoulder range of motion		
– External rotation	76% (166/217)	B7100
– Abduction	30% (65/217)	B7100
– Internal rotation	24% (52/217)	B7100
– Range of motion unspecified	5% (11/217)	B7100
– Range of motion unspecified	18% (38/217)	B7100
Elbow range of motion		
– Flexion	40% (87/217)	B7100
– Extension	13% (28/217)	B7100
– Supination	11% (24/217)	B7100
– Pronation	9% (20/217)	B7100
– Pronation	7% (15/217)	B7100
Range of motion physical examination indexes		
Mallet scale	30% (66/217)	B7100/B7101
Gilbert classification	9% (20/217)	B7100
Active movement scale	6% (12/217)	B7301
Toronto test score	4% (9/217)	B7300
(B) Body functions		
Muscle strength indexes		
Medical Research Council	14% (31/217)	B7301
Narakas	6% (12/217)	B7301
Raimondi scale	5% (11/217)	B7300
Gilbert-Raimondi scale	4% (9/217)	B7300
Al-Qattan classification	2% (4/217)	B7300/B7301
Hand strength (grip)	1% (2/217)	B7300
Towel test	0.5% (1/217)	B7301
Lovett scale	0.5% (1/217)	B7301
Motor score composite	0.5% (1/217)	B7301
Louisiana State University Health Sciences Center grading system	0.5% (1/217)	B7100/B7300
Miami Shoulder	0.5% (1/217)	B7100/B7101
Duclos and Gilbert scale	0.5% (1/217)	B7300
Functional Scoring System for NBPP	0.5% (1/217)	B7100/B7301
Impairment rating scale for NBPP	0.5% (1/217)	B7300/B7301/B750/B830/ B840
Muscle strength upper limb (other/not specified)	1% (2/217)	B7301
Nerve function		
Electromyography	11% (23/217)	B7300
Semmes Weinstein test	0.5% (1/217)	B270
Stereognosis (Moberg-Dellon)	0.5% (1/217)	B265
Questionnaire		
Self developed questionnaire assessing self mutilation	0.5% (1/217)	B1801/B189
Self developed questionnaire assessing limb integration into daily activities	0.5% (1/217)	B7108
Self developed questionnaire assessing type and extent of problems experienced in terms of arm function	0.5% (1/217)	B1522
Satisfaction with cosmetic appearance (asked during follow up)	0.5% (1/217)	B1801

Table 2, continued

Outcome measures	Sum of all studies % (n)	ICF classification
(C) Activities and participation		
Self developed set of activities to evaluate arm and hand function Questionnaire	0.5% (1/217)	D410/D440/D445
Children's assessment of participation and enjoyment (CAPE)	0.5% (1/217)	D166/D170/D210/D2400/D3600/ D4554/D5606/D6200/D630/D710 D810/D820/D850/D910/D9100/ D920/D9200/D9201-5/D9300
ABILHAND Manual Ability Measure	0.5% (1/217)	D4402/4408/D4453/D449/ D5100/D5400-1/D5408/D550/D560
Vineland Adaptive Behavior Scales (writing subscale)	0.5% (1/217)	D140/D145/D166/D170
Functional Limb Preference Assessment	0.5% (1/217)	D4401/D4402
Body Structures and Activities and Participation Self developed questionnaire assessing body structures, activities and participation	0.5% (1/217)	S750/B760/D4554/D465/D4750
Body Functions and Activities and Participation Questionnaire		
American shoulder and Elbow Surgeons Standardized Shoulder assessment Form	0.5% (1/217)	B28014/D4150/D4308/ D4452/D4454/D5100/D5202/D5309/ D5400/D8509/D9201
Shoulder pain and disability index	0.5% (1/217)	B28014/D4300-1/D4458/D5100/D5400
Developmental outcome and behavioural outcome	0.5% (1/217)	B126/B130/B140/B1400-1/ B152/B1521/B1528/B5253/B6202/ D7100/D7104/D7500/D7504
Self developed questionnaire assessing arm function, daily activities and limb appearance	0.5% (1/217)	B1801/B710/D510/D5100-1/ D5202/D530/D5400/D5402/D550
(D) Body Functions, Activities and Participation and Environmental Factors		
Questionnaire		
Pediatric Outcomes Data Collection Instrument (PODCI)	2% (4/217)	B1300/B134/B152/B1800-1/B280/D170 D4100/D4103/D4105/D4153-4/D4300/ D4452/D4500-2/ D4451-2/D4702/D4750/ D5100/D5202/D5400/D550/D560/D640/D7200/ D7500/D820/D839/D9200-1/ E1201/E310/E330/E399/E420/PF*/HC*/NC*
Pediatric Evaluation of Disability Inventory (PEDI)	0.5% (1/217)	B140/B1140-1/B11420- 1/B630/B789/B6202//D155/D1551/D160/D163/ /D1750/D2100/D310/D315/D330/ D335/D349/D445/D455/D460/D465/ /D4103-4/D4153/D4200/D4301/D4308/D4402 /D4500/D4508/D4550-1/D4558/D4602/ D510/D5100-2/D5201-2/D5208/D530/S5300- 1/D54003/D5408/D550/D560/D620/ D6409/D6509/D710/ D7203/D815/D820//D9109/D9200/E1100/ E115/E125/E155/E325/E340/E1150-1/ E1200-1/E1251/E1400/E1550-1/E2109/E298/NC*
Self developed questionnaire assessing writing abilities	0.5% (1/217)	B280/B28010/B28013-14/B760/ B780/D145/D170/D4153/ E1151/E1300-1/ND
Self developed questionnaire assessing problems in adult patients with NBPP	0.5% (1/217)	B1801/B28016/B265/B7101/B7109/ B840/B780/B7800-1/D4401/D4302/ D4451/D510/D5202/D540/D630/D650/ D845/E1201/E355/PF*
Self developed questionnaire assessing sports participation	0.5% (1/217)	B1528/B2800/B798/D9201/ E1401/E299/E310/E330/ E5800/NC*
Body Functions and Environmental Factors Self developed questionnaire assessing healthcare satisfaction	0.5% (1/217)	B1522/E310/E320/E340/E355

*PF = Personal Factors; *HC = Health Condition; *NC = Not Classified;

to two unique ICF categories in the Body Functions component: B7100 (mobility of a single joint) and B7101 (mobility of several joints). The British Medical Research Council motor grading scale was linked to one unique ICF category; B7301 (Power of muscles of one limb). With respect to Body Structures, the MRI was most frequent, and was linked to five ICF categories: S7200 (bones of shoulder region), S7201 (joints of shoulder region), S7202 (muscles of shoulder region), S73000 (bones of upper arm) and S73001 (elbow joint).

The ICF component Activities and Participation was represented in some questionnaires or indices, however, these instruments were represented in 15 outcome measures, used in only 18 studies. Only five instruments could be linked to three different ICF components. These instruments, the PODCI (Pediatric Outcomes Data Collection Instrument) [31], the PEDI (Pediatric Evaluation of Disability Inventory) [32] and three self-developed questionnaires, one to assess sports participation [33], one to assess writing abilities [34], and one to assess experienced problems in adult patients [35] which were used in 8 studies, comprised concepts related to Body Functions, Activities and Participation and Environmental Factors. Overall, Environmental factors were represented in 6 outcome measures, employed in 9 studies.

Twenty-two concepts were not classified and could only be linked to components in general. Five of these concepts related to age, three in the PODCI questionnaire and two in the self developed questionnaire assessing experienced problems in adult patients [29], were linked to the ICF component Personal Factors, which is not yet further specified in categories. Six of these concepts (1%), relating to general health in the PODCI, were linked to the component Health Condition. Eleven of these concepts (1%), two in a self developed questionnaire to assess sports participation [33], one in a self developed questionnaire to assess writing abilities [34] and eight in the PEDI could not be linked to any of the ICF components because they are not covered by a specific ICF category. The Pediatric Evaluation of Disability Inventory was already analyzed and linked to the ICF by Ostensjo et al. [36] and the identified ICF categories, from this study, were used for our analysis.

4. Discussion

This systematic review on outcome measures used in clinical studies in patients with NBPP shows that

there is considerable variation. Our results are largely in line with a recent systematic review [17], published after our study was carried out, and also concluding that there is a large diversity and lack of standardization of the use of outcome measures in NBPP. There are however some differences. First, that review included clinical studies from 1980, whereas we have selected studies from 1996, to make sure that the findings would adequately reflect currently used outcome measures, related to interventions, which are still common. Second, in contrast with our study they have included case reports and case series. As mentioned earlier case series are more likely to be descriptive and qualitative, and less likely to use standardized outcome measures. Thirdly, and most importantly, the authors did not categorize the content of the outcome measures on the same level of detail as employed in the present study, and did not use a standardized method [18]. Therefore it is conceivable that not every item has been linked to the ICF in that study, which may explain why the results are not exactly the same. For example the PODCI and PEDI questionnaires were found to cover only the domain Activities and Participation in the study by Chang et al. whereas in our analysis in which all different items (questions) of these questionnaires were linked to the ICF, by two researchers independently, these questionnaires were found to cover three domains; Body Functions, Activities and Participation and Environmental Factors. Furthermore, we have provided all ICF classification codes, which give more information about the variability among outcome measure within ICF domains. With the more profound method of analysis employed in the present study, current gaps in outcome measurement could be identified in more detail.

A total of 57 different outcome measures were used in 217 studies. Although not all of the studies addressed the same research issues, this remarkable high number of outcome measures makes it difficult to interpret results and compare different treatment strategies. Measures of shoulder and or elbow range of motion and MRI of the shoulder were most frequently applied (17–76% of the studies). The concepts derived from these outcome measures were all related to the ICF component Body Functions and Body Structures. The contents of 15 of the 57 outcome measures could be linked to the ICF components Activities and Participation. Only six outcome measures comprised concepts related to Environmental factors. These instruments were used in only 0.5–2% of the studies, warranting the conclusion that measuring the outcome of

NBPP on the level of the ICF components Activities and Participation, Environmental and Personal factors is rare and there is no consensus on which outcome measure is the most appropriate for this patient population.

The results of this study are noteworthy, as diminished functional use of the arm is likely to affect daily functioning in all areas of life, such as self care (e.g. washing hair), sports, writing skills, or the usage of utensils. The PODCI and the PEDI questionnaires are the only validated outcome measures identified in this study that address three different components of the ICF. These outcome measures were, however, only used in 5 studies and, although designed to measure the impact of upper extremity conditions in children, are not specifically developed for usage in patients with NBPP.

The variation in outcome measurement is large, which may hamper improvement of NBPP treatment based on sound evidence. This study underlines the need for consensus on outcome measurement. It remains to be established to what extent the set of outcome measures should include disease specific or generic outcome measures. In case new measurement instruments specifically for patients with NBPP need to be developed, it is important to explicitly take the patient perspective into account. This can be obtained by involving patients and parents in the development such a new outcome measure. However, generic questionnaires for children and adolescents, covering multiple areas of quality of life, such as the TAAQOL (TNO-AZL Questionnaire for Adult Health-Related Quality of Life), TACQOL (TNO-AZL Questionnaire for Children's Health-Related Quality of life), TAPQOL (TNO-AZL Questionnaire for Preschool Children's Health-Related Quality of Life) or PEDSQL (Pediatric Quality of Life Inventory) may also be useful to identify the impact of NBPP on different aspects of functioning from the patient's perspective [37–40]. These outcome measures are validated for patients in different age groups, and their generic nature allows comparisons with groups of patients with other conditions as well as with healthy peers. These measures of quality of life were developed in collaboration between health care providers and patients.

Regarding the methodological quality of the studies, the large majority had a moderate or low score, mainly because most studies retrospectively described the outcome of surgical interventions for NBPP in children, without using a control group. In this patient category a control or sham procedure may be consid-

ered unethical, as it is very difficult not to treat children for the purpose of research. A number of studies concerned retrospective comparisons of different treatment options, which is prone to confounding by indication. In addition, sample sizes were small in many studies, which is likely to be due to the rarity of the disease, resulting in health care providers and researchers only having access to a small selected study population. Given the relatively low overall methodological quality of the studies, no comparison of the use of outcome measures in high and low/moderate quality studies could be made. The scoring of the methodological quality of the studies did however give insight into the overall quality of current clinical studies in this field. Moreover, the detailed analysis as employed in the present study gives comprehensive information about areas for improvement of the methodology in this field of research.

This study has a number of limitations. First, articles before January 2000 were not included in this systematic review and therefore some outcome measures may not have been identified. For example, Choi et al. [41] developed a 78-item questionnaire with items on injury, treatment course, recovery period following surgery, present status, education, employment, social history, discrimination and harassment and quality of life. Although this questionnaire was used in 32 adult patients, it might have provided some useful information. Furthermore, there was a lack of information in many articles regarding the follow-up period, type of lesion or information on prior surgical treatments in observational studies with no specific intervention outcome. This lack of information may have led to an over- or underestimation of the average of these variables. In addition, in some cases it was unclear whether the reported study population had been subject in other studies. Papers may therefore have been incorrectly considered as individual studies, resulting in an overestimation of the total number of patients in the identified studies. Regarding the usage of the NOS scale to judge the methodological quality of studies, the cut-off points to define the demarcation between high-, moderate- and low-quality scores vary in the literature, with some authors defining 8 out of nine as high-quality whereas others define 6 out of nine as high-quality [42–46]. In our study we defined a score of minimum 6 stars out of seven as a high-quality score.

5. Conclusion

This study shows that there is a high variability among used outcome measures in clinical studies on

NBPP. Most studies focus on the ICF components Body Functions and Body Structures, whereas assessments of Activities and Participation and Environmental Factors were relatively uncommon. For the patient these latter domains are far more important. Whilst the fact that health professionals think they consider these domains in the commonly used clinical, physician based scores, some discrepancy with the patient's expectation exists. An in-depth understanding of the impact of NBPP on all four domains of the ICF is important to optimize management of NBPP. The development and usage of outcome measures covering all aspects of functioning is warranted.

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Conflict of interest

The authors have no conflict of interest to declare.

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Appendix A

Search strategies for different databases

PubMed

((“Brachial Plexus Neuropathies” [Mesh:NoExp] OR “Brachial Plexus Neuropathies” [tw] OR “Brachial Plexus Neuropathy” [tw] OR “Brachial Plexus Diseases” [tw] OR “Brachial Plexus Disease” [tw] OR “Brachial Plexus Disorders” [tw] OR “Brachial Plexus Disorder” [tw] OR “Brachial Plexopathy” [tw] OR “Brachial Plexopathies” [tw] OR “Brachial Plexus injury” [tw] OR “Brachial Plexus injuries” [tw] OR “brachial plexus palsy” OR “brachial plexus palsies” [tw] OR “Brachial Plexus lesion” [tw] OR “Brachial Plexus lesions” [tw] OR (“traction injury” [tw] OR “traction injuries” [tw] OR “Traction/adverse effects” [Mesh] OR neurotme* OR axonotme* OR “root avulsion” [tw] OR “obstetric paralysis” OR “obstetrical paralysis” OR “obstetrical paralyses”) AND “brachial plexus”)) AND (birth OR birth-related OR congenital OR neonatal OR congenital* OR neonat* OR obstetric-induced OR obstetric OR obstetrical OR neonate OR neonates OR newborn OR newborns OR infant OR infants OR child)) OR (“Erb Paralysis” [tw] OR “Erb Paralyses” [tw] OR “Erb-Duchenne Paralysis” [tw] OR “Erb Duchenne Paralysis” [tw] OR “Erb’s Palsy” [tw] OR “Erb Palsy” [tw] OR “Erb’s Palsies” [tw] OR “Erbs Palsy” [tw] OR “Klumpke Paralysis” [tw] OR “obstetric brachial plexus” [tw] OR “obstetrical brachial plexus” [tw] OR “brachial plexus birth” OR “Paralysis, Obstetric” [mesh] OR klumpke-dejerine OR dejerine-klumpke OR (dejerine [tw] AND klumpke [tw]))

Web of Science

(TI = (“brachial plexus” OR “brachial plexopath*” OR (“traction injur*” OR neurotme* OR axonotme* OR “root avulsion” OR “avulsion injur*” OR “obstetric paralysis*” OR “obstetrical paralys*”) AND “brachial plexus”)) AND TS = (birth* OR child* OR newborn* OR infant* OR congenital* OR neonat* OR obstetric-induced OR obstetric*)) OR TI = (“Erb Paralysis*” OR “Erb-Duchenne Paralysis*” OR “Erb Duchenne Paralysis*” OR “Erb’s Pals*” OR “Erb Pals*”

OR “Erbs Pals*” OR “Klumpke Paralysis*” OR “obstetric brachial plexus” OR “obstetrical brachial plexus” OR “brachial plexus birth*” OR “klumpke-dejerine” OR “dejerine-klumpke” OR (dejerine AND klumpke))

Cochrane

“Brachial Plexus Neuropathies” [Mesh:NoExp]

Brachial Plexus OR Brachial Plexopathy OR Brachial Plexopathies

AND birth OR birth-related OR congenital OR neonatal OR congenital* OR neonat* OR obstetric-induced OR obstetric OR obstetrical OR neonate OR neonates OR newborn OR newborns OR infant OR infants OR child Erb Paralysis OR Erb Paralysis OR Erb-Duchenne Paralysis OR Erb Duchenne Paralysis OR Erb’s Palsy OR Erb Palsy OR Erb’s Palsies OR Erbs Palsy OR Klumpke Paralysis OR obstetric brachial plexus OR obstetrical brachial plexus OR brachial plexus birth OR klumpke-dejerine OR dejerine-klumpke “Paralysis, Obstetric” [mesh]

PsycINFO

((brachial plexus OR brachial plexopath*) AND (birth* OR child* OR newborn* OR infant* OR congenital* OR neonat* OR obstetric-induced OR obstetric*)) OR Erb Paralysis* OR Erb-Duchenne Paralysis* OR Erb Duchenne Paralysis* OR Erb’s Pals* OR Erb Pals* OR Erbs Pals* OR Klumpke Paralysis* OR obstetric brachial plexus OR obstetrical brachial plexus OR brachial plexus birth* OR klumpke-dejerine OR dejerine-klumpke OR (dejerine AND klumpke)

EMBASE

((exp Brachial Plexus Injury/ OR exp Brachial Plexus Neuropathy/ OR Brachial Plexus Neuropath*.mp OR Brachial Plexus Dis*.mp OR Brachial Plexopathy*.mp OR Brachial Plexus injur*.mp OR brachial plexus pals*.mp OR Brachial Plexus lesion*.mp OR ((traction injur*.mp OR neurotme*.mp OR axonotme*.mp OR root avulsion.mp OR Avulsion Injury/ OR obstetric paralysis*.mp OR obstetrical paralysis*.mp) AND (Brachial Plexus/ OR brachial plexus.mp))) AND (exp Birth/ OR exp Birth Injury/ OR exp Child/ OR exp Newborn/ OR exp Infant/ OR birth.mp OR birth-related.mp OR congenital*.mp OR neonat*.mp OR obstetric-induced.mp OR obstetric.mp OR obstetrical.mp OR newborn*.mp OR infant*.mp OR child*.mp) OR (Erb Paralysis*.mp OR Erb-Duchenne Paralysis*.mp OR Erb Duchenne Paralysis*.mp OR Erb’s Pals*.mp OR Erb Pals*.mp OR Erbs Pals*.mp OR Klumpke Paralysis*.mp OR obstetric brachial plexus.mp OR ob-

stetrical brachial plexus.mp OR brachial plexus birth.mp OR klumpke-dejerine.mp OR dejerine-klumpke.mp OR (dejerine.mp AND klumpke.mp))

CINAHL

((MH “Brachial Plexus Neuropathies”) OR brachial plexus OR brachial plexopath*) AND (birth* OR child* OR newborn* OR infant* OR congenital* OR neonat* OR obstetric-induced OR obstetric*) OR Erb Paralysis* OR Erb-Duchenne Paralysis* OR Erb Duchenne Paralysis* OR Erb’s Pals* OR Erb Pals* OR Erbs Pals* OR Klumpke Paralysis* OR obstetric brachial plexus OR obstetrical brachial plexus OR brachial plexus birth* OR klumpke-dejerine OR dejerine-klumpke OR (dejerine AND klumpke)

PEDro

obstetric brachial plexus OR obstetric brachial plexus OR obstetrical brachial plexus OR brachial plexus birth Erb Paralysis OR Erb-Duchenne Paralysis OR Erb Duchenne Paralysis OR Erb’s Palsy OR Erb Palsy OR Erbs Palsy OR Klumpke Paralysis OR klumpke-dejerine OR dejerine-klumpke

Appendix B

Reference list of all 217 selected studies in alphabetical order according to the first author listed.

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Appendix C

Newcastle-Ottawa Quality Assessment Scale case control studies

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Exposure categories. A maximum of two stars can be given for Comparability.

Selection

- 1) Is the case definition adequate?
 - a) yes, with independent validation *
 - b) yes, eg record linkage or based on self reports
 - c) no description
- 2) Representativeness of the cases
 - a) consecutive or obviously representative series of cases *
 - b) potential for selection biases or not stated
- 3) Selection of Controls
 - a) community controls *
 - b) hospital controls
 - c) no description
- 4) Definition of Controls
 - a) no history of disease (endpoint) *
 - b) no description of source

Comparability

- 1) Comparability of cases and controls on the basis of the design or analysis
 - a) study controls for _____ (Select the most important factor.)*
 - b) study controls for any additional factor * (This criteria could be modified to indicate specific control for a second important factor.)

Exposure

- 1) Ascertainment of exposure
 - a) secure record (eg surgical records) *
 - b) structured interview where blind to case/control status *
 - c) interview not blinded to case/control status
 - d) written self report or medical record only
 - e) no description
- 2) Same method of ascertainment for cases and controls
 - a) yes *
 - b) no
- 3) Non-Response rate
 - a) same rate for both groups *
 - b) non respondents described
 - c) rate different and no designation

Newcastle-Ottawa Quality Assessment Scale cohort studies

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Exposure categories. A maximum of two stars can be given for Comparability.

Selection

- 1) Representativeness of the exposed cohort
 - a) truly representative of the average _____ (describe) in the community *
 - b) somewhat representative of the average _____ in the community *
 - c) selected group of users eg nurses, volunteers
 - d) no description of the derivation of the cohort
- 2) Selection of the non exposed cohort
 - a) drawn from the same community as the exposed cohort *
 - b) drawn from a different source
 - c) no description of the derivation of the non exposed cohort
- 3) Ascertainment of exposure
 - a) secure record (eg surgical records) *
 - b) structured interview *
 - c) written self report
 - d) no description
- 4) Demonstration that outcome of interest was not present at start of study
 - a) yes *
 - b) no

Comparability

- 1) Comparability of cohorts on the basis of the design or analysis
 - a) study controls for _____ (select the most important factor) *
 - b) study controls for any additional factor * (This criteria could be modified to indicate specific control for a second important factor.)

Outcome

- 1) Assessment of outcome
 - a) independent blind assessment *
 - b) record linkage *
 - c) self report
 - d) no description
- 2) Was follow-up long enough for outcomes to occur
 - a) yes (select an adequate follow up period for outcome of interest) *
 - b) no
- 3) Adequacy of follow up of cohorts
 - a) complete follow up – all subjects accounted for?
 - b) subjects lost to follow up unlikely to introduce bias – small number lost – > ____ % (select an adequate %) follow up, or description provided of those lost)*
 - c) follow up rate < ____% (select an adequate %) and no description of those lost
 - d) no statement

Table showing distribution of total scores on the NOS scale of all 216 studies

Score on NOS scale	Cohort studies n (%)	Case control studies n (%)
7 stars	1/204 (0.5%)	1/12 (8%)
6 stars	18/204 (9%)	1/12 (8%)
5 stars	61/204 (30%)	3/12 (25%)
4 stars	64/204 (31%)	3/12 (25%)
3 stars	48/204 (24%)	2/12 (17%)
2 stars	12/204 (6%)	2/12 (17%)

Tables showing the scores on the different items of the NOS-scale of all 216 studies.

Table showing 204 studies, which were scored with the NOS-scale for cohort studies, and the distribution of the scores on the different items.

Item NOS-scale cohort studies (n = 204)	A (n =)	B (n =)	C (n =)	D (n =)
1) Representativeness of exposed cohort	5	158	41	0
2) Selection of non-exposed cohort	1	0	203	–
3) Ascertainment of exposure	189	12	3	0
4) Demonstration outcome of interest not present	78	126	–	–
5) Assessment of outcome	4	186	13	1
6) Was follow-up long-enough?	116	88	–	–
7) Adequacy of follow up	74	20	20	90

Table showing 12 studies, which were scored with the NOS-scale for case-control studies, and the distribution of the scores on the different items.

Item NOS-scale case-control studies (n = 12)	A (n =)	B (n =)	C (n =)	D (n =)	E (n =)
1) Is the case definition adequate?	6	6	0	–	–
2) Representativeness cases	6	6	–	–	–
3) Selection of controls	3	5	4	–	–
4) Definition of controls	7	5	–	–	–
5) Ascertainment of exposure	9	1	1	–	1
6) Same method for cases and controls	11	1	–	–	–
7) Non-response rate	7	3	2	–	–