“Let’s speak the same language”

Outline of the iPluto project

Background

It is difficult to assess from the available literature optimal treatment strategies for children with a neonatal brachial plexus palsy (NBPP) - or ‘obstetric brachial plexus lesion’. Comparison of outcome data presented by different centers is impossible due to the use of 1) many different outcome measures to evaluate results; 2) different follow-up periods after interventions and 3) different patient ages at the time of assessment.

Objective

The goal of the iPLUTO study group is to define a universal dataset to evaluate upper limb function of NBPP children. This dataset will allow for comparison of results between different clinics if prospectively used. It goes without saying that treating physicians should not feel limited by the iPluto dataset. The iPluto dataset should be regarded as the basic information that should be minimally be collected, and additional assessments should continue to according to the researchers’ interest.

In the future, pooling of standardized results may enable multicenter studies, but this is not the scope of the current project. It is not the intention of this project to set specific treatment guidelines or to interfere with current treatment policies, but only to. The goal is to create an international minimal standard for evaluation and expression of results of treatment. Acquiring this goal would be a major step forward and can only be reached in close collaboration with experts in the field.

Requirements of the Datasets

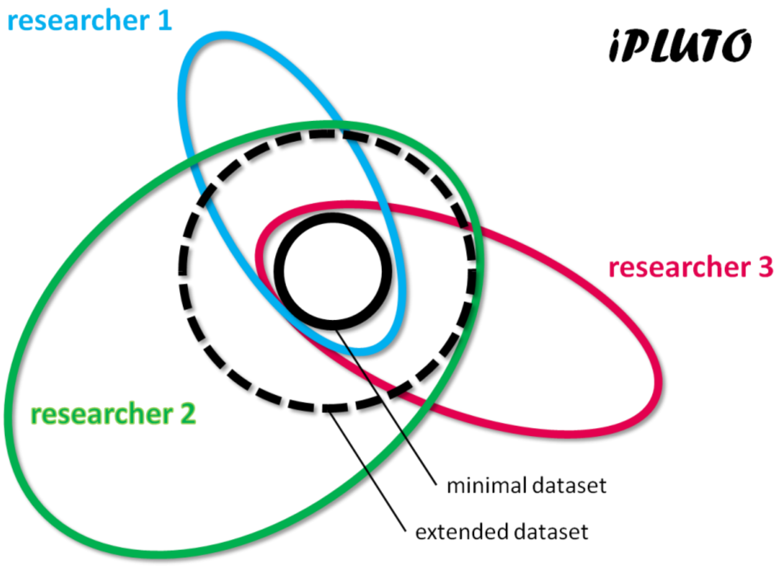
1) The minimal dataset should be applicable in routine clinical care in every center, within a confined amount of time.
2) Collected outcome measures should be well defined to avoid assessment bias and/or inter observer variability, preferably using validated outcome scales.
3) Various items should be included, such as
    a. movement and range of motion (both active and passive) of various joints
    b. force of specific muscles
    c. functional outcome scales (e.g. Mallet-scale, AHA, BPOM...)
    d. assessment of sensation and pain
    e. patient reported outcome measures (PROMs)
4) All applicable domains of the ICF ('International Classification of Functioning, Disability and Health') from the World Health Organization should be assessed. Development of a formal ICF-‘Core set’ according to the standards of the WHO may be a secondary spin-off apart from development of a universal dataset.
5) Standardized time points for the collection of data should be used. The age of the infant will be used, and not the follow-up time after a specific intervention. The

minimal number of evaluation moments will be limited to increase participation. A first proposal would be at the age of 1 / 3 / 5 / 7 years.

   a. one year, because this is a plateau for spontaneous neurological recovery. Additionally, this time point may serve as a baseline before results of treatment interventions will have taken an effect.
   b. three years, because this reflects the final stage of spontaneous recovery, and a plateau for shoulder function in children who were treated with early nerve reconstruction.
   c. five years, because by this time an end-stage is reached for nerve reconstruction of the shoulder, and a plateau is reached for hand function. Additionally, it could serve as a pre-school assessment of function.
   d. seven years, because by this time most secondary surgical procedures will have been performed and an end stage for hand function is reached. Limitations in the first year(s) of school and during leisure (e.g. sports) can be identified at this age because of sufficient cooperation.

6) A set of variables will be determined to define initial severity of the lesion (e.g. Narakas classification), and spontaneous recovery in the course of the first year. A first proposal would be serial investigation of key functions at 1-3-6-9 months, and age by which elbow flexion against gravity has recovered.
7) Besides the minimal dataset, development of an extended dataset is intended for more elaborate evaluation, for instance to set a standard age for time-consuming evaluation by means of the AHA.

The final set of items and time points will be defined by consensus by contributors to iPluto.



Methods

The main tool to reach consensus on the datasets will be the use of short internet surveys in four rounds. A Delphi-derived technique will be applied. Additionally, one or two consensus meetings will be endeavored after completion of the internet surveys.

The first round of the internet surveys will use open end questions to record the methods that clinicians currently use. The second round will use the results of the first round and evaluation methods obtained from the literature (in available systematic reviews) will be added. Participants will be asked to rate the different evaluation methods on validity and applicability using a Likert scale. Additional remarks as ‘free text’ can be made to explain the choices and preferences. In the third round, results of the second round will be revealed for each question, and participants are asked to rate the items again. In this way feedback from the second round will narrow the ratings of items during the third round. Participants will be asked if an item should be part of the minimal or extended dataset.

After the third round, results will be analyzed whether a consensus is reached on the validity and applicability of specific items. Depending on the analysis, a fourth round may be necessary for specific items if consensus is not reached in the third round. Results from the final round will be the basis for a consensus meeting.

Timeline

The timeline of the project to complete the internet surveys and consensus meetings is one year. The first preliminary dataset will be published online (http://iPluto.org) and in an international scientific magazine, preferably open-access. In the second and third year of the iPLUTO project physicians are asked to use the minimal dataset in clinical practice at the appropriate time points. At the 2019 Narakas meeting, the first practical experience and clinical results will be presented and discussed. This might potentially might lead to amendment of the datasets and a next (perhaps final) version of the dataset will be set.

Contributors

All physicians taking care for children with a NBPP can join the project. Care will be taken that various disciplines will be represented. Contributors will be recruited by email; mail addresses will be collected from delegate lists from Narakas meetings. Contributors can apply at will on the project website.

For the Delphi surveys, one person will represent a brachial plexus center. Thereby, bias by vote overrepresentation from centers with many physicians will be avoided. It is assumed that this representative communicates the overall view that the specific center. All contributors will be mentioned - in alphabetical order - in resulting publications. Authorship will depend on amount of involvement.