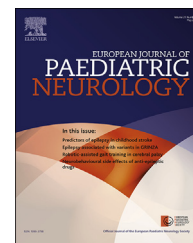




ELSEVIER

Official Journal of the European Paediatric Neurology Society



Original article

Long-term therapy with intrathecal baclofen improves quality of life in children with severe spastic cerebral palsy



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ARTICLE INFO

Article history:

Received 18 August 2016

Received in revised form

28 January 2017

Accepted 30 January 2017

Keywords:

Cerebral palsy

Intrathecal baclofen

Spasticity

Child

ABSTRACT

Introduction: Children with severe spastic cerebral palsy (CP) are highly limited in daily life activities causing a reduced quality of life (QoL). This is partly due to an increased muscle tone causing pain and contractures. Continuous intrathecal infusion of baclofen (ITB) reduces the spasticity of affected patients. The hypothesis of the present study was that ITB leads to a significant improvement of QoL in non-ambulant children with CP.

Patients and Methods: 13 patients (10 male, 3 female, mean age 14 years) were included. Mean time between pump implantation and follow-up was 60 months (range, 12–100). QoL was assessed before and after baclofen pump implantation using standardized questionnaires (CP CHILD, KINDL). Spasticity was evaluated using the modified Ashworth Scale (MAS) at the two time points.

Results: QoL evaluated with the CPCHILD questionnaire and the KINDL improved from pre-implantation to follow-up. MAS markedly decreased from 3.8 to 1.7. All interviewed participants indicated that their expectations had been met and that they would choose ITB treatment again.

Conclusion: Intrathecal treatment of baclofen is an excellent method for spasticity management in children with severe cerebral palsy. Quality of life sustainably improves, parents' satisfaction is high and the level of spasticity decreases. Therefore, baclofen treatment can be highly recommended in non-ambulant children with CP suffering from spasticity.

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1. Introduction

With a mean prevalence of 2.4/1000 live births and no indication of any decrease cerebral palsy (CP) is the most common

physical disability affecting children in developed countries.¹ It is considered as the main cause of spasticity. Two thirds of all children with CP suffer from spasticity,² contracture and stiffness leading to a variety of orthopaedic problems may be the consequences. In severely affected children spasticity

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<http://dx.doi.org/10.1016/j.ejpn.2017.01.016>

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frequently causes pain, sleeping disorders, and increased energy requirements. Moreover, caregivers of these children have to deal with interference of positioning, transfers and daily hygiene. Even simple tasks like dressing can become problematic.³

Beside physical therapy, botulinum toxin A (BoNT-A), oral medication or even surgery has been established to address spasticity by reducing the muscle tone. However, a substantial group of severely affected children does not respond sustainably to these therapies.^{4,5}

Oral medication including dantrolen, tizanidine, benzodiazepines and baclofen offer a systemic approach to spasticity.⁶ Nevertheless, unwanted side-effects such as sedation and somnolence are frequently reported.^{7,8}

In the recent years, intrathecal baclofen treatment (ITB) has gained increasing interest and seems to be an effective treatment option for spasticity in cerebral palsy.^{9–11} It was approved for the treatment of spasticity in 1996. With a special pump and catheter system baclofen is infused directly into the spinal canal and around the spinal cord. By blocking excitatory neurotransmitters in the dorsal horn of the spinal cord baclofen, a GABA-B receptor agonist, inhibits presynaptic pathways and thereby decreases tone. ITB maximizes the dose delivered to spinal receptors and minimizes side effects.

According to the World Health Organization (WHO) quality of life (QoL) is defined as “the individual's perception of their position in life, in the cultural context and value systems in which they live and in relation to their goals, expectations, standards and concerns”.¹² Only a few studies have addressed quality of life in children with CP and concluded that these children have a worse quality of life compared to healthy children.¹³ For example, severely limited self-mobility is significantly associated with a reduced mean score for physical wellbeing; intellectual impairment is significantly associated with a reduced mean for moods, emotions and autonomy. Speech difficulties are associated with a reduced mean for relationships with parents. Additionally, pain represents a common finding and its presence is associated with lower QoL in all domains. Continuous ITB reduces both spasticity and pain and therefore might subsequently improve quality of life in CP patients.

Previous studies reporting QoL in children with spasticity and ITB treatment have found a significant improvement.^{9,14} However, long-term follow-up examinations are rare. The aim of this study was therefore to evaluate QoL in severely affected CP patients treated with ITB in a long-term run.

1.1. Patients and methods

Following approval from the local ethical committee (EK No 25-149ex12/13) all patients with cerebral palsy (CP) who underwent baclofen pump implantation between 2005 and 2012 were included. The type of CP was described using a standardized methodology¹⁵ and the severity of the motor disorder was determined by the Gross Motor Function Classification System (GMFCS).^{16,17} Moreover, age, gender, existing comorbidities, date of pump implantation, complications and the number of pump changes were assessed.

In our department ITB treatment is only performed in individuals with CP who are severely affected with a GMFCS

level IV or V. Baclofen testing via lumbar puncture before pump implantation is done in each patient in order to exclude non-responders. The definitive baclofen dosage is adjusted to the patients' needs.

Quality of life (QoL) was assessed before and after baclofen pump implantation using standardized questionnaires in the national language (CPCHILD, KINDL).^{18–20} Spasticity was evaluated using the modified Ashworth Scale (MAS) at the two time points. In addition, parents were asked by a person not involved in the treatment (KG) whether or not they would choose ITB treatment for their child again. They were also asked if they would recommend ITB therapy and if ITB made nursing of the child easier. The minimum time of follow-up was set at 12 months.

1.2. CPCHILD

The CPCHILD questionnaire consists of 36 items distributed over six sections. Questions are referred to personal care; positioning, transfer, and mobility; communication and social interaction; comfort, emotions, and behaviour; health; and overall quality of life. Each section is rated on a scale describing the degree of difficulty ranging from “no problem” to “impossible”. A further section determines the importance of the caregivers' rating of each of the questionnaires' items towards the child's overall quality of life. Therefore, an ordinal scale was used reaching from 1 (least important) to 5 (most important).

The results of the CPCHILD questionnaire range between 0 and 100. A score of 0 represents the best possible outcome and a score of 100 represents the worst possible outcome. Additionally, the personal data of the child, sex, date of birth, and the years the child has spent in school are evaluated by the CPCHILD.

1.3. KINDL

The KINDL questionnaire was designed to assess QoL in children and adolescents. It has to be completed by the patient itself or the parents.²¹ The KINDL questionnaire suits to patients aged between 3 and 17 years and is applicable to healthy and non-healthy children. It consists of the following six dimensions: ‘physical well-being’, ‘mental wellbeing’, ‘self-esteem’, ‘family’, ‘friends’ and ‘education/training’. In each dimension 4 items have to be rated. The final evaluation of the questionnaire results in transformed values ranging from 0 (worst) to 100 (best). As the majority of patients in this study could not be interviewed about their own situation, the caregiver's version of the questionnaire was used.

1.4. Modified Ashworth Scale (MAS)

For the measurement of the patients' spasticity the modified Ashworth Scale (MAS) was used.²² Spasticity was measured for the muscle groups of the upper (shoulder, elbow, wrist, finger, thumb) and lower limbs (hip, knee, ankle). Scores range from 4 (maximum spasticity making passive movement extremely difficult) through 3, 2, 1+, 1, 0 (normal with no resistance to movement). Scores for all muscles were added to give a total for each assessment, counting the score 1 + as 1.5.

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