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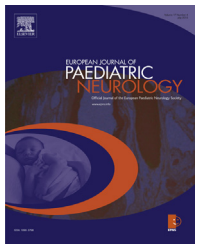

Original article

The effect of continuous intrathecal baclofen on sitting in children with severe cerebral palsy

*Natalie Gray**, *Michael Vloeberghs*

Queens Medical Centre, Nottingham University Hospital, Nottingham, UK

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ABSTRACT

Aim: To investigate the effect of intrathecal baclofen (ITB) on sitting in children with cerebral palsy with severe spasticity; and identify potential sub-groups of patients at particular risk of deterioration.

Method: Twenty three children with cerebral palsy, mean age 10 yrs 10 mo were assessed before and after ITB treatment using the Sitting dimension of the Gross Motor Function Measure. Sitting prior to treatment was compared to sitting following ITB treatment in the same children. Exploration of sub groups was also attempted to investigate affects of ITB on sitting according to age and severity of motor impairment.

Results: No significant difference was found in sitting before ITB treatment compared to sitting following insertion of an ITB pump ($p = 0.09$). No specific age group or classification of motor impairment demonstrated significant deterioration in sitting following ITB treatment.

Conclusion: Sitting does not improve or deteriorate in children following treatment with ITB, independent of age or severity of motor impairment.

1. Introduction

Intrathecal baclofen (ITB) is becoming an established treatment for the management of severe spasticity. Research is building in the effects of this treatment in children with severe cerebral palsy, with reports of reducing spasticity and spasms leading to benefits in the areas of comfort, ease of care and quality of life.[1–9] Less clear is the effect of ITB on active function and independence due to few high quality studies.[2–9] This partly reflects the challenges of research in this field with small patient numbers and difficulties evaluating change in complex severe disability.

One topic of debate is the effect of ITB on sitting balance. Clinicians consider this as central stability, essential for control of movement for functional limb activities, as well as comfort and seating and the achievement of upright posture for eye contact.[10,11] It is also evident that parents place high importance on their child's sitting, shown by the frequency of this as a priority goal of treatment.[12,13] There are hypotheses that reduced truncal spasticity following ITB can lead to improved sitting balance.[14] Experts also feel improved sitting is achievable following ITB in recommending it as a goal of treatment in children of higher ability.[5]

* *Corresponding author*. Physiotherapy Department, Queens Medical Centre, Nottingham University Hospital, Derby Road, Nottingham NG7 2UH, UK. Tel.: +44 0115 849 3312; fax: +44 0115 875 4676.
E-mail address: natalie.gray@nuh.nhs.uk (N. Gray).

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However, care needs to be taken in using this anti-spasticity treatment as it has also been hypothesised that abnormal increased tone may be used by the child to maintain an upright posture.[5,14] This has been reinforced by several expert panels, which encourage caution and careful assessment of candidates for ITB due to the potential loss of 'axial righting function'.[5,9,15] These opinions appear to be based predominantly on experience, with the literature identifying few reports of changes in sitting following ITB. Scheinberg et al.[16] observed poorer sitting balance and truncal tone in a single case study, Gray et al.[13] reported 82% of patients subjectively identified an improvement but 15% reported deterioration in sitting following ITB in those who set it as a goal, whilst Krach et al.[17] collected subjective feedback from parents of children and adults regarding trunk control following ITB treatment as part of a larger satisfaction questionnaire, with equal reports of improvement and deterioration. These discrepancies correlate with a perceived variation in current clinical opinion. As yet no study has looked to substantiate these concerns or to identify trends or potential vulnerable groups at particular risk of deterioration in sitting balance following ITB.

This study aims to identify the effect of ITB on sitting in children with cerebral palsy with severe spasticity and explore vulnerable sub-groups of patients at particular risk of deterioration.

2. Method

This investigation was completed using secondary analysis of data from the Nottingham ITB controlled study to investigate the wider effects of ITB in children with severe cerebral palsy.[8]

Children were recruited from the Nottingham ITB centre over a 4-year period using the following criteria: diagnosis of cerebral palsy; aged between 4 and 16 years at time of referral; presenting with severe spasticity of grade 3 or above on the Modified Ashworth Scale[18] in two or more limbs interfering with function or care.

Assessments for each child were made on 3 occasions: 1. at initial referral, 2. at pump insertion and 3. nine months after pump insertion. Insertion of a baclofen pump was often naturally delayed due to waiting list or funding issues. This achieved two periods of observation: baseline period and treatment period.

This study used a within subject comparison method. Changes in sitting in these children during the baseline period was analysed and compared to changes in sitting in the subsequent treatment period with an ITB pump in situ.

Examination of sub groups was also attempted to investigate affects of ITB on sitting according to age and severity of motor impairment. Severity of motor impairment was classified using the Gross Motor Function Classification System (GMFCS) graded 1 (minimal impairment) to 5 (severe impairment).[19]

The outcome measure used was the Sitting dimension of the Gross Motor Function Measure 88 (GMFM).[20] The original study used the GMFM in its entirety with the aim of evaluating overall functional movement. For this investigation, data from just the Sitting dimension was used. This outcome measure is recognised as a sensitive, reliable and valid measure of change in motor function, designed specifically for use with children with severe cerebral palsy.[7,20] The author also advocates its use in sub sections, allowing this further analysis.[20] The Sitting dimension consists of 20 progressively challenging functional tasks in sitting, which are scored against documented criteria. The sum of these scores are then calculated and reported as a percentage.

Participants were included who had 3 complete assessments using the chosen outcome measure, resulting in a baseline period and a treatment period averaging 9 months each. Changes in each assessment period and comparison of the two monitored periods were statistically analysed using paired sample *t* tests.

Signed consent was obtained from the carers to participate in the study, who also agreed to the publication of the results. The study was approved: Queens Medical Centre Nottingham Audit number 1361. Permission was granted from the principle investigator of the original study[8] to allow secondary analysis of the data.

3. Results

Twenty three children met the criteria for this investigation. The baseline period averaged 8.6 months (range 6–12 months), with the treatment period averaging 9.6 months (range 6.5–12 months). This baseline period allowed the evaluation of change in sitting without treatment.

No children with minimal motor impairment (GMFCS I or II) were referred for ITB treatment. Patient characteristics are shown in Table 1. The mean dose of intrathecal baclofen at the final assessment was 158 mcg, ranging from 50 mcg to 530 mcg.

Results of the analysis are shown in Table 2, with trendlines shown in Fig. 1. The data reports a mean deterioration of 3.17% in the sitting dimension of the GMFM over 9 months prior to ITB treatment. Following 9 months of ITB, the same children demonstrated a mean improvement in sitting of 2.90%. The changes within each assessment period were not statistically significant ($p = 0.125$ and $p = 0.22$ respectively). Changes in sitting during the baseline period compared to

Table 1 – Details of participants.

N	Age (yrs:mo)		Gender	GMFCS			CP type		Dyskinesia present	
	Mean (SD)	Range	M/F	III	IV	V	Diplegic	Quadriplegic	Yes	No
23	10:10 (3:6)	4:0–15:9	16/7	3	15	5	12	11	3	20