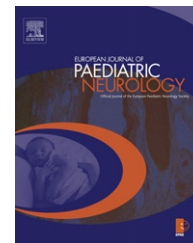




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Original article

Goals and outcomes for non ambulant children receiving continuous infusion of intrathecal baclofen

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ABSTRACT

Aim: To evaluate the success of goals and compare these to actual outcomes in severely disabled children receiving continuous intrathecal baclofen [ITB].

Method: 37 non ambulant children with severe spasticity were assessed just before implantation of a pump for ITB, and 9 and 18 months afterwards. Three key goals were chosen for treatment by the family and therapist. These were reviewed at the assessments, together with caregivers' views of the outcome of treatment in 14 different aspects. At the first and last assessment, the degree of deformity of the hips and spine were reviewed, and Orthopaedic Surgeons were also asked to predict what surgery would be needed in the next 2 years.

Results: The most common successful outcomes were ease of nursing care, better sitting, spasm reduction, more relaxed/better mood, and improved sleep. This was reflected in the goals selected which were therefore realistic for this treatment. All 3 pre-set goals were achieved by 80% of children. Deformities of the hip and spine continued to occur. The predicted number of orthopaedic operations before and after ITB remained unchanged.

Interpretation: ITB is a major treatment for children with severe disability and should be undertaken with understanding of what can and cannot be achieved, therefore allowing realistic goals to be set.

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What this study adds

- All three goals pre-set by family and therapists before ITB are achieved by 80% of children.
- The most common outcomes were improved ease of nursing care, with little effect on deformity or orthopaedic surgery.
- The decision on using ITB depends on the formation of realistic goals in the light of likely outcomes, and knowledge of possible problems.

1. Introduction

Continuous infusion of intrathecal baclofen (ITB) through a pump implanted subfascially in the abdomen has been shown to be safe and effective in the management of severe spasticity in children with cerebral palsy.^{1–3} In the assessment of a treatment, distinction needs to be made between goals, which are what the patient and caregivers wish to be achieved, and the actual outcomes. Goals have been used extensively in directing treatments in children and adults^{3–5}

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and must be set between caregivers and health professionals. The success of particular goals depends on the likely outcomes from ITB which differ according to the level of disability. For non-ambulant children changes may be expected in comfort and ease of care rather than active function. This group of children often develop deformities of the spine and hips, as well as soft tissue contractures of the muscles, which may be affected by ITB. The resulting effect on the amount of orthopaedic surgery necessary is unclear.^{6–8}

This cohort study investigated the goals which had been set by caregivers for ITB over 18 months in a large number of non ambulant children with severe spasticity. This was set against changes in a range of areas, including deformities of the spine and hips and the amount of anticipated orthopaedic surgery. The participants were also part of a controlled prospective study of ITB in children, which also investigated function, participation in society and quality of life.⁹

2. Method

2.1. Subjects

Children attending the national Nottingham Childrens ITB service were recruited between 2003 and 2007 who met the following inclusion criteria:

1. They were to be fitted with an ITB pump on the basis of severe spasticity that reduced function, caused pain or interfered with ease of care.
2. They had a diagnosis of cerebral palsy, were non ambulant; Gross Motor Function Classification (GMFCS) groups IV–V,¹⁰ and aged between 5 and 15 years.
3. Able to be assessed at three specific times; before pump fitment, then 9 and 18 months after.

2.2. Assessments

These were done on the day before the pump was fitted, and at 9 and 18 months afterwards.

Spasticity was measured by a Paediatrician and a Physiotherapist using the Modified Ashworth Scale¹¹ for all limbs, resulting in 10 measurements for each child which were reported as a mean score.

Prior to pump insertion, 3 specific goals were set between the caregiver, physiotherapist and if possible the child, which were considered to be important and realistic. Goals included function, ease of care, mood, or the prevention of deformity.

These goals were set as a simple statement implying overall benefit in all aspects. For example “we want to achieve better seating” was taken to include all aspects of seating, including comfort and position. These goals were reviewed at subsequent assessments, when the caregivers rated whether in their terms the goals were achieved satisfactorily, or not.

Caregivers were also asked to judge if definite gains were made in a range of 14 items thought to be affected by ITB, for example improvement in spasms or better sleeping, many of which overlapped with the specific goals which had been set. They were also asked to rate how pleased they were with ITB on a simple scale of 1–10.¹²

Finally, caregivers were asked a series of questions in order to identify complications in association with the pump and any side effects from the medication.

Outcomes in terms of changes in deformity of the spine and hips were reviewed at 18 months and compared to pre treatment data. Children were under the care of an orthopaedic surgeon at their local hospital, who decided exactly when they were x-rayed. The degree of scoliosis was assessed from the Cobb angle on radiograph, together with clinical examination. Spines were classified into 5 groups: normal (Cobb angle < 5°); mild scoliosis (Cobb angle 5–15°); moderate scoliosis (Cobb angle 15–30°); severe scoliosis (Cobb angle >30°); and spines that have received surgery. Hip displacement was assessed by measurement of Reimers migration percentage from the appropriate pelvic radiograph. Hips were classified into 4 groups: stable (migration percentage < 30°); subluxed, (migration percentage >30°); dislocated hips; and those that have received surgery.

A questionnaire was sent to the local orthopaedic surgeon before and after 18 months of ITB treatment, asking them what operations were definitely planned in the next 2 years.

Signed consent was obtained from carers for this study which was approved by the local Nottingham ethics committee and Trent MREC.

3. Results

Thirty-seven children completed the study, of which details are given in Table 1.

Five children experienced complications with the pump or catheter system over 18 months of treatment (Table 2), 4 of which required corrective surgery, with the symptom of swelling resolving spontaneously. One further child was excluded from the study when the pump was removed following infection around the pump site.

Side effects of ITB are given in Fig. 1. Over 18 months, 20 children reported a total of 21 side effects at 9 months, 4 of

Table 1 – Details of subjects.

n	Age (yrs)		Sex m/f	Weight (kg) mean (sd)	Medications during observation period		GMFCS		CP type Diplegic/Quad	Dyskinesia	
	mean (SD)	median (range)			Baclofen	Diazepam	IV	V		Present	Absent
37	10.16 (3.25)	10.0 (3–15)	19/18	28.08 (9.29)	0	4	18	19	13/24	6	31

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