

Intrathecal Baclofen Therapy in Severely Disabled Cerebral Palsy Patients - Efficacy and Cost-benefit Analysis

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Introduction

Cerebral palsy (CP) is caused by non progressive lesion in central nervous system motor centers, during their development (1). CP has an incidence of 2-3 per 1000 live births in industrialized countries (2). Surveillance of Cerebral Palsy in Europe (SCPE) classifies patients, based in their neurological signs, in five categories: unilateral spastic CP, bilateral spastic CP, choreo-athetotic CP, dystonic CP and ataxic CP (3). Spastic CP, either bilateral or unilateral, is the most common form of this condition (4). Spasticity can cause pain, sleeping disorders and interference with positioning, transfers, dressing and body hygiene (2), causing a negative impact on the patient's and caregiver's quality of life (5). Intrathecal baclofen therapy (ITB) has been proved to have efficacy in this disease, however its cost-benefit might be questioned. Our aim is to assess its efficacy and cost-benefit in the treatment of non-ambulatory patients with spastic cerebral palsy.

Methods

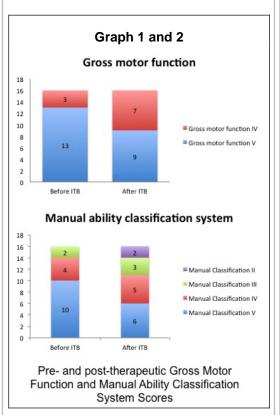
The authors conducted a retrospective analysis of all patients with severe spastic CP that were implanted with baclofen pump, at our center, between 2000 and 2013. The exclusion criterion was a followup inferior to 12 months. The data collected for analysis from clinical records was: demographic data, modified Ashworth score, Peen Spasm Frequency score, Gross Motor Function score, Manual Ability Classification System score, before and after implantation and length of follow -up. Each patient and/or the caregiver were inquired in order to obtain the Numeric Rating Scale (NRS) score for improvement in several daily-life items as well as life quality improvement after ITB. Data regarding cost of treatment at our center were also collected. Quality of life was also assessed applying EQ-5D-3L before and after implantation. Statistical analysis was performed with Microsoft Excel 2011.

Results

Sixteen patients met the study criteria. The mean age was 19.72 ± 10.37 years (9-42) and the average follow-up was 3.7 years (range 1-13 years). After ITB there was significant improvement in modified Ashworth score and Peen Spasm Frequency score - Table 1.

Table 1		
Variable	Before implantation (mean ± SD)	After implantation (mean ± SD)
Modified Ashworth scale	3.6 ± 0.5	1.9 ± 0.5
Peen spasm scale	2.0 ± 1.3	0.7 ± 0.8

Four patients improved from Gross Motor Function score V to IV and 9 patients diminished 1 point in Manual Ability Classification System score - $\underline{\text{Graph 1}}$ and 2.



There was improvement in all daily life activities, especially in hygiene, dressing and wheelchair posturing. The mean NRS for patient and caregiver life quality improvement was higher than 8 - Table 2.

Variable	NRS (mean ± SD)
Pain	7.18 ± 2.18
Movement execution	7.47 ± 1.5
Hygiene	7.47 ± 1.24
Dressing	7.53 ± 1.3
Physiotherapy	7.6 ± 2.17
Transfers	6.67 ± 2.58
Wheelchair posture	7.28 ± 2.33
Wheelchair maneuvering	6.57 ± 3.45
Meals	5.73 ± 3.34
Sphincter control	5.33 ± 4.27
Sleep quality	7.08 ± 3.42
Patient life quality	8.2 ± 1.5
Caregiver life quality	8.13 ± 1.7
Satisfaction with treatment	8.33 ± 1.6

Concerning cost-benefit analysis, we

observed an average 0.14 quality of life (QOL) improvement in EQ-5D-3L score. In our center the treatment cost was 33045€/QALY.

Overall 100% of ITB patients were satisfied and 87% would go through the procedure again.

Discussion

Our results were similar to previous studies, both in terms of clinical benefits (6,7) and costs (8). Although the costbenefit limit varies from country to country, the overall cost of 33045€ /QALY is within the accepted limits for the majority of European Countries and US.

Conclusions

ITB is effective in reducing spasticity and spasm frequency in severally disabled CP patients. This reduction facilitates daily life activities, which improves both the patient's and the caregiver's quality of life, within acceptable cost-benefit limits.

Learning Objectives

Confirm efficacy and cost-benefit of intrathecal baclofen treatment of non-ambulatory patients with severe spastic cerebral palsy.

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