Health economy

Cost-effectiveness analysis of the Inerventions method

– A pilot study comparing Inerventions method to other interventions for spasticity treatment for children with Cerebral Palsy in Sweden.

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Abstract:

Background: Cerebral palsy (CP) is a motor disorder characterized by a velocity-dependent increase in tonic stretch reflexes, often resulting in impaired voluntary muscle control, difficulty relaxing muscles, difficulty initiating rapid movements, and the inability to regulate controlled movements. Objective: To assess the cost-effectiveness of Inerventions method and compare it with conventional medical treatments, e.g. baclofen, botolium toxin, surgery, for children with cerebral palsy in Sweden. Methods: An analytic model, based on both qualitative and quantitative research, was used to study the cost-effectiveness of Inerventions method compared to alternative treatments. Standardized measurements (CPUP, uppföljningsprogram för cerebral pares) and patient interviews/surveys, was used to assess the treatment effectiveness in randomly selected patients' medical conditions. Costs (in sek at April 2012 values) were obtained by estimations from suppliers, hospitals and healthcare agencies. Sensitivity analysis was performed to compensate for data uncertainty. Results and conclusion: Preliminary results showed that Inerventions method was more effective than all alternative treatments in this study, and less costly than baclofen and surgery (with similar costs as botulinum toxin). This points to a new treatment method for children with cerebral palsy worth paying by decision makers.

Introduction

Cerebral palsy (CP) is the most common cause of physical disability in children, with a prevalence of about 2 per 1000 newborns in western countries (about 200 newborns every year in Sweden) (1). Cerebral palsy in childhood is often associated with spasticity, a motor disorder characterized by a velocity-dependent increase in tonic stretch reflexes (2). This often results in impaired muscle control, difficulty relaxing muscles, difficulty initiating rapid movements, and the inability to regulate controlled movements. Spasticity of cerebral origin can severely impair a child's ability to perform basic tasks such as speaking, eating, and walking (3). Moreover, these patients are at risk of secondary conditions that cause a loss of musculoskeletal function, spine and lower extremity joint deformities, and deterioration in quality of life (4). These often cause an enormous emotional and financial burden for the patients and caregivers (5).

Current treatments for children with cerebral palsy include oral and intrathecal administered baclofen (3), injections of botulinum toxins (4), as well as selective dorsal rhizotomy and orthopedic surgery (6). Baclofen is a small molecule drug with inhibitory effects on spinal cord reflexes and the brain (7). Botulinum toxins bind to neuromuscular junction and result in partial flaccid paralysis (4). Selective dorsal rhizotomy isolates the spasticity-causing nerves to be destroyed, whereas orthopedic surgery lengthens the tendons or cuts part of the affected muscles to release the tightness and spasticity related to cerebral palsy (6). Inerventions method is a new treatment method based on electrodes stimulation of muscles, which simultaneously stimulate the body's reflex system to reduce spasticity. The positioning of electrodes is tailored to the patient's specific medical needs (Inerventions AB).

The aim of this study is to assess the cost-effectiveness of Inerventions method compared to conventional treatments in the context of the Swedish healthcare system.

Methods

We studied the costs and health benefits for patients before and after implementing Inerventions method, and compared it with conventional treatments for the phase of treatment. The selection of patients was randomized. The perspective of cost-effectiveness analysis was that of the healthcare, meaning that all relevant resources consumed within the care sector were taken into account.

Specific cost sections to be included in this study was investigated by means of patient interviews, expert opinions and literature, as listed in Table 1. Unit costs were obtained from suppliers, hospitals, and healthcare agencies (Table 1). The quantities of various resource usages are collected from patient interviews and surveys. Total annual costs were calculated from unit costs multiplied by quantities of usage. The costs were valued using the Swedish guidelines for pharmacoeconomic research and real unit prices including taxes (8). Costs were estimated for the year 2012 in Swedish kronors (SEK). Due to the roughness of the estimates, we did not take into account the interest over the depreciation periods. We discounted costs that were not available for the year 2012 with 3% per year according to the Swedish pharmacoeconomics guidelines.

Resource category	Resource content	Unit cost (SEK)	Source of information
Intervention	Baclofen (oral)	928-2,1960per year	FASS
	Botulinum toxin	2,000-8,000 per injection	FASS, Literature
	Surgery	41,400	Akademiska sjukhus
	Elektrodress	9,000-16,200 per year	Inerventions AB
Combined medication	Alvedon, Ipren	1-5 per dosage	FASS
Physiotheraphy	Salary, adminitrative costs	256 per hour	Försäkringskassan
Assistive device	Wheelchair	45,000-200,000	Hjälpmedel Stockholm
	Seat/chair	15,000-30,000	Anatomic SITT AB
	Stand and walk support	6,820-37,500	Etac Sverige AB
	Back and leg support	500-1,000	
Personal assistence	Salary, education, administrative costs	267 per hour	Försäkringskassan
Measurment tests	X-ray	250 per visit	Literature[9]
Special medical care	Primary care	1,617 per visit	Literature[10]
	Specialist care	4,808 per visit	Literature
	Hospitalization	30,269 per stay	Literature[10]
Oppurtunity costs	Study absence for patient	477 per day for primary school 516 per day for high school	SCB
	Study/work absence for caregiver	2,218 per day	Försäkringskassan
Adjustive living	Bath and toilet device	10,460-11,850	Etac Sverige AB
	Lifting device	18,750-31,250	
Extra resources in school	Personal assistance	267 per hour	Försäkringskassan
Complications	Side effects, repeated surgery	variable	Akademiska sjukhus

Table 1 Unit costs of healthcare related to the treatment of children with cerebral palsy.

Outcome measures: For assessment of the health benefits, we used the CPUP (uppföljningsprogram för cerebral pares) standard measurement criteria on hip, knee, and foot, as well as patient interviews/ surveys. Surveys included the application of VAS (Visual analogue scale), a straight horizontal line with anchor points 'completely unhelpful' (score 0) and 'completely helpful' (score 100) as a measure for rating pain, anxiety, fatigue, etc (11). The VAS has previously shown preliminary reliability and validity for both child self-report and parent-proxy report (11). We used VAS for individually formulated problems (Table 2). We plotted these estimates on a cost-effectiveness plane. Cost-effectiveness plane has a horizontal axis representing the effect and a vertical axis representing the costs.

Ethics

The study was anonymous, and we obtained informed consent from the parents, and in some cases from the patients if they were aged 12 years or older and capable of understanding the nature and impact of the study.

Results and Discussion

Cost: The unit costs of different interventions as well as related resources are listed in Table 1.

Effectiveness: The medical conditions of children with cerebral palsy were measured before and after implementing Inerventions method, according to the CPUP criteria.

Among the 34 patients measured, all patients showed mild to significant degree of improvements on hip, knee and foot (Figure 1). Among the 15 patients interviewed and 17 patients surveyed, 30 patients reported mild to significant improvements whereas 2 reported none to worse effects of implementing Inerventions method (Figure 2C). Common improvements were muscle relaxation, body strength (e.g. hand grasp) and daily activities (e.g. speaking, toilet use). Interestingly, patients who have experienced positive effects reported that the improvements last longer with time, whereas the incremental improvements became smaller with time. Potential negative sides include irritation on the skin and the difficulty to use Inerventions method treatment on the foot (due to bone structures). Nevertheless, Inerventions method remains the least invasive method of treatment. Patients also rated the effectiveness of Inerventions method as well as alternative treatments (baclofen, botulinum toxin, and surgery) on a VAS scale, with the resulting scores Inerventions method > baclofen, botulinum toxin > surgery (Figure 2). The effectiveness of alternative interventions is discussed in the following section 'Cost-effectiveness analysis'.

Gross motor function
Body structure and function (arm, ankle, figure, back, leg, knee, foot)
Sitting and standing
Functional mobility (walking distance, use of stairs, use of wheelchair)
Daily activity (eating, sleeping, physical activity)
Pain
Complications
Need for caregiver

Table 2 Measurement criteria of treatment effectiveness for children with cerebral palsy, using VAS.

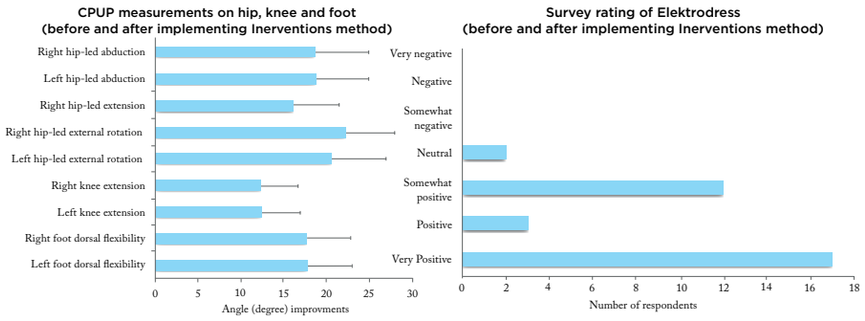

Figure 1A. Improvements of 34 patients' medical conditions on hip, knee and foot angles before and after implementing Inerventions method, as measured following the CPUP criteria.
Figure 1B. Patient satsifaction after using the Inerventions method

Cost-effectiveness analysis: As shown in figure 3, the cost-effectiveness analysis showed that Inerventions method was more cost-effective than: (1) baclofen and surgery, as it was more effective and less costly; (2) botulinum toxin, as it was more effective and similarly costly. Interestingly, baclofen was the most expensive, presumably due to the high frequency and cumulative consumption. On the other hand, surgery was the least effective and the situation varied greatly among individuals.

Baclofen was reported to have efficacy in reducing spasticity among cerebral palsy patients. However, it has side effects such as fatigue, dizziness, headache and nausea (12). Between the two common routes of baclofen administration, intrathecal baclofen has been shown to reduce spasticity with greater efficacy and fewer side effects, compared to oral delivery of baclofen (13- 15). Oral baclofen seems more commonly as all surveyed patients in this study have applied oral baclofen. Oral baclofen is also commonly used as combined medication with surgery. Despite the clinical benefits, cost is a barrier to more widespread use of baclofen therapy (3). Botulinum toxin was reported by patients to reduce spasticity immediately after the first few times of injections, lasting for about three months each time. The conditions are then reversed, and further injections are not as effective --- a phenomenon termed secondary unresponsiveness which has been attributed to the development of neutralizing antibodies against botulinum toxin (4). Moreover, com-

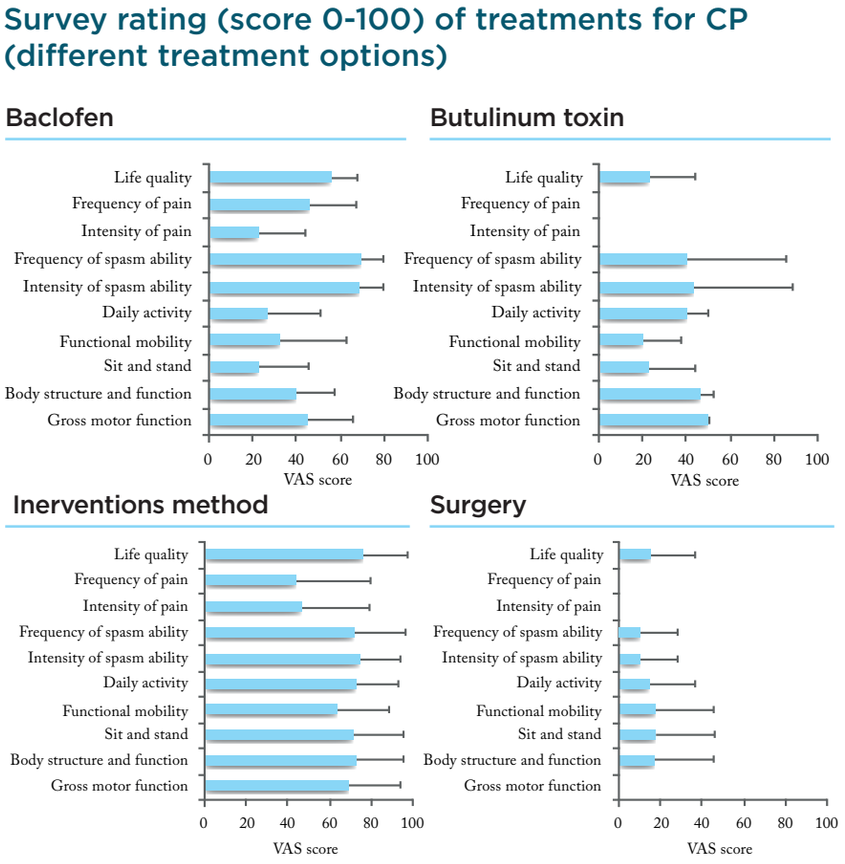

Figure 2 A-D. VAS rating of baclofen (A), botulinum toxin (B), Inerventions method (C) and surgery (D) as treatment methods for children with cerebral palsy.

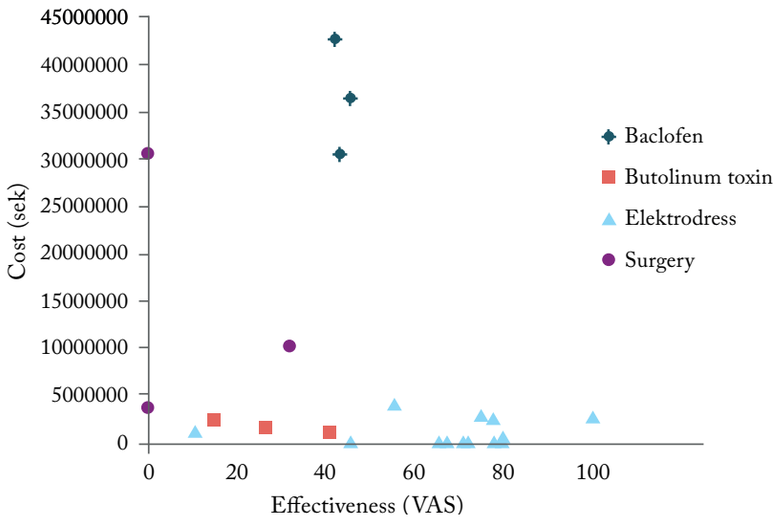

Figure 3. Cost-effectiveness analysis of different treatments for children with cerebral palsy.

monly reported are pain around the injection site, frequent falls from balance problems, and generalized fatigue (4). Botulinum toxin is a relatively cost-effective treatment, as botulinum toxin administration to cerebral palsy children resulted in a 51% reduction in the healthcare cost compared to orthopedic surgery (9). Finally, surgery was the least appreciated measure, and individual variations were significant. Orthopedic surgery is usually used to reduce the effects of spasticity that are resistant to other forms of treatments (16). Some patients also reported surgery failures, where their medical conditions became worse after the surgical procedures (e.g. the patient could not stand up after surgery whereas this was possible before surgery). The primary cost driver of surgery was hospital stay, accounting for 63% of the managing costs (9). In addition to the high financial cost, surgery is also closely associated with the intangible cost of pain, probability of adverse consequences, and lost productivity. Therefore, surgery was considered a less favorable option and best delayed until the child's tendons and joints have grown to a reasonable size, since outcome is more difficult to predict in younger child (9).

Sensitivity analysis: Sensitivity analysis showed similar results of cost-effectiveness for different interventions for children with cerebral palsy, with some differences in the magnitude of costs (figure 4).

Moreover, during the interviews of 15 patients, several potential cost changes before and after implementing Inerventions method were identified:

-cost increase: increase of assistive device such as leg support (increase 500-1000 sek).

-cost decrease: intake of Baclofen decreased from 3 to 2 pills/day (saving 928 sek/year); physical therapy decreased from 4-5 times/week to 2-3 times/week (saving 24,576 sek/year); operations were cancelled (saving 41,400 sek); study absence for patients decreased from 20% to none (saving 30,000 sek/year); work absence for caregivers decreased from 1-2 days/week to none (saving 106,464-212,928 sek/year).

This could potentially range from a yearly cost increase of 1000 sek to a yearly cost saving of 309,832 sek/year per patient.

Limitations: There are a few limitations in this study: first, the study only encompass a limited number of subjects (34 for CPUP measurements, 15 interviews and 17 surveys); second, there might be potential biases where patients that have experienced significant positive (or negative) effects are more inclined than others to answer the survey; third, more follow-up studies will be needed to study the incremental costeffectiveness and lifetime cost-effectiveness of Inerventions method as compared to alternative treatments.

Conclusions

This pilot study suggest the superior cost-effectiveness of Inerventions method (as compared to baclofen, botulinum toxin and surgery) for children with cerebral palsy and, from an economic point of view, justify the reimbursement of Inerventions method for this group of patients in Sweden.

Least-costly scenario

Most-costly scenario

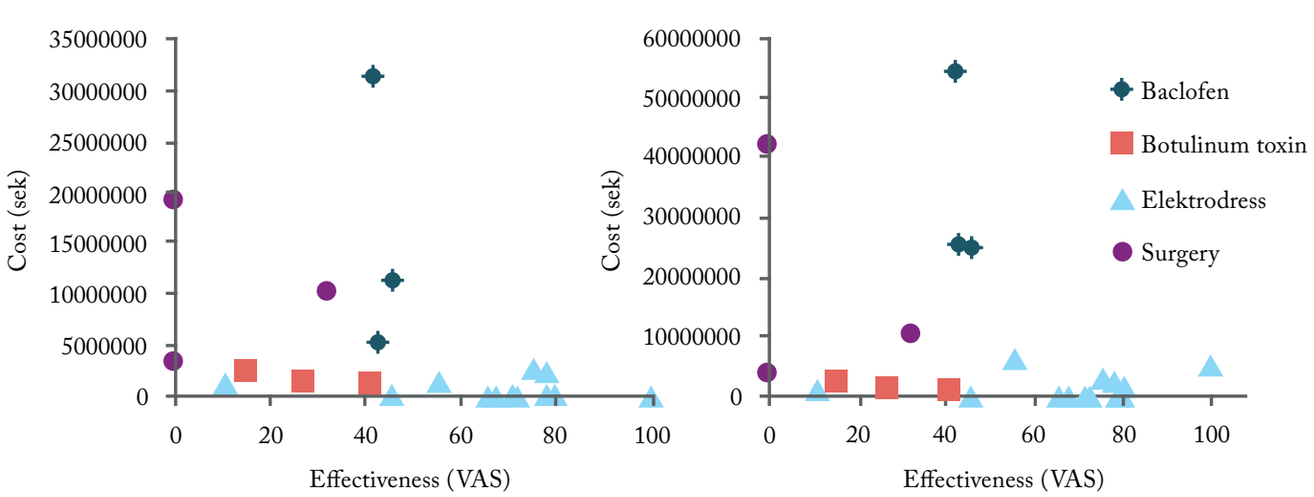

Figure 4. Sensitivity analysis of cost-effectiveness for different treatments for children with cerebral palsy: (A) least costly scenario, (B) most costly scenario.

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Inerventions is a company in in field of medical that has developed a new and unique assistive device for people with spasticity, inmobility and increased muscle tension.

Mollii provides electrical stimulation trough a specially designed garment and helps the body to relaxation, increased movement through activity.

Mollii is an assistive device for people with spasticity and increased muscle tension due to cerebral palsy, stroke, Multiple Sclerosis, Parkinson´s disease, spinal impairment or other neurological impairment. Mollii can also be used for rehabilitation in pain management.

Mollii previously called Elektrodress.

Throughout out the development of Mollii, Inerventions has worked together with researchers at CTMH, Centre of Medical Technology and Health, Smart Textiles, MedTech West.

CTMH Centre is a collaboration between the Karolinska Institutet, Kungliga Tekniska Högskolan and Stockholms läns landsting.

Smart Textiles is a center of expertise on textile inovation and textile solutions.

MedTechWest is a collaboration between Chalmers Tekniska Högskola, Sahlgrenska Universitets sjukhuset and Västra Götalandsregionen.

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