Intrathecal Baclofen Therapy



Intrathecal baclofen was first introduced in 1985 to manage childhood hypertonia. There has been an evolution in thought as to how candidates should be identified and what forms of hypertonia respond to this treatment.

Indications

Intrathecal Baclofen Therapy Indications.

Screening test

A successful trial may confirm predetermined goals, which may include improved mobility/positioning, decreased time/improved independence for activities, less home exercise, better wheelchair tolerance, decreased caregiver time, improved sleep, and reduced pain, or may modify goals and expectations. Individuals should not be tested in the presence of active medical issues (e.g., MS exacerbations, active urinary tract infection, nonhealing wounds). Oral antispasmodics can be weaned before trial if a goal is to eliminate them. The standard baclofen test dose is a 50-mcg bolus, 25 mcg in very small children or patients who rely on spasticity for mobility. Patients unresponsive to the standard dose may require 75 mcg or 100 mcg; 24 hours should elapse between bolus doses. Cardiopulmonary parameters should be checked frequently during the first two hours postinjection, and spasticity measures assessed at least twice within four hours. Observation continues until the patient is stable and recovers from hypertonia. Adverse events include spinal headaches, nausea/vomiting, urinary retention, hypotension, seizures, drowsiness/sedation, respiratory depression, and coma. Before implantation, team members must discuss starting dose, drug concentration, delivery mode, pump size and location, and catheter tip placement. Patients/caregivers should understand the commitment necessary for ITB therapy ¹⁾.

Technique

Intrathecal Baclofen Technique

Complications

Intrathecal baclofen complications

Case series

The objective of a study of Berntsson et al., from Sweden was to assess the effectiveness of the ITB in patients with inherited ataxia suffering from severe painful spasms and/or spasticity.

A total of 5 patients with spinocerebellar ataxia 3 or 7 or Friedreich's ataxia were included in this observational multicenter study. The patients were interviewed and completed outcome measures assessing pain (The Brief Pain Inventory), fatigue (Fatigue Severity Scale), and life satisfaction (LiSAT-9) before and 1 year after the treatment. Spasticity (Modified Ashworth Scale) and spasm frequency (SPFS) were measured objectively for each patient.

The mean treatment time was 1.9 years. Evaluation of established standard forms revealed symptomatic relief from spasticity, spasms, pain, and fatigue in addition to improved body posture, sleep, and life satisfaction after ITB treatment.

They reported the potential beneficial effects of ITB treatment in patients with inherited ataxia who also suffer from spasticity/spasms. ITB treatment indication in neurological disorders allows for extension to the treatment of spasticity/ spasms in patients with hereditary ataxia ²⁾.

2017

A study aimed to investigate beneficial and adverse effects of Intrathecal Baclofen (ITB) bolus injection and pump therapy in patients with cerebral palsy (CP) and to compare outcomes to patients with acquired brain injury such as traumatic brain injury and cerebral hypoxia. ITB test trials were performed in 37 patients (19 CP and 18 acquired brain injury). Based on ambulatory function, CP patients were divided into 2 groups: 11 patients with nonambulatory CP and 8 patients with ambulatory CP. Change of spasticity was evaluated using the Modified Ashworth Scale. Additional positive or negative effects were also evaluated after ITB bolus injection. In patients who received ITB pump implantation, outcomes of spasticity, subjective satisfaction and adverse events were evaluated until 12 months post-treatment. After ITB bolus injection, 32 patients (86.5%) (CP 84.2% versus acquired brain injury 88.9%) showed a positive response of reducing spasticity. However, 8 patients with CP had negative adverse effects. Particularly, 3 ambulatory CP patients showed standing impairment and 1 ambulatory CP patient showed impaired gait pattern such as foot drop because of excessive reduction of lower extremity muscle tone. Ambulatory CP patients received ITB pump implantation less than patients with acquired brain injury after ITB test trials (P=.003 by a chisquared test). After the pump implantation, spasticity was significantly reduced within 1 month and the effect maintained for 12 months. Seventeen patients or their caregivers (73.9%) were very

satisfied, whereas 5 patients (21.7%) suffered from adverse events showed no subjective satisfaction.

ITB therapy was effective in reducing spasticity in patients with CP and acquired brain injury. Before ITB pump implantation, it seems necessary to perform the ITB bolus injection to verify beneficial effects and adverse effects especially in ambulatory CP ³⁾.

2016

In a single center study Motta et al investigated the complications occurring before and after the introduction of the new Ascenda intrathecal catheter (Medtronic Inc.) in pediatric patients treated with intrathecal baclofen therapy (ITB) for spasticity and/or dystonia.

This was a retrospective review of 508 children who had received ITB, 416 with silicone catheters in the 13 years between September 1998 and September 2011 and 92 with Ascenda intrathecal catheters in the 3 years between September 2011 and August 2014. The authors evaluated major complications such as infections, Cerebrospinal fluid fistulas treated, and problems related to the catheter or pump, and they compared the 2 groups of patients who had received either a silicone catheter or an Ascenda catheter implant. RESULTS One hundred twenty patients in the silicone group (29%) and 1 patient in the Ascenda group (1.1%; p < 0.001) had a major complication. In the silicone group 23 patients (5.5%) were affected by Cerebrospinal fluid fistula and 75 patients (18%) experienced 82 catheter-related events, such as occlusion, dislodgment, disconnection, or breakage, which required catheter replacement. In the Ascenda group, only 1 patient (1.1%) was affected by Cerebrospinal fluid fistula. CONCLUSIONS To the authors' knowledge, this study is the first in the literature to compare the performance of the new Ascenda catheter, introduced in 2011, with the traditional silicone catheter for intrathecal drug infusion. In their analysis, the authors found that the Ascenda catheter can reduce major complications related to the catheter after ITB pump implantation. Further investigation is necessary to expand on and confirm their results ⁴).

Case reports

The case of a young woman who received intrathecal baclofen therapy (ITB) and subsequently became pregnant and had a normal delivery. A 28-year-old woman with flexion myelopathy had anterior decompression with fusion at C4/5 and C5/6 levels. Clinical symptoms improved after surgery. However, when she was 29 years old, her symptoms steadily advanced to Modified Ashworth Scale 3 spasticity level in the lower legs, with pain in both of them and urinary retention tendency. Since a 25 µg intrathecal baclofen injection improved her symptoms, an ITB pump system was implanted. After surgery, lower limb spasticity and urinary retention improved. Two years after ITB pump implantation, the patient married and became pregnant. The patient intended to have normal delivery but the induction of labor was ineffective and childbirth was completed by Cesarean section with lumbar anesthesia. The infant's Apgar score was 8 at 1 min and 9 at 5 min, and birth-weight was 2,704 g. We measured the baclofen concentration in the patient's breast milk using high-performance liquid chromatography/tandem mass spectrometry. The level of baclofen in the breast milk was very low (0.617 ng/ml) and the predicted pharmacological effect on the infant was judged to be negligible. No withdrawal symptoms or muscle tone abnormalities were found after birth. Our findings indicate that ITB therapy could be considered for young women with severe spasticity, even if they plan to have children 5).

A report describes the successful management of painful spasms in a 65-year-old woman with Friedreich's ataxia (FA) via intrathecal baclofen (ITB) therapy following unsuccessful medical treatments.

To Kalyvas et al., knowledge, this is the third reported case in the literature. Unfortunately, the pathophysiological characteristics of muscle spasms in FA are not well explored and understood while the therapeutic mechanisms of the different treatments are rather vague. Taking into consideration the suggested spinal atrophy in FA, the clinical resemblance of FA and chronic spinal injury muscle spasms, together with the rapid ITB therapy effectiveness in alleviating FA muscle spasms, they attempted to suggest a putative pathophysiological mechanism acting at the spinal level and possibly explained by the presence of independent spinal locomotor systems producing muscle spasms. Specifically, overexcitement of these centers, due to loss of normal regulation from upper CNS levels, may result in the uncontrolled firing of secondary motor neurons and may be the key to producing muscle spasms. However, further research under experimental and clinical settings seems to be necessary ⁶.

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