Best Practices in Intrathecal Baclofen Therapy: Patient Selection

Michael Saulino, MD, PhD[1], Cindy B. Ivanhoe, MD[2], John R. McGuire, MD[3], Barbara Ridley, RN, FNP[4], Jeffrey S. Shilt, MD[5], Aaron Boster, MD[6]

[1]MossRehab, Elkins Park, PA, [2]Mentis Neurorehabilitation, Baylor College of Medicine, Brain Injury and Stroke Program at TIRR-Memorial Hermann, Houston, TX, [3]Medical College of Wisconsin, Milwaukee, WI, [4]Alta Bates Summit Medical Center, Berkeley, CA, [5]Idaho State University, Boise, ID, [6]The Ohio State University, Wexner Medical Center, Columbus, OH

Background/Objectives

Intrathecal baclofen therapy (ITB) is Food and Drug Administration-approved for management of severe spasticity of spinal/cerebral origins. An expert panel sought consensus on best practices for selecting appropriate patients for ITB therapy.

Methods

22 invited practitioners currently managing >3,200 ITB patients participated in a day-long facilitated discussion. They relied on a broad structured literature search that ultimately identified 285 peer-reviewed papers relevant to patient selection. In addition, they had access to an online survey deployed in 2013, which compiled results from 42 physicians who each managed at least 25 ITB patients.

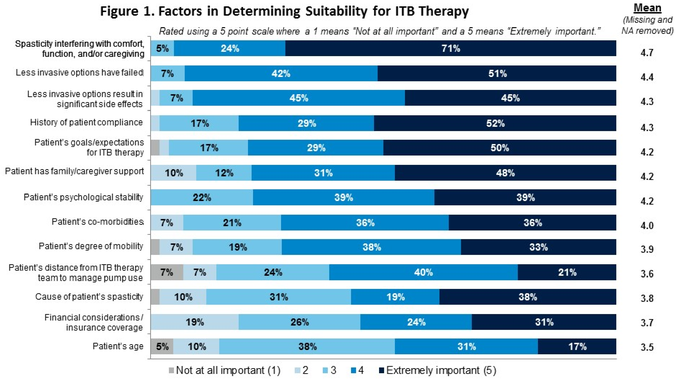
Results

The 2005 SPASM consortium defines spasticity as “disordered sensori-motor control, resulting from an upper motor neuron lesion, presenting as intermittent or sustained involuntary activation of muscles.” Many factors affect patient suitability for ITB therapy, as illustrated by the survey results in Fig. 1.

Spasticity management often allows individuals to achieve higher function. When cognition is impaired, ITB controls spasticity without the cognitive side effects of some oral medications. Patient/caregiver education is crucial, within a supportive environment utilizing all available resources. Goal setting allows the patient/caregivers and treatment team to address expectations and treatment in the framework of pathology, impairment, disability, and handicap.

Figure 1. Factors in Determining Suitability for ITB Therapy

Rated using a 5 point scale where a 1 means "Not at all important" and a 5 means "Extremely important."



ITB therapy can be considered for problematic spasticity involving muscles or muscle groups during all phases of diseases, including progressive neurologic diseases. Patients may benefit from ITB as monotherapy or in combination with other treatments. Thus, ITB therapy should not be exclusively reserved for individuals who have failed other approaches. In ambulatory patients, ITB combined with rehabilitation can be effective in certain patients. ITB is also highly effective in managing spasticity in pediatric patients, who may suffer limb deformity, joint dislocation, and poor motor function from spasticity and muscle tightness on the growing musculoskeletal system.

ITB is contraindicated in patients with hypersensitivity to baclofen, which is rare, or active infection. Some patients with an adverse reaction to oral baclofen may be mistakenly classified as having an allergic reaction, and they may benefit greatly from ITB. Relative contraindications include unrealistic goals, unmanageable mental health issues, psychosocial factors affecting compliance (e.g., unreliable transportation, frequent phone number changes), and financial burden. Vascular shunting for hydrocephalus is not a contraindication, but concurrent use may affect cerebrospinal fluid flow. Implanting surgeons, spasticity management physicians, patients and caregivers should discuss seizures, or prior abdominal or pelvic surgery, before proceeding to an ITB screening trial.

Conclusions

Consideration of ITB therapy should be undertaken in all patients with inadequately controlled, problematic spasticity, in all phases of disease processes.

Study supported by Medtronic plc.