Best Practices in Intrathecal Baclofen Therapy: Screening Trial

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Background/Objectives

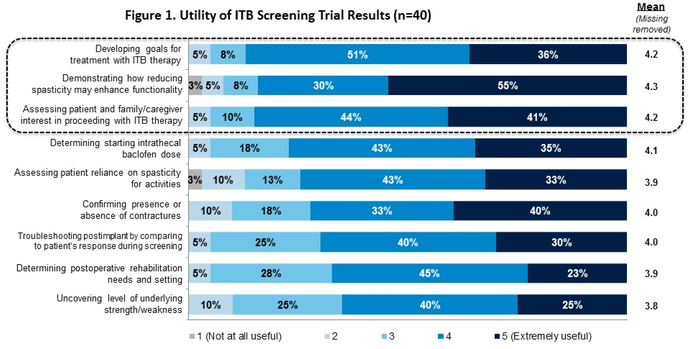
A preimplant screening trial allows assessment of intrathecal baclofen (ITB) for severe spasticity before pump implantation. An expert panel sought consensus on best practices for screening trials for ITB therapy.

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 130 peer-reviewed papers relevant to screening. 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

Survey respondents cited the utility of screening results for developing goals for ITB therapy, demonstrating reduced spasticity and enhanced functionality, and assessing patient/caregive interest in proceeding with ITB therapy (Figure 1). Preprocedure planning assesses general medical stability, anticoagulation/infection status, and potential weaning of oral medications and timing of neurolytic procedures. Individuals should not be trialed in the presence of active medical issues (e.g., MS exacerbations, active urinary tract infection, nonhealing wounds), which can confound or obscure the trial effects. Decubitus ulcer in close proximity to the lumbar puncture site is a contraindication, but asymptomatic bacterial bladder colonization is not an absolute contraindication. Oral antispasmodics can be weaned before trial if a goal is to eliminate them. Anticoagulant management must be considered before trial.



Appropriate venues (inpatient hospital, ambulatory surgical centers, outpatient clinics) provide safe delivery of medication, monitoring and evaluation of the patient, lumbar puncture equipment, and an accessible space for gait evaluation. Conscious sedation may be necessary for children. 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 2 hours postinjection, and spasticity measures assessed at least twice within 4 hours of injection. Observation should continue until the patient is medically stable and recovers from hypertonia. Adverse events may include spinal headaches, nausea/vomiting, urinary retention, hypotension, seizures, drowsiness/sedation, respiratory depression, and coma. Protocols for each should be in place.

A successful trial achieves pre-determined goals that may include improved mobility speed, safety and quality, decreased time/improved independence for ADLs, and a decrease in home exercise stretching time. Passive goals may include improved positioning, better wheelchair tolerance, decreased caregiver time, improved sleep, and reduced pain. Long-term goals of chronic ITB infusion may not be fully realized during screening. Rehabilitation postimplant is crucial to attaining improved function.

Before implantation, team members must discuss starting dose, drug concentration, delivery mode, pump size and location, and catheter tip placement. Patients/caregivers should also understand the commitment necessary for successful ITB therapy.

Conclusions

A screening trial helps identify appropriate candidates for ITB therapy.

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