Multidisciplinary Multiple Sclerosis Clinic Approach to Intrathecal Baclofen Therapy: From Patient Selection to Optimization of Therapy

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Abstract

Intrathecal Baclofen (ITB) is a FDA approved therapy for severe spasticity of both spinal and cerebral origin with documented positive clinical outcomes for patients with Multiple Sclerosis (MS), however, this therapy is underutilized in the MS patient population. The prevalence of spasticity in MS is high with clinical manifestations in an estimated 60% of MS patients; 40-70% of patients report impairments as a result of their spasticity.

Objective

- To provide insight and spread awareness to MS care providers about the multidisciplinary approach to spasticity care in a large MS center.

What is Spasticity?

Spasticity, a component of upper motor neuron syndrome, is a sensory motor processing disorder characterized by a velocity-dependent resistance to passive muscle stretch. Spasticity is caused from damage in the central nervous system to motor pathways, corticospinal/pyramidal tracts from the brain descending to the spinal cord. This results in upper motor neuron lesion and can cause intermittent or sustained involuntary activation of muscles. Spasticity can result in increased tone, stiffness, pain, spasms, and cramping.

The clinical manifestations of spasticity include:

- Increased muscle tone
- Brisk deep tendon reflexes
- Spread of activity to distant segments
- Clonus with sustained stretch

The severity of spasticity varies, impacting mobility, function, comfort and quality of life. If left untreated spasticity can result in significant medical complications and is associated with increased disability.

What is ITB Therapy?

Baclofen administered directly into the intrathecal space, thereby bypassing the blood brain-barrier. As a result, effective concentrations of baclofen can be achieved at a fraction of the typical oral dose. During the ITB test dose, baclofen is administered directly via lumbar puncture into the CSF to determine its effectiveness. Once effectiveness is established, a catheter is placed in the intrathecal space and advanced until the tip is at the desired level in the thoracic spine. The catheter is tunneled subcutaneously and connected to a pump which is implanted under the skin in the abdomen or flank. ITB can be a successful intervention for those with moderate-severe spasticity. However, given spasticity is a complex and dynamic process, it is ideal to utilize the multidisciplinary team through all phases of therapy.

Our Multidisciplinary Team

- Patient and family members/caregivers
- Health Care Providers (Neurologists, Nurse Practitioners, Physical and Occupational Therapists, Registered Nurses, Medical Assistants, Social Worker, Surgeons and Interventional Radiologist)

Patient Selection

In order to be considered for ITB therapy, the patient must have the following:

- Hypertonicity that causes significant impairment
- Failed oral antispasmodic medications or unable to tolerate a multidrug regimen or dose escalation due to adverse effects
- Failed or inadequate response to botox injections (if applicable)
- Physical modalities are ineffective
- Committed to attend frequent appointments/family/caregiver support/transportation
- Willingness to actively participate in physical and occupational therapies

Patient Education

- Education is key; begins with initial discussion regarding ITB therapy with patient and family/caregiver and continues through each phase of therapy.
- OhioHealth MS Center ITB Test Dose Information Packet includes:
  - Preparing for ITB Test Dose Day
  - What to expect on ITB Test Dose day/overview of process
  - Pre and post procedure instructions
  - Possible ITB Test Dose side effects
  - Signs of baclofen overdose and withdrawal
  - Follow up appointment to discuss results
  - Medtronic patient education website www.baclofenpump.com

ITB Test Dose/Trial

- Patient and family/caregiver arrive to MS Clinic at 7am
- Initial assessment by Multidisciplinary team (MD,CNP, Neuro PT) includes:
  - Passive range of motion (ROM) using goniometer to assess restricted ROM
  - Manual muscle strength testing (including isolated strength testing)
  - Spasticity rating (using Modified Ashworth Scale)
  - Reflex grading
  - Assess transfer and/or gait and videotape if applicable
- Patient subjectively rates pain using 0-10 scale and spasm frequency each hour
- Lumbar puncture is performed and 50-100 mcg of intrathecal baclofen is injected
- Patient is reassessed hourly for the next 6 hours
- Discharged to home once baclofen wears off and return of spasticity

Goals of ITB Therapy

It is essential as a team that we identify and clearly communicate the individual goals of therapy, provide education about potential complications of therapy, and ensure commitment from the patient/family/caregiver to attend frequent office visits during the titration and optimization phases of therapy.

It is imperative that prior to referral for implantation the patient/family/caregiver understand and agree to the following:

- To be seen in clinic weekly to bi-weekly for ITB pump adjustments while the ITB pump is being titrated/optimized (Optimization may take 6-12 months)
- To attend all scheduled refill visits (most often done every 1-3 months, but can be as infrequent as every 6 months for some patients)
- Baclofen will likely uncover weakness, therefore agree to participate in PT and OT for strengthening when recommended
- The signs and symptoms of baclofen withdrawal; itching, increased stiffness, fever, sedation, confusion, muscle breakdown, and in extreme cases kidney damage, seizures and possibly death
- The signs and symptoms of baclofen overdose; floppy limbs, sedation, confusion, seizures, and in extreme cases respiratory and cardiac depression and death
- To present to the emergency room with signs/symptoms of baclofen withdrawal or overdose
- To carry an up-to-date bottle of oral baclofen at all times in case of baclofen withdrawal symptoms
- To carry the Medtronic ID card with important pump information

Implantation Phase

- Referral placed to Neurosurgeon or Interventional Radiology for implantation.
- Possible risks associated with ITB pump implantation include complications of surgery and anesthetics:
  - Infections which include skin, bladder, pneumonias, epidural abscesses and meningitis; the 2 latter being very serious and possibly life threatening and necessitating removal of the pump.
  - Leakage of spinal fluid causing fluid accumulation either on the back or around the pump. Leakage can cause a headache which is worse sitting or standing and gets better lying flat and may need blood injected to seal the leak. The catheter may kink, break or dislodge in up to 10% of cases and would require a repeat surgery to fix it.
- Starting dose of baclofen 500mcg/ml concentration at 25mcg/day
- Overnight stay in hospital with 23 hour observation
- Keep incisions clean/covered and wear abdominal binder for 23 hours per day for 4 weeks
- Schedule follow up in MS clinic in 1 week for ITB dose adjustment and surgeon in 1-2 weeks for post-op check up.

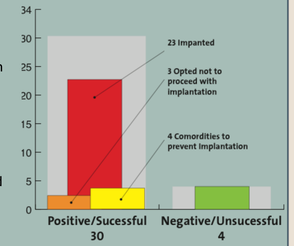
Titration/Optimization Phase

Patients are asked to return to the clinic biweekly during titration/optimization phase. At each visit we assess the following:

- Response and tolerability to most recent ITB dose adjustment
- Muscle strength and tone (Modified Ashworth Scale)
- Gait or transfer evaluation
- Improvement in functional goals
- Improvement in caregiver ease of care
- Self reported spasticity and pain (0-10 scale)
- Initiate PT/OT when appropriate
- Taper oral antispasmodics

Results

Since August 2015, thirty-four patients have been evaluated using the OhioHealth MS Center multidisciplinary approach ITB test dose. Thirty of those patients had successful ITB test dose trials with significant improvement in spasticity; four were deemed unsuccessful. Of the thirty successful ITB test dose patients, twenty-three have been implanted with ITB pump, three opted not to proceed, and four patients have co-morbidities that prevent implantation at this time.



Conclusion

Inadequately controlled spasticity has a profound impact on quality of life in patients with MS. Although ITB has been an FDA approved therapy since 1992, with wide availability and proven effectiveness, it remains underutilized. ITB therapy can be extremely beneficial to patients with MS, allowing their spasticity to be effectively controlled with minimal adverse effects, maximizing function, reducing painful spasms and improving quality of life. ITB management requires long-term commitment of a dedicated MS multidisciplinary team and ongoing evaluation of the patient's response while managing their complex health needs.

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