Managing Severe Spasticity
Presentation Outline

• What Is Spasticity?

• Pathophysiology of Spasticity

• Common Etiologies

• Spasticity Management Goals and Spectrum of Care

• ITB Therapy for Severe Spasticity
What Is Spasticity?

Ariel F.
Receiving Medtronic
ITB Therapy since 2007
Understanding Spasticity

- An abnormal increase in muscle tone caused by injury of upper motor neuron pathways regulating muscles
- May be caused by injury or disease of the central nervous system (brain or spinal cord)
- A velocity-dependent increased resistance to passive stretch
- Characterized by exaggerated tendon jerks
- May be accompanied by hyperexcitability of the stretch reflex
Limitations Associated with Severe Spasticity

- Functional Impairments
  - Pain, fatigue, sleep difficulties, joint contractures, bowel and bladder dysfunction
- Activity and Participation
  - Difficulty with positioning, walking, mobilizing a wheelchair, transferring to and from bed, toilet, or car
  - Difficulty with ADLs
  - Reduced intimacy, vocational disability, and social isolation

Pathophysiology of Spasticity

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What Causes Spasticity?

Theory

- Imbalance between descending excitatory and inhibitory impulse to the alpha motor neuron:
  - Spasticity of cerebral origin results from lack of descending inhibitory input from subcortical nuclei in the brain
  - Spasticity of spinal origin results from interruption of descending tracts that inhibit or modulate alpha and gamma motor neurons
Inhibitory Input vs. Loss of Inhibitory Input

Normal Muscle Tone

Loss of Descending Inhibitory Input
Common Etiologies

Andrina M.
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Common Etiologies

Spasticity of Spinal Origin
- Spinal Cord Injury
- Multiple Sclerosis

Spasticity of Cerebral Origin
- Stroke
- Brain Injury
- Cerebral Palsy
Spinal Cord Injury (SCI)

- There are approximately 12,000 new cases of SCI per year, but recent data is limited\(^1\)
  - Since 2000, the majority of injuries have resulted in incomplete tetraplegia (30.1%) and complete paraplegia (25.6%)
- Anson and Shepherd (1996) reported the following statistics on 348 patients post-SCI:\(^2\)
  - 62% are living with spasticity that does not interfere with functioning
  - 12% are living with severe spasticity that interferes with activities of daily living
- Spasticity management does not interfere with spinal cord injury medical management

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Traumatic Brain Injury (TBI)

- Traumatic brain injury is a leading cause of death and life-long disability\(^1\)
- An estimated 1.7 million TBI-related deaths, hospitalizations, and emergency department visits occur each year\(^2\)
- 17% of those living with TBI not affecting the mid-brain (and pons) experience spasticity\(^3\)
- For those with injuries affecting the mid-brain, spasticity is seen in greater than half (53%) of the population\(^3\)
- Spasticity management does not interfere with brain injury medical management

Cerebral Palsy (CP)

- About 800,000 children and adults in the United States have CP\(^1\)
- Each year, approximately 10,000 babies born in the U.S. will develop CP\(^1\)
- Spasticity management does not interfere with cerebral palsy medical management

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Spasticity Management Goals and Spectrum of Care

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Potential Goals of Spasticity Management

- Decrease spasticity
- Improve functional ability and independence
- Decrease pain associated with spasticity
- Prevent or decrease incidence of contractures
- Improve ambulation
- Facilitate hygiene
- Ease rehabilitation procedures
- Save caregivers’ time
Severe Spasticity Spectrum of Care

Common Treatment Options Offered at Spasticity Management Centers

- Prevent Nociception
- ITB Therapy
- Rehabilitation Therapy
- Patient and Family
- Oral Drugs
- Injection Therapy
- Orthopedic Treatments
- Neurosurgery
ITB Therapy for Severe Spasticity

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What Is ITB Therapy?

- A treatment for individuals with severe spasticity due to:
  - Stroke
  - Multiple Sclerosis
  - Brain Injury
  - Spinal Cord Injury
  - Cerebral Palsy
- Can be used with or in place of orally administered antispastic medications
- Nondestructive, adjustable, and reversible therapy (by pump explantation)
- For patients who experience severe spasticity of cerebral origin (must be at least 1 year post trauma in cases of traumatic brain injury)
- A treatment for the management of severe spasticity for patients who have had ineffective results or intolerable side effects from oral baclofen (for severe spasticity of spinal origin)
How ITB Therapy Works

• Uses an implantable, programmable SynchroMed® II pump to deliver precise amounts of Lioresal® Intrathecal (baclofen injection) directly to the site of action at the spinal cord via the cerebrospinal fluid

• Because ITB Therapy delivers baclofen directly to the spinal cord, a fraction of the oral medication dose may be needed
The SynchroMed II Infusion System

- Consists of two fully implantable components
  - SynchroMed II pump
  - Intraspinal catheter
- Uses a clinician programmer to deliver precise and customized therapy to patients
- Can deliver medication at either a constant rate or a variable rate
Device Reliability

- SynchroMed II 20 mL pumps are 98.3% reliable* (event-free) at 48 months and 51 months¹

- SynchroMed II 40 mL pumps are 99.2% reliable* (event-free) at 48 months and 51 months¹

*Reliability is the probability a pump remains event-free through the time interval. Events are defined as any change that prevented delivery of the therapy to the intended location, required surgical intervention to correct, and were related to a problem with the pump.

Optional ITB Therapy Screening Test

- A standard screening test is optional to determine if ITB Therapy is appropriate for the patient.
- The screening test allows the patient to try the therapy before committing to the implant.
- An intrathecally administered test dose of baclofen injection is given via a lumbar puncture.
  - In a single study, 97% of patients with spasticity of spinal origin demonstrated a positive response to the screening test\(^1\).
  - In a single study, 86% of patients with spasticity of cerebral origin demonstrated a positive response to the screening test\(^2\).
- Possible adverse events include hypotonia, somnolence, nausea, vomiting, headaches, and dizziness.
- A screening test is contraindicated in the presence of active infection and in patients who demonstrate hypersensitivity to oral baclofen.

Benefits of ITB Therapy

• Reduced spasticity and spasms and increased independence allowing people to better perform activities of daily living including feeding or dressing themselves, sitting more comfortably, or transferring more easily.

Benefits of ITB Therapy (Continued)

• More than 94% of caregivers are satisfied with ITB Therapy\(^1\)
• 82% of subjects/caregivers indicated they would repeat the decision to receive the treatment\(^2\)

Adverse Events

• Possible adverse events may include:
  – Hypotonia
  – Somnolence
  – Nausea
  – Vomiting
  – Headaches
  – Convulsion
  – Dizziness
  – Paresthesia

• Overdose and withdrawal, although rare, have been identified and in extreme cases may be life threatening

• Possible device complications may include:
  – Catheter or pump moving within the body or eroding through the skin
  – Catheter leak, tear, kink, or dislodgement, resulting in underdose or no baclofen infusion
  – Pump failure may cause overdose or underdose of intrathecal baclofen
Contraindications

ITB Therapy and implantation of the SynchroMed programmable pump are contraindicated:

- In the presence of infection or spinal anomalies
- When the pump cannot be implanted 2.5 cm or less from the surface of the skin
- In patients whose body size is not sufficient to accept the pump bulk and weigh
- In patients with hypersensitivity to baclofen

Safety and effectiveness in pediatric patients below the age of 4 have not been established.
Patient Care Pathway and Referral Process

Cindy H.
Receiving Medtronic ITB Therapy since 1996
ITB Therapy Patient Care Pathway

1. **Patient Selection**—Essential to therapeutic success
2. **Optional Screening Test**—Trial dose of Lioresal® Intrathecal (baclofen injection) via lumbar injection
3. **Pump Placement**—If screening test yields positive results, a Medtronic SynchroMed® II Drug Infusion System is implanted
4. **Rehabilitation and Titration**—Dose titration, which may be accompanied by inpatient and/or outpatient rehabilitation
5. **Management**—Outpatient follow-up for pump refill of Lioresal Intrathecal
Step 1: Patient Selection

- Appropriate patient selection is essential to therapeutic success
- Consider ITB Therapy for patients who:
  - Have severe spasticity of cerebral or spinal origin\(^1\)
  - Demonstrate positive response to a single bolus dose of Lioresal\(^\circledast\) Intrathecal (baclofen injection) during the screening test\(^1\)
  - Are refractory to oral baclofen or experienced intolerable side effects at effective doses\(^1\) (spasticity of spinal origin)
  - Have experienced traumatic brain injury at least 1 year prior to being considered for long-term ITB Therapy\(^1\)
  - Have sufficient body mass to support the bulk and weight of the pump\(^2\)

1. Lioresal Intrathecal package insert
2. Medtronic information for prescribers for SynchroMed pump
Step 2: Optional Screening Test

To determine if a patient is appropriate for ITB Therapy, they first receive an intrathecally administered test dose of baclofen injection via lumbar puncture.

- The bolus is large enough (50-100 mcg) to significantly reduce spasticity in appropriate patients.
- Patients who do not respond to the bolus are not considered candidates for ITB Therapy.
Step 3: Pump Placement

• The catheter is inserted into the lumbar region and advanced to the T10-12 region. It can also be advanced higher for an increased effect on the upper extremities.
• An abdominal incision is made for the pump
• The catheter is connected to the pump
• The entire pump and catheter system is placed subcutaneously
• An initial dose is programmed based on the patient’s response during the screening test
• Surgical complications are possible and include infection, headache, spinal fluid leak, meningitis, and paralysis
Steps 4 & 5: Rehabilitation, Dose Titration, and Ongoing Management

Rehabilitation Therapy
- May help manage weakness, loss of motor control, and low endurance

Dose Titration
- Determine initial daily dose
- Achieve steady therapeutic state
- Increase dose to achieve desired clinical effect

Ongoing Management
- Schedule refill appointments
- Perform ongoing monitoring and management
Patient Videos

• To view Patient Videos and learn more about the Baclofen pump please visit the Medtronic Website at:

  http://professional.medtronic.com/pt/neuro/itb/edu/Pre-implant-patient-education-resources/index.htm#tabs-4

Click frame to play
Medtronic Resources

  A resource for health care professionals interested in learning more about ITB Therapy
- [www.Medtronic.com](http://www.Medtronic.com)
  General information on Medtronic for patients and clinicians (or call 866-669-3649)
  A resource for spasticity patients
- [www.Spasticity.com](http://www.Spasticity.com)
  A resource for patients considering or currently receiving ITB Therapy
- **Coverage and Authorization Services: 800-292-2903**
  For information or questions on reimbursement for Medtronic Neurological therapies. Available Monday-Friday, 7:00 am–6:00 pm Central Time
- **24-hour Technical Services Hotline: 800-707-0933**
- **Customer Service: 800-328-0810**
- **Patient Services: 800-510-6735**
  Available Monday-Friday, 8:00 am–5:00 pm Central Time
- **ITB Therapy Ambassador Program: 800-503-4110**
  Available Monday-Friday, 7:00 am–6:00 pm Central Time