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Chapter

# MS Progress Notes...

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## Intrathecal Baclofen Pump Therapy for Spasticity in Multiple Sclerosis

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### Spasticity

Spasticity is defined as a motor disorder characterized by a velocity dependent increase in tonic stretch reflexes (muscle tone) with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex [Lance 1980]. Commonly, spasticity is described as muscle stiffness, tightening, or spasms associated with involuntary jerking, pain, and weakness [Erwin 2011]. Spasticity is seen in up to 84% of persons with multiple sclerosis (MS). In up to a third of these individuals, their spasticity is significant enough to require modification or elimination of certain activities of daily living [Rizzo 2004]. An individual with spasticity will benefit from an expert evaluation to identify specific treatment goals. Not all cases of spasticity need aggressive treatment. There are times when spasticity may be useful, such as when lower extremity extensor spasticity assists with transfer or ambulation. Appropriate spasticity treatment goals include improving function (gait, transfers), ease of care (hygiene, dressing), position (wheelchair seating), and reducing spasms (which may be painful and interrupt sleep).

There are a number of options available for treating spasticity, including both pharmacologic and non-pharmacologic interventions. In terms of pharmacologic interventions, oral medications are the first line. These include drugs such as baclofen, tizanidine, diazepam, cyclobenzaprine, and clonidine. The problem with these medications is their high incidence of side effects which limits their usefulness. Up to 15% of users experience dizziness, and up to 63% experience drowsiness with these medications [Erwin 2011]. Side effects occur even at doses still too low for adequate spasticity control. This is why the concept of intrathecal baclofen (ITB) therapy came about.

### Intrathecal Baclofen (ITB) Therapy

ITB therapy is a system wherein an implantable pump delivers liquid baclofen directly into the spinal canal. The pump is about the size and shape of a hockey puck. A handheld programmer is used by the physician/nurse to control the pump and make necessary rate adjustments.

Compared to oral baclofen, ITB requires a much lower dose of baclofen to produce greater reductions in spasticity, with significantly less side effects.

ITB therapy has actually been FDA approved for the treatment of severe spasticity since 1992. However, studies and experience show that this modality is not well known nor much utilized by MS patients and their physicians. When used, ITB is often employed quite late in the disease course. A NARCOMS survey published in 2004 revealed that only 1% of patients receiving treatment for spasticity used ITB, compared with the estimated 13% of all MS patients who may be potential ITB candidates [Rizzo 2004]. Only 25% of oral spasticity medication users reported that their physicians had discussed ITB with them. Furthermore, less than half of all MS centers at that time had a comprehensive spasticity management program in place [Erwin 2011].

ITB is particularly appropriate for individuals with substantial bilateral lower extremity spasticity. On the other hand unilateral lower extremity spasticity maybe better addressed with targeted botulinum toxin or phenol injections. Note however that ITB need not be used exclusively, but may be used in concert with these injections, oral agents and non-pharmacologic modalities.

Studies have shown that in patients with severe spasticity, ITB therapy significantly decreased spasticity and spasms [Gudesblatt 2011, Guillaume 2005, Ordia 2002, Middel 1997, Coffey 1993]. These in turn led to decreased pain, less fatigue, better sleep, increased physical activity and improved balance and gait. In addition, many individuals were able to achieve long-term goals, including eliminating the need for a wheelchair, regaining the ability to walk at home without an assistive device, and even returning back to work [Rawlins 2004].

### ITB Patient Selection

Appropriate candidates for ITB therapy are those with significant spasticity (Ashworth/modified Ashworth score  $\geq 3$ ) or spasms (Spasm frequency score  $> 2$ ), in

whom oral medications proved ineffective and/or poorly tolerated, and who are willing and able to regularly follow up at the clinic [Erwin 2011].

Ideally, the patient should be referred for ITB therapy evaluation when the EDSS approaches 4.0 (patient has disability but is still able to ambulate without an assistive device), rather than the usual practice of referring later at EDSS  $\geq$  6.5 (patient requires bilateral assistive devices to ambulate or may already be non-ambulatory) [Erwin 2011].

### **ITB screening trial and implantation**

Once the patient is deemed a good ITB candidate, he/she is scheduled for an ITB screening trial. During the trial the patient receives a small test bolus of intrathecal baclofen through a spinal tap. This is usually done in an outpatient day observation setting. The patient is evaluated throughout the day to determine whether or not the patient's spasticity, spasms, and function improve after the test bolus. The patient is also monitored for development of any adverse reactions to the drug.

If the screening trial is successful, the patient is electively admitted on another day to have the ITB system implanted in the operating room, by an experienced surgeon. The pump is implanted subcutaneously in the abdomen. The catheter is attached to the pump catheter port, threaded around the flank, to the back, into the spinal canal, and is anchored at the upper-lumbar or lower-thoracic level. The patient is observed in the hospital overnight and discharged the next day. There are times, however, when the patient may need a few days of inpatient rehabilitation for baclofen titration and physical and occupational therapy before being discharged home.

### **ITB management**

After the system is implanted, it may take several weeks to months to gradually titrate the baclofen to optimal dosing. This requires good patient compliance to regularly follow up at the clinic. The patient must also be diligent with pump refill schedules as the pump should not be allowed to run dry. The pump has an operating life of about seven years, after which it needs to be replaced. The intrathecal catheter, if still intact, does not necessarily need to be replaced together with the pump. Complications are rare when best practices are followed. However, significant and at times life threatening complications may occur with abrupt baclofen withdrawal (e.g. pump failure or reservoir running dry), or baclofen delivery overdose. The patient and caregivers must be educated on the signs and symptoms of baclofen withdrawal/overdose and the need to contact the provider or the emergency room in a timely manner. Important factors in the successful treatment of spasticity with ITB include appropriate patient selection,

education of patients and caregivers about realistic goals and expectations, careful dose titration over time, early involvement of rehabilitation therapists, and good patient compliance with clinic follow-ups.

ITB is best utilized as a component of a comprehensive spasticity management program. Such a program is run by a multi-disciplinary team composed of a physician, nurse or nurse practitioner, physical therapist, occupational therapist, and clinical coordinator.

With all these factors in place, the patient can expect good functional outcome and a safe and rewarding experience with ITB therapy.

### **Abbreviations**

**EDSS:** Expanded Disability Status Scale

**FDA:** Food and Drug Administration

**NARCOMS:** North American Research Committee on Multiple Sclerosis

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