Information Guide to Intrathecal Baclofen Pump Program

Introduction:

The Intrathecal Baclofen Pump is a surgically implanted device which allows delivery of a small amount of anti-spasticity medicine (Lioresal or Baclofen) to be delivered around the spinal cord. Because the medicine is delivered directly to the space around the nerves to the legs, patients can have more tone relief with less medicine and less sedation. The aim of this procedure is to decrease spasticity in patients with brain injury, cerebral palsy, spinal cord injury, multiple sclerosis, etc.

What is Spasticity?

Ideally, muscles have enough tone or resistance to movement to maintain our posture against gravity. They give us stability around joints but still provide flexibility to allow smooth movement. Spasticity is increased tone or stiffness to movement. Injury to the brain or spinal cord may cause changes in muscle tone or the ability to coordinate movement.

What is the Pump?

A Baclofen Pump is a device that is about the size of a hockey puck which is implanted under the skin of the abdomen. A catheter is then connected to the space surrounding the spinal cord. The pump is filled with Baclofen (Lioresal). It has a small computer inside that allows it to deliver small amounts of medicine continuously. This computer can be adjusted by a programming “mouse” that is waved over the skin. The pump is also able to deliver different amounts of medication at different times in the day. This allows adjustment of a patient's tone to make them the most comfortable and functional they can be.

The pump holds an amount of drug that usually lasts two to three months. The pump is refilled by a small injection through the skin, which can be numbed beforehand with EMLA cream. It takes about 10 minutes and is virtually painless. It can be done by a home health agency if the patient lives a far distance from a physician’s office.

Historical Background of Intrathecal Baclofen Pumps:

Intrathecal Baclofen has been in common use for people with severe spasticity due to spinal cord injury (SCI) or multiple sclerosis (MS) for the past several years. Because of the success in treating symptoms in these groups of patients, the medication became approved for cerebral-origin spasticity in 1996. This includes brain injuries that are acquired, such as traumatic brain injury (TBI), and injuries that are congenital, such as cerebral palsy (CP). This procedure offers an adjustable way to provide this medication, and thus allows the physician to tailor it to an individual patient's needs.
Which Patients Benefit Most From Intrathecal Baclofen Pump?

Not every child or adult with spasticity will benefit from an Intrathecal Baclofen Pump. The most important criteria is whether the patient’s spasticity is severe and interferes with motor skills and if reduction in spasticity would improve quality of life.

Some Criteria Considered Important Include:

- Severe spasticity interferes with daily care, independence, or movement.
- Conservative measures have failed to control spasticity.
- A supportive family who understands the commitment to follow up with medical care and therapy.
- Ability to be followed at regular intervals for medication refills and adjustments of dose.
- A regular physical therapy (PT) and occupational therapy (OT) program in place or ability to participate in therapy after pump placement.

Contraindications to Baclofen Pump:

- Allergies to Baclofen (Lioresal).
- Current pregnancy.
What are the Possible Complications?

Intrathecal Baclofen Pump placement takes several hours and a 2 day to 2 week hospital stay is usually required. Two incisions are made - one in the abdomen for placement of the pump and a small one in the back for the catheter. As with any neurosurgical procedure, there are risks.

- **Surgical Risks for Implantation of the Pump:**
  - Wound infection and meningitis are possible but can be controlled by antibiotics.
  - Temporary leakage of cerebral spinal fluid, which can cause headache.
  - Risks associated with the use of general anesthesia are inherent in any surgery.
  - Sensory deficits or changes such as paresthesias, numbness or difficulty with position sense may be possible but are generally temporary if they occur.

Once the Pump is Implanted:

- Mechanical problems with the catheter, such as disconnection, blockage, kinking, breaking, or leaking. If these occur, the catheter is replaced.
- Leakage of fluid into the space around the pump. This goes away with gentle pressure.
- Infection of any of the portions of the pump, catheter, or the tissues in or around the spinal cord. These would be treated with antibiotics.
- Overdose of Baclofen, which can lead to changes in consciousness. This is treated by emptying the Baclofen from the pump or adjusting the dosage.
- Pump malfunctions which can lead to under dosage of the Baclofen with withdrawal symptoms.

How do we know it will work?

The Test Dose: Once the patient has been determined clinically to be a possible candidate for the Baclofen Pump, a test dose of Baclofen injected around the spinal cord will be done to see if the medicine works. The first step will be to obtain insurance preapproval for the Pump placement and all of the necessary treatment. Then the test dose will be scheduled as a “short stay” (one day) outpatient hospitalization. A meeting with a nurse, PT and OT, and a rehab physician is arranged. A videotape of each patient will be made and function assessed.

Patients will be admitted to Children’s Medical Center early on test day and should not have eaten anything since the night before. An intravenous line will be placed. Then, a small amount of Baclofen is injected into the space around the spinal cord by lumbar puncture. The patient’s reaction to this (vital signs, tone, range of motion) will be measured throughout the day. If there is a significant decrease in muscle tone, the Baclofen pump is likely to be successful. There are three potential amounts of medicine that can be tested, so if a person does not respond to the lowest dose, another test dose of a higher amount of medicine will
be scheduled at a later date. If there is still not a significant response to the highest possible dose, the pump will not be implanted.

**What does a Baclofen Pump accomplish?**

Intrathecal Baclofen Pump is not a miracle procedure. Remember the only symptom of CP, SCI, MS, or TBI is changes in spasticity. This may mean fewer caregivers are needed, walking is easier, speech is clearer, arm function is better, or bladder continence may even improve. Of course, the gains seen are individual and are dependent on a patient’s function prior to surgery, the intensity of therapy following surgery, and their response to the medication.

**Who Should be Contacted for More information?**

Please feel free to call Elizabeth Moberg-Wolff, MD, at 706-721-5277. Address: BT 2644, Medical College of Georgia, Augusta, GA 30912.

**Why is Therapy required after Surgery?**

The importance of postoperative therapy and rehabilitation medicine follow-up cannot be stressed enough. Patients with CP or TBI have learned ways of movement which work for them. They have used these movement patterns continuously, and they feel “normal” to them. After surgery, they are usually weaker. Their muscles feel looser to them, and they may be concerned they are not able to do the things they used to do. They need to learn new skills, and care givers may need to learn new methods of helping them. Oral medications will continue to be weaned, so a patient is on the fewest medications possible. Overall, the changes in tone occur gradually, so patients have plenty of time to adjust.

**Will Additional Surgeries be Needed?**

Problems with the Intrathecal Baclofen Pump or catheter can require another operation. This will be necessary if there is a need to revise the catheter or the pump. Also, the pump has a battery which has an average life of about five years. The rate at which the battery is drained depends on the rate at which the medicine is being pumped (i.e., if the pump is set at a faster rate, battery power will be depleted faster.) When the battery’s power is depleted, the pump portion in the abdomen needs to be surgically replaced. The surgery, while reducing spasticity and therefore allowing greater movement, does not eliminate all of the effects of cerebral palsy and brain injury. Typically, patients with spasticity have reduced range of motion in certain movements. Though the tightness resulting from spasticity is reduced, the contractures that develop over time will occasionally require surgery. Conservative methods to stretch contractures, such as casting, splinting, and stretching, will be attempted first. There will be cases where surgical releases will be necessary. This is not recommended until the patient has had at least 6 to 12 months of postoperative therapy and still has significant contractures.

**Surgical Procedure:**

Once the decision has been made to do the procedure, the surgery can be scheduled at Medical College of Georgia Hospital.

The surgery involves a several-inch skin incision along the abdomen below the belly button and between the ribs and hip bone. The pump device is placed in the tissues that
are underneath the skin and muscle of the belly, where a pouch is created. A catheter is then tunneled through the soft tissue around the side of the belly wall around the back. A small amount of bone on the spine is cut away to allow passage of the tip of the catheter to space that is around the end of the spinal cord and the nerves that are exiting there. The pump and catheter are surgically secured with sutures. The total hospital stay varies but is usually one day. An inpatient rehabilitation stay may be recommended, or outpatient therapy arranged, postoperatively.