

Information about Intrathecal Baclofen Pumps

- Clinic Information
 - Intrathecal Baclofen Clinic is within the Division of Developmental Medicine.
 - Clinicians
 - Steve Couch, MD
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- Pump Information
 - Medtronic SynchroMed II Pump delivers baclofen in high concentration to spinal cord receptors to treat severe spasticity. The 8840 N'Vision programmer is used to interrogate and program the pump.
 - Pump is implanted subfascially in abdomen and a catheter tunnels posteriorly, entering the intrathecal space to deliver medication. It enters at about L3 level and goes to anywhere from T10 to C2 level.
 - **Typical dose range** = 150 and 1200 mcg/day. Most of our patients are on 400-800 mcg/day.
 - There are two **programs**:
 - Simple Continuous infusion = a set amount drips out of catheter tip every hour
 - Flex dosing = boluses of baclofen can be programmed at regular intervals
 - There are two pump **sizes**, 20 and 40 ml reservoirs
 - **Concentrations**: Lioresal (baclofen) comes in 500 and 2000 mcg/ml. Competitor Gablofen comes also in 1000 mcg/ml, though we do not have patients with this concentration. Some patients are in the Gablofen trial with a 3000 mcg/ml concentration.
 - **Refills** are done at least every 6 months, but usually more often depending on how high the dose (or pump rate) is and therefore how much medication is being used. It is a sterile procedure done in clinic in which the area is cleaned with chlorhexidine, betadine, and alcohol and a needle is then inserted into the pump to add medication to the drug chamber.
 - **Alarm date** refers to the date at which the medication in the drug reservoir should be at a set point, which we have set to 2.0 ml on most patients. Refill should be done prior to the alarm date. Some patients have a higher low reservoir alarm if they are known to miss appointments or if the child becomes stiffer just prior to refill.
 - Medication is FDA approved to be in pumps for only 6 months, so maximum refill interval time is 6 months
 - Require **replacement** every 4-7 years for battery life and wearing of gears in pump. The ERI (Elective Replacement Indicator) refers to when the pump needs to be replaced. When it reaches 0, the pump will still typically work for about 2 months.
 - Patients CAN have a **MRI** with the pump, but the magnetic field may make rotors stick together and temporarily stop the pump. It usually restarts within 20 minutes, but a clinician needs to use the programmer to check logs and make sure it has. There should not be a clinical effect for a brief pause in therapy. Nothing needs to be programmed on pump beforehand.

- Minimum rate is 96 mcg/hour for the 2000 mcg/ml concentration. If patient has overdose, pump can be set to minimum rate but should not be stopped.
- Possible pump problems
 - Pump is very reliable and is almost never the problem
 - Catheter is usually the problem. Issues can include dislodgement, migration, fracture/break, and kink/occlusion. If catheter problem, pump is usually not aware of a problem and an alarm will not sound.
 - Pump runs out of medication
 - The wrong concentration was put in during refill
 - Programming errors
 - Pocket refill (medication was put into pocket around pump and not into pump)
 - Infection
- Pump alarms
 - Non-critical alarm: One beep which sounds once an hour. This signals that the drug in the reservoir has reached the low reservoir volume and pump needs to be refilled.
 - Critical alarm: Two tone (ambulance) sound every 10 minutes. This signals that the pump has stopped or is out of medication. This is an emergency situation and the plan needs to be enacted to get them to the ED as soon as possible.
- Symptoms of Baclofen Withdrawal
 - Severe itching (without a rash)
 - Excessive Sweating
 - Changes in how child acts (confused, agitated, hallucinations)
 - Suddenly very rigid or spastic muscles
 - Fever from increased muscle work
 - Irritable
 - More movement – anecdotal
 - Labile blood pressure
 - Insomnia
 - Seizures can occur
 - Can lead to rhabdomyolysis, DIC, organ failure, cardiac arrest, and death
 - Can be confused with autonomic dysreflexia, malignant hyperthermia, sepsis
- Management of withdrawal
 - Potential problems are programming and refill errors, pump running out of medication, infection, and catheter problems. Keep in mind some increase in stiffness can be seen in patients with spasticity when sick, dehydrated, very constipated, having seizures, infection, and when in pain.
 - Most families have oral baclofen on hand at home to give in the case of emergency that has been prescribed. They may have given 1 tablet at home (of 10 or 20 mg depending on intrathecal dose; it is stated in ITB clinic note or patient summary) before enacting plan to go to ED.
 - There is no direct oral to intrathecal ratio. Patients may have 10 or 20 mg on hand. Probably, pump doses 100-250 mcg/day are about (oral) 10mg TID; 250-500

mcg/day are about 20mg TID, 500-750 mcg/day are about 30 mg TID or QID, and higher is probably not possible orally.

- Management will include oral medications, including baclofen and often tizanidine and valium. If patient is admitted to the PICU, they may use Precedex (dexmedetomidine) which is an IV only alpha-2 agonist that can be used as a drip. ITB Pump team will make recommendations.
- CBC is recommended to look at whether child may have infection
- Full physical exam is recommended to rule out other problems, like ear infection as pain can cause increased spasticity.
- Last ITB clinic note can be reviewed to see what dose patient is on and to check alarm date. There is also a document scanned into EMR under name “pump settings” that is the printout from the programmer.
- Pump series is often recommended to see if there any obvious pump or catheter problem. If so, Neurosurgery should be consulted.
- If catheter is disconnected, it is pumping baclofen into a body space and it is usually not a problem. The total 24hr dose and volume is at most 1.2 mg and 0.6ml, so there are no negligible effects.

- Symptoms of Baclofen Overdose

- Drowsiness
- Lightheadedness
- Dizziness
- Respiratory depression
- Seizures
- Hypotension
- Hypotonia
- Loss of consciousness
- Can lead to coma

- Management of overdose

- Main potential problem is programming errors. Rare for pump or catheter to have problem causing overdose.
- Respiratory support may be needed and child will most likely need PICU admission
- Pump can be turned down to minimum rate with programmer

- Significant swelling over pump or lumbar spine incision

- Potential problems are infection, pocket refill, and catheter problems.
- If refill was done recently, look at clinic note to see if any problems were noted under “refill procedure” portion of note. Jennie will often include a comment about possible problem if she suspected there could be an issue.
- Pump series is recommended to see if any obvious pump or catheter problem. If so,
- Recommend CBC in ED to look at possible infection.

- Alarms sounding

- Non-critical alarm: One beep every hour that means pump is running low on medication. Look at last ITB clinic note to see alarm date and what rate child is on. Family may think they heard alarm, but it may not actually be sounding.
- Critical alarm: Ambulance sound every 10 minutes that means pump is out of medication and/or has stopped. Oral baclofen should be initiated. A magnetic field (such as MRI) could have caused pump to stop temporarily and it should restart after patient is removed from magnet.