

# Intrathecal Baclofen (ITB) Pumps and Baclofen Withdrawal



Patients may call the SCIC if they are worried about their pump. The main reason for calling would be that the pump is sounding an alarm.

The pumps have two alarms:

### **Non-critical**

- Single tone every hour
- This is not critical patient should be seen by us within next 24 hours

### **Critical**

- Two tone sound like siren every 10 minutes
- Patients pump may not be working so withdrawal is likely and should be seen by Rehabilitation Consultant ASAP

For example if the pump runs dry, or ceases to function ie battery fails

- Itching without rash
- Sudden worsening of spasticity in absence of other factors
- Blood pressure rises, autonomic dysreflexia symptoms
- High fever
- Altered mental status

### **Actions**

- Initiate life-sustaining measures if indicated
- Contact the On-call Rehabilitation Consultant
- Patient may have 2mg clonazepam tablet or oral baclofen which can be administered on advice of on-call Rehabilitation Consultant

For example if the pump delivers too much baclofen, or a bolus is miscalculated)

- Drowsiness
- Dizziness/Light-headedness
- Slow and shallow breathing
- Seizures
- Loss of consciousness

### **Actions**

- Maintain airway/breathing/circulation. Intubation and respiratory support may be necessary
- Contact on-call Rehabilitation Consultant

Severe spasticity is a significant problem for many patients with a spinal cord injury (SCI) or other upper motor neurone lesion. It can cause pain, sleep disturbances, loss of independence and mobility. Intrathecal baclofen has been shown to be effective in the treatment and management of severe spasticity of either cerebral or spinal origin. Reduction in spasticity can lead to ease of care, reduction of oral medications, reduction in the incidence of complications such as contractures and pressure sores.

Intrathecal baclofen should be considered as a treatment option only when spasticity in patients is refractory to oral anti-spasticity medications and other local measures are either inadequate or inappropriate.

### **Mode of Action**

Baclofen is an analogue of the inhibitory neurotransmitter gamma amino butyric acid (GABA). Its exact mechanism of action is not fully understood, however, the predominant effect appears to be inhibition of monosynaptic and polysynaptic reflexes at the spinal level.

### **Mode of Delivery**

Baclofen can be administered orally and intrathecally via a subcutaneously implanted pump. When baclofen is administered orally it does not easily cross the blood-brain barrier but is distributed equally between brain and spine. This can lead to centrally mediated adverse effects such as dizziness, drowsiness and confusion without adequate relief of spasticity.

By delivering baclofen directly into the intrathecal space, via a subcutaneously implanted pump, the blood-brain barrier can be bypassed and the patients receive full benefit of the drug without adverse side effects.

### **Types of Intrathecal Baclofen Pump**

Different types of pump are available; the most commonly used is a battery dependent electronic model that can be programmed by telemetry (wireless communication) which allows the dose of baclofen to be varied over a 24 hour period. The battery life of these pumps is between 5-7 years following which the whole pump needs replacing. The other pump does not have a battery and relies on a pressurised gas chamber to drive delivery of the drug. Common to both types of pump are a reservoir where the drug is stored and a catheter which links the pump to the intrathecal space. The pump is implanted into a subcutaneous abdominal pocket and the catheter into the intrathecal space with the tip of the catheter situated around T10 or higher depending on the level of injury.



### Medtronic Synchromed II

- Battery life 5-7 years
- Programmable via N'Vision Telemeter
- Variable dose



### Johnson & Johnson Codman Pegasus Pump

- No battery
- Constant flow pump
- Dose can only be changed by changing concentration of drug

## Introduction

Patients undergoing an ITB test dose will usually be admitted to their SCIC centre for the trial

- Patient should continue their oral anti-spasticity medication throughout the trial.
- Anti-platelet agents can be continued
- Routine blood tests are not mandatory.

The patient may be assessed by a Physiotherapist/clinician prior to the test dose. The doctor will then administer the test bolus through a lumbar spinal catheter which is inserted using sterile technique. The baclofen will act over the next 4-6 hours. The physiotherapist/clinician will repeat their assessments during this time.

## Complications

The patient should be monitored for the following complications following the ITB test dose.

- Low pressure headache
- CSF leak
- Meningitis
- Hyper-sensitivity reactions
- Excessive weakness leading to temporary reduction in function
- Transient hypotension especially if patient receiving high doses of Tizandine, responds to fluid replacement.

The implantation of Intrathecal Baclofen Pumps is usually carried out by the Neurosurgical Team. The Baclofen Pump Team normally attends theatre along with the Medtronic reps if appropriate. Implantation may be of a completely new system, revision of pump only or revision of pump and catheter.

### Pre-operative

- Follow usual pre-assessment procedure for the Trust
- Continue usual oral anti-spasticity medication
- DVT prophylaxis according to Trust policy

### Operation

- Patients will usually have two incisions, one in the lumbar spine for placement of the catheter and one abdominal for the pump pouch.
- If only the pump is being replaced and the existing catheter remaining in situ, they will only have one incision.

### Post Operative

- Patients are normally admitted to the HDU for the first 24 hours post operation in case of complications relating to bolus/priming of the baclofen pump.
- A period of post operative bed rest for 24 hours is recommended to minimise the risk of CSF leak around the catheter. If there is no swelling around the catheter entry point the patient is encouraged to get out of bed the first post-operative day.
- Sutures or staples can be removed after 7-10 days. This is normally done by the Neurosurgical Team or District Nurse.
- Monitor patients for signs of baclofen over-dose or withdrawal. If associated with the implantation procedure these would normally be experienced 4-6 hours after operation. See separate page at front of booklet for signs and symptoms. **Contact Rehabilitation Team ASAP.**
- Infection in the pump pouch, if suspected take appropriate samples for microbiological examination and start on broad spectrum intravenous anti-biotic treatment and modify depending on micro results. The anti-biotics may have to be continued for 2-3 weeks if the infection can be controlled. If there is evidence of suppuration, the pump will invariably require explantation. **Contact Neurosurgical Team ASAP.**

- Haematoma in pump pouch usually resolves spontaneously
- Leaked CSF collection is usually detected in the spinal wound. May collect in pouch as well, Managed conservatively.
- Persistent seroma also managed conservatively
- Pump displacement/inversion (rare)
- Catheter to pump disconnection
- Pump malfunction (rare)

**If you have any worries regarding the patient do not hesitate to contact either the Neurosurgical Team, Rehabilitation Consultants or Baclofen Pump Team.**

## Introduction

Patients with an intrathecal baclofen pump must come back at regular intervals in order to have the pump reservoir refilled with intrathecal baclofen. The frequency of the refill will depend on the volume of the pump reservoir and the daily dose that the patient is receiving. In general, the higher the dose the more often a patient will require a refill.

## The Baclofen Pump Refill Clinic

The pumps have an alarm which will sound when the reservoir is down to 2ml, however normally patients are booked into refill appointment 2 weeks before the date of the alarm to ensure some extra time should a patient not be able to make an appointment. If the alarm is sounding there is still a few more days before the pump will run dry.

## Procedure

During a refill, telemetry with the N'Vision programmer is performed to collect all the information regarding the pump and residual volume of the reservoir. The pump is then emptied and refilled through the self-sealing port in the centre of the pump using sterile technique by a trained clinician.

It is very important that a pump refill is not attempted using anything other than the refill kit provided by the manufacturer. Using a standard hypodermic needle will irrevocably damage the pump.



If patients require an MRI, they should inform the radiographer/radiologist that they have an implanted drug delivery pump and the make and model. The pumps are compatible with MRI scanning, but it is essential that the patient is seen by one of the Baclofen Pump Team within 20 minutes of finishing their scan to ensure that the pump is still working. The magnetic field of the scanner will stop the pump operating whilst the patient is in the scanner, but it should automatically re-start once the patient is removed from the field. The Baclofen Pump Team will interrogate the pump with the N'Vision programmer to ensure that the pump has re-started normally

## Background

Intrathecal Baclofen Pumps are used in the treatment of severe spasticity where oral medication has not proved to be effective.

They consist of an implantable pump which contains a reservoir of drug, and a catheter which links the pump to the intra-thecal space.

The pump is implanted into a subcutaneous abdominal pocket and the catheter is inserted into the intra-thecal space in the lumbar region, with the tip located in the thoracic region of the spine (**Figure 1**).



**Figure 1 - Baclofen pump with intra-thecal catheter**

The programmable pumps deliver the drug as required directly to the intra-thecal space which overcomes some of the problems associated with oral anti-spasticity medication.

The pumps are refilled at regular intervals by percutaneous injection of intra-thecal baclofen into the pump, through a special self sealing port in the pump body. The programmable pumps contain a battery which has an estimated life of 5-7 years, therefore the pumps need to be replaced when the battery expires. Normally only the pump is replaced whilst the catheter is left in situ.

This leaflet explains the process of pump replacement and associated catheter priming and what potential risks or side effects may be encountered by the patient in the immediate post operative period.

### Revision of a Baclofen Pump

As described earlier, when a baclofen pump reaches the end of its battery life it needs to be replaced, in such a way that the patient does not experience any loss in therapy. Rapid baclofen withdrawal can be life threatening as the body reacts with rebound spasticity which can lead to rhabdomyolysis, multiple organ failure and in some cases death.

### The Drug Path

In an intra-thecal baclofen pump system it is important to understand the drug pathway. The drug is located in 3 separate parts of the system, which are shown in **Figure 2**.



**Figure 2 - Components of the drug pathway in an intra-thecal baclofen pump system**

- 1 The catheter (which is accessible via the catheter access port **A**)
- 2 The pump tubing (a small section of tubing between the reservoir and the catheter which is not accessible)
- 3 The pump reservoir which is accessible via the self sealing port **B**

Before a new pump is placed in the patient it is filled with intra-thecal baclofen on the sterile field by injection through the self sealing port (B). This fills only the reservoir as the pump tubing is not accessible.

Under normal circumstances when the catheter is not being replaced, it is disconnected from the old pump and aspirated to ensure that it has been emptied of old drug. This also enables us to know that the catheter is patent and there are no blockages in the tube.

When the catheter is connected to the new pump, the drug is only present in the pump reservoir. Therefore the pump tubing and the catheter need to be primed with drug in order that drug delivery can be continuous. The pumps deliver incredibly small volumes of drug each day so allowing it to run at its normal rate in order to prime the catheter would mean that the patient would have a period of days without therapy which could cause baclofen withdrawal syndrome.

### **Priming the Drug Path**

In order to prime the drug path it is essential that we know the volume of the path. This means knowing the volume of the pump tubing and the catheter volume. The catheter volume is determined from knowing the catheter model and also its length. In some cases the catheter length is shortened during implantation. It is essential to know if any of the catheter was removed when it was placed in order to calculate the catheter volume.

The priming of the drug path (ie pump tubing and catheter) is done by programming the pump to deliver a bolus dose of an exact volume to fill the path of the drug over a short time period (20 minutes). If this bolus volume does not correspond to the volume of the drug path then an over-dose or under-dose may occur. The effect of a drug overdose would expect to be seen 4-6 hours after the pump has been primed.

The table below shows the different priming situations that may occur.

Situation	Where is drug	Priming protocol	Expected Outcome
<b>New pump and new catheter</b>	Drug in pump reservoir only, no drug in catheter or pump tubing	Prime whole system with a priming bolus following closure	No adverse effect so long as correct catheter volume used
<b>New pump, old catheter, aspirated</b>	Drug in pump reservoir only, no drug in catheter or pump tubing	Prime whole system with a priming bolus following closure	No adverse effect so long as correct catheter volume used
<b>New pump, old catheter, not aspirated</b>	Drug in pump reservoir and catheter but not in pump tubing	Prime pump tubing prior to connection to catheter (requires 10 minutes)	No adverse effect so long as correct catheter volume used

If the catheter volume is unknown then the safest option is to replace the catheter with a new one and carefully document the model and amount of catheter cut if any.

If it is not possible to replace the catheter, then the only safe option is to clamp the catheter to ensure no drug is lost from the end, and then prime the pump and pump tubing on the sterile field and connect the old catheter to the new pump. This will ensure that therapy is continuous, but you are not able to check the patency of the catheter.

### Signs of Over-dose and Under-dose (withdrawal)

**Overdose** would occur if the bolus volume was larger than the catheter and tubing volume. The effects would be seen 4-6 hours after bolus.

#### Signs of over-dose

- Drowsiness
- Dizziness/light-headedness
- Slow and shallow breathing
- Seizures
- Loss of consciousness

#### Actions

- Maintain airway/breathing/circulation. Intubation and respiratory support may be necessary
- Contact on-call Rehabilitation Consultant

**Under-dose (withdrawal)** may occur if the pump is not delivering correctly or the bolus volume was smaller than the catheter volume.

### **Signs of under-dose (withdrawal)**

- Itching without rash
- Sudden worsening of spasticity
- Blood pressure rises, autonomic dysreflexia symptoms
- High fever
- Altered mental status

### **Actions**

- Initiate life-sustaining measures if indicated
- Contact the on-call Rehabilitation Consultant
- Give 2mg clonazepam (faster acting than oral baclofen)

### **Other considerations of patients having baclofen pump surgery**

Most of the patients at this hospital who have a baclofen pump for spasticity, have a spinal cord injury, so they should receive the normal nursing care for a spinal patient, including correct mattress, turning, bladder and bowel management.

If only the pump has been replaced, there will be an abdominal incision. If a catheter has been implanted there will be a further incision in the lum