INTRATHECAL BACLOFEN (ITB): ADMINISTRATION AND PATIENT MANAGEMENT - CHW

PRACTICE GUIDELINE ©

DOCUMENT SUMMARY/KEY POINTS

- Children with cerebral palsy often have significant movement disorders such as spasticity and dystonia that interfere with daily care and participation in life.
- Baclofen acts to suppress skeletal muscle spasms and reduce muscle tone & spasticity.
- Intrathecal (into the CSF around the spinal cord) administration enables baclofen delivery directly to the site of action, allowing for smaller doses with fewer systemic side effects.
- Intrathecal baclofen (ITB) therapy is offered to selected patients who are not well-controlled on other medications.
- The ITB test-dose procedure is performed to assess a child's response to treatment and is done prior to the decision to proceed to a pump implant. Staff involved in the care of patients having an ITB test-dose should be aware of possible baclofen overdose symptoms. Standard escalation of care processes, including Clinical Emergency Response System (CERS) should be followed.
- If overdose is thought to occur, consideration should be given for the child to be specialled (1:1 Nurse: Patient) and for the Bed Manager/After Hours Nurse Manager (AHNM) to be contacted to arrange admission.
- Children with an intrathecal baclofen pump are at risk of complications including baclofen withdrawal and baclofen overdose. These children may present to the Emergency Department with acute symptoms.

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CHANGE SUMMARY

- Additions to original guideline have been made to include baclofen pump troubleshooting and management of intrathecal baclofen withdrawal and overdose.
- 5/03/21: Minor review. Updated references.

READ ACKNOWLEDGEMENT

- All clinical staff (medical, nursing and allied health) involved in the administration of ITB and subsequent patient management should read this document.
- Sydney Children's Hospital Network (Westmead Campus) [The Children's Hospital at Westmead (CHW)] is the state-wide service for children being considered for ITB therapy. At this stage, all paediatric ITB related procedures and troubleshooting are only performed at CHW.
- Training/Assessment Required – The procedure outlined in this practice guideline may only be carried out by Kids Rehab clinical staff who have been trained in the procedure

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1 Background

Baclofen is a derivative of the inhibitory neurotransmitter gamma-aminobutyric acid (GABA). As a GABA agonist, baclofen binds to GABA receptors in the spinal cord, increasing the inhibitory action to suppress skeletal muscle spasms and reduce muscle tone and spasticity[1].

Baclofen crosses the blood brain barrier poorly and thus, when given enterally, may not reach spinal cord receptors at sufficient concentrations to have therapeutic action without causing side effects[2]. Intrathecal administration enables baclofen delivery directly to the site of action, allowing for smaller doses with fewer systemic side effects.

An intrathecal baclofen (ITB) pump is a programmable drug infusion system that consists of an implanted pump and an intrathecal catheter. The pump is available with reservoir sizes of either 20mL or 40mL. An external programmer is used to change dosing based on specific goals of treatment. The dose can be prescribed to deliver a continuous infusion over a 24 hour period or prescribed at different scheduled doses throughout a 24 hour period[3,4].

1.1 Treatment

Best established use of ITB is in patients with severe spasticity in the lower limbs, commonly found in children with cerebral palsy classified as level IV–V according to the Gross Motor Function Classification System (GMFCS)[5]. There is some evidence that ITB is effective for treating generalised dystonia[6].

Selection of patients for ITB should follow a consistent approach[7,8]. Children over the age of 8 years are generally considered for the treatment. The process starts with the child having a comprehensive multidisciplinary team assessment to confirm presence of spasticity/dystonia, management of factors that may be contributing to tone and care issues and a trial of oral medications. If ITB is being considered, a response to therapy can be tested before a pump is implanted by way of a test-dose, in the form of a lumbar puncture and injection of a bolus dose of baclofen[1,9].

2 Risks

Intrathecal baclofen therapy has known risks and complications[10,11,12], including device related problems from the pump and catheter which can cause baclofen withdrawal or overdose. Overdose is specifically monitored for when the child is in hospital for a test dose procedure.

Signs of ITB withdrawal include:

- Pruritis
- Exaggerated rebound spasticity and muscle rigidity
- Altered mental state, irritability
- Fever

Signs of ITB overdose include:

- Drowsiness, dizziness, altered level of consciousness
- Respiratory depression

- Seizures
- Hypotonia

Drug side effects can include:

- Inability to urinate for 2-3 days which is never a permanent condition
- Increased constipation
- Tiredness

Some catheter related risks include:

- Infection
- Catheter related complications eg migration, breaks, kinks
- CSF leaks
- Precaution is also needed if a child with an ITB is having an MRI or surgical procedure:

MRI – the magnetic field of an MRI scanner can cause a temporary stall of the pump rotor. During this time baclofen is not delivered to the patient and if left unchecked can lead to baclofen withdrawal. As a precaution, any child undergoing an MRI must have their pump interrogated and the logs read by Kids Rehab staff 2 hours following completion of the MRI. Please refer to the Medtronic website for further information regarding MRI safety for intrathecal baclofen pumps https://www.medtronic.com/us-en/healthcare-professionals/products/neurological/intrathecal-baclofen-therapy-systems/synchromed-ii.html

Diathermy - short wave (monopolar) diathermy should not be used within 30cm of the pump due to the risk of heating the tissue surrounding the metal of the pump. Overheating can change the drug delivery and potentially cause an overdose. Bipolar cautery should be used as an alternative. All patients having a surgical procedure involving diathermy should have their ITB pump interrogated post operatively by the Kids Rehab staff.

http://www.twmu.ac.jp/NIJ/ITB/ITB.pdf

3 Intrathecal Baclofen Test Dose Processes

3.1 Pre-admission process

1. Children are initially assessed in the Cerebral Palsy and Movement Disorder Clinic (CPMD) by the ITB team [Doctor, Clinical Nurse Consultant (CNC), Occupational Therapist (OT), Physiotherapist (PT), and Social Worker]. If a child is thought to be a suitable candidate, an admission date is discussed and agreed to with the team and family. Further education and written information is given to the family at this time.
2. During the clinic appointment, it should be determined if Anaesthetic or Interventional Radiology support is likely to be required. In this case, the test dose may need to be considered as a Day Admission procedure.
3. Once a date for the test dose has been determined, a follow up review by the ITB team should be done a minimum of 1 month prior.
4. The doctor seeing the child in clinic is responsible for the following:
    - **i.** Consent form for the procedure (form SCHN020.001) as well as clinical photography and the electronic admission form in PowerChart (eRFA), as the procedure is generally done under nitrous sedation as a day admission.
    - **ii.** Order the intrathecal baclofen required for the test dose via the eMM, 2 x ampoules of 50 micrograms/mL may be need to be requested, depending on the agreed dose.
5. **Suggested intrathecal test dose guideline**[9]:

    For spasticity:

    - Children 4 - 7 years / < 18kg: 25 micrograms
    - Children > 7 years / > 18kg: 50, 75 or 100 micrograms, depending on severity of spasticity[1]

    For dystonia:

    - Children 4 - 7 years / < 18kg: 50-75 micrograms
    - Children > 7 years / > 18 kg: 50-100 micrograms

    Dose is given over at least 1 minute via lumbar puncture
6. A weaning regimen of oral baclofen is given to the family in the assessment clinic (see Step 1 above) to commence prior to the admission date. This regimen will vary for each child and be determined by the child's Rehabilitation Consultants. Consideration should be given to other drugs that may influence the outcome of the lumbar puncture procedure (e.g. anticoagulants). Consultation with relevant sub-specialty team may be required as part of this decision making.
7. ITB therapy team contacts the child's community therapists to discuss possible goals of treatment for the test dose.

Families are contacted by the Kids Rehab CNC prior to the admission date to discuss progress of baclofen weaning. If necessary, oral diazepam may be needed to assist spasm control.

3.2 At Admission

Children are usually admitted at 8am on the scheduled day. A review of the child is performed at this time by the Kids Rehab team, including CNC and Registrar/Consultant performing:

- A medical physical assessment,
- Confirming fasting times
- Mark the spine and apply EMLA cream
- The Kids Rehab Physiotherapist and Occupational Therapist perform a comprehensive assessment that includes: Barry Albright Dystonia Scale, Modified Ashworth Scale, modified Tardieu scale on muscle tone, range of movements, video-recording of transfers and dressing procedures especially if these are goal areas. The assessment procedure will be video-recorded for future reference and discussion with families
- Check the patient's weight and confirm prescribed dose to be administered

3.3 Intrathecal Baclofen Test Dose Procedure

1. **The child is fasted from 4.30am.** Morning medications can be given with a small amount of water. This may include a small dose of enteral baclofen.
2. Ward staff are to have available:
    - Lumbar Puncture kit (from Kids Rehab treatment room cupboard)
    - Filter for drawing up baclofen
    - Extra-long and short spinal needles
    - Sterile gown, gloves & mask
    - Lignocaine 1%
    - 5mL syringe (for lignocaine)
    - 3mL syringe (for baclofen)
3. The ITB test dose procedure is performed in a procedural room with monitoring equipment. Suction and nitrous oxide should also be available: The CNC is available to administer the nitrous gas and a ward RN should be available to assist with the procedure for monitoring and positioning the child during the procedure.
4. Procedure commences at 8.30am. The procedure may only be carried out by Kids Rehab medical staff who have been trained in the procedure.
5. Follow hospital Lumbar Puncture ePolicy (Policy No: 2014-9039). In addition perform the following:

i. **Draw up Lignocaine** for local anaesthetic in a 5**mL syringe** to distinguish it from the syringe containing the baclofen. Place the used ampoule of lignocaine next to the syringe in a separate clean container. Ensure that the local anaesthetic lignocaine is not injected in to the epidural space. Discard this syringe after lignocaine is administered.

ii. **Draw up the baclofen** for intrathecal administration in a 3**mL syringe;** performed by the doctor performing the test-dose procedure. Place the used ampoule of baclofen next to the syringe in a separate clean container. The baclofen is to be double checked and signed as per medication orders. Ensure the correct concentration is used. The 50 micrograms/mL ampoules are used for test doses.

3.4 Following Test Dose Procedure

1. Children are recovered on a ward with resuscitation equipment available for immediate use if required.
2. A full set of observations should be performed 15 minutely for the 1st hour, then hourly for 6 hours or until the patient is discharged. These are recorded on the age-appropriate NSW Health Standard Paediatric Observation Chart.
3. If the child enters the Yellow Zone Criteria (or staff or a family member is concerned) on the NSW Health Standard Paediatric Observation Chart, a Clinical Review by the Rehabilitation Registrar (pager 7181) should be initiated promptly.
4. If child deteriorates into the Red Zone (or there is a serious concern by any staff or family member), in line with standard procedure, escalation to a Rapid Response Call or an arrest call should be made immediately.
5. If overdose has occurred, consideration should be given to increase observation of the child (as per ePolicy 2008-8040, Increasing Nurse: Patient Ratios).
6. The effects of baclofen peaks at 2-4 hours post-injection then gradually wears off by 8 hours.
7. Child should be observed for possible reactions to baclofen that may indicate overdose (see above, Section 2 Risks). If overdose is suspected see 3.5 below. In addition, please notify the medical team if the child has not voided urine following the test dose.
8. Kids Rehab Team assessments (including muscle tone) are performed at 1, 2, 4 & 6 hours post-procedure. A reduction in the Barry Albright Dystonia Scale of at least 25% and/or a change in the Modified Ashworth score are considered a positive test dose response. Achievement of family goals is also considered.
9. Once the child has tolerated sitting up after the procedure they can usually also have access to their wheelchair however this will be led by the therapy team. Transfers into and out of bed often gives the team important information about the child's response to the intrathecal baclofen injection.

10. Prior to discharge, the Kids Rehab Team meet with the family to discuss test dose response and follow-up plans. The family is also given a regimen to restart oral baclofen if appropriate.
11. Children are discharged once the Kids Rehab Team has assessed if the ITB effects have worn off and it is safe to discharge the child. If there are concerns about the child's recovery from the procedure, they may need to be admitted overnight

4 Continuous ITB infusion

Following a positive test dose where the child has responded to a bolus dose of baclofen, they may progress to having a baclofen pump implanted. The pump delivers a constant dose over a 24 hour period.

Children are seen in the Neurosurgical pre-admission clinic prior to pump implant and as part of this should have routine MRSA screening performed: *(Guideline: 2008-8118).*

4.1 Maintenance Dosing

1. Pharmacy Sterile Suite is notified of the appropriate baclofen prescription for each child's baclofen pump refill and prepares and dispenses the syringe of medication to fill into the baclofen pump reservoir. The standard concentration of intrathecal baclofen used at CHW is a neat solution of 2000 micrograms / ml. Children identified through the test dose procedure as requiring a low baclofen dose may require a more dilute concentration of baclofen of 1000 micrograms / ml. The size of the pump will determine the volume filled ie either 20mls or 40mls.
2. Children are started on a continuous dose based on their response at the time of test dose. [4] The test dose is generally doubled as the starting continuous dose. For example an effective response to 50 micrograms at test dose, start the continuous infusion at 100 micrograms over a 24 hour period; an effective response at 100 micrograms, start the continuous infusion at 200 micrograms over a 24 hour period.
3. Daily dose increases of 50 micrograms / day, for the 3 days the chid remains in hospital post operatively can be done.
4. Further dose increases are done in the clinic outpatient setting. Increases to the daily dose by 5-15% every 3-7 days can be done, depending on the child's response, as measured by reduction in tone or excessive movements.
5. A stable daily dose is generally reached after a 3-6 month period. A maximum dose will vary for each child depending on their movement disorder type, but can reach up to 1000 micrograms / day for children with significant dystonia.
6. ITB refills are done in the clinic setting. The timing of this will depend on the dose, as indicated from the pump data when it is interrogated using the Synchromed II Clinician Programmer. Drug stability for the Medtronic Synchromend II pump is 180 days in the reservoir so a refill must occur before this time.
7. Families are educated about potential complications from this therapy so they are able to report an accurate account of their child's usual tone and behaviour and any changes

that may occur with suspected pump problems. The most common problems with ITB therapy are baclofen withdrawal or overdose.

5 ITB troubleshooting

5.1 Baclofen Withdrawal

Baclofen withdrawal is a known risk of ITB therapy and is considered a medical emergency[10]. The aim of early treatment is to manage symptoms and to prevent progression to a cascade of increasing muscle rigidity, rhabdomyolysis, disseminated intravascular coagulation, DIC, multi-organ failure, cardiac arrest and death. Baclofen withdrawal may resemble autonomic dysreflexia, sepsis, malignant hyperthermia, or neuroleptic malignant syndrome. Symptoms usually evolve over a 1 – 3 day period[10, 12, 13].

5.1.1 Causes of ITB withdrawal

Withdrawal implies a reduction in delivery of baclofen to the intrathecal space. This can be due to:

1. Missed refill appointment resulting in low pump reservoir volume
2. Pocket refill – usually the result of human error during pump reservoir refill, where the baclofen is injected into the subcutaneous tissues around the pump rather than the reservoir.
3. Human error in reprogramming of the pump.
4. Pump dysfunction
5. End of battery life – pump batteries normally last 5-7 years, an alarm will sound if the battery is low
6. Motor stall
7. Catheter dysfunction - the catheter can disconnect from the pump, kink, fracture and/or migrate out of the intrathecal space.
8. Withdrawal may occur if weaning down of the baclofen dose is occurring, or as rebound symptoms after treatment for baclofen overdose.
9. Planned emergency removal of a pump secondary to infection or pump malfunction.

5.1.2 Presenting symptoms and signs of ITB withdrawal

Can include:

- Increase in spasms and muscle tone
- Pain
- Pruritus
- Sweating and flushed
- Fever

- Restlessness/agitation or change in cognitive status
- Hallucinations/delirium/delusions/paranoia
- Poor sleep – unable to settle at night
- Tachycardia
- BP increased or decreased

5.1.3 Initial management of ITB withdrawal

1. During work hours families who suspect a pump problem call the Kids Rehab CNC on 9845 2815, page 6431 or the Kids Rehab Fellow on call on 6401 or 6446. Outside work hours, families phone the Kids Rehab physician on call via switchboard. Patient history and troubleshooting at this point often determine how quickly the child needs to attend hospital, either their nearest hospital or CHW. The consultant may instruct the family to start high dose oral baclofen.
2. Initial management should be instigated by the emergency physicians in ED[17]. If possible, Kids Rehab should be called once the child has been initially assessed. This can be done while investigations for differential diagnosis are being done.
3. **DO NOT PERFORM A LUMBAR PUNCTURE** – there is a risk that the catheter will be damaged in the process
4. The Kids Rehab may ask for the following information when called:
    a. Whether the child is sweating and if they have high or low tone
    b. What medicine the child has been given already, for example oral baclofen, diazepam
    c. Date of last refill/implantation/change of dose (as per most recent letter in the patient's Action Plan, see Powerchart or Health-e-care). Have they had a recent MRI (can cause motor stall)
5. Initial management includes looking for a differential diagnosis/cause such as:
    d. Assessing abdomen, examining for signs of swelling, redness or tenderness over the baclofen pump site.
    e. Assessing lumbar spine to look for signs of swelling over laminectomy scar
    f. Pain triggers such as constipation, GORD, dysmenorrhea, urinary retention, renal calculi, abdominal pathology, ingrown toe nail, fractures, pressure ulcers, recent surgery
    g. Infection – pneumonia, UTI, cellulitis, osteomyelitis, meningitis
    h. Allergic reaction – pruritus, hypotension, general distress
6. X-rays of the pump and catheter are required – the aim is to visualise the entire length of the catheter to the catheter tip[14]. As a minimum:
    i. AP view of the pump – to identify the orientation of the pump, catheter access port and pump catheter connection and also an AP view of the spine where

you may or may not be able to identify the tip (usually the tip is in the cervical spinal region)

j. Lateral/oblique view of the pump – allows visualization of the catheter into the intrathecal space – around L2/3. This will also allow a view behind the pump to ensure the catheter is not coiled.

k. Upper thoracic/cervical spine X-ray - to visualise the entire course of the catheter and the tip.

l. Interpretation of the catheters is difficult, especially in children with spinal rodding. The new catheters (since 2011) are less radiopaque and more difficult to see on plain X-Ray. However the tips are radiopaque.

5.1.4 Medical treatment of ITB withdrawal

If there is no obvious differential and the child has continuing symptoms:

1. Give stat dose oral baclofen:
    a. < 30kg 10 mg stat then 4 – 6 hrly, max dose 60mg / day
    b. > 30kg 20mg stat then 4 – 6 hrly, max dose 120mg
    c. Oral doses are administered even though the baclofen pump may also be delivering a dose.
2. Cyproheptadine hydrochloride (Periactin)[10,15,16] orally 4 mg 8-hourly initially to help with pruritus. Increase to maximum of 8mg – orally 8-hourly depending on positive and negative effects, e.g. drowsiness.
3. Diazepam 2.5 - 10 mg every 4-6 hours as required to help with spasms, agitation and anxiety
4. If symptoms continue that resemble dystonic status (sweating, low grade temperature, agitation, pruritus, altered consciousness, tachycardia, tachypnea, hypo/hypertension and an inability to settle or sleep, IV medication may need to be considered. This will generally require management in PICU).
5. Escalation plan - call PICU registrar/fellow on call
6. Ensure adequate hydration – may require iv fluids

5.2 ITB Overdose

Overdose may occur insidiously or suddenly. There is no specific antidote for baclofen overdose[15]

5.2.1 Causes of ITB overdose

1. Human error – during re-programming the pump
2. Pump malfunction – over-delivery of baclofen[10]
3. Catheter malfunction – migrated or kinked resulting in surge of baclofen with unkinked/moves position

4. New patient with a sensitivity to baclofen
5. Wrong drug concentration

5.2.2 Presenting symptoms and signs of ITB overdose

Can include:

- Dizziness
- Drowsiness/delirium and confusion – can lead to coma
- Hypotonia
- Reduced respiratory rate – can lead to apnoea
- Bradycardia/tachycardia
- Seizures
- BP instability

5.2.3 Initial management of ITB overdose

1. During work hours families who suspect a pump problem call the Kids Rehab CNC on 9845 2815, page 6431 or the Kids Rehab Fellow on call on 6401 or 6446. Outside work hours, families phone the Kids Rehab physician on call via switchboard. Patient history and troubleshooting at this point often determine how quickly the child needs to attend hospital, either their nearest hospital or CHW.
2. Initial management will be instigated by the emergency physicians in ED. However it is important that the Kids Rehab physician on call is called as soon as the child has been initially assessed.
3. Utilise Poisons Information Centre Hotline Ph: 13 11 26 for advice
4. Exclude differential diagnoses including:
    a. Sepsis
    b. Electrolyte imbalance/ hypoglycaemia
    c. Intracranial event
    d. Seizures/non-convulsive status
    e. Deliberate/accidental overdose of enteral medication, e.g. anticonvulsants
5. Initial investigations include:
    f. FBC, CRP, ESR, CK, EUC, LFT's, blood cultures, glucose
    g. Consider drug levels – e.g. anticonvulsants, benzodiazepines
    h. MSU, CXR, throat swab, NPA
6. Consider neuroimaging **DO NOT PERFORM A LUMBAR PUNCTURE** – there is a risk that the catheter will be damaged in the process.
7. The Kids Rehab team may require the following information:

i. Pulse, BP, saturations, temperature, level of alertness using GCS+/- AVPU scale.

j. A general assessment of tone

k. Any other medications that have been given

l. Date of the last refill/implantation/change of dose (as per most recent letter in the patient's Action Plan, see Powerchart or Health-e-care)

5.2.4 Medical management of ITB overdose

1. Supportive care of the patient.
2. Stop further drug administration.
3. Reduce concentration and total amount of drug in the CSF.

   There is no specific antidote for treating overdoses of intrathecal baclofen, but the following steps can be considered:

4. Residual baclofen solution removed from the pump reservoir and catheter
5. Patients with respiratory depression should be intubated and ventilated, if necessary, until the drug is eliminated
6. Cardiovascular function should be supported
7. In the event of convulsions, intravenous diazepam may be administered cautiously

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