Level of Evidence
Clinical Guidelines
Royal Children's Hospital

The Hierarchy of Evidence

The Hierarchy of evidence is based on the National Health and Medical Research Council (2000) and Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001)

I Evidence obtained from a systematic review of all relevant randomised control trials.

II Evidence obtained from at least one properly designed randomised control trial.

III-1 Evidence obtained from well-designed pseudo-randomised controlled trials (alternative allocation or some other method).

III-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case control studies, or interrupted time series with a control group.

III-3 Evidence obtained from comparative studies with historical control, two or more single–arm studies, or interrupted time series without a parallel control group.

IV Evidence obtained from case-series, either post-test or pre-test and post test.

V Expert opinion without critical appraisal, or based on physiology, bench research, or historically based clinical principles.

Clinical guidelines are based on reviews of the best available evidence. **Level 1 evidence represents the gold standard for intervention studies;** however it is not available for all areas of practice and for some guidelines it may be appropriate to utilise results from studies with lower levels of evidence. Some clinical guidelines may also be informed by experts in the field, locally (RCH) and internationally (Journal articles) (expert opinion) etc. This NHMRC Hierarchy can be used to grade evidence. Please record details on the evidence table and return to Clinical Quality and Safety (CQS) with guideline draft. The Evidence table can be filled out electronically or printed and used as a hard copy.

Please contact Jody Smith Clinical Guideline and Path Coordinator on ext 6956 if you have any concerns or require assistance.

Hospital Clinical Guidelines
EVIDENCE TABLE

GUIDELINE TOPIC: Intrathecal Baclofen Therapy

Please record all references used in developing the clinical guideline. This form must be filled out electronically and emailed to Jody.Smith@rch.org.au
NB: If you need assistance with completing this table, please contact Jody Smith on x 6956.

Reference ***(include author, year of publication, journal title volume and issue, pages)***	**Method**	**Evidence level (I-IV)**	**Summary of recommendation from this reference (point form)**
Olesch C Intrathecal Baclofen Protocol written by Royal Children's Hospital, Melbourne	Unpublished departmental protocol.	V	Information reflects was it believed to be best practice and based on good clinical principles. It is based on expert clinical opinions that have not been critically reviewed.
N Zuckerbraun, Ferson S, Albright L, Vogeley E. (2004) Intrathecal Baclofen Withdrawal: emergent recognition and management Paediatric Emergency Care. V 20 (11) p:759-64	Illustrative case	V	• High Index for suspicion for malfunction and subsequent baclofen withdrawal must be kept • Early recognition and treatment required to minimise morbidity and mortality. • Withdrawal associated with: rebound Spasticity, hyperthermia, pruritus hypotension, rhabdomyolysis, disseminated intravascular coagulation
Shirley K, Kothare S, Piatt J, Adirim T. (2006) Intrathecal Baclofen Overdose and withdrawal., Paediatric Emergency Care, V (22) p: 258-261	Illustrative case	V	• Baclofen toxicity may be confused with sepsis, intracranial hemorrrahge, hypoglycaemia, and electrolyte. • Symptoms:flacidity, hyporeflexia, respiratory depression, apnoea, seizures, coma, autonomic instability, hallucinations, hypothermia, and cardiac conduction abnormalities • Emergency physicians must be aware of the mechanics of the pump and spinal catheter systems and of the management of baclofen toxicity and withdrawal

Tilton A (2004) Management of Spasticity in Children with Cerebral Palsy. Seminars in Pediatric Neurology 11(1) p58-65	review	V	• Over view of ITB management • Outlines differences between types of therapy for cerebral palsy and the role baclofen plays amongst the treatment repertoire
Gilmartin R, Bruce D, Storrs B, Abbott R, Krach L, Ward J, Bloom K, Brooks W, Johnson D, Madsen J, Mclaughlin J, Nadell J, (2000) Intrathecal Baclofen for management of Spastic Cerebral palsy: Multicenter Trial. Journal of Child Neurology (15) 2, p71-77	Clinical Trial	III-3	• Ashworth scale is effective in assessing affect ITB trial dose has on Spasticity • 12 centre clinical trial to further assess the safety and efficacy of continuous intrathecal infusion of baclofen in patients with spastic cerebral palsy • sample size of 44 showed that reduction of spasticity could be maintained during long-term, continuous infusion of baclofen. Date focussed on reduction in lower extremities but revealed significant reduction in upper extremities as well. • Use of continuous ITB has been demonstrated as effective method of reducing spasticity, the treatment is relatively safe, minimally invasive and reversible.. • A sizeable percentage of people with cerebral palsy will benefit from continuous ITB therapy. • Study demonstrated ITB trial one off dose of 50mcg should be suitable for most patients. Small percentage of patients will need 75mcg. Rarely 100mcg dose should be required.
Albright L, (2003) Neurosurgical Treatment of Spasticity and other Pediatric movement disorder. Journal Of Child Neurology, 18(1) p: 67-78	Journal article	V	Overview of ITB therapy and other neurosurgical treatments for Spasticity
Albright AL, (1996) Intrathecal Baclofen in Cerebral Palsy Movement Disorders. Journal of Child Neurology, 11 (1) p29-35	Illustrative Case	V	• Overview of ITB therapy, all aspects of care. • Additional observations are underway to quantify the effects of continuous intrathecal baclofen infusion on communication, disability and dystonia. • Baclofen overdoses are unusual and are usually caused by pump programming errors.

Lew S, Psaty E L, Abbot R *(2005)* An unusual cause of overdose after Baclofen pump implantation: case report. Neurosurgery. 56(3)	Case Report	IV	• Details a novel complication associated with the insertion of an Intrathecal baclofen pump. • Importance of considering subdural catheter placement as differential diagnosis. • Signs and symptoms of incorrect catheter placement, • Appropriate monitoring must be performed in suspected cases because of the possibility of spontaneous or induced overdose by a sudden communication between the subdural and subarachnoid compartments.
Rawlins P (2004) Intrathecal Baclofen Therapy over 10 years. Journal of Neuroscience nursing, December 36 (6) p322-327	Chart Review	IV	• Based on subjective reporting by patients and their care team 50 patients achieved short term goals within three months as a result of the baclofen therapy. • Retrospective chart review and database development intended to identify trends in ITB management to better choses, educate and treat patients with severe spasticity • The substantial frequency of side effects and complications during long term ITB therapy indicates the need for a committed team to manage ITB
Management of Childhood Spasticity: A neurosurgical Perspective, Mandigo, C., Anderson, R., Pediatric Annals 35:5 May 2006, pages 354-362	Journal Article with Illustrative Cases	V	• How to manage trial of ITB. • Neurosurgical treatment of spasticity will continue to evolve and be refined as procedures and techniques are appropriately evaluated with reliable and validated outcome measures
Albanese A, Barnes M, Bhatia K, Fernandez-Alfarez E, Filipini G, Gasser T, Krauss J, Newton A, Rektor I, Savoiardo J, Valls-Sole J, European A systematic review on the diagnosis and treatment of primary (idiopathic) dystonia and dystonia plus syndromes: report of an EFNS/MDS-ES Task Force., Journal of Neurology, (13) p 433-444	Systematic review	III-2	• All the available evidence on outcome class IV and furthermore no standardised dystonia scales have been used; thus results are difficult to compare. Controlled studies have only been performed on the screening procedure to select candidates for long term treatment. There is no evidence to set the procedure in perspective with other treatments. • There is insufficient evidence to use this treatment in primary dystonia; the procedure can be indicated in patients where secondary dystonia is combined with spasticity.

Scheinberg A, O'Flaherty S, Chaseling R, Dexter M, (2001) Continuous intrathecal baclofen infusion for children with cerebal palsy: a pilot study. Journal of Pediatric Child health, 37 p: 283-288.	Pilot study	III-3	• Study of two subjects and measuring the change from baseline caused by continuous intrathecal baclofen at regular intervals over 6 months. • Both subjects demonstrated a reduction in spasticity.
Zahavi A, Geertzen J, Middel B, Staal M, Rietman JS. (2006) Long term effect (more than 5 years) of intrathecal baclofen on impairment, disability, and quality of life in patients with severe spasticity of spinal origin, Journal of Neurology Neurosurgery Psychiatry, 75, p: 1553-1557	Observational longitudinal study	IV	• Study aimed to evaluate long term change in impairment, disability and health related functional status in patient's treated with intrathecal baclofen for severe spasticity resulting from spinal pathology. • Long term study (five years) to determine long term effects of ITB> concluded that generally causes significant improvement in level of impairment but small group had worsening
Albright AL, Ferson S,(2006)Intrathecal Baclofen therapy in children, Neurosurg Focus 21 August	Journal Article	V	• Guideline for patient selection, guideline for trouble shooting, side effects and complications • ITB effectively treats spasticity for at least 17 years and it is and effective treatment for dystonia for at least 10 years • Multiple studies have contained reports of improved function, but no randomised controlled studies have been done. The complications of ITB therapy continue. The costs of ITB treatment are also appreciable, both in terms of pump implantation and ongoing refills. Cost/benefit studies are needed.