CASE-NOTE REVIEW OF INTRATHecal BACLOFEN IN THE MANAGEMENT OF SPINAL/SUPRA-SPINAL SPASTICITY IN THE SPINAL CORD INJURY UNIT

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Overview of outpatient ITB refill service

- Outpatient intrathecal baclofen (ITB) pump refill service
- 1 Consultant
- 1 SCIU nurse
- 21 adult patients (19 spinal, 2 supra-spinal)
- Equipment
  - Medtronic N’Vision Clinician Programmer model 8840
  - Lioresal intrathecal baclofen injection
  - Refill kit model 856X
Aims

• Overview of spasticity in SCI
• Protocols and care pathways for ITB services
• Case-note review
  - Prompted by several cases of poorly controlled spasticity and local case concerns (compounded ITB)
  - Local withdrawal of compounded VP ITB 3000mcg/mL (pharmacy instruction)
  - Lioresal ITB 2000mcg/mL with major service implications
• Conclusions
Spasticity: definition

• A motor disorder characterized by a velocity-dependent increase in tonic stretch reflexes (‘muscle tone’) with exaggerated tendon jerks, resulting from hyper-excitability of the stretch reflex, as one component of the upper motor neuron syndrome.’¹

• Decq²:
  - intrinsic tonic spasticity
  - intrinsic phasic spasticity
  - extrinsic spasticity

• Prevalence in SCI³,⁴
Spasticity: negative and positive effects

<table>
<thead>
<tr>
<th>NEGATIVE EFFECTS&lt;sup&gt;5,6&lt;/sup&gt;</th>
<th>POSITIVE EFFECTS&lt;sup&gt;7,8,9,10&lt;/sup&gt;</th>
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<tbody>
<tr>
<td>restricts ADLS</td>
<td>stability in sitting and standing</td>
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<tr>
<td>prevents effective walking and self-care</td>
<td>facilitates performance of some ADLS</td>
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<tr>
<td>pain, fatigue and sleep deprivation</td>
<td>facilitates performance of some transfers</td>
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<tr>
<td>safety compromise</td>
<td>increases spastic muscle bulk and strength (↓ osteopenia)</td>
</tr>
<tr>
<td>contractures, pressure sores and infections</td>
<td>increases venous return (↓ incidence of DVT)</td>
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<td>negative self-image</td>
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<tr>
<td>complicates the role of the caregiver</td>
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<tr>
<td>inhibits rehabilitation efforts</td>
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Spasticity assessment scales<sup>7,11</sup>
Severe spasticity: multi-disciplinary team care

Common Treatment Options

- Prevent Nociception
- ITB Therapy$^\text{SM}$
- Rehabilitation Therapy
- Oral Drugs
- Orthopedic Treatments
- Injection Therapy
- Neurosurgery

1. Baclofen 9,13,14
2. ITB 15,16,17,18
ITB therapy

• Indications
• Reduction in negative systemic side effects
• Literature for effectiveness in MS, SCI, BI and stroke
• Effective as an anti-spasticity treatment in SCI but little data on function or QOL \(^{15,16,17}\)
• Recent reviews: effect of ITB on positive spasticity phenomena and QOL \(^{18}\)
• Possible complications
Clinical protocols, care pathways, guidelines.....

• No specific national guidelines for ITB in the management of spasticity of spinal origin; variable local protocols
• NHS Commissioning Board ‘Clinical Commissioning Policy: Intrathecal Baclofen’
• NICE (clinical audit tool)- ‘Spasticity in children and young people: intrathecal baclofen’
• Medtronic- patient selection, pre-implant education resources, post-implant education and patient care
Data collection sheet (1)

- **Unique identifier:**
- **Gender:**
- **Age range:**
  - 15-24 □
  - 25-34 □
  - 35-44 □
  - 45-54 □
  - 55-64 □
  - >65 □
- **Origin of spasticity:**
  - Spinal □
  - Supra-spinal □
- **Diagnosis:**
  - Traumatic spinal cord injury □
  - Non-traumatic spinal cord injury □
  - Traumatic brain injury □
  - Hypoxic brain injury □
  - Cerebrovascular accident □
  - Cerebral palsy □
  - Hereditary spastic paraplegia □
  - Other □

- **Functional classification of injury:**
  - Paraplegia □
  - Tetraplegia □
  - Complete □
  - Incomplete □
  - Wheelchair user- Yes □
  - No □
  - Yes- Manual □
  - Powered/Electric □
- **Pump manufacturer/model:**
- **Date of insertion of current pump:**
  - First pump □
  - Replacement pump □
  - If replacement, time from original pump insertion

- **Other medications prescribed for spasticity:**
  - Yes □
  - No □

- **Current concentration/dose of ITB:**
  - 1000mcg/ml □
  - 2000mcg/ml □
  - 3000mcg/ml □
  - Dose (mcg/day):

- **Current manufacturer of ITB:**
  - Victoria Pharmacy □
  - Lioresal □
  - Other □

- **Poor spasticity or spasm control during last year:**
  - Yes □
  - No □

- **Current manufacturer of ITB:**
  - Victoria Pharmacy □
  - Lioresal □
  - Other □

- **Potential secondary causes identified?**
  - Yes □
  - No □

- **Change in manufacturer/concentration during last year:**
  - Yes □
  - No □

- **Adjustments to ITB dose during previous year:**
  - Yes □
  - No □

- **Response to dose adjustment:**
  - Yes □
  - No □

**Common complications**

- UTI □
- Pressure sore □
- Chest infection □
- Bladder calculus □
- Renal calculus □
- Pain □
- Catheter problem □
- Faecal impaction □
- Ingrown toenail □
- DVT □
- Heterotopic ossification □
- Post-traumatic syrinx □
- Other □
Reported pharmacological complications of ITB (under/overdose):

Response at next refill appointment to altered concentration/manufacturer:

- **Technical complications:**
  - Pump problem- Yes □ No □
  - Catheter problem- Yes □ No □
- **Neurosurgical referral during previous year:** Yes □ No □
  - Reason-______________

- **ITB pump refill appt (most recent):**
  - Assess patient’s general condition and response to ITB therapy? Yes □ No □
  - Identify need for dose titration? Yes □ No □
  - Confirm system performance? Yes □ No □
  - Refill pump? Yes □ No □
  - Determine interval to next refill? Yes □ No □
  - Programme pump? Yes □ No □
  - Document patient care/prescribing information? Yes □ No □
  - Conduct ongoing information about ITB when relevant? Yes □ No □
  - Schedule next refill appt? Yes □ No □
  - Verify battery life of pump? Yes □ No □
  - Check reservoir alarm status? Yes □ No □
  - Critical/non-critical alarm review? Yes □ No □
Demographics: gender breakdown

- Male: 14
- Female: 7
Demographics: age range

AGE RANGE
- 15-24
- 25-34
- 35-44
- 45-54
- 55-64

NUMBER OF PATIENTS
- 2
- 4
- 6
- 8
- 1
Demographics: diagnosis

- 16: Traumatic Spinal Cord Injury
- 2: Non-Traumatic Spinal Cord Injury
- 1: Hypoxic Brain Injury
- 1: Cerebral Palsy
- 1: Hereditary Spastic Paraplegia
Demographics: functional classification of injury level

9 TETRAPLEGIA
12 PARAPLEGIA
Demographics: complete versus incomplete injury

- Complete: 12
- Incomplete: 7
- Supra-Spinal Spasticity (N/A): 2

Legend:
- COMPLETE
- INCOMPLETE
- SUPRA-SPINAL SPASTICITY (N/A)
Demographics: all non-ambulant (wheelchair users)

- MANUAL: 10
- POWERED: 8
- MANUAL POWER-ASSISTED: 2
- SPECIALIST SUPPORTIVE SEATING: 1
Demographics: first versus replacement ITB pump

(8840 SynchroMed IIB)

- First ITB Pump: 13
- Replacement ITB Pump: 8

Legend:
- First ITB Pump
- Replacement ITB Pump
Number of ITB pumps per patient

- 1 pump: 8 patients
- 2 pumps: 6 patients
- 3 pumps: 3 patients
- 4 pumps: 3 patients
- 5 pumps: 1 patient
Increased spasticity or poor spasm control
Number of patient refill attendances with increased spasticity
Potential secondary factors identified with an episode of spasticity

- ITB PUMP SKIN EROSION/CELLULITIS
- CHEST INFECTION
- NEUROPATHIC PAIN
- ITB CATHETER DISLODGED
- INFECTION (SURGICAL WOUND)
- FRACTURE (FEMUR)
- PAIN/HYPERSENSITIVE PUMP SITE
- HIP PAIN
- UTI/RENAL CALCULUS
- RENAL/BLADDER CALCULUS
- UTI/PRESSURE SORE
- PRESSURE SORE
- UTI

NUMBER OF EPISODES
Classification of spasticity

- Increased Tone
- Increased No. of Spasms
- Increased Tone and Increased No. of Spasms
Objective assessment of tone

METHOD OF ASSESSMENT OF TONE

HISTORY AND MAS

HISTORY AND EXAM

CLINICAL HISTORY WITHOUT EXAM

NO. OF PATIENTS
ITB dose adjustments ↑

![Bar chart showing the number of dose increases per category]
ITB manufacturer/concentration adjustment

- YES: 17
- NO: 4
Altered clinical status after manufacturer adjustment?
Other medications prescribed for spasticity
Other medications prescribed for spasticity

- Baclofen: 5
- Dizepam: 1
- Tizanidine: 2
- Clonazepam: 2
- Botulinum Toxin (IM): 1
Other medications prescribed for spasticity

1: **BACLOFEN** and **TIZANIDINE** - ↑ spasms

2 (CP): **BOTULINUM TOXIN IM**

3: **BACLOFEN** and **CLONAZEPAM** - ↑ spasms (pump exploration with IT catheter replacement)

4: **CLONAZEPAM** and **DIAZEPAM** - violent leg spasms (pump exploration)

5: **BACLOFEN** - ↑ spasms (pump replacement date surpassed)

6: **BACLOFEN** and **TIZANIDINE** - increased leg spasms (pump exploration)

7: **BACLOFEN** and **TIZANIDINE** - reduced to 0 after new ITB pump inserted
Technical complications

- Pump problem: 1 patient
- Catheter problem: 2 patients
- Suspected pump problem: 2 patients
- Suspected catheter problem: 1 patient
Most recent ITB refill appointment

ITB pump refill appointment (most recent):
- Assess patient’s general condition and response to ITB therapy? Yes No
- Identify need for dose titration? Yes No
- Confirm system performance? Yes No
- Refill pump? Yes No
- Determine interval to next refill? Yes No
- Programme pump? Yes No
- Document patient care/prescribing information? Yes No
- Conduct ongoing information about ITB when relevant? Yes No
- Schedule next refill appt? Yes No
- Verify battery life of pump? Yes No
- Check reservoir alarm status? Yes No
- Critical/non-critical alarm review? Yes No

100% compliance with all of the above steps
Conclusions

- 16/21 (76%) had symptoms of spasticity at some point over the year.
- 1 patient reported improvement in spasticity following a change in manufacturer to licensed ITB.
- Previous off license use of VP ITB had been satisfactory, although research studies only involved Lioresal.
- National guidelines do not exist for service users and local protocols vary.
- Proposed Care Pathway for ITB Therapy (West Midlands Rehab Centre, March 2003).
- Future directions - local and national guidelines for service users to standardize care and support audit and research.
References


