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Disciplines
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SPINAL CORD INJURY

Critically Appraised Topic

Prepared by: Morgan Williams
Date: November 14, 2008
Review date: November 11, 2008

**Focused Question:**

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**Clinical Scenario**

| Roughly 70% of those experiencing a spinal cord injury are spastic 1 year after their injury (Kirshblum, 1999). The increase in tone for many interferes with functional activities of daily living (grooming, hygiene, and self-care skills), sleep, self-esteem, mood, and sexual function. In some cases the spasticity can cause pain (Marciniak, Rader, & Gagnon, 2008). Many different treatments exist to address problematic spasticity, including rehabilitation modalities (cold, electrical stimulation, etc), pharmacological (Diazepam, Dantrolene, Clonidine, Tizanidine), injection techniques (peripheral nerve block, botulinum toxin), surgery (Rhizotomy, nerve cuts), stretching, and splinting.  
Possible clients that would benefit from this treatment, according to this research, might be men and women who have sustained a spinal cord injury and are experiencing the secondary effect of spasticity in the upper or lower extremities or even in muscles that control bowel and bladder functions. Years since injury do not seem to make a significant difference in both treatment approaches (electrical stimulation or botulinum toxin injections).  
Occupational therapists are interested in knowing what evidence exists that supports using botulinum toxin injections versus transcutaneous electrical nerve stimulation (TENS) to treat spinal cord injury related spasticity. |

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Prepared by: Morgan Williams   Date: 11-14-08
Summary of key findings
Summary of Levels I, II, III

Of the four Level I-III studies that examined the treatment of spasticity to improve participation in areas of occupation, one (MacDonald, Fink, Huckabay, Monga, & Wilt, 2007) looked at the treatment of Neurogenic detrusor overactivity with botulinum toxin injections, one (Richardson, et al., 2000) looked at the treatment of focal spasticity with botulinum toxin injections to improve passive movement, one (Skold, et al., 2002) examined the effects of functional electrical stimulation training for treating spasticity, and finally (Ji-sheng, Xiao-hong, Yu, Sheng-cheg, 1994) studied the effects of transcutaneous electrical nerve stimulation in treating spasticity. The key findings, with subfindings, follow.

- In a systematic review (MacDonald, et al., 2007), botulinum toxin (BTX-A and BTX-B) injections resulted in significant decreased number of Urinary Incontinence (UI) episodes compared to placebo, RTX, and a lower dose of BTX-A injections. All subjects who received BTX-A or BTX-B injections had at least 1 free week of UI episodes. The effects were lost between 24 weeks and 18 months.
  1. Adverse effects were mild and minimal (only 5 subject reports out of 104 participants)
  2. One study reported significant improvements in 5 out of 9 domains on the King's Health Questionnaire of quality of life.
- In a well controlled level I study (Richardson, et al., 2000), the group that received BTX-A injections had significantly better Ashworth Scale scores, improved Motor Function/Rivermead scores for the lower limb group, decrease in problem severity, and increased goal attainment.
  1. Even though the upper limb group did not produce significant scores, 3 of the 27 subjects who received injections reported a return to work due to improved hand function, meaning there was a noteworthy functional improvement for some.
  2. They concluded that BTX-A reduces tone and increases ROM which may lead to improvement in focal disability within a rehab program. This is significant findings for occupational therapists.
- In a cohort study (Skold, et al., 2002), functional electrical stimulation (FES) was performed for 30 minute sessions 3 times weekly for 6 months.
  1. Muscle tissue volume increased in the training group by 10%
  2. Decrease in Modified Ashworth Scores for 6 months, but not in subject rating of spasticity level
  3. Overall, no conclusive results were provided for the treatment of spasticity with FES
- In a before and after study (Ji-sheng, et al., 1994), high frequency (100Hz) transcutaneous electrical nerve stimulation for 30 minutes a day for 3 months was effective in relieving muscle spasticity
  1. Decrease in Modified Ashworth Scores, lasting only 10 minutes each day; the therapeutic effects became consolidated after consecutive daily treatments for 3 months
2. They concluded that TENS is non-invasive and comes with little to no side effects.

**Summary of Levels IV, V**

<table>
<thead>
<tr>
<th>Of the two Level IV &amp; V studies, one (Lockley &amp; Freeman, 2005) examined the effect of a multi-disciplinary approach (including BTX-A injections) in treating a patient with spinal cord injury related spasticity, and one (Kirshblum, 1999) reviewed literature on different treatment options in addressing spinal cord injury related spasticity. Both studies suggest interventions that can be experimented with on similar patients. The Level IV study (Lockley &amp; Freeman, 2005) describes its treatment in detail, as the literature review briefly describes different treatment option protocols to inquire further into if interested. Through both studies, it is proposed that careful observation of change seen in the patients will allow the practitioner to determine continuation or discontinuation of the experimental treatment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>- In a case report (Lockley &amp; Freeman, 2005), tested the effectiveness of a program that combined BTX-A injections and rehabilitation in treating a woman who was unable to carry out her daily standing and walking program, which further inhibited her ability to perform some of her daily activities. The program included goal setting, identifying factors that triggered her spasms, a self-management home program including problem solving techniques, and two rounds of BTX-A injections. At follow-up, 20 months after the start of the program, her goals were fully achieved, the Ashworth Scale score was zero, her spasm pain scale was 0/10, and her frequency score was 1/4.</td>
</tr>
<tr>
<td>1. Clinical importance: re-evaluation of progress using patient feedback and relevant/objective outcome measures and goals, close partnership between patient and therapist, strong emphasis on patient education, self-management over the long-term, and focus on the patient’s goals vs. medical impairment issues.</td>
</tr>
<tr>
<td>2. The direct effect of BTX-A injections lasted about three to four months, but the patient experienced continued reduction in resting tone without the side effects of “weakness” when standing or walking.</td>
</tr>
<tr>
<td>- In a literature review (Kirshblum, 1999), many treatment alternatives for spinal cord injury related spasticity were reviewed, including TENS and BTX-A injections.</td>
</tr>
<tr>
<td>1. TENS applied to dermatome associated with the spastic muscle was shown to have a 2 hour duration effect and a decrease on the Modified Ashworth Scale.</td>
</tr>
<tr>
<td>2. BTX-A effects were shown to peak at 2-6 weeks and lasts for 3-5 months; improvements in nursing care, hygiene, patient comfort (decrease in pain), and functional activity; drawback reported include cost and waiting of a few days to see results.</td>
</tr>
<tr>
<td>3. Overall study conclusion is that none of the detailed treatments in the study are exceptional.</td>
</tr>
</tbody>
</table>
**Bottom line for occupational therapy practice**

Occupational therapists are mainly concerned that their patients can live their life as independent as possible, doing the meaningful activities that they desire to do. In our spinal cord injured patients, spasticity can be a problematic secondary effect that makes it difficult for them to participate fully in life. Research on the treatment of spasticity is so important for occupational therapists to know about in order to be an advocate for delivering the best treatment for our clients.

The interventions that were tested and found beneficial in the Level I-III studies reviewed here include using botulinum toxin injections and transcutaneous electrical nerve stimulation to address problematic spasticity. Occupational therapists can be involved in referring clients to receive BTX-A injections or be administers of TENS. Occupational therapists can assure their patients that these interventions have been tested and found successful in improving participation with some patients. One study suggested the importance of rehab therapies in conjunction with BTX-A injection treatments (Richardson, 2000). Overall, the four Level I-III studies have pointed towards BTX-A injections being the most effective in treating spinal cord injury related spasticity. The injections have a longer lasting effect and minimal adverse effects. TENS can be useful for some patients, and is non-invasive, but has a much shorter duration, requiring more treatments.

The experimental case report writers described the multi-disciplinary treatment, including BTX-A injections, in detail, but the literature review had inconclusive findings.

The ideal intervention for the treatment of spinal cord injury related spasticity is still unknown. Further research needs to be completed.

**Review process:**

- Titles of those studies retrieved by online database searches were reviewed
- Abstracts of those studies whose titles addressed the topic were reviewed
- Abstracts were read and those studies that did not address the question or did not meet inclusion criteria were not used
- The remaining studies (N=6) were retrieved either from Pacific University library system, interlibrary loan (Illiad), online sources, personal collection
- Studies that were published before 1994 were eliminated (N=1)
- Each study was read and those not meeting inclusion criteria were further deleted (N=4)
- Each of the remaining studies was analyzed and the evidence table was completed. For this question, six studies were analyzed
Inclusion criteria

- Published between 1994 and 2008
- All levels of evidence, including case reports (Level V), were located and reviewed
- Majority of participants were persons with spinal cord injury
- Participants were adults (> 18 years)
- Written in English

Exclusion criteria

- Longitudinal observational studies of natural history of recovery
- Descriptions of programs or of treatments without testing effects
- Written before 1994
- If majority of participants did not have spinal cord injury (i.e. stroke, MS)

Search strategy

<table>
<thead>
<tr>
<th>Categories</th>
<th>Key search terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient/client population</td>
<td>Spinal cord injury(ies)</td>
</tr>
<tr>
<td>Intervention</td>
<td>Botulinum toxin, transcutaneous electrical nerve stimulation, functional electrical stimulation, spasticity and TENS, spasticity and SCI, treatment alternatives and SCI, muscle spasticity and Transcutaneous electrical nerve stimulation and SCI, muscle spasticity and Botulinum Toxin and SCI, botulinum toxin and transcuatenous electrical nerve stimulation</td>
</tr>
<tr>
<td>Comparison</td>
<td>Systematic reviews, randomized control trials, meta-analysis, case report</td>
</tr>
<tr>
<td>Outcome</td>
<td>Decrease spasticity</td>
</tr>
</tbody>
</table>

Audit trail

- The only limit used while researching for studies: peer-reviewed
- Limits used for selecting articles for reviewing: I am not an experienced researcher, search was thorough but not exhaustive, also see inclusion/exclusion criteria

<table>
<thead>
<tr>
<th>Databases</th>
<th>Terms</th>
<th>Retrieved</th>
<th>Reviewed</th>
<th>Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cochrane</td>
<td>Botulinum toxin &amp; Spinal Cord Injury (SCI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>TENS &amp; SCI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Transcutaneous electrical nerve stimulation (TENS) &amp; SCI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spasticity &amp; SCI</td>
<td>8</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Spasticity &amp; TENS</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>
Treatment alternatives & SCI | 4 | 1 | 1
CINAHL
Muscle spasticity & TENS & SCI | 89 | 2 | 1
Muscle spasticity & botulinum toxin & SCI | 10 | 2 | 1
Botulinum toxin & TENS | 1 | 1 | 1
Medline
Systematic review & botulinum toxin & SCI | 5 | 1 | 1
Systematic review & TENS & SCI | 0 | 1 | 1
Case report & SCI | 6 | 1 | 1
Class handout
Spasticity & SCI | 1 | 1 | 0
Personal
OT & botulinum toxin | 1 | 1 | 0

**Quality control/Peer review process**
Only the author reviewed these articles. The studies were read twice and reviewed further when questions arose.

**Results of search:**
*Summary of study designs of articles selected for appraisal*

<table>
<thead>
<tr>
<th>Level of evidence</th>
<th>Study design/methodology of selected articles</th>
<th>Number of articles selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Systematic reviews, meta-analysis, randomized controlled trials</td>
<td>2</td>
</tr>
<tr>
<td>II</td>
<td>Cohort, case control</td>
<td>1</td>
</tr>
<tr>
<td>III</td>
<td>Before and after</td>
<td>1</td>
</tr>
<tr>
<td>IV</td>
<td>Single subject, case series</td>
<td>1</td>
</tr>
<tr>
<td>V</td>
<td>Case report, expert opinion (lit review)</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Qualitative studies</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td><strong>Total:</strong> 6</td>
<td></td>
</tr>
</tbody>
</table>

**Limitations of studies appraised:**

**Levels I, II, III**

*Level I*
Heterogeneity of the sample and the inability for the researchers to control the rehabilitation that the participants were receiving before their inclusions in the trial (Richardson, et al., 2000)

*Level II*
Small sample size, incomplete information on how participants were recruited and no clear clinical importance (Skold, et al., 2002)

*Level III*
Inadequate information on participant recruitment and data collection process; absence of control group (Ji-sheng, et al., 1994)
<table>
<thead>
<tr>
<th>Levels IV, V</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level IV</strong></td>
</tr>
<tr>
<td>No controls for intervening variables; no statistical analyses; inability to generalize the results</td>
</tr>
<tr>
<td><strong>Level V</strong></td>
</tr>
<tr>
<td>Minimal information on participants from the various treatment studies reviewed; no controls for intervening variables; no statistical analyses</td>
</tr>
</tbody>
</table>
**Articles selected for appraisal:**


**References:**