Introduction

• Lower limb spasticity is a common disabling feature in children with cerebral palsy.
• In addition to interfering with daily activities, mobility and personal hygiene, spasticity can be associated with pain, discomfort, and psychological disturbance.²
• Spasticity treatments include physiotherapy, oral pharmacotherapies, toxin injections, and orthopedic surgeries.²
• In Canada, toxin therapy is indicated for a specific subset of pediatric lower limb spasticity (equinus foot deformity), however there is evidence that this treatment is being used off label to treat a wider range of spasticity patients.
• In Canada, health resource use among this patient population is largely unknown, including the proportion of patients receiving toxin therapy.
• The objective of this study was to characterize resource use associated with management of pediatric lower limb spasticity.

Methods

• A resource use questionnaire was developed and administered to a sample of Canadian physicians who regularly treat children with lower limb spasticity.
• A clinical expert provided guidance during questionnaire design.
• Questionnaire sections included:
  • General information (including setting of treatment, measurement scales, treatment goals).
  • Use of toxin therapy and use of oral pharmacotherapies.
  • Annual frequency of hospitalizations and ambulatory care (including outpatient visits, physiotherapy, and radiology).
  • Questionnaire participants were identified through scientific publications, employment with known treatment centers in Canada, and referral from other study participants.
  • Physicians were contacted via email with requests to collaborate, and the 30-minute phone questionnaire was administered by a trained researcher.
• Questionnaire results were synthesized and ranges of numerical responses were reported.

Results

Study sample

Six physicians from pediatric hospitals and rehabilitation centers across Canada completed the questionnaire (Figure 1). All physician respondents treated patients with lower limb spasticity in outpatient clinic settings.

• Medical specialties included orthopedics, pediatrics (including developmental and neurology subspecialties), and pediatric neurosurgery.

Questionnaire results

• General functioning, health related quality of life (HRQoL), and pain were indicated as elements of the patients’ condition that were most important to target with spasticity treatment.
• Among pediatric spasticity patients, resource use was reported to differ for unilateral compared to bilateral spasticity, and by baseline gross motor function, as measured by the gross motor functional classification system (GMFCS; Table 1).
• Questionnaire results indicate that pediatric spasticity patients are primarily managed in the outpatient setting.
  • Annual outpatient visits include specialist office (2-3 per year), physiotherapy (6-20 per year), and botulinum toxin A injections (2-4 per year).
  • Hospitalizations for spasticity management are rare, but may occur in this population for other complications of cerebral palsy (e.g. intractable seizures).
  • Radiology visits may include annual hip surveillance X-rays.
  • Current pharmacotherapies for lower limb spasticity include oral baclofen, (which is more likely to be used in patients with bilateral spasticity and GMFCS IV-V) and botulinum toxin A, including off-label use, as it has historically only been indicated in specific subtypes of lower limb spasticity.
  • Lower limb orthopedic surgeries such as hip adductor releases, tibiofemoral lengthening, and hamstring lengthening are common in this population.
  • Neurosurgeries such as rhizotomy and baclofen pump insertion occur less frequently and among severe cases only.

Effect of toxin therapy on resource use

There was consensus among clinicians, that toxin use affected overall resource use:

1. Toxin therapy may delay time to orthopedic surgeries, facilitate casting and the use of orthoses, and reduce the number of repeat surgeries required.

Results (cont.)

2. With toxin therapy, it may be possible to reduce dose of oral baclofen, or discontinue this medication use all together. This reduces the risk of unwanted side effects associated with oral baclofen.
3. There is a variable effect of toxin therapy on health resource use (Figure 2). Within the first year after initiating toxin therapy, resource use may increase slightly (due to increased ability to undergo physiotherapy), or stay the same. During the second year after initiating a toxin, resource use may stay the same, or slightly decrease. In the third and subsequent years after toxin initiation, resource use will likely decrease, by approximately 30-50%.

Limitations

• Limitations of this analysis include a relatively small sample size of clinical experts.
• While experts were sought from across the country, there were no respondents from central or eastern Canada, and it is possible that treatment patterns could differ in these areas, as differences in healthcare system organization exist across provinces.
• Respondents indicated a high level of variability at the individual level.

Conclusions

• There is a lack of published evidence describing health resource use for children with lower limb spasticity in Canada.
• These patients are treated primarily in outpatient clinic settings, with high use of physiotherapy.
• Toxin therapy is a common treatment in Canada, despite being used off-label for this indication.
• Anecdotal evidence from Canadian physicians suggests that toxin therapy and continued long-term treatment may allow:
  • Reduced oral pharmacotherapies,
  • A delay to orthopedic surgeries,
  • Reduced need for outpatient services such as physiotherapy.

Table 1. Description of pediatric GMFCS levels²

<table>
<thead>
<tr>
<th>GMFCS Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Walks without limitations</td>
</tr>
<tr>
<td>II</td>
<td>Walks with limitations</td>
</tr>
<tr>
<td>III</td>
<td>Walks using a hand-held mobility device</td>
</tr>
<tr>
<td>IV</td>
<td>Self mobility with limitations; may use powered mobility</td>
</tr>
<tr>
<td>V</td>
<td>Transported in a manual wheelchair</td>
</tr>
</tbody>
</table>

Table 2. Description of pediatric GMFCS levels²

<table>
<thead>
<tr>
<th>Treatment year</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3+</th>
</tr>
</thead>
<tbody>
<tr>
<td>No toxin therapy or non-response to toxin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spasticity management 2-3</td>
<td>2-3</td>
<td>2-3</td>
<td>2-3</td>
</tr>
<tr>
<td>PT - 60 viable</td>
<td>10-20% on oral baclofen</td>
<td>10-20% on oral baclofen</td>
<td>10-20% on oral baclofen</td>
</tr>
<tr>
<td>Effectively treated with toxin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spasticity management 2-3</td>
<td>2-3</td>
<td>2-3</td>
<td>2-3</td>
</tr>
<tr>
<td>PT - 60 viable</td>
<td>10-20% on oral baclofen</td>
<td>10-20% on oral baclofen</td>
<td>10-20% on oral baclofen</td>
</tr>
<tr>
<td>Oral baclofen dose reduction or elimination</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PT - 60 viable</td>
<td>10-20% on oral baclofen</td>
<td>10-20% on oral baclofen</td>
<td>10-20% on oral baclofen</td>
</tr>
<tr>
<td>PT - 60 viable</td>
<td>10-20% on oral baclofen</td>
<td>10-20% on oral baclofen</td>
<td>10-20% on oral baclofen</td>
</tr>
</tbody>
</table>

Figure 1. Participating physicians’ geographical locations in Canada

Figure 2. Treatment pathway for children with lower limb spasticity in Canada