TITLE: Functional Electric Stimulation (FES) for Children with Cerebral Palsy: Clinical Effectiveness

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CONTEXT AND POLICY ISSUES

Cerebral palsy encompasses a variety of non-progressive clinical syndromes characterized by abnormalities of motor activity and posture, causing an affected voluntary movement to become uncoordinated, stereotypic and limited. Although the primary lesion is known to be static, neurologic symptoms may evolve with increasing age. Cerebral palsy shows high variability in terms of severity and motor impairment, and may have a substantial impact on patients and their family.

A multidisciplinary approach is imperative and treatment aims at improving daily function and maximizing quality of life. Electrical stimulation is one of the interventions offered to children with cerebral palsy, with the objective of increasing muscle strength. There are different types of electrical stimulation, usually considered minimally invasive. However, in the same way as other interventions administered to improve symptoms of patients with cerebral palsy, electrical stimulation is sometimes considered experimental and uncertainty remains regarding its efficacy on clinically relevant outcomes.

This report will review evidence from studies assessing the clinical effectiveness of functional electrical stimulation (FES) for children with cerebral palsy. This information could aid in decisions pertaining to the use of FES equipment in children suffering from this condition and more broadly in purchasing decisions and consulting.

RESEARCH QUESTION

What is the clinical effectiveness of FES including FES cycling for children with cerebral palsy?
KEY MESSAGE

The evidence included in this review suggests efficacy of FES on both impairment and activity limitations in children with cerebral palsy. However, small sample sizes, inadequate report of quality assessment of the primary studies and the high variability in the condition and in the intervention protocols lessen the strength of evidence regarding the clinical effectiveness of FES on functional mobility in this population.

METHODS

A limited literature search was conducted on key resources including PubMed, EBSCO CINAHL, The Cochrane Library (Issue 3, 2011), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI (Health Devices Gold), EuroScan, Canadian and major international health technology agencies, and a focused Internet search. The search was limited to English language articles published between January 1, 2006 and March 18, 2011. No filters were applied to limit the retrieval by study type.

There are several types of electrical stimulation. For the purpose of this report, only references pertaining to FES were considered relevant.

SUMMARY OF FINDINGS

The literature search identified one systematic review which included a meta-analysis.⁴ Health technology assessments, randomized controlled trials, non-randomized studies and evidence-based guidelines were also searched, but no literature was found.

Potentially relevant publications which did not meet inclusion criteria are listed as supplemental references in the appendix.

Systematic reviews and meta-analyses

Cauraugh et al. (2010)⁴ conducted a systematic review and meta-analysis using the World Health Organization International Classification of Functioning to evaluate the effect of three types of electrical stimulation including FES on impairment and activity limitations in children with cerebral palsy. This systematic review focused on the leg and gait patterns; hence studies involving either the arms or the trunk were excluded. A total of 17 studies met the inclusion criteria, amongst which 12 studies were randomized controlled trials and 5 studies employed a non-randomized design. Treatment protocols consisted of FES, neuromuscular electrical stimulation or therapeutic electrical stimulation administered across several sessions as an intervention for gait deficits. Only five studies pertained specifically to FES (two randomized controlled trials and three studies employing a non-randomized design). These five studies were published between 2004 and 2008. In one study there were 2 treatment sessions, in one study there were 12 treatment sessions and in the remaining three studies the treatment duration ranged between 4 and 12 weeks.

Fourteen studies reported impairment outcome measures, including range of motion, torque and strength while 15 studies reported activity outcome measures, including gross motor function and gait parameters. Amongst the studies focusing on FES, two reported impairment outcome measures and four reported activity outcome measures. A summary of the main findings is presented in Table 1 and Table 2.
Table 1: Effect of FES in children with cerebral palsy

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of studies*</th>
<th>Number of patients*</th>
<th>Standardized mean difference†</th>
<th>Statistical significance, p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impairment</td>
<td>2</td>
<td>35</td>
<td>0.618</td>
<td>p&lt;0.01</td>
</tr>
<tr>
<td>Activity limitations</td>
<td>4</td>
<td>58</td>
<td>0.717</td>
<td>p&lt;0.0002</td>
</tr>
</tbody>
</table>

FES=Functional electrical stimulation;

* Number of studies and number of patients contributing to the summary estimates by meta-analysis.
† For each study included in the meta-analysis, mean effect sizes were calculated and these values were compared in standardized mean differences calculations to produce overall effect sizes.  

Table 2: Effect of Electrical Stimulation Protocols (FES, NMES or TES) in children with cerebral palsy

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of studies*</th>
<th>Number of patients*</th>
<th>Standardized mean difference† (SE)</th>
<th>Statistical significance, p-value (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impairment</td>
<td>14</td>
<td>N=302 n=158 active group n=144 control group</td>
<td>0.616 (0.10)</td>
<td>p&lt;0.0001 (0.420 to 0.812)</td>
</tr>
<tr>
<td>Activity Limitations</td>
<td>15</td>
<td>N=416 n=215 active group n=201 control group</td>
<td>0.635 (0.136)</td>
<td>p&lt;0.0001 (0.369 to 0.901)</td>
</tr>
</tbody>
</table>

CI=Confidence interval; FES=Functional electrical stimulation; NMES=Neuromuscular electrical stimulation; SE=Standard error; TES=Therapeutic electrical stimulation.

* Number of studies and number of patients contributing to the summary estimates by meta-analysis.
† For each study included in the meta-analysis, mean effect sizes were calculated and these values were compared in standardized mean differences calculations to produce overall effect sizes.  

The results of the meta-analyses showed statistically significant improvement with FES on both impairment and activity limitations. The authors concluded that the medium summary effect sizes observed with the three types of electrical stimulation support their use as an intervention in children with cerebral palsy experiencing walking impairment and activity limitations.

This systematic review was limited due to the small number of studies assessing each type of electrical stimulation interventions, especially with regard to FES which was assessed in only five studies. There were some inconsistencies in the results from the individual studies. The effect size for improvement in impairment and activity limitations reached statistical significance in some studies but not in others. It is unknown whether this is due to the low sample size or to an absence of effect of the intervention. In addition, the quality assessment of the primary studies seems somewhat simplistic and consequently, it is difficult to appraise adequately the quality of the studies included in the systematic review. There is also no appraisal of the validity, reliability and clinical relevance of the outcome measurements used in the primary studies.

Furthermore, cerebral palsy is a condition characterized by high variability between patients in terms of symptom intensity and impact on motor function. Although the authors indicate that the majority of patients experienced diplegia or hemiplegia, the patients’ levels of impairment in the
included studies remain unknown. There also appears to be high variability amongst the various electrical stimulation protocols, including location on the body, duration, frequency and intensity. These specific protocol parameters used in the included studies have to be considered when applying the results to individual patients.

Limitations

We identified only one systematic review which assessed a number of electrical stimulation methods including FES. There were two randomized controlled trials and three non-randomized studies pertaining specifically to FES and insufficient information precluded an adequate appraisal of the quality of these studies.

Interpretation of the results is difficult, considering the high variability between patients and amongst the various electrical stimulation protocols. In addition, no information is available with regard to real-life improvement on patients’ daily activities, which would aid assessing the clinical relevance of the results.

The limited number of articles identified could be due to the literature search period being limited to five years, which would have excluded older studies. However, the systematic review in this report included primary studies published between 1994 and 2008, and enlarging the search period may lead to inclusion of potentially out-dated studies.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

The literature search for this rapid review identified one systematic review including meta-analyses evaluating the effect of three types of electrical stimulation including FES in children with cerebral palsy. Amongst the studies focusing on FES, impairment outcome measures were evaluated in two studies and activity outcome measures were evaluated in four studies. The literature search did not identify any evidence regarding other health outcome measures.

The results of the meta-analyses show statistically significant improvement with FES on both impairment and activity limitations in children with cerebral palsy. However, small sample sizes, inadequate reporting of quality assessment of the primary studies and the high variability in the condition and in the intervention protocols lessen the strength of the evidence regarding the clinical effectiveness of FES on functional mobility in this population and results need to be viewed with caution.

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REFERENCES:


APPENDIX: Further Information

Randomized controlled trial (involving neuromuscular electrical stimulation)


Non-randomized studies (involving related interventions)

Neuromuscular electrical stimulation


FES protocol after Botulinum toxin injection


Review articles (non-systematic methodology)


Additional references

Conference abstract on the use of FES

Prototypes development for FES cycling systems