Therapeutic electrical stimulation following selective posterior rhizotomy in children with spastic diplegic cerebral palsy: a randomized clinical trial

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A randomized controlled trial was carried out to determine the effectiveness of therapeutic electrical stimulation (TES) in improving the function of children with spastic cerebral palsy (CP), who had undergone selective posterior lumbosacral rhizotomy more than a year previously. Children were randomly assigned to groups to receive TES for 1 year, or to have no TES. The primary outcome was the change in the Gross Motor Function Measure (GMFM), a quantitative and validated measure for use in children with spastic CP. There was a statistically significant and clinically important improvement in outcome for the treated children, with the mean change in the GMFM score at one year being 5.5% compared with 1.9% in the untreated group (P=0.001). TES was simple to use, had no significant complications, and was well accepted by the children and their caregivers, as indicated by an average compliance of 93% for the application of TES on a nightly basis over the course of the study. It was concluded that TES may be beneficial in children with spastic CP who have undergone a selective posterior rhizotomy procedure more than 1 year previously.

Electrical stimulation of muscles has been used for many years to increase muscle strength and decrease spasticity, but the relationship of the stimulation parameters to outcome is little understood. Whatever stimulation parameters have been used, the therapy has generally been carried out in patients who are awake, with the aim of causing either isometric or isotonic muscle contraction.

A different approach to the electrical stimulation of muscles was tried by Pape et al. (1990), who used low-intensity electrical stimulation delivered during sleep. This technique, called therapeutic electrical stimulation (TES), did not cause active contraction of muscle, and could be used continuously while the patient was asleep. TES has been used by Pape et al. in both children and adults with a variety of motor disorders, and in children this therapy was associated with functional improvements in spastic CP and myelomeningocele (Lechty 1993, Pape et al. 1993). Although more than 2 000 patients have been treated with TES by Pape and her colleagues at the Magee Clinic (Lechty 1993), there has been little scientific evaluation of the effectiveness of TES. It was our intention to evaluate TES in a scientific manner.

In a pilot study at British Columbia's Children's Hospital (BCCH), the feasibility and effectiveness of TES performed for 12 months was explored in three groups of children: 1) five children with spastic diplegia who had selective posterior lumbosacral rhizotomy for spasticity more than 2 years previously, who had been stable in the previous six months, and who were able to walk with or without aids; 2) five children with congenital or acquired hemiplegia with a spastic hand; and 3) five children with myelomeningocele and bilateral quadriceps strength against gravity. Our experience indicated that TES was simple to perform, was well tolerated by children and their caregivers, and there were few technical problems and no significant complications associated with the therapy. The results suggested that TES might be beneficial for the group with spastic diplegic CP who had stabilized after a selective posterior rhizotomy procedure, by increasing strength, decreasing spasticity, and improving motor function as assessed by the Gross Motor Function Measure (GMFM) (Russell et al. 1989). For the children with spastic hemiplegia, TES tended to increase strength and decrease spasticity in the upper and lower limbs, but had little effect on functional abilities as assessed by either the GMFM or Quality of Upper Extremity Skills test (DeMatteo et al. 1993). In the myelomeningocele population, increased lower-limb strength was observed after TES, and in two children there was an improvement in bladder and/or bowel function.

In the pilot study, the most positive results were observed in the subjects with spastic diplegia who had a prior selective posterior rhizotomy. Therefore this group of children was chosen for a randomized clinical trial to determine the effectiveness of TES in improving motor function as assessed by the GMFM. We had hoped to do a double-blind study with the subjects and caregivers and the assessors blinded to the treatment used. However, for technical reasons it was not possible to design for the non-treated group an acceptable placebo which would allow blinding of the patients and caregivers, thus the study was single-blind only.

Method

The study was approved by the Ethics Committees of the University of British Columbia and British Columbia's

Children's Hospital. Parents were informed of all aspects of the study and consent was obtained from parents who were informed that they were free to withdraw their child from the study at any time. The study was a randomized controlled single blind-trial comparing the effect of TES for 8 to 12 hours per night for 1 year, with no TES. Randomization was blocked and stratified on baseline ambulatory status (walks unaided, walks with aids, does not walk). The randomization scheme was generated from a table of random numbers by one investigator who was not involved in patient therapy or assessment. Patients were entered into the study if the following criteria were met: 1) they were aged between 3 years and 15 years at the time of referral; 2) they had spastic CP such that motor function was impeded but had some form of upright ambulation, and more than one year had elapsed since selective posterior lumbosacral rhizotomy; 3) they were able to cooperate with the assessments; 4) they had undergone no surgical procedure affecting lower-limb function in the previous 12 months; 5) they had not participated in any previous trials of TES; 6) parents were agreeable to their child being randomly assigned to a TES group or non-TES group for a period of 12 months.

TES was delivered using a Medtronic Respond II muscle stimulator (Medtronic Neuro, Minneapolis, MN, USA), for 8 to 12 hours per night, with the apparatus on for 8 seconds' and off for 8 seconds' duration with a 2-second rise time, for a pulse duration of 300 ms, and a frequency of 35 pulses per second. The amplitude was kept low, at a strength barely noticeable by the patient, usually less than 10 milliamps. Treatment was carried out for a minimum of 6 nights per week and was continued for 12 months.

TES was applied to the abdominal and most proximal lower-limb muscles demonstrating weakness, or to the antagonists of spastic lower-limb muscles. Muscles stimulated included the abdominal muscles, gluteal muscles (medius and maximus), quadriceps femoris, and tibialis anterior. The most proximal muscles which were grade 3 or less on the manual muscle test (MRC Scale) (Daniels 1972), were the first muscles stimulated. Two muscle groups were stimulated at the same time, for example, abdominals and gluteals, or, if the abdominals were good or normal, quadriceps and gluteals. Electrodes were placed over the belly of the muscle, with the positive electrode above the negative electrode, according to the placement protocol established at the Magee Clinic of Ontario. Parents were provided with polaroid pictures of electrode placement on their child to assist them in placing the electrodes accurately. At 3-month intervals the treatment was moved to more distal muscle groups if the proximal groups attained good or normal (grade 4 or 5) muscle power. Disposable electrodes were used, and replaced as needed by the manufacturer's representative.

Children were assessed at the start of the study and at the conclusion of the project. In addition, all children had an interim review at 6 months. Assessments were performed by physiotherapists who were trained in the use of the GMFM in children with CP. Six months after the start of the study, the team of assessors met for a review of the GMFM and other outcome measures, to ensure that all assessors were continuing to apply the measures in the same way. These physiotherapists were not involved in the ongoing treatment of the study patients, and information about the patients' assigned treatment group was withheld from the physiotherapists assessing outcome.

The GMFM was chosen as the primary outcome and end point of the study. Its validity, reliability, and responsiveness have been demonstrated in a population of patients similar to those which were studied (Russell et al. 1989). A number of other parameters were assessed as secondary outcome measures: 1) The seated postural control measure (Fife et al. 1991); 2) Muscle strength (kg) of hip extensors, abductors, quadriceps, and ankle dorsiflexors using a hand-held myometer (Hyde et al. 1983); 3) Muscle tone of hip adductors, knee flexors, and ankle plantar flexors using a modified Ashworth scale (Bohannon and Smith 1987); 4) Range of motion at hips, knees, and ankles measured with a goniometer using standardized anatomical landmarks and the methods as proposed by the American Academy of Orthopedic Surgeons (Joint Motion: method of measuring and recording. American Academy of Orthopedic Surgeons, Chicago 1965); 5) Physiological cost index (Butler et al. 1984).

Following the baseline assessment, the parents or other caregivers of children randomly assigned to the TES group were instructed about the treatment protocol by the clinical coordinator, and about maintenance of the equipment by the manufacturer's representatives. Parents were provided with a diary in which to record, on a daily basis, whether or not treatment was carried out, duration of treatment, and observations regarding effects. These diaries were monitored on a monthly basis by the clinical coordinator. Parents were advised to contact the coordinator with any questions regarding the treatment, and the manufacturer's representative in the event of equipment failure. Records were kept of all such contacts. Parents were instructed to continue with any other therapy which the child was receiving, and not to modify any ongoing therapy program. If the child was receiving active treatment by a physiotherapist, the therapist was contacted and given similar instructions.

The primary outcome measure was the mean change in GMFM score over the 12-month period in the TES and non-TES groups, and these scores were compared with a t-test for independent means. The secondary outcome measures were compared in the TES and non-TES groups using χ^2 tests for categorical scales (seated postural control measure, Ashworth scale of muscle tone) and t-tests for continuous scales (myometric assessments of muscle strength and tone, range of motion, physiological cost index).

Compliance with the treatment and untoward effects of TES were assessed. The number of nights that TES was actually used was extracted from the patient diary and expressed as a percentage of the total expected minimum use of 6 nights per week to obtain a measure of compliance. If treatment in any week was carried out for 7 nights, for the purposes of calculating the compliance, using the percentage above, these 7 nights were counted as only 6. The frequency of complications and problems related to the equipment was recorded from patient diaries and from phone calls to the clinical coordinator or to the manufacturer's representative.

Sample size was estimated for comparison of mean change scores in two independent groups. The parameters chosen were $\alpha = 0.05$ (two tailed) and $\beta = 0.10$. A relatively small β (high power) was chosen since this was a potentially beneficial treatment without apparent adverse effects, and it was therefore desirable to minimize the chance of a false negative result. A clinically important difference was chosen as 1.825% on the GMFM scale based on the example described by Russell et al.

(1989) for assessment of a non-invasive therapy. Standard deviation of the change scores in our pilot project was used to estimate the population variance at 1.5% on the GMFM scale. Using these parameters and standard sample size calculation tables (Machin and Campbell 1987), the requirements were 22 patients per group or a total of 44 patients who were eligible and agreed to participate.

Results

Twenty-two children were randomly assigned to each arm of the study. Two children in the therapy group and one in the control group dropped out after randomization because of social reasons that did not permit the caregivers to bring the child back for the assessments required by the study protocol. No assessments of outcome were possible on these three patients.

Children in the TES group ranged in age from 4.3 to 10.0 years (mean 7.2 years), and in the control group from 5.1 to 10.3 years (mean 7.3 years). The mean time between the posterior rhizotomy procedure and the start of the study was 35.0 months for the TES group (range 14 to 67 months), and 34.8 months for the control group (range 13 to 67 months).

The comparability of the treatment and control groups was assessed by examining baseline measurements of all of the outcome measures, including GMFM, physiological cost index, sitting scale, and the 20 measures of range, spasticity, and strength. There were no significant differences between the two groups at baseline (Table I). There was no significant difference between the two groups with respect to the number of contacts between parents and investigators. Two parents in the TES group contacted the investigators outside the planned assessments, one for clarification of the original instructions, and the other to return a failed stimulator.

PRIMARY OUTCOME

The mean change in GMFM in the treatment group was 5.5% and the mean change in the non-treatment group was 1.9%, for a difference in means of 3.6% (95% confidence intervals for the difference in means = 1.7% to 5.4%). These means were significantly different (t=3.88, P=0.001). In order to give an idea of what GMFM improvements of 5.5% and 1.9% mean in functional terms, the specific functional changes are detailed for sample patients from the treatment and non-treatment groups, who showed approximately the mean improvement in GMFM scores for their respective groups (Tables II and III).

SECONDARY OUTCOMES

For ambulatory patients the mean change in GMFM in the treatment group was 4.3% and in the non-treatment group 1.9% (P=0.07). For patients who were ambulatory with the aid of assistive devices the mean change in GMFM was 4.5% in the treatment group and 2.0% in the control group (P=0.10), and for non-ambulatory patients the mean change in GMFM was 8.1% in the treated group versus 1.9% in the controls (P=0.03).

There were 22 other secondary outcome measures, including physiological cost index, seated postural control measure,

Table I: Mean baseline values and mean change between values at baseline and at 1 year for all outcome measures in both TES and non-TES groups

	Mean values at baseline			*Mean change from baseline to 1 year*		
	TES	*Non-TES*	*P*	*TES*	*Non-TES*	*P*
GMFM score (%)	67	69	0.78	5.5	1.9	0.001
Seated postural control measure	5.7	6.0	0.50	0.8	0.4	0.08
Physiological cost index	1.6	1.4	0.71	−0.4	−0.5	0.72
Muscle strength (kg force)						
L hip extensors	2.1	2.2	0.93	1.6	1.7	0.94
R hip extensors	2.4	2.0	0.54	1.2	1.8	0.29
L hip abductors	2.0	2.5	0.38	0.7	1.1	0.28
R hip abductors	2.0	2.9	0.24	1.2	0.6	0.27
L knee extensors	7.4	8.2	0.45	1.9	1.2	0.45
R knee extensors	7.1	8.2	0.34	1.7	1.6	0.82
L ankle dorsiflexors	3.0	3.5	0.45	0.6	0.5	0.79
R ankle dorsiflexors	3.2	3.0	0.86	0.3	0.7	0.55
Spasticity (Ashworth scale)						
L hip adductors	1.9	2.2	0.25	0.2	0.2	0.97
R hip adductors	2.0	2.3	0.28	0.3	0.2	0.82
L knee flexors	2.5	2.7	0.44	0.2	0.1	0.81
R knee flexors	2.5	2.6	0.94	0.2	0.3	0.51
L ankle plantar flexors	2.5	2.7	0.29	−0.2	−0.1	0.98
R ankle plantar flexors	2.6	2.7	0.81	0.0	−0.1	0.86
Range of motion (degrees)						
L hip abduction	39	31	0.25	3.9	2.7	0.91
R hip abduction	32	33	0.51	10.1	−2.4	0.07
L knee extension	142	143	0.94	2.3	−2.5	0.46
R knee extension	143	143	0.93	−2.0	−2.6	0.92
L ankle dorsiflexion	10	7	0.32	3.1	3.5	0.91
R ankle dorsiflexion	8	7	0.75	4.8	3.0	0.65

TES = therapeutic electrical stimulation group; Non-TES = non-therapeutic electrical stimulation group.

and strength, spasticity, and range of movement at various joints. Each of these was tested at baseline and at 12 months, and there was no statistically significant difference between the treatment and non-treatment groups in any of these outcome measures (Table I).

In 17 of the 20 children receiving TES, improvements were noted by the primary caregivers, usually the parents. In the 21 untreated children, the caregivers commented on positive changes in seven. For the children who could walk, either alone or with aids, the improvements included a more normal appearance when walking, better endurance, better balance, improved level of ambulation, and better sitting. An improved level of ambulation was noted in two children on TES, but in none of the untreated children: one child was able to discard crutches when walking in the home, and the other child switched from a walker to crutches. In the children who were unable to walk, none of the five untreated children improved according to the parents, but five of six on TES showed better sitting ability.

Compliance for using TES ranged from 63% to 100% (mean 93%), with 18 of the 20 patients being above 87%.

Prior to TES one child had periodic extrusion of subcutaneous sutures from an incision for a hamstring lengthening procedure done many months previously. This seemed to be aggravated temporarily by TES, and was associated with the lowest compliance for using TES. There were no other complications from the application of TES and few technical problems. Leads were occasionally inadvertently pulled out of the stimulator, and this was easily corrected by using adhesive tape or elastic bands to secure the leads in place, and by avoiding direct traction to the points of attachment of the leads to the stimulator. Sometimes electrodes came off during the night, and this occurred if the contact gel dried out too much before application, or when the electrodes were old and needed replacement. Parents learned to avoid drying out of the gel by moistening the electrodes with some water.

Discussion

A number of studies have suggested that electrical stimulation of muscles might be effective in allowing patients with upper motor neuron lesions to improve voluntary motor function. In two children with spastic hemiplegia, Dubowitz et al. (1988) noted improved ankle dorsiflexion on the affected side with repeated electrical stimulation of the ankle dorsiflexors to cause active dorsiflexion for 3 hours daily for 8 weeks. Merletti et al. (1978) compared electrical stimulation plus standard physiotherapy with physiotherapy only, in a randomized study of 49 hemiplegic patients, and found that patients receiving electrical stimulation of the peroneal nerve showed increased voluntary ankle dorsiflexion compared to the control non-stimulated group. Peckham et al. (1975) studied 10 patients with quadriplegia and found that with a combination of isotonic and isometric electrically induced exercises of finger flexors, the strength and fatiguability of the muscles were improved. Kraft et al. (1992) showed that electrical stimulation of sufficient strength to initiate a muscle contraction during exercise was more effective than exercise alone in improving function of the arm and hand in adults with hemiplegic stroke. Carmick (1993a) has reported improvement of lower-limb function in two subjects and upper-limb function in three subjects (Carmick 1993b) using electrical stimulation in conjunction with a dynamic, task-oriented model of motor learning in children with CP. Hazlewood et al. (1994) found an increase in passive range of movement at the ankle and ankle dorsiflexion strength in children with hemiplegic CP after electrical stimulation of the anterior tibial muscles. The treatment was applied for 1 hour daily for 35 days, and was of an intensity which caused ankle dorsiflexion to just less than the limit of passive range.

Electrical stimulation of muscles has also been proposed as a method of relieving spasticity. Vodovnik et al. (1987) and Franek et al. (1988) were able to reduce spasticity in patients with spinal-cord injuries by electrical stimulation of lower-limb muscles, but the parameters of the stimulation were quite different in the two studies. Robinson et al. (1988) noted improvement in spasticity in spinalcord-injured patients by stimulating quadriceps to cause isometric contraction, but the improvement lasted only for 24 hours after stimulation ceased.

In the above studies, electrical stimulation was carried out while patients were awake, and the aim was to cause a muscle contraction, either isometric or isotonic. A large variety of stimulation parameters were used, and the optimal type of stimulation in any particular situation is not known.

Pape and colleagues (Pape et al. 1990) have used TES in a large number of adults and children with a variety of motor disorders, and have claimed significant positive effects (Lechky 1993). However, scientific study of TES has been limited to a series of six children with spastic CP in whom a significant improvement in Peabody Developmental Motor Scales scores was noted after 6 months of TES, with regression in scores when TES was discontinued for 6 months, followed by further improvements when TES was reinstituted (Pape et al. 1993). The mechanism by which such low-level stimulation might produce a beneficial effect is not known, but it has been proposed by Pape that TES increases the blood flow and metabolic activity of muscle and increases muscle bulk and contractility (Pape et al. 1990).

Table II: Functional improvements in items assessed by GMFM for a child in the TES group whose improvement in score was closest to the mean for the group

Start of study (pre-TES)	*End of study (post-TES)*
Could not balance on 1 foot	1-foot balance for 5 s
Could not run	Runs 15 feet
Jumps – just clearing floor	Jumps 5 inches
Could not walk along line	Walks 5 steps along line
Could rise to stand while pushing on floor	Rises to stand without using hands

Mean improvement for TES group was 5.5%; child's score illustrated improved by 5.6%.

Table III: Functional improvements in items assessed by GMFM for a child in the non-TES group whose improvement in score was identical to the mean improvement (1.9%) for the group

Start of study (no TES)	*End of study (no TES)*
Could not balance on 1 foot	1-foot balance for 5 s
Could not run	Runs 15 feet

Our randomized controlled trial, carried out on a limited population group, resulted from our interest in selective posterior rhizotomy, the requests from many parents of children with previous rhizotomy to be referred to the Magee Clinic for TES, and the findings of our initial pilot study which suggested that this was a group of patients in whom TES might have a beneficial effect.

The results indicated a statistically significant improvement in outcome for the treated children using the GMFM, with the difference in means between the two groups being 3.6%. The extent of improvement is considered to be clinically important according to the prior work of Russell et al. (1989), and is reflected in the greater functional gains in the treated, compared with non-treated, children as detailed in Tables II and III. This was in keeping with the observations of the primary caregivers with respect to the changes they noted in the treated versus untreated children. When the patients were subdivided into three groups, namely ambulatory, ambulatory with assistive devices, and non-ambulatory, the difference in mean improvement in GMFM between the treated and untreated patients was greatest in the non-ambulatory group. Since the study was not designed to look at the effects of TES in these three subgroups, this finding has to be interpreted cautiously, and needs to be validated with further studies. It may be that the apparent increased benefit of TES in the non-ambulatory children reflects a better sensitivity of the GMFM score to changes in function of non-ambulatory relative to ambulatory patients, rather than a lesser effect of TES in the ambulatory groups.

Of the other secondary outcome measures examined, two, the physiological cost index and the sitting scale score, were functional measures and no difference between the treated and untreated groups was shown. Lower-limb spasticity and strength were also assessed, and there was no difference between the treated and untreated children. This study does not lend support to the hypothesis that TES works by increasing muscle bulk and contractility (Pape et al. 1990).

It is important to note that the negative results with respect to the secondary outcomes do not exclude a positive effect of TES on any of these outcomes since the study had little power to show an improvement in any of the secondary outcome measures. For example, if the intention had been to look for improvement in muscle strength, TES would have been applied to one muscle group only for the duration of the study and the sample size may have been very different, with potentially different results. The same considerations apply to the other secondary outcomes.

This study confirmed that TES was simple to use, had minimal complications, and was well accepted by children with spastic CP and their caregivers, as indicated by the high compliance with the application of TES on a nightly basis over the course of the 1-year study.

One of the drawbacks of the study was the lack of sham electrical stimulation in the control group, so that one might question whether the positive result in the TES group was simply a placebo effect. Sham stimulation was considered in the design of the study, but was rejected because the electrical stimulation was such that although there was no muscle contraction, the child could feel a tickling sensation when the stimulator was on, and neither we nor the manufacturers of the stimulators could conceive of a way of blinding the child or parent to the treatment used. It is possible that the placebo effect influenced the comments of the caregivers, but it is considered unlikely that this could have influenced the GMFM results, since the therapists doing the assessments were blinded to the child's treatment.

Conclusion

The non-invasiveness of TES and the ease with which it can be used, makes this form of treatment very attractive to caregivers of children with disabilities. The current randomized controlled trial showed a statistically significant and clinically important improvement in motor function for children with spastic CP and previous selective posterior lumbosacral rhizotomy, who received TES for 1 year compared to a similar group who had not received TES. This is the first randomized controlled study to show an improvement in motor function in children with spastic CP as a result of the use of electrical stimulation.

Further studies are indicated to confirm our findings, to examine the effectiveness of TES in ambulatory versus non-ambulatory groups of children with spastic CP, and to investigate the mechanism by which TES and other low-level electrical stimulation affects motor function. It must be stressed that these results are not generalizable to the larger population of children with spastic CP who have not undergone a selective posterior rhizotomy.

Accepted for publication 21st November 1996.

Acknowledgements

This study was supported by grants from British Columbia's Children's Hospital Miracle Network Telethon fund for clinical investigative initiatives, and British Columbia Medical Services Foundation.

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