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Relief of spasticity in SCI men and women using rectal probe electrostimulation

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Although there are numerous approaches to the treatment of spasticity, many patients are still unable to find a satisfactory method of managing their spasms with acceptable side effects. In the course of our fertility studies using rectal probe electrostimulation (RPES) in SCI men to produce ejaculation, we observed that a majority of the men experienced significant relief of their spasticity for many hours. This report describes a prospective, single-blinded study of this phenomenon in six SCI men and three SCI women who underwent RPES a total of 71 times. The mean age of the subjects was 28.2 years (21–41), the mean time from injury was 6.0 years (0.5–15); there were three paraplegic and six quadriplegic persons: four were Frankel class A and five were class B. Although all subjects had moderate to severe spasticity, only four took anti-spasm medications; one had undergone surgery for implantation of an epidural stimulator. The effectiveness of RPES on spasticity was evaluated by each subject for frequency of spasms and interference of daily activities and by independent, blinded assessors for tone, frequency of spasms and DTRs; four patients underwent quantitative videotape analysis of the pendulum test and two underwent somatosensory evoked potentials (SSEPs) to evaluate electrical activity in the central nervous system. Treatment variables included varying probe sizes and number of stimulations. All subjects experienced good to excellent decrease in tone, frequency of spasms and interference with ADL from 3 to 24 hours depending on treatment variables used. Mean duration of relief was 8.2 hours. Only one man ejaculated consistently with stimulation and there was no difference in spasticity relief between men and women and between the anejaculatory and ejaculatory males. There was no relation between subject age, age of injury, level or completeness of injury and relief of spasticity. All subjects felt RPES was more effective than medications, stretching or other modalities in relieving spasms, including the one subject with the epidural stimulator. No untoward effects were reported.

Keywords: spinal cord injury; spasticity; disability; electrostimulation.

Introduction

Spasticity is a common complication of spinal cord injury (SCI). It frequently interferes with an individual's work, sleep, self-care and recreational activities and can contribute to increased morbidity. Over the years, a number of approaches to the treatment of spasticity have been developed but many patients are still unable to find a satisfactory method of managing their spasms with acceptable side effects. During our work with rectal probe electrostimulation (RPES) in anejaculatory SCI men, we observed that a majority of the subjects experienced significant relief from their spasticity for many hours. This paper describes a prospective, single-blinded study of this phenomenon in both SCI men and

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women who were having significant problems controlling their spasticity.

Patients and methods

Patients eligible for RPES were men or women with a history of traumatic SCI who were 18 years of age or older, medically stable and interested in undergoing RPES to evaluate its effects on their spasticity. After providing informed consent, subjects had a complete medical history and physical examination with special attention to their neurological status. Laboratory evaluations included a baseline urinalysis, urine culture and sensitivity, complete blood count and HIV test. Subjects with urinary tract infection were treated with appropriate antibiotics and repeat urinalyses and urine cultures were performed as needed.

Rectal probe electrostimulation was performed in the outpatient clinic using a modification of the procedures we have employed in treating anejaculatory men for more than 8 years.[1] Each subject underwent RPES a minimum of six times spaced 1–4 weeks apart. Treatment variables included the use of a small (0.75–1.0 inch) or large (1.25 inch) probe and either 7 or 15 stimulations. Three subjects underwent a placebo treatment with insertion of the rectal probe but with no stimulations and zero voltage. During stimulation sessions, electrical parameters ranged from 7–15 volts and 150–575 milliamperes with a 60 cycles/second sine wave. Stimulations lasted approximately 1 second and a typical procedure lasted 5–10 minutes.

The effects of RPES were evaluated in subjects using the following methods.

Independent observer method

Neurological examination by a 'blinded', independent observer was made to assess the frequency of spasms using the Penn spasticity scale[2] and the degree of muscle tone in the legs in paraplegic subjects and in all four extremities in quadriplegic subjects using the Ashworth muscle tone scale.[2] In addition, deep tendon reflexes in the lower extremities and ankle clonus were evaluated. Assessments were made with subjects in standardized positions either lying on an examining table or seated in their wheelchairs. The independent observations were made by two physical therapists who were trained and supervised by one individual and underwent periodic testing to assess interrater reliability. The observers were 'blinded' to the treatment variables used and were out of the room while RPES was being administered.

Subject assessment

Subjects assessed the frequency of their spasms using the Penn spasticity scale and the interference of spasticity on selected selfcare activities using a 5 point scale with zero being no interference and 4 being maximum intereference which makes the activity impossible to perform. The independent observations and the subject assessments were made prior to each stimulation, within 1 hour following stimulation and then 2–4 hours poststimulation whenever possible. Additional assessments by the subject were made throughout the day at 1–2 hour intervals and then at the time of telephone contact 24 hours later.

In addition to the independent observations and subject assessments of the effects of RPES on spasticity, we performed a quantitative videotape analysis of the pendulum test on four subjects before and after treatment with RPES. The pendulum test has been described as a useful method of assessment in spastic hypertonia.[3,4] Subjects were tested in a supine position with the thighs supported on a padded examination table and the legs below the knees allowed to hang over the end of the table. The foot of the left leg elevated to the level of the body so that the knee assumed a fully extended position without lifting the thigh off the examination table. A video camera was positioned to the left side of the subject so that the entire leg was visible to the camera throughout the test. The foot was released and the leg was allowed to swing in an unrestrained manner. This technique has been reported previously to discriminate reliably between spastic spinal cord injured and able bodied subjects and has an excellent correlation with the Ashworth score.[5]

In two subjects, we performed SSEPs to monitor electrical activity in the spinal cord and brain in response to a standard stimulus of peripheral nerves prior to and after treatment with RPES. Recordings were made with the Nicolet CA 2000 evoked potential system supported by the CA 2000 EP operating system. One median nerve and both posterior tibial nerves were stimulated using EKG electrode pads and recordings were made over the spine below and above the level of injury and over the skull using a standard technique.

Results

Characteristics of subjects and their response to RPES are shown in Table I. Six male and three female subjects underwent a minimum of six treatments with RPES on 71 occasions. Six subjects were quadriplegic and three were paraplegic; the mean age was 28.2 years with a range of 21–41 years. Time from injury was 6.0 years with a range of 0.5–15 years; four subjects were Frankel A and five were Frankel B. The maximum hours of relief ranged from 9–24 hours for both quadriplegic and paraplegic subjects with a mean of 7.8 hours and 9.5 hours of relief in each group, respectively, which was not a statistically significant difference. Likewise, there was no significant correlation of the effect of RPES on spasticity with the age of the subject, duration of injury, level of injury or completeness. Subject 6 had an extremely low threshold for ejaculation and had an antegrade emission with each RPES. He had a maximum of 12 hours of relief with a mean of 9.6 hours over 18 sessions. The females experienced slightly longer relief than the males with a maximum of 15.0 hours compared to 13.3 hours of relief. An analysis of the probe size, number of stimuli, voltage and milliamperes did not reveal any significant correlation with the amount of relief provided. Figure 1 shows the change in mean Ashworth scores for six quadriplegic and three paraplegic subjects before and within 1 hour poststimulation. The difference in the scores was statistically significant ($p < 0.01$) for both groups using the Wilcoxon signed rank test.

Of the five subjects who were taking antispasticity medications, all five felt that RPES was more effective than their medications. Six patients experienced complete flaccidity for a number of hours following some stimulations which was a level of relief that none of their medications or other modalities ever achieved. Further, subjects noted that RPES was more effective than stretching or use of the Regys machine or other modalities including the one subject who had undergone a trial of epidural stimulation. Seven of the nine subjects said they would be interested in using a home model on a regular basis if available as a method of treating their spasticity.

Subjects who were at risk for dysreflexia all experienced elevation of blood pressure which was satisfactorily controlled with a combination of 20–40 mg nifedipine and/or $\frac{1}{150}$ mg sublingual nitroglycerine. Capsules of nifedipine were chewed and swallowed

Table I Characteristics of subjects and response to RPES

	Level of injury	Sex	Age	Duration of injury (yrs)	Frankel class	No. of sessions	Maximum (mean) relief (hrs)
Quads							
1	C4–5	M	32	10	B	11	24 (10.3)
2	C4–5	M	20	0.75	A	6	9 (4.2)
3	C5–6	M	34	15	B	6	9 (7.7)
4	C7	F	41	1	B	6	12 (5.2)
5	C7	M	21	0.5	A	6	14 (5.2)
6	C8–T1	M	27	9	B	18	12 (9.6)
Paras							
7	T3	F	27	3	A	6	24 (14.8)
8	T4	F	32	14	B	6	9 (5.2)
9	T7	M	22	1	A	6	12 (7.7)

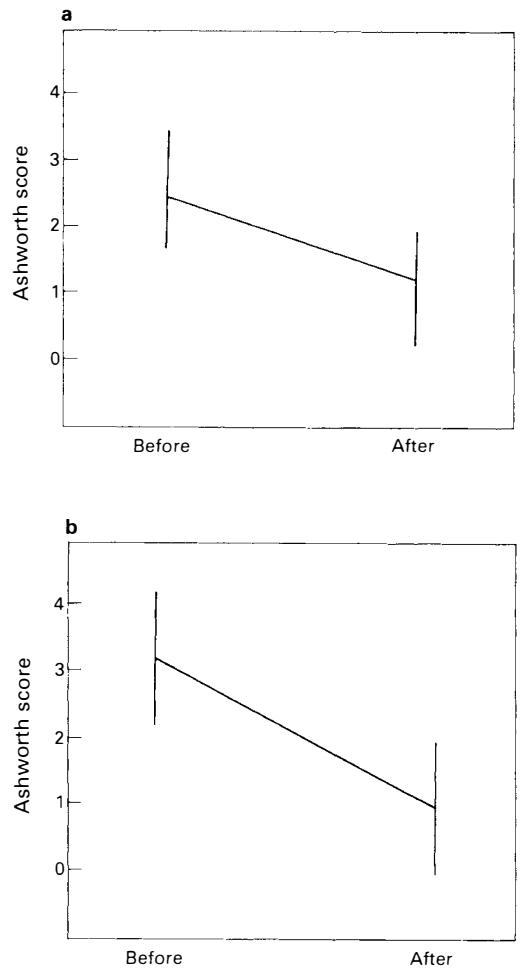

Figure 1 Ashworth muscle tone scores (mean ± SD) before and after treatment with RPES for (a) six quadriplegic patients (53 sessions) and (b) three paraplegic patients (18 sessions).

which has been shown to be more effective than when given sublingually.[6] There were no injuries to the rectal mucosa and subjects did not report any unpleasant or unacceptable side effects. There was no significant relief achieved by any of the subjects who underwent placebo testing with insertion of the probe in the rectum but no application of voltage.

Figure 2 depicts the digitized quantitative kinematic analysis of the videotaped pendulum test of subject 3. The top panels show the angular displacement of the knee during unrestrained free swing prior to electrical stimulation by rectal probe (a) and immediately after stimulation (b). The bottom panels show the whirlpool plot of the knee angular displacement on the X-axis and the knee angular velocity on the Y-axis prior to electrical stimulation by rectal probe (c) and immediately after stimulation (d). Improvement in the pendulum test is shown by an increase in the amplitude of oscillation after the initial swing and the orderly decrease in knee angular velocity as the angular displacement gradually decreases. The phase plane plot in Figure 2(d) illustrates this change by the large concentric circles which appear similar to a whirlpool. The whirlpool pattern typifies the kinematic pattern of the pendulum test of an able bodied subject. In general, these characteristic improvements

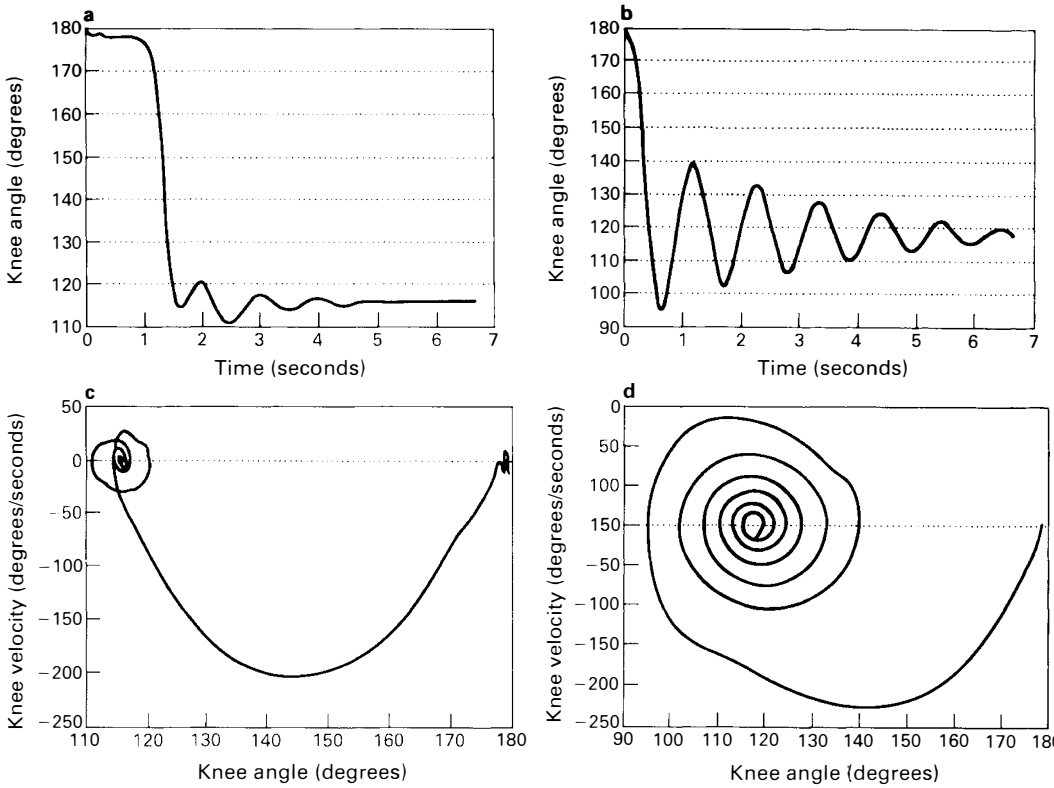

Figure 2 Kinematic analysis of the pendulum test for subject 3: (a) and (b) angular displacement of the knee over time; (c) and (d) phase plane plot of angular velocity vs angular displacement of the knee; (a) and (c) before electrical stimulation by rectal probe; (b) and (d) poststimulation.

were observed in all four subjects videotaped. In addition to the pendulum test, SSEPs were performed in two subjects. Typical electrical activity recorded on the prestimulation evaluations were abolished on the poststimulation recordings below the level of injury.

Discussion

This study describes a prospective, single-blinded evaluation of the effects of RPES on spasticity in SCI men and women. It provides a more objective and detailed analysis of the changes in patients' spasms than was obtained in an earlier study of electrical stimulation of SCI men who were being treated for anejaculation.[7] During that investigation, we made the unexpected observation that RPES has a profound effect on spasticity in SCI men. Because of the possibility that ejaculation itself might explain most of this phenomenon, we purposely expanded this study to include women and to provide a low enough stimulus to men whenever possible to avoid ejaculation. Of the six male subjects, one (number 5, a 27 year old quadriplegic subject) ejaculated while the rest remained anejaculatory. His maximum relief was 12 hours compared to an average maximum of 13.3 hours for the quadriplegic subjects as a group and 13.8 hours for all nine subjects.

All subjects experienced an increase in spasticity during the short interval of stimulation which may, by itself, produce some transient muscle fatigue. However, it is unlikely that this explains either the depth or the duration of relief. There is a growing literature which reflects variable success by treating spasticity with electical stimulation but usually only with short term effects.

These investigators are stimulating peripheral nerves or transcutaneously in the perineal region.[8–11] Although our technique does not involve percutaneous stimulation or direct stimulation of an exposed nerve, it does involve stimulation within a body cavity which may provide better access to nerves adjacent to the lower portion of the spinal cord.

Why RPES should be so effective is not clear although there are several possible explanations: (1) there is a rich supply of nerves in the periprostatic area that feed into the lumbosacral cord so not just a single nerve is being stimulated; (2) the stimulus is delivered closer to the cord than more traditional forms of peripheral nerve stimulation; (3) the lumbosacral cord is rich in internuncials and short, inhibitory fibers that may enhance and prolong the antispasticity effect; and (4) the stimulation may provoke a humoral agent that has antispasticity properties. The preliminary studies in two subjects with SSEPs suggest that the stimulation is strong enough to abolish poststimulation recordings over the spinal cord below the level of injury. The exact reason for this phenomenon is unknown. It may reflect a depletion refractory period poststimulation or be the result of stimulation of inhibitory fibers. More work will need to be done to further clarify a possible mechanism. Although ejaculation may account for some relief, it is difficult to see how it would explain the whole phenomenon in the face of achieving excellent spasticity relief in three females on 18 separate sessions of RPES in addition to the five men who did not ejaculate during a total of 35 RPES sessions (excluding three placebo trials when no current was delivered and no significant relief of spasticity was achieved).

The principal side effect in this group of subjects was dysreflexia in persons with injuries at T6 or above. Because even a small amount of stimulation produces dysreflexia, we routinely premedicate all subjects with chew and swallow nifedipine 20–40 mg and supplement this with sublingual nitroclycerine $\frac{1}{150}$ mg as needed. This protocol differs from our earlier study in which we used sublingual nifedipine. However, since then the medical literature has suggested that chewing and swallowing the nifedipine capsules are more effective since sublingual absorption is thought to be extremely limited while the majority of the drug is absorbed directly through the gastric mucosa.[12] Consistent with this observation, we found that subjects in this study required less nifedipine (20–40 mg) compared with the amount used in our earlier work (40–60 mg).

Conclusions

The procedure we have described with its beneficial effects on spasticity in both SCI men and women is clearly not a practical solution at the present time for the daily management for excessive spasms. However, in contrast to our earlier study, it now appears that lower levels of stimulation are also effective in relieving spasticity. With this in mind, we are designing different electrode configurations which will use low levels of electrical current to stimulate both the posterior anterior walls of the rectum to further reduce potential irritation of the rectal mucosa. With these and other design changes, it remains our goal to develop portable, programmable stimulators for use at home on a regular basis in carefully selected and trained subjects.

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