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BME 74A
FA1192
Fall 92

Functional Electric Stimulation: Its Efficacy and Safety in Improving Pulmonary Function and Musculoskeletal Fitness

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ABSTRACT. Arnold PB, McVey PP, Farrell WJ, Deurloo TM, Grasso AR. Functional electric stimulation: its efficacy and safety in improving pulmonary function and musculoskeletal fitness. Arch Phys Med Rehabil 1992;73:665-8.

• The efficacy and safety of functional electric stimulation (FES) in improving cardiovascular and musculoskeletal fitness in individuals with spinal cord injury was evaluated. Ten males and two females aged 16 to 46 years began an FES program from three months to 22 years after injury. Seven patients had paraplegia and five had quadriplegia. The FES protocol consisted of three phases: (1) leg extension, the stimulation of the quadriceps muscle group only, first without and then with weights; (2) ergometry, the stimulation of quadriceps, hamstrings, and gluteal muscles to produce a bicycling motion; and (3) resistance, the addition of resistance during the bicycling motion described in phase 2. Values for tidal volume, oxygen consumption, and the respiratory quotient were obtained during each phase. Tidal volume and oxygen consumption levels increased significantly ($p < .001$) from the start of FES to both the ergometry and the resistance phases. The respiratory quotient improved significantly ($p < .001$) from the start of FES to resistance but not from the start of FES to ergometry. Thigh and calf girths were measured at the start of FES and during resistance. Thigh girths increased significantly from the beginning of the program to the resistance phase, $p < .002$ for the right leg and $p < .001$ for the left. Calf girth, however, showed no significant increase. Based on these improvements and the absence of any serious complications, we believe that FES is an effective and safe method to improve cardiovascular and musculoskeletal fitness in individuals with spinal cord injury.

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KEY WORDS: Electric stimulation therapy; Ergometry; Paraplegia; Quadriplegia; Spinal cord injury

It has been shown that functional electric stimulation (FES) improves cardiovascular and musculoskeletal fitness for individuals with spinal cord injury (SCI).¹⁻⁴ Petrofsky and Phillips,⁵ Petrofsky and associates,⁶ Petrofsky and Phillips,⁷ and Hendershot and colleagues⁸ developed an FES system for both the upper and lower extremities. Petrofsky and Phillips⁷ reported upper extremity improvements with a 72% increase in arm strength and a 7% increase in arm girth after the FES protocol was used on the biceps and triceps for six weeks. A multicenter study⁴ showed similar improvements, as well as some aerobic training effects, in the leg muscles of patients with SCI. However, the spinal cord injured subjects in that study had normal ranges of joint motion and little muscle spasticity, characteristics which do not apply to all individuals with SCI. Our study evaluated the efficacy and safety of FES in a more diverse group of individuals with SCI who had a longer length of

time after injury. Thigh and calf measurements and the results of pulmonary function studies obtained before and during FES were used to quantify the changes. Safety was judged according to the problems that were encountered and resolved during FES.

METHODS

In 1985, an FES program was started at our Children's Hospital using the protocol of Petrofsky and Phillips.⁷ Since the size of the institution's facility and staff allowed 12 outpatients to be treated, we studied this number of subjects. Patients were scheduled to receive FES either two or three times a week, depending on when they could attend and what time slots were available. The study included ten males and two females, ranging in age from 16 to 46 years (mean, 22.8 years). Seven patients had paraplegia and five had quadriplegia, with the level of injury ranging from C5 to T4. All of the patients had complete transections of the spinal cord, with the exception of one patient with incomplete paraplegia who had sensation in his left leg. The patients started the program from three months to 22 years after the injury (mean, 7.2 years).

Preprogram Screening and Measurements

Before beginning the program, each patient underwent a physical examination to review spinal history and any problems that could cause difficulties such as pressure sores or spasticity. Radiographs were taken of the hips, femora, and knees because these areas of the skeleton would be

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Submitted for publication October 17, 1990. Accepted in revised form August 18, 1991.

No commercial party having a direct or indirect interest in the subject matter of this article has conferred or will confer a benefit upon the authors or upon any organization with which the authors are associated.

Presented at the Annual Assembly of the American Academy of Physical Medicine and Rehabilitation and the Annual Session of the American Congress of Rehabilitation Medicine, October 21, 1987, Orlando, FL.

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0003-9993/92/7307-0011\$3.00/0

stressed during the FES program. None of the 12 patients was excluded from the program based on the results of this screening. The following measurements were obtained: thigh girth (20cm above the adductor tubercle); calf girth (10cm below the tibial tubercle); range of motion at the hip, knee, and ankle; blood pressure; heart rate; and pulmonary function including tidal volume, oxygen consumption, and respiratory quotient using the Beckman Metabolic System.^a Pulmonary function studies were done at 2.5 months into the leg extension phase, 2.5 months into the ergometry phase, and six months into the resistance phase for the ten patients who had complete data available (see FES Protocol). Thigh and calf girths were measured at the start of FES and during the resistance phase, which ranged from 12 to 14 months later.

FES Protocol

The FES protocol consisted of three phases: (1) leg extension phase, the stimulation of quadriceps muscles only, starting with no weight and increasing to a maximum of 5lb on each leg; (2) ergometry phase, the synchronous stimulation of quadriceps, hamstrings, and gluteal muscles to produce a bicycling motion; and (3) resistance phase, the addition of resistance during the bicycling motion described in the ergometry phase. The REGYS 1 unit^b was used for phases 1 and 2 and the ERGYS 1 unit^b was used for phase 3.

In phase one, three surface electrodes were applied to the quadriceps muscle group to stimulate it with no greater than 130mA of electricity. This produced leg extension at the knee joint through a range of motion predetermined by the REGYS 1 unit. Each patient continued this phase until he or she was able to complete 45 leg extensions with 5lb of weight on either ankle. Depending on the patient's condition and length of time after the injury, this phase lasted from one week to four months (mean, three months). On average, pulmonary function variables were measured 2.5 months into this phase. In the ergometry phase, the patient began by "bicycling" for 1 to 2 minutes via electric stimulation. The time was increased gradually to a total of 30 minutes—a five-minute warm-up period of bicycling followed by 25 minutes of bicycling at 50rpm. (Our patients took from one to four months [mean, three months] to reach this level). Pulmonary function variables were measured at an average of 2.5 months into this phase. In the third phase, resistance was added to the bicycling motion. The ERGYS 1 unit was programmed to add from zero to $\frac{7}{8}$ kp of resistance, depending on the fitness of the patient. Typically, patients in our study reached maximum resistance levels of only $\frac{4}{8}$ to $\frac{5}{8}$ kp. If the bicycling rate fell below 35rpm, then the unit automatically shut off because the resistance level was too much for the patient to overcome. When this occurred, either the patient resumed bicycling at a lower level of resistance, or a therapist would assist the patient by hand pedaling the unit, so that the patient would be able to continue the exercise. Variables were measured six months into the resistance phase on an average, and all patients continued the FES resistance phase after measurements were obtained. Stretching exercises were added to the Newington protocol to lessen the increased muscle spasticity that some

of the patients were having. Fifteen to 20 minutes before the electrodes were applied, a therapist helped each patient do a series of stretching exercises for the hamstrings, quadriceps, gluteal, and calf muscles.

RESULTS

All values and measurements improved. Statistical tests for all the improvements were based on the data from ten patients since two of the 12 patients were unable to have the final pulmonary function studies scheduled during the resistance phase.

Pulmonary Function

The changes in the pulmonary function studies are given in table 1. The ten patients who completed the study showed significant increases in tidal volume when leg extension phase values were compared to values obtained during ergometry ($p < .001$) and during resistance ($p < .001$). Similarly, oxygen consumption increased significantly during ergometry ($p < .002$) and during resistance ($p < .005$) when compared to leg extension phase values. Interestingly, three patients showed a decrease in oxygen consumption from the ergometry phase to the resistance phase (1216.7mL at ergometry and 462.7mL at resistance) and this decrease was large enough to lower the average oxygen consumption from the ergometry phase to the resistance phase for all ten patients. However, when oxygen consumption values for these three patients were excluded, the average level during the resistance phase for the other seven patients was 1110.3mL and 929.8mL for the ergometry phase. The respiratory quotient for the ten patients increased significantly when leg extension phase values were compared to values obtained during resistance ($p < .05$) but did not improve significantly ($p < .10$) when leg extension phase values were compared to values obtained during ergometry. The two patients who did not have final pulmonary function studies showed an increase in oxygen consumption between the first two phases, with one patient's

Table 1: Improvement in Pulmonary Function During FES ($n = 10$)

	Baseline: Beginning Leg Extension Phase	2.5 Months into Phase 2, Ergometry	6 Months into Phase 3, Resistance
Tidal volume (mL)	539.4 ± 299.7	1083.7 ± 458.4*	1163.1 ± 409.1*
Oxygen consumption (mL)	309.2 ± 255.1	1015.9 ± 494.8 [†]	916.0 ± 440.3 [‡]
Respiratory quotient	.732 ± .138	.785 ± .152	.886 ± .100 [¶]

The length of time from the start of FES to phase 2 averaged three months and the length of time from phase 2 to phase 3 averaged three months.

* $p < .001$ when compared to phase 1 (ANOVA); [†] $p < .002$ when compared to phase 1 (ANOVA); [‡] $p < .005$ when compared to phase 1 (ANOVA); ^{||} $p < .10$ when compared to phase 1 (Freidman χ^2); [¶] $p < .05$ when compared to phase 1 (Freidman χ^2).

values increasing from 138mL to 606mL and the other's from 230mL to 986mL. In addition, the tidal volume increased from 308mL to 757mL for the first patient and from 560mL to 709mL for the second. One of the patients showed a large increase in the respiratory quotient, from .78 initially to .98 at ergometry.

Musculoskeletal Fitness

Changes in thigh and calf girth measurements are given in table 2. The ten patients showed significant increases in thigh girth from the start of FES to resistance ($p < .002$ for the right thigh and $p < .001$ for the left). The slight increase in calf girth, however, was not statistically significant ($p < .42$ for the right and $p > .25$ for the left), probably because the gastrocnemius and soleus muscles were not directly stimulated during the cycling. One of the two patients who did not have final pulmonary function studies during the resistance phase showed large increases in thigh girths (46.6cm to 48.6cm for the right and 45.8cm to 48.9cm for the left) and calf girths (25.3cm to 27.5cm for the right and 25.0cm to 28.4cm for the left) from the beginning of FES to the resistance phase.

Problems

One patient's blood pressure increased from 120/80 at rest to 155/100 on the first day of FES. After the patient started taking an antihypertensive medication (50mg/d of hydrochlorothiazide, Diuril), his blood pressure decreased to a maximum of 140/90 and he was able to complete the study while taking the medication. Three of the ten patients still had problems with spasticity during FES even after stretching. Small daily doses (10mg/d) of baclofen (Lioresal), a muscle relaxant and antispastic drug, reduced the frequency of spasms in two patients. The third patient had spasticity in the quadriceps during the leg extension phase which was overcome by increasing the weight which the patient had to lift. In all the patients, uncontrolled spasticity was markedly reduced from pre-FES levels. Although increased muscle strength caused the spasticity to become more intense for all patients, they felt it became less frequent and shorter in duration, making it more tolerable. One patient who started the FES program was concurrently being treated for thrombophlebitis with an anticoagulant (coumadin, 5mg and 7.5mg in daily alternating doses). The FES program had no adverse effects on this patient and it increased both her calf and thigh girths and improved her cardiovascular health.

Finally, due to the constant motion of the lower extremity during phases 2 and 3, sometimes the electrodes would lose contact with the skin. This was overcome by applying them with the Universal Electrode Patch.^c

DISCUSSION

In our study, pulmonary function improved during the ergometry and resistance phases of the FES program. Thigh girth increased significantly from the leg extension phase to the resistance phase, and to a lesser extent calf girth in-

creased during the same period. In addition, data from the two patients who did not have final measurements suggest that the leg extension phase and the ergometry phase account for some improvement in cardiovascular and musculoskeletal variables. A study by Chamblin and associates¹ in 1989 showed a significant increase in quadriceps strength ($p < .005$) in ten patients after a 12-week leg extension phase and a significant increase in thigh circumference ($p < .005$) after a four- to six-month ergometry phase. Also, during the ergometry phase, oxygen consumption increased by an average of 52% (range, 3% to 105%, $p < .005$). These cardiovascular and musculoskeletal improvements are consistent with our study. In 1986, Ragnarsson and associates³ and Pollack and coworkers⁴ used the same FES protocol that we used and had similar results. The investigators³ reported an increase in muscle bulk, a trend toward aerobic training, and a safe outcome in 20 patients during the three phases of FES. Then, in a case study⁴ of two patients, oxygen consumption increased by 40% after 3.5 months of FES and an additional 30% for one of the patients who continued on the FES program for 18 more sessions (six weeks). One of the patients had C6 quadriplegia and started FES five years after injury; the other had T4 paraplegia and started FES three years after injury. Also, the increased respiratory quotient indicated that their aerobic capacity was improved.⁴ In our study of ten patients, these two findings were similar—ie, oxygen consumption increased nearly threefold and the respiratory quotient increased by over 20% when initial values were compared with values obtained during the resistance phase. In our study, there was a longer length of time after the injury: three months to 22 years compared with a range of two to ten years in the study of 20 patients by Ragnarsson and associates.³ Of interest in our study was the fact that three of the patients took a long time before they could pedal the bicycle unassisted for 20 minutes. The fact that these patients started the FES program ten years or more after injury could be the reason for this, although a small sample size did not allow this to be a statistically significant factor. In three of our patients, the oxygen consumption increased at the beginning of FES and then decreased between the ergometry and the resistance phases. This is because initially, the increase in exercise causes changes in the blood flow and oxygen consumption of the stimulated muscles. As these muscles become more efficient and better trained, they require less current for stimulation. Therefore, because less oxygen is necessary and less shunting of blood occurs, the effect is a decrease in systemic oxygen consumption.

In summary, our study adds further support to the efficacy and safety of FES. More studies are needed to determine the level of SCI, the patient's age, or other variables may determine which patients would benefit most from FES and if there is a correlation between the number of years after an injury and the musculoskeletal and cardiovascular benefits of FES.

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Suppliers

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- c. Connecticut Medical, Inc., 731 Wethersfield ave, Hartford, CT 06114.

