

The efficacy of thermocoagulation of the tibial nerve and a polypropylene ankle-foot orthosis on spasticity of the leg in stroke patients: results of a randomized clinical trial

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Objective: To investigate the efficacy of thermocoagulation of the tibial nerve and a polypropylene ankle-foot orthosis (AFO) on spasticity of the leg in stroke patients with a spastic equinus or equinovarus foot.

Design: A placebo-controlled randomized clinical trial with a 2 x 2 factorial design.

Setting: Outpatient clinic, Department of Rehabilitation Medicine, Academisch Ziekenhuis Vrije Universiteit Amsterdam.

Subjects: 60 stroke patients (17 women, 43 men), with a median age of 58 years and a median period of 34 months poststroke, with at least independent walking capacities at home.

Main outcome measures: Change in spasticity, muscle tone, ankle clonus, Achilles tendon reflex, ankle range of motion (ROM), motor function of the leg, and balance, measured six and 15 weeks after randomization.

Results: Thermocoagulation, rather than the AFO, reduced spasticity, muscle tone, Achilles tendon hyperexcitability, and ankle clonus. At six-week follow-up, the effects on Achilles tendon reflex and ankle clonus were the most pronounced; reflex excitability was reduced in 59% of the patients treated with thermocoagulation, as compared to 14% of the placebo-treated patients, whereas ankle clonus was reduced in 55% and 0% of the patients, respectively. Reduced spasticity was found in 35% of the actively treated, as compared to 10% of the placebo-treated patients. For muscle tone, the percentages of improved patients in each group were 45% and 24%,

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respectively. After 15 weeks the differences between the groups were smaller. No clinically relevant improvement was found with regard to ROM, the Fugl-Meyer lower extremity and balance scores, walking ability and walking speed.

Conclusion: Thermocoagulation is effective for the reduction of spasticity in stroke patients with a spastic equinus or equinovarus foot. No effect on spasticity of the AFO could be demonstrated. When the efficacy of thermocoagulation and the AFO are judged in terms of functional abilities, however, the effects seem of little value.

Introduction

Spasticity is one of the most common impairments in patients with a central nervous system disorder. Spasticity is a highly variable, complex, and still incompletely understood syndrome, characterized by 'excess' as well as 'deficit' impairments associated with muscle activation, muscle length and muscle stiffness, respectively.^{1,2} In stroke patients, spasticity typically includes velocity-dependent hypertonus, hyperexcitable tendon reflexes and clonus.^{3,4} These clinical features are observed in various combinations of severity, and can be very disabling. With respect to the leg, the disabling effects of spasticity include, for instance, difficulties in transfer activities, standing balance, and walking. It may prevent patients from achieving independence in activities of daily living.

This article describes the results of a randomized clinical trial on the efficacy of radiofrequency thermocoagulation of the tibial nerve and an ankle-foot orthosis (AFO) in stroke patients with a spastic equinus or equinovarus position of the foot. Rehabilitation medicine is aimed at the prevention and reduction of disabilities and handicaps.^{5,6} However, thermocoagulation and the AFO are aimed at reducing spasticity locally controlling spastic equinus or equinovarus deformity of the ankle, thus reducing 'impairments' which can be transformed into functional improvements, i.e. walking ability and walking speed at the 'disability level'.⁷ The outcome measures described in this article are primarily chosen at the impairment level. If no improvements are seen at the impairment level, functional improvements are not expected either. Improvement of walking ability without a simultaneous

reduction of spasticity should be interpreted as a nonspecific treatment effect. This article focuses on the results at the impairment level. It discusses briefly the relationship with functional changes.

Patients and method

Study design

The study consisted of a placebo-controlled randomized clinical trial with a 2 × 2 factorial design, resulting in four study groups.⁸ The first experimental treatment consisted of tibial nerve blocking with percutaneous radiofrequency thermocoagulation (300 kHz, Model RFG 3b Lesion Generator, Radionics Inc., Burlington, Massachusetts, USA). Thermocoagulation (TH) of peripheral nerves is a new application employed for the relief of local spasticity. It is an outpatient procedure, which lasts 45–60 minutes. To date, one case-study and two uncontrolled clinical trials about this new treatment application have been published.^{9–11} In this study, the tibial nerve was blocked, after local anaesthesia with 5 cc lidocainechloride 2%, at the popliteal fossa, while the temperature was brought up to 80°C within 40 seconds, and held constant for the next 60 seconds. This procedure was repeated twice, after a slight change of position of the needle within the nerve. Placebo thermocoagulation (PTH) consisted of the same protocol, including anaesthetizing the tibial nerve. However, radiofrequency energy output was zero. The thermocoagulation procedure was performed on one occasion.

The second experimental treatment consisted of a custom-made AFO in five degrees of dorsiflexion, which was compared with a placebo AFO

(PAFO) with a free range of dorsiflexion and plantar flexion. During the study period, patients were stimulated to use the prescribed orthosis each day, at least in the daytime.

After informed consent, patients were randomized to one of four treatment groups: group 1, TH + AFO; group 2, PTH + AFO; group 3, TH + PAFO; and group 4, PTH + PAFO. Randomization was carried out with sealed envelopes, prepared in advance by an independent statistician, using random permuted blocks. Usual medical or paramedical procedures were kept unchanged during the trial.

Study population

Patients, between the ages of 18 and 75 years, with walking problems caused by a spastic equinus or equinovarus position of the foot, were included if they had suffered a first ischaemic or haemorrhagic cerebrovascular accident at least four months previously. In addition, patients had to have sufficient communicative and cognitive abilities as well as a satisfactory general condition. Exclusion criteria were: more than one previous stroke; a brainstem infarction; rheumatic, neurologic or orthopaedic co-morbidities interfering with walking ability and walking speed; a structural shortening of the calf muscles; and contraindications for one or both treatments.

The inclusion and exclusion criteria were mainly assessed by common physical examination. To determine whether walking problems were caused by a spastic equinus or equinovarus position of the foot, the physician observed the patient while walking with shoes and orthotic devices as compared to walking barefoot. Furthermore, neurologists' reports on stroke and further clinical details, including any relevant investigations, such as computerized tomographic scans of each patient, were requested. Patients were also excluded if a diagnostic block with a local anaesthetic had a disabling effect on standing or walking.

Measurement methods

Scores of spasticity, muscle tone, reflex activity, ankle clonus and range of motion were assessed by physical examination, using ordinal semiquantitative scales (see Table 1). Spasticity is defined as a velocity-dependent increase of the

stretch reflex, resulting in palpable velocity-dependent resistance during passive dorsiflexion of the ankle. Muscle tone is defined as the passive resistance to stretch offered by the calf muscles when externally manipulating the foot, and was quantified according to the Ashworth scale.¹² Spasticity was differentiated from muscle tone by either a quick passive movement or a slow passive movement of the foot. Furthermore, Achilles tendon reflex and ankle clonus were evaluated. To gain more information about the length of the gastrocnemius and soleus muscle, passive dorsiflexion of the ankle, both with extended knee and 90° flexion of the knee, were measured by using a plastic full-circle goniometer. The motor function of the leg as well as the sitting and standing balance were assessed according to the Fugl-Meyer Assessment Scale.^{13,14} The 'motor function of the lower extremity' scale consists of 17 items (maximum score of 34 points), whereas the 'balance' scale consists of seven items (maximum score of 14 points). Most items consist of standardized motor activities which are to be performed independently by the patient. The scoring involves direct observation of the performance and is rated on an ordinal three-point scale (0 = cannot be performed; 1 = can be partially performed; 2 = can be fully performed).

Baseline measurements were performed on one occasion prior to the diagnostic treatment, whereas the follow-up measurements were performed six and 15 weeks after randomization, respectively. All measurements were performed by the same evaluator, assisted by an administrative assistant. Both of them were unaware of the treatment assignment and had no information about previous scores. The tests were carried out at the human movement laboratory of the department.

Statistical analyses

For all outcome measures the differences between baseline scores and each follow-up score were calculated. For the passive dorsiflexion, cumulative distributions of the change scores were calculated and graphically displayed. The non-parametric Kruskal-Wallis test, with correction for ties, was used to analyse the differences across the four groups, whereas the Mann-Whitney U-test was used to analyse the differences

between two groups (thermocoagulation versus placebo thermocoagulation; AFO versus PAFO).^{15,16} The analyses were carried out with SPSS-PC+ version 4.01 (SPSS Inc., Chicago, Illinois, USA).

Results

Patients

Sixty stroke patients (17 women and 43 men) with a median age of 58 years (range 21–72 years)

Table 1 Baseline characteristics of the participants

Characteristic	Group 1 TH/AFO (n = 15)	Group 2 PTH/AFO (n = 16)	Group 3 TH/PAFO (n = 15)	Group 4 PTH/PAFO (n = 14)
<i>Gender</i>				
Female	3	3	7	4
Male	12	13	8	10
<i>Age (years)</i>				
Median	58	55.5	58	60.5
Range	21–71	33–69	26–66	41–72
<i>Months poststroke</i>				
Median	34	39.5	47	24.5
Range	5–64	5–143	12–154	9–185
<i>Hemiplegic side</i>				
Left	7	7	4	8
Right	8	9	11	6
<i>Type of stroke</i>				
Haemorrhagic	6	4	3	2
Ischaemic	9	12	12	12
<i>Spasticity</i>				
0 = not present	2	3	3	4
1 = present	8	4	8	3
2 = exaggerated	5	9	4	7
<i>Muscle tone</i>				
0 = no increase	3	3	–	–
1 = slight increase	6	2	6	3
2 = more marked increase	5	6	7	6
3 = considerable increase	1	5	2	4
4 = passive movement impossible	–	–	–	1
<i>Achilles tendon reflex</i>				
0 = areflexia	–	–	1	–
1 = hyporeflexia	–	1	1	–
2 = normoreflexia	1	–	1	3
3 = moderate hyperreflexia	5	3	5	5
4 = severe hyperreflexia	9	12	7	6
<i>Ankle clonus</i>				
0 = not present	1	2	3	3
1 = < 5 beats	5	1	3	3
2 = ≥ 5 beats	9	13	9	8
<i>Fugl-Meyer Assessment Scale</i>				
Median	29.5	31.5	31.3	29.0
Range	16.5–40.0	21.5–38.0	24.5–39.5	17.5–42.5
<i>Sickness Impact Profile ambulation (%)</i>				
Median	44.5	43.3	48.1	50.4
Range	10.7–58.2	29.8–67.2	12.5–72.5	27.9–63.2
<i>Walking speed (m/s) comfortable with shoes</i>				
Median	0.45	0.44	0.42	0.32
Range	0.17–1.39	0.19–0.85	0.08–1.15	0.17–1.09

TH: thermocoagulation; PTH: placebo thermocoagulation; AFO: ankle-foot orthosis; PAFO: placebo ankle-foot orthosis.

and with a median time since stroke of nearly three years (34 months; range 5–185 months) participated. Table 1 shows the main patient characteristics. Two patients failed to attend the follow-up measurements at six weeks because of hospitalization for reasons not related to the treatments or treatment outcomes. Three other patients withdrew between the first and the second follow-up. Reasons for withdrawal were unknown in two cases (both group 2), whereas one patient (group 4) was very disappointed with the treatment results.

Effects on spasticity and related impairments

For each outcome measure the total number of improved patients is presented as a percentage. Patients were defined as improved if their follow-up score was at least one point less than their baseline score (Table 1). Table 2 presents the results after six weeks. With respect to spasticity, muscle tone, Achilles tendon reflex, and ankle clonus, the number of improved patients of groups 1 and 3 (both thermocoagulation groups) is higher as compared to groups 2 and 4 (both placebo thermocoagulation). The effects on Achilles tendon reflex (chi square, 10.07; d.f., 3; $p = 0.0179$) and ankle clonus (chi square, 24.23; d.f., 3; $p = 0.00001$) are the most pronounced. Further analysis of the data revealed that the reduction of these impairments was entirely due to the efficacy of thermocoagulation (groups 1 + 3, $n = 29$ versus groups 2 + 4, $n = 29$), rather than due to the efficacy of the AFO (groups 1 + 2 ver-

sus groups 3 + 4). Reduced spasticity was found in 10 patients (35%) treated with thermocoagulation as compared to three placebo-treated patients (10%) ($z = -2.067$; $p = 0.0387$). For muscle tone, the number of improved patients in both groups were 13 (45%) and seven (24%) respectively ($z = -1.229$; $p = 0.219$). The effects on Achilles tendon reflex and ankle clonus are the most pronounced; reflex excitability was reduced in 17 patients (59%) treated with thermocoagulation, as compared to four (14%) of the placebo-treated patients ($z = -3.110$; $p = 0.0019$), whereas ankle clonus was reduced in 16 (55%) and none (0%) of the patients respectively ($z = -4.669$; $p = 0.00001$).

Furthermore, at six-week follow-up it turned out that in the thermocoagulation group seven patients improved on all four clinical parameters, two patients on three parameters, nine patients on two parameters, four patients on one parameter only, whereas seven patients did not improve at all. In the placebo thermocoagulation group, however, 17 patients did not improve on at least one parameter, 10 improved on one parameter, and the remaining two patients improved on two parameters. None of the placebo-treated patients simultaneously improved on three or four parameters.

After 15 weeks, the differences between the groups are smaller (Table 2). Still, with respect to Achilles tendon reflex and ankle clonus, the differences between the four groups are statistically significant (chi square, 11.35; d.f., 3; $p = 0.01$

Table 2 Number of improved patients (%) after six weeks and 15 weeks, with respect to spasticity, muscle tone, Achilles tendon reflex and ankle clonus, for each study group

Outcome measure	Group 1 TH/AFO	Group 2 PTH/AFO	Group 3 TH/PAFO	Group 4 PTH/PAFO
<i>a) At 6-week follow-up (n)</i>	14	16	15	13
Spasticity	5 (36%)	1 (6%)	5 (33%)	2 (15%)
Muscle tone	6 (43%)	4 (25%)	7 (47%)	3 (23%)
Achilles tendon reflex	9 (64%)	2 (13%)	8 (53%)	2 (15%)
Ankle clonus	10 (71%)	0 (0%)	6 (40%)	0 (0%)
<i>b) At 15-week follow-up (n)</i>	15	14	15	13
Spasticity	6 (40%)	3 (21%)	7 (47%)	1 (8%)
Muscle tone	3 (20%)	6 (43%)	5 (33%)	4 (31%)
Achilles tendon reflex	8 (53%)	3 (21%)	7 (47%)	1 (8%)
Ankle clonus	8 (53%)	1 (7%)	5 (33%)	1 (8%)

TH: thermocoagulation; PTH: placebo thermocoagulation; AFO: ankle-foot orthosis; PAFO: placebo ankle-foot orthosis.

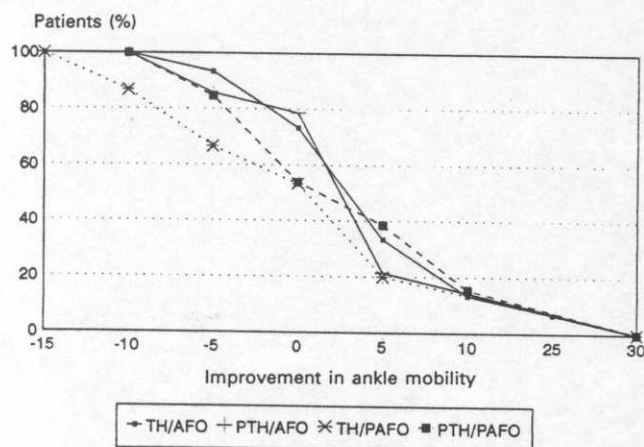
and chi square, 13.73; d.f., 3; $p = 0.0033$, respectively).

Effects on range of motion

The AFO in five degrees of dorsiflexion may improve ankle ROM, because of prolonged static stretching of the calf muscles. The changes in passive dorsiflexion of the ankle, both measured with extended knee and 90° flexion of the knee, are indicators for changes in muscle length of the gastrocnemius muscle and the soleus muscle, re-

spectively. Any changes were expected to be the most pronounced after 15 weeks, i.e. after prolonged stretching of the calf muscles by the AFO. In Figure 1, scores on the abscissa of more than 0° indicate an improvement of the range of motion. On the ordinate, one can read the cumulative proportion of patients of the four treatment groups as a percentage. The curves of all groups are almost identical, and the differences between the groups were neither clinically nor statistically significant. The same holds for the results after six weeks, which are therefore not presented.

(a)



(b)

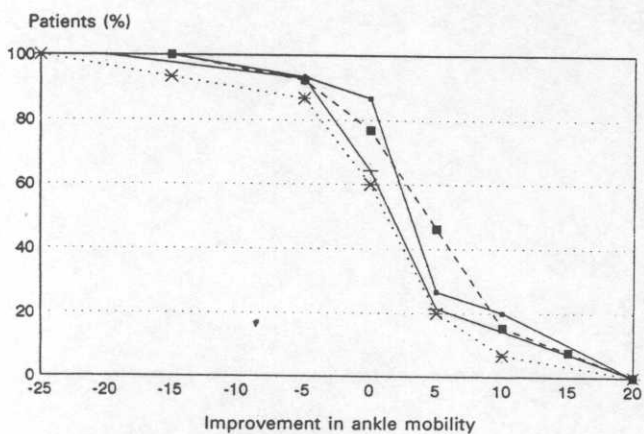


Figure 1 Changes in passive dorsiflexion of the ankle after 15 weeks, measured with (a) extended knee and (b) 90° flexion of the knee; cumulative distributions of the proportion patients per study group. TH: thermocoagulation; PTH: placebo thermocoagulation; AFO: ankle-foot orthosis; PAFO: placebo ankle-foot orthosis.

Effects on Fugl-Meyer Assessment Score

The Fugl-Meyer Assessment Score for the motor function of the lower extremity and sitting and standing balance hardly changed (Table 3). Although our patient population showed a great variety of Fugl-Meyer scores at baseline, ranging from 34% to 83% of the total possible score of 48 points, the median change was 1.5 points (3%), or less, across the four groups.

Functional improvement

Table 4 shows the median improvement of walking ability and comfortable walking speed after three months for each group separately. Walking ability was measured by the Sickness Impact Profile (SIP),¹⁷ whereas comfortable walking speed was measured on an 11 m walkway. It can be concluded that the changes are very small, and are neither clinically nor statistically significant (Beckerman *et al.*, unpublished observations).

As explained before, the authors expected walking ability and walking speed to improve as a result of reduction of spasticity. In Table 5 the median changes per functional outcome measure are presented for the group of patients who improved as opposed to the group of patients who remained unchanged or deteriorated with respect to spasticity, muscle tone, Achilles tendon hyperexcitability, and ankle clonus. The inter-relationship between changes in the muscle function impairments (i.e. spasticity) and functional outcome measures turned out to be very weak (Spearman rank correlation coefficients).

Table 3 Improvement on the Fugl-Meyer Assessment Scale (lower extremity + balance score)

Follow-up	Patients	Median	Range
<i>Improvement after 6 weeks</i>			
1) Thermo/AFO	14	1.0	-5.5/4.5
2) Placebo thermo/AFO	16	1.5	-7.5/7.5
3) Thermo/placebo AFO	15	0.0	-3.5/5.0
4) Placebo thermo/placebo AFO	13	0.0	-3.5/5.5
<i>Improvement after 15 weeks</i>			
1) Thermo/AFO	15	0.75	-11.5/5.5
2) Placebo thermo/AFO	14	1.25	-3.5/6.5
3) Thermo/placebo AFO	15	0.00	-7.5/7.5
4) Placebo thermo/placebo AFO	13	0.00	-3.0/5.5

Note: Negative signs indicate a decline from the baseline scores.
Thermo: thermocoagulation; AFO: ankle-foot orthosis.

Table 4 Median improvement on the functional outcome measures per treatment group at 15-week follow-up

Outcome measure	Patients (n)	Median	Range
<i>SIP ambulation (%)</i>			
1) Thermo/AFO	15	6.45	-4.7/15.0
2) Placebo thermo/AFO	14	3.23	-12.8/13.2
3) Thermo/placebo AFO	15	-2.65	-9.4/21.7
4) Placebo thermo/placebo AFO	13	0.00	-9.0/15.8
<i>Walking speed (m/s) comfortable with shoes</i>			
1) Thermo/AFO	15	0.01	-0.09/0.20
2) Placebo thermo/AFO	14	0.05	-0.15/0.17
3) Thermo/placebo AFO	15	-0.01	-0.34/0.11
4) Placebo thermo/placebo AFO	13	-0.01	-0.07/0.19

Note: Negative signs indicate a decline from the baseline scores.
Thermo: thermocoagulation; AFO: ankle-foot orthosis.

Table 5 Median change in outcome measures after 15 weeks for the improved and nonimproved patients with respect to muscle function impairments after six weeks (number of improved/nonimproved patients in brackets)

Outcome measure	Improved	Nonimproved	Spearman's rho	p-value
<i>Fugl-Meyer Assessment Scale (LE + balance)</i>				
Spasticity (13/39)	0.50	0.00	0.04	0.38
Muscle tone (19/33)	0.00	0.00	0.12	0.20
Achilles tendon reflex (20/32)	-0.25	0.25	0.25	0.04
Ankle clonus (15/37)	0.00	0.00	0.22	0.06
<i>Sickness Impact Profile ambulation (%)</i>				
Spasticity (13/42)	0.00	0.65	-0.00	0.50
Muscle tone (20/35)	0.00	1.20	-0.12	0.19
Achilles tendon reflex (21/34)	3.85	0.00	0.21	0.06
Ankle clonus (16/39)	3.85	0.00	0.21	0.07
<i>Walking speed (m/s), comfortable with shoes</i>				
Spasticity (13/42)	0.040	0.000	-0.10	0.23
Muscle tone (20/35)	0.020	0.000	0.02	0.45
Achilles tendon reflex (21/34)	0.010	0.005	0.04	0.37
Ankle clonus (16/39)	0.035	-0.010	-0.12	0.20

LE: lower extremity.

Discussion

To the authors' knowledge this is the first randomized clinical trial of the efficacy of percutaneous radiofrequency thermocoagulation and a polypropylene AFO in five degrees of dorsiflexion in stroke patients. Even for phenolization of peripheral nerves, a well-known procedure with the same therapeutic intention, no randomized clinical trials have been conducted until now.¹⁸ This randomized clinical trial shows that thermocoagulation, rather than the AFO, can be effective in reducing spasticity in stroke patients with a spastic equinus or equinovarus foot. The disappointing results of the AFO, for instance with respect to the range of motion, are probably due to the high percentage of noncompliance. At the end of the study, 10 patients with an AFO, and 18 patients with a placebo-AFO stated that they had not worn the orthosis every day or nearly every day. Most of the noncompliant patients did use their old orthosis again, resulting in a distortion of the contrast between the study groups. In efficacy studies, compliance to the assigned treatment is of particular importance. However, information about noncompliance to a therapy in itself is valuable and should not be ignored. In fact, inclusion of the noncompliers in the analyses provides an estimation of the effects which are best related to actual clinical practice.

The great challenge in the treatment of spasticity is not just its control and reduction but to restore functional abilities. In this study, outcome measures on both the impairment level as well as the disability level were used, enabling us to investigate their inter-relationship. It can be concluded that, although spasticity and its related impairments were modified by thermocoagulation of the tibial nerve, this did not necessarily lead to the simultaneous improvement of walking ability.

The efficacy of thermocoagulation on muscle function impairments is primarily demonstrated by the use of subjective, semiquantitative outcome measures, in the sense that outcomes did depend upon the evaluator who made them.¹⁹ In order to minimize subjectivity, however, clinical examination of the blinded patients took place by one evaluator who was blinded for the nerve-blocking procedure. A striking point is that

24.4% of the participants showed no positive response to thermocoagulation on any of the four clinical parameters, although only those patients were included who had shown a positive result after a diagnostic block of the tibial nerve. Moreover, the thermocoagulation procedure was performed by a highly skilled physiatrist (JB). (In the placebo thermocoagulation groups 58.6% did not respond.) In order to improve diagnosis, treatment planning and evaluation of rehabilitative treatments aimed at reducing spasticity, there is a need for more valid and responsive measures to quantify spasticity.²⁰ An *a priori* accurate discrimination of therapy responders and nonresponders would be more efficient. Further refinement of the localization of tibial nerve fibres, based on the disappearance of the ankle clonus rather than on the disappearance of contraction of gastrocnemius muscle, might be another possibility to improve the response rate.

Although our participants were able to walk independently, the high SIP ambulation scores as well as the slow comfortable walking speed indicate that there is much room for improvement. Furthermore, a five-year follow-up study showed that functional capabilities poststroke, including walking, are not stable, but further decline.²¹ The search for effective treatment possibilities to improve walking abilities, therefore, remains urgent. However, one should be cautious about believing that rehabilitative interventions improving muscle function impairments or gait parameters will automatically improve walking ability.

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References

- 1 Whyte J, Robinson KM. Pharmacological management. In: Glenn MB, Whyte J eds. *The practical management of spasticity in children and adults*. Philadelphia, PA: Lea & Febiger, 1990: 10. 1-10. 26.
- 2 Young RR. Spasticity: a review. *Neurology* 1994; **44** (suppl 9): S12-S20.
- 3 Little JW, Massagli TL. Spasticity and associated abnormalities of muscle tone. In: DeLisa JA ed. *Rehabilitation medicine: principles and practice*. Philadelphia, PA: Lippincott Company, 1993.
- 4 Glenn MB and Whyte J. *The practical management of spasticity in children and adults*. Philadelphia, PA, Lea & Febiger, 1990.
- 5 Lankhorst GJ, Beckerman H, van Bennekom CAM, Jelles F. Developing research lines in rehabilitation medicine in the Netherlands. *J Rehabil Sci* 1994; **7**: 10-12.
- 6 Duncan PW. Stroke disability. *Phys Ther* 1994; **74**: 399-407.
- 7 Whyte J. Toward a methodology for rehabilitation research. *Am J Phys Med Rehabil* 1994; **73**: 428-35.
- 8 Fleiss JL. *The design and analysis of clinical experiments*. New York: John Wiley & Sons, 1986.
- 9 Kanpolat Y, Caglar C, Akis E, Erturk A, Ulug H. Percutaneous selective RF neurotomy in spasticity. *Acta Neurochir Suppl Wien* 1987; **39**: 96-98.
- 10 Herz DA, Looman JE, Tiberio A et al. The management of paralytic spasticity. *Neurosurgery* 1990; **26**: 300-306.
- 11 Arendzen JH. Percutane thermocoagulatie van perifere zenuwen. Een nieuwe methode bij de behandeling van spasticiteit [PhD thesis]. Groningen: Drukkerij van Denderen BV, 1989.
- 12 Ashworth B. Preliminary trial of carisoprodol in multiple sclerosis. *Practitioner* 1964; **192**: 540-42.
- 13 Fugl-Meyer AR, Jaasko L, Leyman J, Olsson S, Steglind S. The post-stroke hemiplegic patient I: a method of evaluation of physical performance. *Scand J Rehabil Med* 1975; **7**: 13-31.
- 14 Duncan PW, Badke MB. Measurement of motor performance and functional abilities following stroke. In: Duncan PW, Badke MB eds. *Stroke rehabilitation: the recovery of motor control*. Chicago, IL: Year Book Publishers Inc., 1987: 203-17.
- 15 Forrest M, Andersen B. Ordinal scales and statistics in medical research. *BMJ* 1986; **292**: 537-38.
- 16 Altman DG. *Practical statistics for medical research*. London: Chapman & Hall, 1994.
- 17 Bergner M, Bobbitt RA, Carter WB, Gilson BS. The Sickness Impact Profile: development and final revision of a health status measure. *Med Care* 1981; **19**: 787-805.
- 18 Beckerman H, Lankhorst GJ, Verbeek ALM, Becher J. The effects of phenol nerve and muscle blocks in treating spasticity: review of the literature. *Crit Rev Phys Rehabil Med* 1996 (in press).
- 19 Schwartz D, Flamant R, Lellouch J. *Clinical trials*. London: Academic Press, 1980.
- 20 Carey JR, Burghardt TP. Movement dysfunction following central nervous system lesions: a problem of neurologic or muscular impairment? *Phys Ther* 1993; **73**: 538-47.
- 21 Lindmark B, Hamrin E. A five-year follow-up of stroke survivors: motor function and activities of daily living. *Clin Rehabil* 1995; **9**: 1-9.