Task-Specific Physical Therapy for Optimization of Gait Recovery in Acute Stroke Patients

Carol L. Richards, PhD, PT, Francine Malouin, PhD, PT, Sharon Wood-Dauphinee, PhD, PT, J. I. Williams, PhD, Jean-Pierre Bouchard, MD, Denis Brunet, MD

ABSTRACT. Richards CL, Malouin F, Wood-Dauphinee S, Williams JI, Bouchard JP, Brunet D. Task-specific physical therapy for optimization of gait recovery in acute stroke patients. Arch Phys Med Rehabil 1993;74:612-620.

• A randomized controlled pilot trial was conducted to estimate the effects of early, intensive, gait-focused physical therapy on ambulatory ability in acute, stroke patients. Twenty-seven patients with middle cerebral artery infarct of thromboembolic origin confirmed by computed axial tomography scan were stratified and randomly assigned to the experimental group, to a control group that received early, intensive and conventional therapy, or to a group receiving routine conventional therapy that started later and was not intense. Assessments at entry, six weeks, and three and six months by independent evaluators permitted comparisons with reference to clinical measures of motor performance, balance, and functional capacity, and laboratory measures of gait movements. Group results at six weeks demonstrated that gait velocity was similar in the two conventional groups thereby eliminating the timing of the interventions as an important factor. At that point, gait velocity was faster in the experimental group. The difference translated into a moderate effect size of 0.58. The time dedicated to gait training but not to total therapy time was correlated ($r_s = 0.63$) to gait velocity. This effect disappeared at three and six months after stroke. These pilot results justify planning a large trial to test the effectiveness of a therapeutic protocol that focuses on early and intense gait therapy in an effort to facilitate early ambulation following stroke.

KEY WORDS: Gait; Physical therapy; Stroke

Although physical therapy (PT) is generally recognized as beneficial in the treatment of stroke patients, convincing evidence of its efficacy is lacking. First, it is not known if or how PT influences the recovery process after stroke. However, because most of the functional recovery occurs in the first three months following stroke,[1,2] and because studies in animals have shown that neural circuitry changes mediating behavioral recovery occur soon after injury,[3-5] the early initiation of PT should be critical. Secondly, it is not clear what type of PT program would promote optimal functional recovery. Evidence that neural reorganization (sprouting, unmasking) after central nervous system lesions follows growth rules[4,6] and evidence from clinical observations of apparent relearning processes in stroke patients,[7,8] suggests the need to design rehabilitation programs that take these factors into consideration. Such programs should thus follow proper sequencing, provide a rich environment (stimuli from many sources), be motivational, aim for specific skill acquisition, and also be demanding and intensive.[7] Thirdly, because locomotor training represents a functional activity, potentially capable of "forcing the use of unmasked pathways through intense sensorimotor stimuli from multiple sources," and is a purposeful bilateral activity, early emphasis should be put on gait related activities.[7]

Based on this theoretical and clinical information, the main purpose of this study was to answer the following research question: Can an early and intensive, specialized gait training program improve gait performance in stroke patients? The principal objective was to determine if early and intensive PT that emphasized specific gait training promoted (1) a gait outcome and (2) an early return of functional mobility that was superior to that obtained following either early and intensive conventional PT that did not focus on ambulation or conventional PT. Other objectives of the study were to determine if a randomized controlled design was feasible with patients in the first six weeks after stroke, and also to examine patient tolerance and compliance to a rigorous program of physical therapy at this stage of recovery.

METHODS

Experimental Design

The randomized controlled single blind pilot study involved 27 patients.

Patient Selection

All new stroke patients admitted to l'Hôpital de l'Enfant-Jésus between May 5, 1988 and May 31, 1990 with a sus-

From the Physiotherapy Department Faculty of Medicine Laval University and Neurobiology Research Centre (Drs. Richards, Malouin, Bouchard), Hôpital de l'Enfant-Jésus, Quebec City; School of Physical and Occupational Therapy and Department of Epidemiology and Biostatistics (Dr. Wood-Dauphinee), McGill University, Montreal; Department of Clinical Epidemiology (Dr. Williams), Sunnybrook Health Science Centre, Toronto; and the Department of Neurological Sciences (Drs. Bouchard, Brunet), Hôpital de l'Enfant-Jésus, Québec.

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Reprint requests to Carol L. Richards, PhD, PT, Centre de recherche en neurobiologie, Hôpital de l'Enfant-Jésus, 1401, 18e rue Québec, P.Qué. G1J 1Z4.

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pected middle cerebral artery infarct were screened for entry into the study by a nurse-coordinator. The inclusion criteria were the following: resident within 50km of Quebec City; men and women between 40 and 80 years old; zero to seven days after onset of a first stroke (a first episode of a transient ischemic attack lasting less than 24 hours was not considered a first stroke); a clinically identifiable middle cerebral artery syndrome of thromboembolic origin involving subcortical structures confirmed by computed axial tomography scan; under the medical supervision of one of the neurologists in the study and willing to sign an informed consent. The exclusion criteria were: other neurologic problems, such as Alzheimer's disease, Parkinson's disease, or one of the hereditary ataxias, or major medical problems that either had or would incapacitate the functional capacity of the patient or would interfere with the rehabilitation process. Patients entering the study belonged to the "middle band" following the neurological screening process according to criteria defined by Garraway and coworkers.[9] This triage system excluded patients independent in ambulation during the first week following stroke as well as those who were unconscious at onset. All subjects were required to sign an informed consent for participation in the study and all procedures followed were in accordance with the ethical standards of the hospital.

Allocation to Treatment Regimens

Patients were stratified into a good or poor prognostic category according to baseline scores on the Barthel Index[10-15]; patients achieving a score ≤ 20 were placed in a poor whereas those with scores ≥ 21 were placed in the good prognostic stratum. Patients were randomly assigned to one of three treatment groups by a block randomization scheme within each stratum.

Treatment Regimens

All patients received conventional hospital care. The study did not alter usual medical or paramedical procedures. In particular, occupational therapy was provided to all patients according to hospital practice. Physical therapy, however, was specifically organized and delivered in terms of timing, content, and approach.

The experimental group started as early as possible after admission to the study and was provided with an intensive and focused approach to therapy that incorporated use of the tilt table and a limb-load monitor, resisted exercises with a Kinetron[a] isokinetic device, and a treadmill. The goal was to promote gait relearning through locomotor activities that were adapted to the individual level of motor recovery.

For one control group, PT started early and was as intensive as for the experimental group but contained more traditional approaches to care based on older neurophysical techniques and practice. The second control group received therapy as it had been organized and delivered in the institution previously. This started later in the hospital stay, was not intense, and was composed of similar techniques as provided to the other control group.

Measurement of the Physiotherapeutic Input and Patient Outcomes

Patients accepted into the trial were evaluated by the nurse coordinator to judge the severity of stroke. A standardized grading system, the Canadian Stroke Scale,[16] was used to score the neurological status of the patient. Prior to randomization, the patients were also evaluated in terms of motor performance and the ability to perform functional activities.

The motor performance of all the patients was evaluated with the assessment method developed by Fugl-Meyer and colleagues.[17,18] It allocates 24 points to sensation, 14 points to balance, 66 points to the upper extremity, and 34 points to lower extremity function. The scale has reasonable measurement properties[17-20] and has been used in other trials.[21] Functional levels of independence were assessed with the Barthel Index first developed by Mahoney and Barthel.[22] The scale assesses 15 items related to self-care and mobility.[10] Activities of daily living account for 33 points, bowel and bladder control 20 points, and ambulation activities, including the capacity to walk 50m and to negotiate stairs, 47 points. This index has been widely used and has demonstrated high reliability and validity[11-13] and moderate responsiveness.[14,15] These clinical evaluations were completed by independent evaluators, experienced physical therapists from another hospital, who were unaware of the specific research objectives of the study. The initial Barthel score was used to assign the prognostic stratum used in the randomization process.

Through the course of the study (at six weeks, three months and six months after stroke) the same independent evaluator repeated these assessments and also evaluated the ability of the patient to balance. This capacity was estimated with a new Balance Scale developed by Berg and associates.[23] This scale renders a balance score derived from the evaluation of 14 different items, has high reliability, and correlates well with clinical judgments of balance.

At no time were these independent evaluators aware of the group assignments. Most of the patients left the acute care hospital for a rehabilitation institution, chronic care hospital, or home six weeks after stroke and returned to the acute care hospital for follow-up evaluations at three and six months after stroke. In some cases, because of scheduling restraints or because the patient was unable to participate in the laboratory gait evaluations, the independent evaluator went to the patient's home or to the chronic care institution to do the evaluations.

The gait movements and muscle activations were evaluated in the Motor Evaluation Laboratory six weeks, three months, and six months after stroke. Similarly, the evaluators were blind to the patient group assignments. The leg movements were monitored by means of an electrogoniometer and recorded concomitantly with the electromyographic activity (surface electrodes) from four muscles of the affected lower extremity. As the patients walked, events of the gait cycle were determined from signals from pressure-sensitive footswitches attached under the toe, midfoot, and heel regions of both shoes. The duration of the gait cycle as well as the relative durations of the stance, swing, and double support phases were determined from the foot-switch signals that were recorded simultaneously with the electrogoniometer and myosignals by means of a specially designed software on an IBM-PC[b] compatible computer.[24,25]

The patients were requested to walk at free cadence or with assistance along a 6m walkway and the gait records were started and stopped automatically as the patient broke the beam of photocells placed 4m apart in the center of the walkway. The average gait velocity (distance/time) was derived by dividing the 4m distance travelled by the time taken to traverse this distance. When patients required maximal assistance to complete the walking task or walked too slowly, the gait records were started and stopped manually and this made it impossible to calculate the average walking velocity.

After examining the changes in the various gait parameters over time, average gait velocity (cm/s) was selected as the primary gait outcome measure for estimating the effects of treatment. Walking velocity increases with recovery of motor function and has been used as a primary outcome variable in a number of stroke studies.[26-29] Furthermore, little is known about the sensitivity of the movement or muscle activation parameters to changes in locomotor recovery. In fact, one of the secondary purposes of the present study was to examine the relationship between such quantitative gait parameters and scores of functional recovery. These relationships and the changes in the movements and muscle activations over time will be reported separately. Normal data obtained by the same methods in healthy elderly subjects[30] were used for comparative purposes.

During the hospital stay, additional data were compiled. Information related to sociodemographic and clinical characteristics were collected from the screening form, the patient's current and past medical chart, or through a brief discussion with the patient or family. Detailed information was also kept on several aspects of the physiotherapy treatment procedures, not only for the patients participating in the study, but also for the other stroke patients treated in the physiotherapy department. This was done in part to conceal the interest in a selected group of patients and also to obtain baseline information on usual physiotherapy procedures in the hospital. Specifically, data on the timing of implementation of physical therapy, the amount of therapy provided on a daily basis and the actual therapeutic activities were recorded by therapists treating the patients.

Statistical Analysis

The scores for the three clinical tests and selected gait parameters were stored in spread sheet files along with the demographic characteristics of the patients. Descriptive statistics were calculated for sociodemographic, clinical, and laboratory variables. Given the relatively small numbers of subjects in this feasibility study, there was a chance that the compositions of the three treatment groups would be unbalanced with respect to severity of stroke, even though the patients were stratified into good and poor prognostic groups before random assignment to treatment groups. It was thus decided to check for such differences and adjust the analysis to take into account baseline functional capacity as measured by the Fugl-Meyer leg score. Analysis of covariance (ANCOVA) was used to examine differences in gait velocity across the groups. Multiple Classification Analysis with the SPSS/PC+ statistical package[c] was used in the analysis of the data.

RESULTS

Patients in the Study

Over the 25-month study period, a total of 215 stroke patients (patients with transient ischemic attacks were automatically excluded) were screened to obtain the 27 (12.5% of patients screened) patients who participated in the study. Reasons patients were not admitted into the study are presented in table 1 whereas table 2 gives the patient sociodemographic and clinical characteristics by group and by prognostic category. The baseline Fugl-Meyer leg and Canadian Stroke Study scores are included to give an indication of the motor performance of the leg and stroke severity, respectively.

Details of the Physiotherapeutic Input

The physical therapy in the experimental (EXP) group started early (8.3 ± 1.4 days after stroke) was intensive (1.74 ± 0.15 hrs/day given in two sessions) and emphasized specific gait training activities, including treadmill gait training, but also included conventional therapy. For the patients in the early conventional (ECON) group the therapy also started early (8.8 ± 1.5 days) and was intensive (1.79 ± 0.10 h/day in two sessions) but did not emphasize locomotor activities; instead a more traditional approach was used.[31,32] Finally, the patients in the conventional (CON) group did not benefit from either early or intensive physical therapy. They were treated by conventional methods, usually once a day for a mean of 0.72 ± 0.10 hours and the therapy was initiated 13 ± 2.8 days after stroke.

Table 3 gives the amount of physical therapy provided each group. Patients from both the EXP and ECON groups received from 84.4% to 93.6% (of the expected 50 one-hour treatments over the five-week treatment period) of the mean number and mean duration of physiotherapy treat-

Table 1: Patients Rejected by the Screening Process With Reason for Exclusion

Reason	Number of Patients	Percent (%) of Total Number Screened
Motor deficit too small	52	24.2
Complicating disability	43	20.0
Hemorrhagic stroke	22	10.2
Not middle cerebral artery	21	9.8
Second stroke with previous deficits	19	8.8
Outside of age range	16	7.4
Delay in hospital more than seven days after stroke	10	4.7
Residence more than 50km away	5	2.3
Total	188	87.4

Table 2: Sociodemographic and Clinical Characteristics of the Stroke Patients at Onset

Group	Prognosis Category	Gender F	Gender M	Age (yr)	Side R	Side L	FM-L	CSS
Early, experimental	Good (N = 5)	3	2	67.6 (6.2)*	1	4	16.4 (3.6)	5.6 (1.6)
	Poor (N = 5)	2	3	71.6 (8.7)	1	4	10.6 (8.5)	5.0 (1.3)
	Total (N = 10)	5	5	69.6 (7.4)	2	8	13.5 (6.9)	5.3 (1.4)
Early, conventional	Good (N = 3)	2	1	74.0 (11.8)	3	0	21.3 (5.9)	6.3 (1.8)
	Poor (N = 5)	4	1	63.2 (9.8)	3	2	5.6 (2.1)	4.5 (1.4)
	Total (N = 8)	6	2	67.3 (11.2)	6	2	11.5 (8.9)	5.2 (1.7)
Conventional	Good (N = 4)	2	2	73.5 (6.9)	1	3	24.0 (4.1)	7.5 (1.6)
	Poor (N = 5)	1	4	67.8 (7.4)	2	3	4.4 (0.9)	4.8 (0.8)
	Total (N = 9)	3	6	70.3 (7.3)	3	6	13.1 (10.6)	6 (1.8)

N = 27.
* Values give mean ± 1SD in brackets.
Abbreviations: FM-L, Fugl-Meyer leg score (maximum = 34); CSS, Canadian Stroke Scale (maximum = 15).

ments, indicating that the intensity of therapy in terms of time was close to that expected for the five-week treatment period. The EXP group had the highest mean total treatment time but differed little for the total treatment time from the ECON group (fig 1). When compared to the patients in the CON group, the patients in the EXP and ECON groups received about three times the mean total treatment time.

It was also of interest to break the treatment down to show the relative intensity of training dedicated to the subcomponents. Thus, as shown in figure 1, the mean total time dedicated to gait training was highest in the EXP group and corresponded to 27.7% of the mean total treatment time over the five-week period. Interestingly, the time dedicated to gait training was similar in the early ECON and CON groups but represented 20.5% and 37.1%, respectively, of the mean total treatment time.

Figure 2 illustrates the number of patients in each group that could complete the gait tests at six weeks and three months after stroke. If the patient was able to walk with maximal assistance, it was usually possible to measure the muscle activations but not the movements because the patients were unable to tolerate the standing procedures relating to the electrogoniometer placement. Other patients could not complete the walking task even with maximal assistance at the earlier time. Thus, all the patients in the EXP and ECON groups were able to complete the walking task at six weeks, but three of the eight patients in the conventional group were unable to do so, and one of the patients in this group refused to submit to the laboratory evaluations. At three months, all the patients were able to complete the walking task. For some, however, who took too much time to walk across the walkway, it was not possible to calculate the walking velocity with our computer program. In subsequent analyses when velocity was used, the patients for whom velocity could not be measured were dropped from the analysis. This mainly affected the conventional group because at six weeks only four of the seven patients evaluated in this group could complete the task. The effect on the mean velocity was to skew the mean of this group toward that of the good prognostic group (table 4).

Table 4 gives the unadjusted means for the functional scores and gait velocity and the adjusted means for gait velocity for the three groups at baseline and at six weeks. As expected, the different variables reflect the motor recovery over time. Of particular interest are the results for gait velocity (bottom of the table) chosen as the primary outcome

Table 3: Amount of Physical Therapy Provided to Each Group

Group	(N)	Number of PTTs (mean)	Duration of Each PTT (min) (mean)	Mean Daily PTT (hours)
EXP	(9)	46.8 ± 4.5	52.2 ± 4.5	1.74 ± 0.15
ECON	(6)	42.2 ± 5.8	53.6 ± 5.7	1.79 ± 0.10
CON	(8)	19.2 ± 3.1	43.1 ± 5.4	0.73 ± 0.10

Abbreviations: PTT, physical therapy treatment; EXP, experimental; ECON, early conventional; CON, conventional physical therapy.

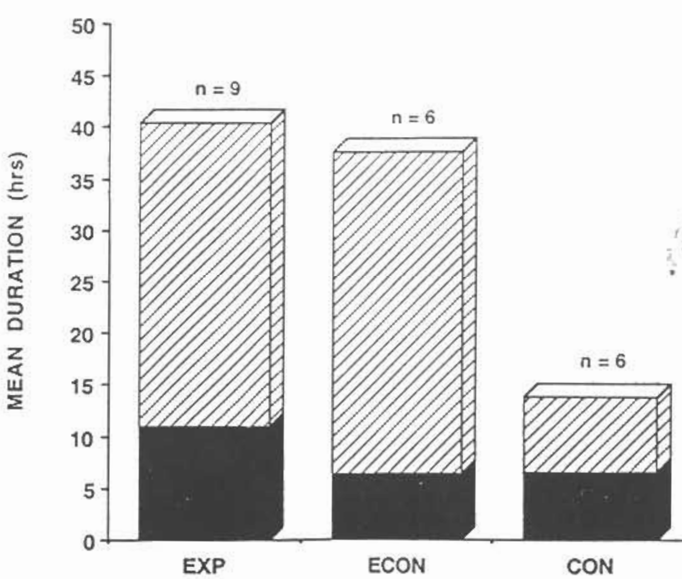

Fig 1—Comparison of the total physical therapy treatment time and the time dedicated to gait training over the five-week therapy period for the three groups of patients. Complete data was available for only six cases in the CON group because patients were discharged according to regular practice. ▨, total; ■, gait.

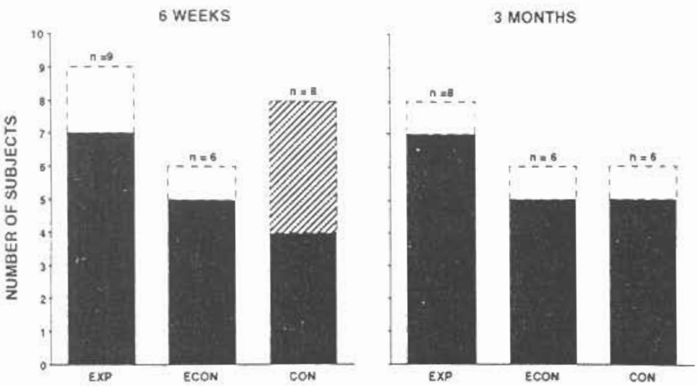

Fig 2—Bar graph indicating the number of hemiplegic patients in each group (experimental: EXP, early conventional: ECON, conventional: CON) capable of completing the walking task with the full analysis system or only with the EMG system at six weeks and three months after stroke. Abbreviations: EXP, experimental; ECON, early conventional; CON, conventional. ■, movements + EMG; – – –, EMG only; ▨, unable.

variable. First note how slowly the patients in all three groups walk at six weeks; 30cm/s represents a velocity equal to about 29% of that of elderly normals.[29] Note also how the loss of four patients in the walking task at six weeks affects the mean velocity for the conventional group.

In figure 3, the scores for the Fugl-Meyer leg (FM-L), the Barthel ambulation, and the Fugl-Meyer balance components are represented as a percent of maximal value instead of a raw score for the different times. The scores for the three clinical tests clearly illustrate that much of the recovery occurs in the first six weeks after stroke and that the rate of recovery is slower between six weeks and three months. This representation emphasizes the tendency of the patients in the EXP group to reach a higher functional score for the FM-L score more quickly. For the Fugl-Meyer balance score, however, the early conventional group had a higher score at six weeks. The scores for these three clinical tests were not significantly ($p > .05$) different among the groups at six weeks and three months after stroke.

The Fugl-Meyer score for leg performance was thought to be the functional measure most closely related to gait speed. As was seen in table 2, the FM-L baseline scores varied markedly by treatment group and prognostic category. The mean scores for the two prognostic groups were relatively close in the EXP group, with the differences being larger for the ECON group and largest for the CON group. This pattern of differences across treatment groups and prognostic categories was observed for other baseline measures as well, including the Canadian Stroke Scale measures. This convinced us that the differences related to the FM-L were not statistical artifacts, but reflected a chance variation in true differences.

An ANCOVA was then used to adjust for group differences at baseline and to increase the precision of the estimate of effects when using gait velocity as the primary outcome measure. At first we controlled for prognostic category and the FM-L leg scores, but because the Barthel and Fugl-Meyer scores were closely related, we decided to only use the FM-L at baseline as the covariate for adjusting the scores.

The next problem was the missing values on gait velocity at six weeks for patients who continued to participate in the study. If the values were excluded, the mean scores for the CON groups would be higher and not reflect the poor performance of the patients who could not walk and the estimated value of treatment effect would be biased. We considered imputing the value "0" to replace the missing ones, but

Table 4: Functional Scores and Gait Velocity by Group at Baseline and at Six Weeks

	Experimental		Early Conventional		Conventional	
	Baseline *n* = 10	6 weeks *n* = 9	Baseline *n* = 8	6 weeks *n* = 6	Baseline *n* = 9	6 weeks *n* = 8
Fugle-Meyer Balance (1-14)	4.7*	8.3	4.1	10.0	5.0	8.1
	(2.2)	(2.0)	(1.8)	(1.9)	(2.2)	(2.7)
Fugl-Meyer Arm (1-66)	12.5	31.7	12.1	33.5	14.8	28.1
	(12.7)	(21.3)	(15.4)	(24.4)	(20.0)	(25.3)
Fugl-Meyer Leg (1-34)	13.5	23.7	11.5	22.7	13.1	20.0
	(6.9)	(6.7)	(8.9)	(9.2)	(10.6)	(10.7)
Barthel Ambulation (1-47)	2.0	25.8	2.1	23.3	2.7	26.8
	(4.2)	(14.8)	(4.0)	(16.6)	(4.1)	(18.5)
Berg (1-56)	—	33.2	—	40.0	—	28.4
		(18.2)		(16.1)		(19.7)
Gait velocity (cm/s)	—	n = 9	—	n = 5†		n = 4‡
		31.3*		23.2*		30.0*
N = 104 (±19.3)		(19.8)		(9.3)		(18.7)
		n = 9‖		n = 6‖		n = 8‖
		31.3		21.8		22.5
		(19.8)		(9.0)		(14.6)

Abbreviation: n, normal values.
* Values give unadjusted means ± 1SD.
† Very slow velocity not measured in one patient.
‡ One patient refused to be evaluated and very slow velocity not measured in three patients.
‖ Value of 15cm/s attributed for missing gait velocity values (adjusted mean).

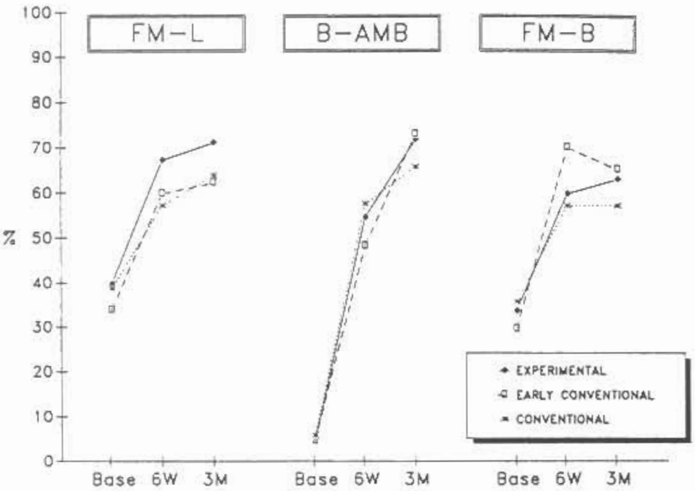

Fig 3—Line graphs depicting the change (in % of maximum score) on three functional scores over time (Fugl-Meyer leg: FM-L, Barthel ambulation subcomponent: B-AMB, Fugl-Meyer balance: FM-B) for the hemiplegic patients in each treatment group.

this would have served to lower the means scores for the CON group thereby over estimating the treatment effect on group differences.

Because the FM-L scores were considered to be the closest clinical measure of walking capacity, the FM-L scores at six weeks were plotted with the gait velocities (fig 4). This plot showed that persons with FM-L scores less than 25 had mean gait velocities of about 15cm/s. After further consideration, it was decided that if patients with poor FM-L scores were given sufficient support and assistance, they could achieve a gait speed of 15cm/s at six weeks, and this value was then used to replace the missing values accordingly. These scores provide the least biased estimate of treatment effects at six weeks.

The next task was to determine which was more important, the timing of therapy or the type of therapy. If the type of therapy was more important, the difference between the EXP and ECON therapy should be greater than the difference between ECON and CON therapy. If timing was more important, the difference between ECON and CON therapy should be greater than the difference between EXP and ECON therapy.

Examination of the adjusted means (fig 5) indicates that the differences between types of therapy are more important than differences in timing of therapy. In fact, the mean gait velocity scores for the two conventional therapy groups are nearly identical. Thus the conventional groups were combined and the analysis was repeated (table 5). One can note that the *f* value for treatment effects is not statistically significant at the 0.05 level. The probability value, however, is a function of sample size as well as treatment effects. The effect size of treatment is 0.58 standard deviation units (effect size = [experimental mean − conventional mean]/standard deviation) and this is a moderately large effect size and is typical of rehabilitation studies.[34] If this effect size were maintained in a randomized trial with a larger number of patients, the result would be an important clinical finding to support change in standard clinical practice.

There was a question as to whether the effects of the five week experimental therapy held over time. When gait velocity was compared for the patients with complete data (a value of 15cm/s was assigned to patients for whom gait velocity could not be measured at any of the times but who remained in the study), the initial advantage in gait velocity for the EXP group disappeared by three months. The mean gait velocity for the EXP group attained a peak at six weeks and thereafter changed little whereas the mean velocity in the patients treated by conventional methods continued to increase at three and six months so that the initial advantage observed in the experimental group disappeared by three months after stroke.

To further examine the issue of training specificity, the relationship between total therapy time and gait velocity

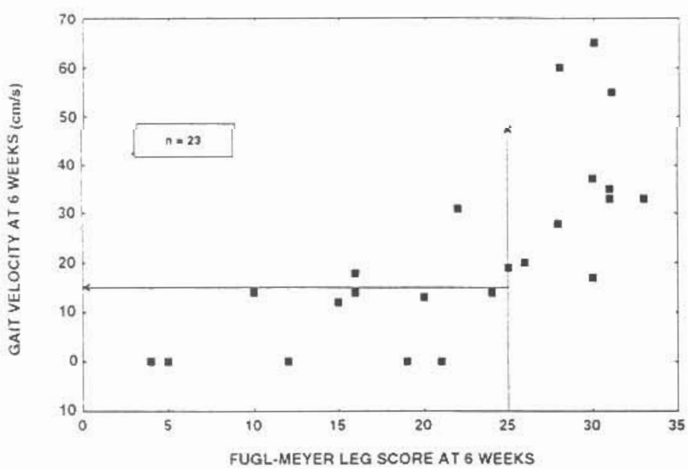

Fig 4—Regression analysis used to estimate the gait velocity in five patients. Gait velocity (cm/s) is given on the y axis and the Fugl-Meyer leg score at six weeks on the x axis.

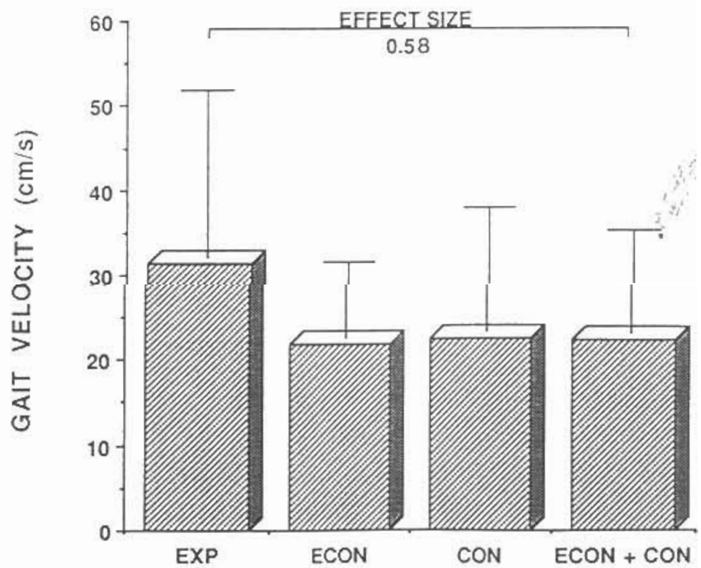

Fig 5—Comparison of the gait velocity in the three groups of patients and when the two conventional groups are combined (ECON + CON). Bars give mean ± 1 SD. Effect size calculated between EXP group and conventional groups (ECON + CON). EXP, experimental; ECON, early conventional; CON, conventional.

Table 5: Analysis of Covariance to Compare the Effects of Experimental and Conventional Physical Therapy Treatment Approaches on the Gait Velocity of Hemiplegic Patients at Six Weeks After Stroke With Adjustment for Fugl-Meyer Leg Scores at Baseline

Treatment Group	N	Unadjusted Means for Gait Velocity (cm/s)	Adjusted Means for Gait Velocity (cm/s)
1. Experimental	9	31.3	32.2
2. Conventional	14	22.2	22.3

Analysis of Variance Results

Source of Variation	Sum of Squares	df	Mean Square	f	Significance of f
Covariate: Fugl-Meyer leg score at baseline	1153.8	1	1153.8	5.93	0.024
Treatment effects	433.7	1	433.7	2.23	0.151
Residual error	3890.4	20	194.5		
Total	5477.9	22	249.0		

Grand mean = 25.7
Regression Coefficient: Baseline Fugl-Meyer Leg Score = 0.85
Multiple R squared = 0.29

was compared to that between therapy time specifically dedicated to gait training and gait velocity in the total sample of patients. Figure 6 illustrates the scatter plots obtained for the Spearman ρ coefficients. This comparison demonstrates that specificity of training and not total therapy time promotes improved gait velocity.

DISCUSSION

This pilot study fulfilled several of its objectives. Firstly, it demonstrated the feasibility of running a randomized controlled clinical trial involving three types of physical therapy for stroke patients. It also highlighted the difficulty in recruiting stroke patients corresponding to highly restricted lesional, functional, and age categories. Although the hospital in which this trial was run is the major neurological hospital for all of the northeastern part of the province of Quebec and receives an estimated 25% of all the stroke patients for its region of the province, accrual of patients was extremely slow. It took 25 months to recruit 27 suitable patients.

This study led to the development of a new PT approach, a specialized gait training therapy, to promote locomotor recovery after stroke. This approach is more intense and task-specific than conventional physiotherapeutic approaches[31,32,35] and emphasizes the need for early intervention. A very positive finding was the ability of the patients to cope with a new therapy emphasizing the practice of specific locomotor activities such as treadmill walking and reciprocal exercises on the Kinetron. This study thus not only made it possible to develop this specialized gait training therapy but also to obtain compliance data on the subcomponents of both this new therapy[36] and the conventional control therapies.

This pilot study also provided valuable information related to the research question of the trial: Is early and intensive specialized gait training therapy superior to conventional methods for promoting recovery of locomotor function after stroke? Despite the small number of patients, the results of this study suggested that the time spent in specialized gait training activities practiced by the patients in the EXP group and not the early intervention was responsible for the more rapid recovery of locomotor function in the experimental group at six weeks when compared to the conventional groups. As shown in figure 6, the time dedicated to gait training but not total therapy time was correlated to gait velocity. Time dedicated to gait training for the patients of the EXP group was about twice that of either the ECON or the CON group. Interestingly, the time dedicated to gait activities was similar for both conventional therapy groups even though the total therapy time of the ECON group was more than twice that of the CON group (fig 1). This result strongly supports a specificity of training effect.

Many clinical reports and motor learning-related findings[8,37] indicate that the best way to learn an activity is to practice that activity, which means task-specific training. The recent report that improved standing balance following standing balance training was not accompanied by a concomitant improvement in the symmetry of the leg movements during gait in hemiparetic patients[38] further supports this specificity of training concept. If we assume that recovery after stroke involves the relearning of motor behaviours, the PT program should emphasize sensorimotor learning in a maturational sequence[39] and be task-oriented[8,38] as in the present study. Beneficial effects of gait training on a treadmill have previously been shown in chronic paraparetic patients[40] and in elderly patients after a hip fracture.[41] One can question whether the 9.1cm/s mean increase in walking speed in the EXP group is clinically relevant. This gain represents about 9% of the mean walking velocity of healthy elderly subjects evaluated in our laboratory. The mean velocity of the EXP group six weeks after stroke was 41% greater than that of the patients in the CON therapy groups and equal to about 30% of the normal walking velocity. The gain of 41% was thus judged to be clinically significant.

As expected, gait velocity increased with time after

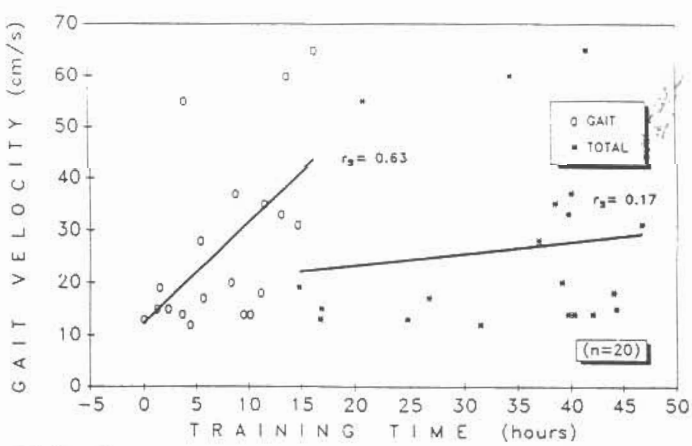

Fig 6—Comparison of two relationships: (1) between total therapy time and gait velocity and (2) between time dedicated to gait training and gait velocity in the total sample of hemiplegic patients. Scatter plots and lines obtained when calculating Spearman correlation coefficients.

stroke[26-28] but remained lower at six months after stroke than mean gait velocity values obtained in studies of etiologically more diverse and more chronic patients.[35,42] On the other hand, the mean gait velocity of the patients in the EXP group at six weeks after stroke was similar to that reported by Brandstater and associates[27] for a group of hemiplegic patients comprised of patients in different stages of motor recovery 1 to 5.5 months after stroke. In a recent study, Olney and coworkers[43] reported that the mean gait velocity of a group of patients who had been treated in a rehabilitation unit and were able to take part in one and a half hours of intermittent walking could be subdivided into three groups according to their self-selected walking velocity: fast (mean = 63 ± 0.8cm/s), medium (mean = 41 ± .08cm/s), and slow (mean = 25 ± .05cm/s). A walking velocity of 31cm/s, attained by the patients in the EXP group as early as six weeks after stroke can thus be considered a good result in a group of patients initially in various stages of motor recovery.[27,29]

At three months the differences among the groups disappeared, suggesting that it may be important to continue therapy at least up to three months after stroke because much recovery occurs between six weeks and three months.[1,2] The five-week intensive therapy period was too short to induce optimal recovery because the gait velocity and clinical scores continued to improve up to and beyond three months after stroke. Because the differences for gait velocity among the groups disappeared at three months, however, it is possible that the cessation of the intensive task-specific therapy in the patients of the EXP group had a detraining effect on these patients when they reverted to conventional therapy or were discharged. It can be assumed that this gait-specific detraining effect would be less marked on the patients of the two other groups. One can argue that maintenance of the therapy regimes up to three months after stroke would have led to even larger differences between the EXP and conventional groups. We believe that these promising results warrant the carrying out of a multicentre randomized controlled trial to test the effectiveness of this new specialized gait training approach relative to conventional physical therapy for the promotion of locomotor recovery after stroke. If the effect size achieved in this study can be maintained in a randomized trial with sufficient patients, it would be an important clinical finding useful in planning physiotherapeutic programs for stroke patients.

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