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ORIGINAL COMMUNICATION

A randomized trial on the efficacy of intensive rehabilitation in the acute phase of ischemic stroke

Andrea Di Lauro
Lorenzo Pellegrino
Giuseppe Savastano
Clemente Ferraro
Michele Fusco
Francesco Balzarano
Mirella Marina Franco
Luciano Gaetano Biancardi
Alberto Grasso

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A. Di Lauro, MD (✉) · L. Pellegrino, MD · G. Savastano, MD
U. O. Neurologia
Azienda Ospedaliera S. Sebastiano
Via Palasciano
81100 Caserta, Italy
Tel./Fax: +39-823/232269
E-Mail: andilauro@libero.it

C. Ferraro, MD · M. Fusco, MD · F. Balzarano · M. M. Franco
U. O. Medicina Riabilitativa
Azienda Ospedaliera S. Sebastiano
Caserta, Italy

L. G. Biancardi · A. Grasso, MD
Dipartimento Scienze Neurologiche
Unità di Neurologia Riabilitativa
Università degli Studi di Napoli Federico II
Naples, Italy

Abstract Sixty patients admitted to hospital for hemispherical ischemic stroke causing severe disabilities were enrolled in the study. The patients were divided in two groups: A and B. The patients in group A were given intensive rehabilitative treatment; those in group B were given ordinary rehabilitative treatment. Both treatments lasted 14 days. At the end of that period, the patients of both groups were sent to the same rehabilitation center to continue treatment, using the same methods for all. The patients were evaluated by means of the modified N. I. H. Stroke Scale and the Barthel-Index on the day of enrolment, on the 14th and 180th day. The results obtained from intensive treatment were no better than those obtained from ordinary treatment.

This study shows that there is no point in adopting an intensive rehabilitative treatment for an ischemic stroke in its acute phase: a more expensive and time-consuming effort does not in any way lead to a better outcome.

Key words cerebrovascular disorders · rehabilitation · intensity

Introduction

Stroke is a leading cause of disability among adults in developed countries [12]. Any treatment that may improve the outcome can greatly reduce the burden that this illness weighs on society. Treatment based on neurological rehabilitation, which has been historically considered basic to therapy in medical centers where stroke patients are treated, has been the subject of numerous studies directed towards examining the theoretical premises of such rehabilitation, the way in which it is carried out, its duration and its effectiveness. Most of the studies published over the last few years have not been conclusive and therefore have not permitted us to choose a specific treatment and/or to individualize reliable criteria to identify responsive patients [1, 3, 13, 15].

There is evidence that intensive rehabilitation compared with conventional rehabilitation produces better functional recovery [7, 8, 9, 16, 18]. The aim of the present research was to compare the results of intensive neurological rehabilitation with those of ordinary rehabilitation. The efficacy of the treatment was tested after 14 and 180 days.

Subjects and Methods

Sixty patients were enrolled in the present study. They were of both sexes and were between 40 and 80 years old. All gave their informed consent prior to their inclusion in the study.

- Inclusion criteria were: hemiplegia caused by hemispherical ischemic lesion (detected by computerized tomography of the skull), unimpaired consciousness, disability due to the stroke of such a severity as to make impossible daily living activities (Barthel-Index ≤ 3).
- Exclusion criteria were: cerebral hemorrhage, hemineglect, disabilities that were not of the hemiplegic type, slight hemiparesis, concomitant sensorial aphasia, severe concomitant cardiac or respiratory disorders, signs that were the outcome of a previous cerebrovascular disorder.
- The patients were randomly assigned to two groups, using a sealed envelopes method.
- Measurement of neurological damage was by the modified N. I. H. Stroke Scale [10, 11].
- Measurement of disability was by the Barthel-Index (version of Wade & Collin) [19].
  These two scales were always used by the same neurologist who did not know to which group the patients belonged. The patients were evaluated within 24 hours and after 14 days and 180 days from the onset of stroke.
- Two different rehabilitative programs were set up and carried out during the first two weeks of hospitalization. On the basis of the content and the duration of each session one treatment was called "intensive" and the other "ordinary". Both began within 24 hours after the stroke.

1. Intensive rehabilitative treatment.
   Duration: 2 hours a day with an interval of 6 hours between the morning and the afternoon treatment.

Contents:

a) Morning treatment
   - exercises of mobilization according to the scheme of Knott & Voss [6], with "active" work (against resistance on the part of the therapist) for about 45 minutes;
   - exercises of proprioceptive recognition;
   - rehabilitative nursing (correct positioning in bed, bedsores prevention, intermittent bladder catheterisation) for 15 minutes.

b) Afternoon treatment
   - exercises of mobilization for about 15 minutes;
   - tactile, kinesthetic and proprioceptive stimulation;
   - exercises of visual stimulation (light sources that vary in intensity, such as television screen and stroboscopic light);
   - cognitive skill exercises;
   - exercises of acoustic stimulation (using a tape-recorder for 45 minutes).

2. Ordinary rehabilitative treatment
   Duration: 45 minutes, once a day.

Contents:
passive and active (if possible) mobilization, bedsores prevention, correct positioning in bed.

The patients in group A were given the intensive rehabilitative treatment; the patients in group B were given ordinary rehabilitative treatment.

Follow-up:
After 14 days of treatment in hospital and after evaluation by modified N. I. H. Stroke Scale and Barthel-Index, the patients were sent to a rehabilitation center for 60 days. During that period they were given the conventional treatment that was used in that center, regardless of whether they were in group A or in group B during the acute phase.

At the end of the 60-day period, the patients left the center and continued the rehabilitative treatment at home or in a day hospital for another 4 months. This last phase of the treatment was not monitored.

Data analysis:
Data were examined by means of Student's t test.
Values of $P \leq 0.05$ were considered statistically significant.

Results

The two groups (A and B) were similar in several characteristics: total number of patients, number of patients of each sex, age and number of drop-outs (due to death – 5/7 –, transfer to other centers – 1/7 –, loss of contact with the therapists – 1/7 – for both groups) (Table 1).

The scoring of the neurological damage and of the consequent disability showed full homogeneity between the two groups at the beginning of the treatment; this scoring after two weeks and after 6 months did not show any difference between the two groups (Tables 2 and 3).

After 14 days, both groups showed the same degree of improvement as far as both measurements were concerned. After 180 days, this improvement increased to the same extent in both groups.

Discussion

To prove the hypothesis that "more is better" we used a rehabilitative treatment which offers more "quality and quantity" than the conventional treatment. We then

Table 1 Patients' Variables

	Group A	Group B
N.	29	31
Male	11 (38%)	14 (45%)
Age* (years)	69.3 (8.0)	67.6 (9.3) P > 0.4**
Drop-out	7 (24%)	7 (23%)

* Values are given as mean (S. D.); ** Student's t Test

Table 2 Evaluation of neurological damage and its evolution (Modified N. I. H. Stroke Scale)

	Group A	Group B
Basal	10.8 (2.8) n = 29	10.6 (2.4) n = 31 P > 0.9*
at 14 days	8.1 (3.0) n = 26	8.4 (2.6) n = 27 P > 0.6*
at 180 days	6.2 (2.8) n = 22	6.5 (2.7) n = 24 P > 0.7*

Values are given as mean (S. D.)
* Student's t Test

Table 3 Evaluation of the degree of disability and its evolution (Barthel Index – Version of Wade & Collin)

	Group A	Group B
Basal	1.4 (1.4) n = 29	1.5 (1.5) n = 31 P > 0.7*
at 14 days	3.2 (2.0) n = 26	3.2 (2.6) n = 27
at 180 days	8.0 (2.8) n = 22	7.7 (3.0) n = 24 P > 0.7*

Values are given as mean (S. D.)
* Student's t Test

checked the supposedly superior treatment regarding the resulting efficacy.

This intensive treatment was set up in such a way as to provide a global (cognitive-motor) approach, that is considered necessary for a more satisfactory outcome [4, 5].

More intensive and more variegated exercises for disabled patients can give better results also because of a placebo effect. This has recently been the object of renewed attention in neurological practice [2].

The results from previous trials, aimed to verify our initial hypothesis that "more is better", were difficult to interpret because these studies were not randomized and the evaluation of patients was not blind [8].

We tried to overcome these difficulties by randomly including in our study only patients with severe disability due to hemispherical ischemic stroke. We thus obtained two groups with homogeneous characteristics. All the evaluations, both at the beginning and at the end of the treatment, were made with proper blind procedures.

The decision to give the intensive treatment only in the 14-day period immediately after the stroke (which is also the average length of stay in hospital) was the natural consequence of a theory commonly shared. The theory is that it is mainly during this initial period that re-education for functional disabilities in pathological conditions is most effective [14].

Our results show that an intensive rehabilitative treatment for the first 14 days in patients with severe disabilities due to hemispherical ischemic stroke did not lead to any improvement after 14 or 180 days, when compared with a conventional treatment.

The better results obtained in patients with acute cerebrovascular disorders when treated in the stroke unit rather than in general medical wards [17], according to our work, cannot be attributed to a greater efficacy of the rehabilitative treatment but to other factors.

This study might have missed a real difference between the outcome of the two rehabilitative approaches. First, the patients enrolled were very severely affected. It may be that a group of less severely affected patients would have benefited. Secondly, the patients received the extra-therapy for only two weeks, and this may be a too short period. Thirdly, it is still possible that a higher number of patients might make clear a subtle difference between the two groups.

Further studies are necessary in this area to determine "what is better" and "for whom".

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