Clinical Study

A prospective, randomized, single-blinded trial on the effect of early rehabilitation on daily activities and motor function of patients with hemorrhagic stroke

YuLong Bai, YongShan Hu *, Yi Wu, YuLian Zhu, Qiang He, CongYu Jiang, LiMin Sun, WenKe Fan

Department of Rehabilitation Medicine, Huashan Hospital, Fudan University, 12 Wulumuqi Middle Road, Shanghai 200040, China

A B S T R A C T

To investigate whether early rehabilitation has a positive impact on the recovery of the activities of daily living and motor function after intracerebral hemorrhagic stroke, 364 patients with hemorrhagic stroke were selected and randomly divided into a rehabilitation group and a control group. The rehabilitation group underwent a standardized, three-stage rehabilitation program. The control group was treated with standard hospital ward, internal medical intervention. The simplified Fugl-Myere assessment scale (FMA) and Modified Barthel Index (MBI) were administered at various time points. The magnitude of improvement was significantly higher in the rehabilitation group than in the control group for both the FMA ($p < 0.05$) and MBI scores ($p < 0.05$). The greatest improvement was observed in the first month post-stroke. Thus, our study shows that early rehabilitation can significantly improve the daily activities and motor functions of patients with stroke.

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1. Introduction

Intracerebral hemorrhage (ICH) accounts for 15% of acute stroke in patients in North America and Europe and nearly 30% of those in Asia.[1] The fatality associated with ICH is higher than that with cerebral infarction.[2–4] Thus, the treatment for ICH has received much attention and undergone major improvement. For example, a growing number of hospitals are developing stroke unit care for patients with ICH, which significantly reduces mortality and improves functional outcomes.[5–7]

An essential role of the stroke unit is early rehabilitation, which has also been shown to be effective for ICH.[8–11] Early studies have shown that patients who undergo early rehabilitation recover much better than those receiving general medical ward care.[12,13] Furthermore, animal model experiments have provided additional evidence that early rehabilitation has an important role in functional recovery after stroke.[14,15]

Besides its role in physical recovery, the effect of early rehabilitation on the psychological well-being of patients with ICH has been discussed.[16,17] Patients undergoing early rehabilitation tend to be less depressed and anxious than those under standard care.[17] However, there have been few studies on the effect of early rehabilitation on the activities of daily living (ADL) and functional independence of patients with ICH.

Our study aims to determine whether early rehabilitation results in better ADL and motor function than traditional care in patients with ICH. The patients were monitored from admission to rehabilitation and followed for six months after discharge. Our results showed that very early rehabilitation can improve the functional recovery of patients with ICH.

2. Methods

2.1. Design

This study used a prospective, randomized, clinical trial design. All measurements were recorded by an assessor who was blinded to the study design and details.

2.2. Participants

This study included 364 patients who suffered from hemiplegia following ICH and were admitted to 21 emergency hospitals in China from 1 January 2002 to 30 June 2003. Written consent was obtained from all participants and the study was approved by the institution review board of Fudan University. The inclusion criteria were that patients: (i) after admission were stabilized within one week of symptoms; (ii) had a Glasgow Coma Scale (GCS) score >8; (iii) had a limb disability; and (iv) were aged between 40 years and 80 years. Patients were excluded if they: (i) had a cerebrovascular disease history with residual symptoms; (ii) had an onset of

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* Corresponding author. Tel./fax: + 86 21 52887820.
  E-mail address: doctorhuyongshan@126.com (Y. Hu).

ICH more than three weeks prior; (iii) had tetraplegia, (iv) had a history of dementia; and (v) were not resident locally. All diagnoses met the diagnostic criteria approved by the 4th Chinese National Conference of Cerebrovascular Disease in 1995 and was confirmed by CT scans or MRI.

2.3. Measurements of daily activities and motor functions

Baseline patient characteristics were collected, including gender, handedness, condition of paralysis, and the time from stroke onset. A pre-stroke history of depression or anxiety was determined from medical records. The simplified Fugl-Myere assessment scale (FMA) and Modified Barthel Index (MBI) were administered at various times, including at admission and at one, three, and six months after the stroke to measure ADL and motor function. If the assessments took place when the patients were still hospitalized, trial staff were informed of an impending assessor visit so that the assessor, who was blinded to study design, would not inadvertently view a rehabilitation session.

2.4. Treatment procedures

The patients were randomized into two treatment groups: the early rehabilitation group ($n = 181$) or the control group ($n = 183$). All patients underwent the same routine internal medical intervention, but those in the rehabilitation group underwent a standardized three-stage rehabilitation program. Patients from both groups could receive help from their relatives.

The standardized three-stage rehabilitation program included physical and occupational therapies and emphasized ADL training immediately after enrollment. These training programs were carried out by therapists in emergency hospitals, rehabilitation centers, and communities and were divided into primary, secondary, and third rehabilitation. The primary rehabilitation, which was aimed at practicing the basic ADL, was conducted at the Emergency Department or Neurology Department during the first month after stroke. The secondary rehabilitation was conducted at the Physical Department during the second and third month after stroke to help develop balance and walking. The third rehabilitation was conducted to enhance ADL and motor functions during the fourth to sixth month. Their relatives or nurses were trained to rehabilitate the patients at home. If patients were transferred to community centers instead, they were visited by therapists who directed their training every two weeks.

During primary rehabilitation, individual physical therapy began within 24 hours of admission and was performed for 45 minutes per day, five days per week. Treatment was conducted by one therapist per patient. If necessary, patients from both groups had access to daily training for unilateral spatial neglect, speech deficit, and for swallowing, bowel, and bladder dysfunction.[18–20]

2.5. Statistical analyses

Data analyses were performed using the Statistical Package for the Social Sciences 16.0 (PASW, IBM, Armonk, NY, USA). The data were entered, corrected, and checked using EpiData 3.0 (EpiData, Odense, Denmark). The baseline characteristics of the patients were compared using the chi-squared test (χ^2) (numerical data) or t-test (continuous data). The FMA and MBI scores were compared using the repeated-measure analyses of variance.

3. Results

3.1. Baseline characteristics

On admission, the rehabilitation group and the control group were comparable on all baseline measures (Table 1). Six months after the stroke, 12 patients (four in the rehabilitation group and eight in the control group) were lost to follow-up, and seven patients (two in the rehabilitation group and five in the control group) died. The mortality rate ($\chi^2 = 1.34$, $p = 0.25$) and the patients lost to follow-up ($\chi^2 = 1.42$, $p = 0.23$) were not significantly different between the two groups.

3.2. FMA scores

The FMA scores are summarized in Fig. 1. The FMA scores increased over the period of six months ($F_{1,343} = 229.9$, $p < 0.05$), and the scores of the rehabilitation group were higher than those of the control group ($F_{1,343} = 42.2$, $p < 0.05$). The interaction between times and intervention group was also significant ($F_{1,343} = 37.2$, $p < 0.05$). Post hoc tests showed that the baseline FMA scores of the two groups were comparable ($p = 0.37$), but the FMA scores of the rehabilitation group were significantly higher than those of the control group at one, three, and six months after stroke (all $p < 0.05$), indicating that patients in the rehabilitation group experienced better recovery of motor function.

3.3. MBI scores

The MBI scores also increased over the period of six months ($F_{1,343} = 196.8$, $p < 0.05$; Fig. 2), and the MBI scores of the rehabilitation group were significantly higher than those of the control group ($F_{1,343} = 53.85$, $p < 0.05$). The interaction between times and intervention group was also significant ($F_{1,343} = 6.7$, $p < 0.05$). Post hoc tests showed that the baseline MBI scores of the two groups were comparable ($p = 0.59$), but the MBI scores of the rehabilitation group were higher than those of the control group at one, three, and six months after the stroke (all $p < 0.05$), indicating that early rehabilitation had a positive role in the recovery of ADL.

4. Discussion

Our study demonstrates that early rehabilitation can improve the recovery of ADL and motor function of patients with ICH. The improvement in the FMA and MBI scores was much higher in the rehabilitation group than in the control group. However, even in the control group, both the FMA and MBI scores showed a moderate and significant increase from baseline. Previous studies suggest that within the first two months after stroke, spontaneous neurological recovery does occur.[21] With the alleviation of hematoma and edema, the brain can partially, or in rare cases fully, restore its function. However, the extent of functional recovery for most patients is limited and therefore additional intervention can be important.

Early rehabilitation is an effective, therapeutic intervention strategy for patients with ICH that leads to better clinical outcomes in both the physical and psychological health of these patients.[8–13] Consistent with previous reports,[22–24] the current study shows that the rehabilitation group experienced better recovery of ADL and motor function than the control group. A closer look at the results reveals that the biggest improvement was achieved in the first month post-ICH with an average intervention of 19 or 20 days. The rate of recovery then gradually slows down and reaches a plateau by the end of six months.