Feasibility and Safety of Acute Phase Rehabilitation After Stroke Using the Hybrid Assistive Limb Robot Suit

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Abstract

Acute phase rehabilitation is an important treatment for improving the functional outcome of patients after stroke. The present cohort study analyzed the feasibility and safety of acute phase rehabilitation using the hybrid assistive limb robot suit in 22 patients, 7 males and 15 females (mean age 66.6 ± 17.7 years). Neurological deterioration, mortality, or other accidents were recorded as adverse events. Baseline characteristics of each patient were recorded at the first hybrid assistive limb rehabilitation. Hybrid assistive limb rehabilitation was conducted for 12.1 ± 7.0 days with the patients in stable condition. Acute phase hybrid assistive limb rehabilitation was performed a total of 84 times with no adverse events recorded except for orthostatic hypotension. Good functional outcomes were obtained in 14 patients. Orthostatic hypotension was observed during the first hybrid assistive limb rehabilitation in four patients, and was significantly associated with intracerebral hemorrhage (p = 0.007) and lower Brunnstrom stage (p = 0.033). Acute phase rehabilitation using the hybrid assistive limb suit is feasible and safe. Patients with intracerebral hemorrhage and lower Brunnstrom stage should be carefully monitored for orthostatic hypotension.

Key words: acute phase rehabilitation, hybrid assistive limb robot suit, stroke, orthostatic hypotension

Introduction

Acute phase rehabilitation is an important part of the treatment for improving the functional outcome of patients after stroke in the acute hospital setting. The hybrid assistive limb (HAL) suit is one of a number of advanced technologies that have been developed for the assistance of stroke patients. This robotic device was originally designed to support elderly patients with muscle weakness, and to assist with independent mobility in people with impaired motor function. However, whether the HAL suit can be used for the rehabilitation of patients with acute stroke without adverse complications remains unclear. The present study investigated the feasibility and safety of the HAL suit in the rehabilitation of patients in the acute phase after stroke.

Materials and Methods

This prospective cohort study was designed to evaluate acute phase rehabilitation after stroke using the HAL robot suit in the Department of Neurosurgery, Fukuoka University Hospital from November 2011 to March 2012. A total of 22 patients, 7 males and 15 females (mean age 66.6 ± 17.7 years) were enrolled. The oldest participant was aged 90 years. The Fukuoka University Institutional Review Board approved the study and informed consent was obtained from all participants or their representatives. The protocol included subjects satisfying the following criteria: hemiplegia or ataxia after stroke, height >120 cm, weight <100 kg, Glasgow Coma Scale (GCS) score >9, systolic blood pressure between 100 and 160 mmHg, oxygen saturation without supplementation >90%, heart rate between 40 and 120 beats per minute, and body temperature <37.5°C. The limitations of height and weight were determined by the size restrictions of the HAL suit, as recommended by the manufacturer (CYBERDYNE...
Fig. 1 Photographs during hybrid assistive limb (HAL) rehabilitation showing the patient in Brunnstrom stage I (left) and standing upright (right) with HAL assistance. Electromyogram (EMG) was detected on the paralytic side while upright. L: left side, R: right side.

Table 1 Outcomes of hybrid assistive limb (HAL) training in stroke patients

<table>
<thead>
<tr>
<th>Outcome</th>
<th>No. of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement of walking and torso posture</td>
<td>2</td>
</tr>
<tr>
<td>Standing with HAL assist</td>
<td>12</td>
</tr>
<tr>
<td>No change in activity</td>
<td>2</td>
</tr>
<tr>
<td>Refusal of second HAL rehabilitation</td>
<td>6</td>
</tr>
</tbody>
</table>

Results

Acute phase rehabilitation using the HAL suit was performed a total of 84 times (mean 3.8 ± 3.1 times). HAL rehabilitation was conducted over 12.1 ± 7.0 days when the vital signs of the patients were stable (Fig. 1).

Following HAL rehabilitation, two patients had improved walking and torso posture, 12 patients could stand with HAL assistance, and two patients showed no change. Six patients withdrew from the study due to depression status, inappropriate size of shoes, and lumbar spondylosis, which prevented correct fitting of the backpack and mounting of the gyroscope and accelerometer required for torso posture estimation (Table 1).

No episode of mortality, neurological deterioration, falling, bone fracture, or skin erosion occurred throughout the acute phase rehabilitation using the HAL suit. However, four patients demonstrated OH as an adverse event, which prevented one patient receiving second HAL rehabilitation. Intracerebral hemorrhage and lower Br were significantly associated with OH, as demonstrated by Fisher’s exact test and U-test (p = 0.007 and p = 0.033, respectively; Table 2). No other variables were associated with OH (Table 2). Lower Br was not associated with any of the clinical characteristics (Kruskal Wallis test, p = 0.266).

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## Discussion

The present study demonstrated that HAL rehabilitation is feasible and safe after stroke in the acute phase. To prevent falls, neurological deterioration, or any other morbidity, the presence of OH should be monitored in patients with intracerebral hemorrhage and lower Br. An elastic stocking on the paralytic side or delaying rehabilitation for a few days enabled us to continue HAL rehabilitation in three of four patients with OH. OH has been attributed to the time after eating, antihypertensive and diuretic medications, and the presence of diabetes mellitus, implying the involvement of autonomic dysfunction. However, we found no significant differences in these variables between the patients with and without OH, as only intracerebral hemorrhage and lower Br were significantly associated with OH. Lower Br was not associated with any clinical characteristic, suggesting that intracerebral hemorrhage and lower Br were not confounding factors. The variable of intracerebral hemorrhage may be an independent risk factor for OH. The severe degree of autonomic dysfunction in patients with intracerebral hemorrhage is a likely mechanism of OH in the present acute setting. Further studies with more cases are required to avoid type II error.

The HAL suit consists of a ‘cybernics voluntary control system,’ which provides complete control using bioelectric signals, and a ‘cybernics robotic autonomous control system,’ which generates the characteristic motor patterns of human motion. The HAL system functions by utilizing several sensing modalities: skin-surface electromyographic electrodes placed on the rectus femoris, vastus lateralis, gluteus maximus, and biceps femoris muscles, potentiometers, and a gyroscope and accelerometer mounted in a backpack for torso posture estimation. The objective of the HAL suit is to increase and assist the voluntary motor functions of stroke patients. We found that some patients exhibited electric signals on the paralytic side, which might have been facilitated by the HAL suit (Fig. 1). Standing with assistance of the HAL suit in the acute phase may not only facilitate the recovery of the paralytic side, but also prevent the non-paralytic side from disuse, allowing patients to have a better quality of life. Indeed, a prospective study reported that earlier and more intensive mobilization after stroke may facilitate more rapid return to unassisted walking and improve functional recovery. We expect that HAL acute phase rehabilitation will also result in earlier and better recovery. Standing and walking are also reported to induce plasticity in the spinal cord network and central pattern generator.

Age,2) depression,4) and cognitive impairment11) are potential negative factors hindering good functional outcomes. In this feasibility study, depression was the main reason for the refusal of HAL rehabilitation. Furthermore, particular attention should be paid to the presence of OH which can induce falls and result in serious consequences.1) The efficacy and indications of acute phase rehabilitation using HAL are being examined in a follow-up cohort study.

## Acknowledgments

The patient and physical therapist provided written informed consent for the use of the photograph in Fig. 1.
Conflicts of Interest Disclosure

None declared. All authors who are members of The Japan Neurosurgical Society (JNS) have registered online Self-reported COI Disclosure Statement Forms through the website for JNS members.

References


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