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Review article

What does best evidence tell us about robotic gait rehabilitation in stroke patients: A systematic review and meta-analysis

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ABSTRACT

Background: Studies about electromechanical-assisted devices proved the validity and effectiveness of these tools in gait rehabilitation, especially if used in association with conventional physiotherapy in stroke patients.
Objective: The aim of this study was to compare the effects of different robotic devices in improving post-stroke gait abnormalities.
Methods: A computerized literature research of articles was conducted in the databases MEDLINE, PEDro, COCHRANE, besides a search for the same items in the Library System of the University of Parma (Italy). We selected 13 randomized controlled trials, and the results were divided into sub-acute stroke patients and chronic stroke patients. We selected studies including at least one of the following test: 10-Meter Walking Test, 6-Minute Walk Test, Timed-Up-and-Go, 5-Meter Walk Test, and Functional Ambulation Categories.
Results: Stroke patients who received physiotherapy treatment in combination with robotic devices, such as Lokomat or Gait Trainer, were more likely to reach better results, compared to patients who receive conventional gait training alone. Moreover, electromechanical-assisted gait training in association with Functional Electrical Stimulations produced more benefits than the only robotic treatment (−0.80 [−1.14; −0.46], $p > .05$).
Conclusions: The evaluation of the results confirm that the use of robotics can positively affect the outcome of a gait rehabilitation in patients with stroke. The effects of different devices seems to be similar on the most commonly outcome evaluated by this review.

1. Introduction

The World Health Organization (WHO) defines stroke as a "rapidly developing clinical signs of focal (or global) disturbance of cerebral function, with symptoms lasting 24 h or longer or leading to death, with no apparent cause other than of vascular origin" [1].

Stroke is the most frequent cause of disability in adults in the industrialized world, and the cost of stroke-related care is increasing rapidly [2]. The Global Burden of Disease 2013 Study has shown that, although stroke incidence, prevalence, mortality, and disability-adjusted life-years rates tended to decline from 1990 to 2013, the overall stroke burden in terms of absolute number of people affected by, or who remained disabled from, stroke, has increased across the globe in both men and women of all ages [3]. Indeed, the annual stroke incidence is approximately 180 patients per 100,000 inhabitants in the industrialized world.

Post-stroke disability may involve mobility and stability of joints, muscle power, tone and reflexes, muscle endurance, control of movement, and gait pattern functions. These impairments lead to problems with transferring, maintaining body position, mobility, balance, and walking. In the first 6 months post stroke, almost all patients experience at least some predictable degree of functional recovery. Although the majority of stroke patients learn to walk independently by 6 months after stroke, gait and balance problems persist through the chronic stage of the condition and have a significant impact on patients' quality life [4].

Recovery of walking function to obtain independence in daily life is one of the main goals of patients after stroke [5] and in gait rehabilitation, and no conventional treatment approach has so far

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proven to be superior [6]. Recovery of walking function mainly occurs within the first 11 weeks after stroke [7]; indeed, patients who experience functional recovery after that time are few [8]. Modern concepts favor a task-specific repetitive approach [9]. Electromechanical-assisted gait training and treadmill training, with and without partial body weight support, are used in combination with over-ground gait training to improve function of patients after stroke. The main difference between electromechanical-assisted and treadmill training is that the process of gait training is automated and supported by an electromechanical solution. Treadmill training with partial body weight support (BWS) enables wheelchair-bound subjects to repetitively practice complete gait cycles. The major limitation of treadmill therapy as a daily routine is the effort required by two or even three therapists in assisting the gait of severely affected subjects, setting the paretic limb, and controlling the trunk movements [8]. Electromechanical devices can be used to give patients intensive practice (in terms of high repetition) of complex gait cycles with a reduced effort for therapist, as they no longer need to set the paretic limbs or assist trunk movements [10].

Electromechanical devices for automated-assistive walking training can be differentiated into end-effector and exoskeleton devices [11]. The definition of an end-effector principle is that patient's feet are placed on footplates, whose trajectories simulate the stance and swing phases during gait training whereas exoskeleton devices are outfitted with programmable drives or passive elements, which move the knees and hips during the phases of gait [12]. Examples of exoskeleton type of devices are the "LOPES" (Lower Extremity Powered Exoskeleton) [13] and the "Lokomat" [14]. Example of end-effector devices are the "G-EO-system" [12], the "Lokohelp" [15] the "Haptik Walker" [16] and the "Gait Trainer GT1" [17].

The main objective of the present review was to compare the effects of different devices used in gait rehabilitation after stroke and provide information about the main differences.

2. Material and methods

2.1. Study selection

We included only randomized controlled trials (RCTs) written in English aimed to study the effects of robotic devices in improving walking in stroke patients. In particular, we selected articles including the comparison between electromechanical devices, such as exoskeleton and end-effector devices. Thus, we selected studies meeting the following criteria: (i) use of robotic treatment versus conventional physiotherapy treatment; (ii) use of electromechanical devices, with and without functional electric stimulation versus conventional physiotherapy treatment; (iii) use of exoskeleton robots versus end-effector robots. On the contrary, we excluded studies met the following criteria: (i) heterogeneity in the groups; (ii) lack of differentiation of subacute patients from chronic patients; (iii) inappropriate randomization. All case-report studies and case-control studies were excluded for lack of sustainability of results, as well as works concerning the development of new technologies. Reviews that evaluated effects of electromechanical and robotic-assisted gait training plus and versus conventional physiotherapy for regaining and improving walking after stroke were also excluded.

2.2. Outcomes

Our primary outcome was the efficacy of exoskeleton robot devices and of end-effector robot devices in stroke patients, measured through the walking speed (m/s) at the end of the intervention. Therefore, we selected studies including one of the following test: 10-Meter Walking Test (10-MWT) [18], 6-Minute Walk Test (6MWT) [19], Timed-Up-and-Go (TUG) [20], and 5-Meter Walk Test (5MWT) [21]. The secondary outcome was the efficacy of robotic treatment in comparison with robotic treatment in combination with the Functional Electrical Stimulation (FES), measured by the Functional Ambulation Categories (FAC) scale, a functional walking test that evaluates ambulation ability [22].

2.3. Search strategy

In order to identify studies that potentially fulfill the inclusion criteria, a research was conducted in the electronic bibliographic Cochrane Library, Medline and PEDro databases, besides in the Library System of the University of Parma (Italy), up to June 2015 without language restrictions for relevant articles. Terms used in the search of the articles were "Lokomat"; "Gait Trainer"; "Lokohelp"; "G-EO system"; "Lokomat stroke"; "Stroke AND robotics"; "Gait AND robotics AND stroke"; "Gait AND electromechanical AND stroke"; "Gait Trainer AND robotics AND stroke"; "Gait Trainer AND electromechanical AND stroke".

At first, the titles of the identified publications were read, and the studies having connection with post-stroke robotic rehabilitation were selected. Then, the abstracts of the articles were read, in order to discard the ones that did not meet the inclusion criteria. In case of uncertainty, or when the abstract was not available, the entire article was read.

2.4. Data analysis

The main analysis concerned the comparison of robotic rehabilitation versus conventional rehabilitation, subdividing the studies by type of electromechanical device used (exoskeleton or end-effector). We also performed a subgroup analysis by subdividing the studies according to the elapsed time from stroke: patients in the sub-acute phase (within six months), and patients in the chronic phase (more than six months). Finally, the comparison between robotic treatment alone and robotic treatment in combination with FES was performed.

Since many studies used different outcome scales, the treatment effect of an intervention was estimated by pooling the standardized mean difference (SMD) with 95% confidence interval (CI). Heterogeneity was quantified by the estimated between-study variance τ^2 and I^2. When the level of heterogeneity was higher than 75%, we considered the results obtained by the application of the random effects model. All data were analyzed using Comprehensive Meta-analysis 3 (Biostat, Englewood, USA). P-values lower than 0.05 were considered statistically significant.

3. Results

Fig. 1 represents our study selection process. A total of 3881 records were identified after having searched by using the aforementioned keywords, and 3 additional records identified through other sources. After reading title and removing duplicates, 60 articles were identified. Twenty-seven articles were further excluded during the phase of abstract reading. All case-report studies and case-control studies were excluded for lack of sustainability of results. Eight articles were not available in full text and journals were not present in the catalogs of our library. Four of the 17 remaining studies were excluded, given that they were systematic reviews. Thus, only 13 randomized controlled trials were selected for our work, with a total of 673 participants (mean age at baseline: 61.8 ± 5.6 years), as reported in Table 1. The mean ± SD trial duration was 4.6 ± 1.9 weeks, and it was significantly longer in

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