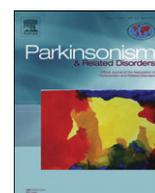




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Robot-assisted gait training versus equal intensity treadmill training in patients with mild to moderate Parkinson's disease: A randomized controlled trial

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ABSTRACT

Background: There is a lack of evidence about the most effective strategy for training gait in mild to moderate Parkinson's disease. The aim of this study was to compare the effects of robotic gait training versus equal intensity treadmill training and conventional physiotherapy on walking ability in patients with mild to moderate Parkinson's disease.

Methods: Sixty patients with mild to moderate Parkinson's disease (Hoehn & Yahr stage 3) were randomly assigned into three groups. All patients received twelve, 45-min treatment sessions, three days a week, for four consecutive weeks. The Robotic Gait Training group ($n = 20$) underwent robot-assisted gait training. The Treadmill Training group ($n = 20$) performed equal intensity treadmill training without body-weight support. The Physical Therapy group ($n = 20$) underwent conventional gait therapy according to the proprioceptive neuromuscular facilitation concept. Patients were evaluated before, after and 3 months post-treatment. Primary outcomes were the following timed tasks: 10-m walking test, 6-min walking test.

Results: No statistically significant difference was found on the primary outcome measures between the Robotic Gait Training group and the Treadmill Training group at the after treatment evaluation. A statistically significant improvement was found after treatment on the primary outcomes in favor of the Robotic Gait Training group and Treadmill Training group compared to the Physical Therapy group. Findings were confirmed at the 3-month follow-up evaluation.

Conclusions: Our findings support the hypothesis that robotic gait training is not superior to equal intensity treadmill training for improving walking ability in patients with mild to moderate Parkinson's disease.

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1. Introduction

Gait impairment is one of the primary movement disorders in Parkinson's disease (PD) [1–3]. It is characterized by a reduced gait speed, shortened stride length and longer double support phase [2]. Thus, one of the primary goals in PD rehabilitation is to improve walking ability [4]. The use of training programs focused on task-

specific activities have been encouraged to improve walking ability, in line with the increased retention of motor skill learning observed in adults with mild PD after task practice [5]. On this basis, a wide range of conventional Physical Therapy (PT) approaches has been employed to treat PD, even though there is no consensus as to "best-practice" in the different phases of illness [4].

Forced use, task-specific, intensive, gait rehabilitation programs based on treadmill training (TT) have been reported to effectively improve gait speed, walking distance and stride length in mild to moderate PD [6]. In addition, robotic gait training (RGT) has been observed to improve gait speed, walking capacity, stride length and fatigue in patients with PD [7]. However, its effectiveness on walking impairment has been evaluated only in early stage PD [7,8], where it is not superior to TT [8]. Considering that gait hypokinesia

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between RGT and equal intensity TT without body-weight support in patients with mild to moderate PD. Conversely, we observed that patients who underwent RGT and TT significantly improved gait speed and walking capacity compared to those who performed PT according to the PNF approach.

As to the RGT vs. TT comparison, our findings about individuals with mild to moderate PD seem to confirm those recently reported by Carda and colleagues regarding patients with early stage PD [8]. However, from a rehabilitative point of view, it is important to point out that only patients in the RGT group obtained clinically significant improvements in both primary outcomes (>0.25 m/s in the 10 MWT and >82 m in the 6 MWT) after treatment [24]. In order to explain these findings, the characteristics of our study population have to be considered. Indeed, patients with mild to moderate PD (H&Y 3) not only have gait hypokinesia but also suffer from an impairment of balance [9], which is a key element for the ability to walk [25]. As to the effect of RGT on balance, a recent study examined thirty-one patients with PD (H&Y 3–4) treated with the GT1 machine, reporting statistically and clinically relevant improvements in postural instability after treatment [26]. On the other hand, despite TT has been reported to improve balance skills in PD, its effectiveness has been mainly evaluated in patients with H&Y <3 [27–29]. Our results showed that balance significantly better improves after RGT than after TT. Thus, it is plausible that patients in the RGT group improved gait speed and walking capacity in a more clinically relevant way than patients who underwent equal intensity TT due to the greater effect of RGT on a fundamental element for walking ability such as balance. This would be in keeping with the GT1 machine characteristics, which is an end-effector system that allows a constant balance from one leg to the other during training, according to the slow walking speeds used [26]. Moreover, the role of body-weight support cannot be neglected, considering that impaired load receptor function has been found to contribute to gait impairment in PD [30]. In particular body-weight support has been suggested to influence lower leg extensors activity as well as load receptor proprioceptive feedback mechanisms that are essential for the maintenance of balance during gait [30]. In this study, only the RGT group had a support of body-weight, in line with previous studies [7,8]. Conversely, we decided to not support body-weight in the TT group, because the combination of body-weight support with TT still remains unclear in PD and is not strictly recommended [6,8].

Consistent with previous findings, we observed that patients who underwent RGT and TT improved walking ability more than by conventional PT [6,7]. In this study we based PT on the PNF approach consisting of exercises performed lying in bed (see Table 1). Conversely, patients in the RGT and TT groups performed an intensive training based on a great number of step repetitions. Thus, even though the PNF approach has been previously proposed for training gait in patients with PD [7,15], it is plausible that the scant effects of conventional PT observed in this study may be due to its low intensity. On this basis, further studies with matched-dose intensity are needed in order to draw any definitive conclusion on the effectiveness of PT vs. RGT or TT.

Regarding previous studies about the use of RGT for improving gait in PD, only one randomized controlled trial evaluated the effects of the GT1 machine in patients with H&Y 2.5–3, reporting statistically but not clinically significant improvements in the 10 MWT and the 6 MWT [7]. This was partially not confirmed by the present study that found also clinically significant improvements in gait speed and walking capacity after treatment with the GT1 machine in patients with H&Y 3. This probably occurred because RGT was more intensive in this study due to the higher training speed.

This study has several limitations. First, we did not compare RGT and equal intensity TT with the same amount of body-weight

support. Second, considering the PT group as a placebo group, it would have been useful to compare the three groups on a scale of satisfaction or expectancy. Third, we did not compare RGT and TT with a PT program of the same intensity of energy expenditure.

In conclusion, our findings support the hypothesis that RGT is not superior to equal intensity TT for improving walking ability in patients with mild to moderate PD. Considering that some parameters, such as balance, seem to improve better after RGT than after TT, further multicenter trials dealing with gait training in PD are needed to clarify the role of robotic and electromechanical devices in terms of effectiveness related to the phase of illness.

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