A critical appraisal of "Stride management assist exoskeleton vs functional gait training in stroke"

By

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Abstract

This paper was written to apply the learned process of critically appraising a research study, an important skill needed as a physical therapist when determining effectiveness of interventions and its use in clinical practice. A clinical question of interest was formulated and a study was selected through the use of several online databases including PubMed and Physiotherapy Evidence Database to answer the question. The study “Stride management assist exoskeleton vs functional gait training in stroke” was critically appraised through careful examination of the strengths and weaknesses of the paper’s Introduction, Methods, Results and Discussion. Although there were weaknesses found in each section, the strengths of this study outweigh the weaknesses. In conclusion, “Stride management assist exoskeleton vs functional gait training in stroke” is a high quality paper that provides evidence in favor of using exoskeletons to improve clinical gait outcome measures and corticomotor excitability in chronic stroke patients.

Key words

Stroke, exoskeleton, gait, appraisal

Introduction

The purpose of this critical appraisal is to learn and apply the process of carefully assessing a research study to understand the study's strengths and weaknesses. This is important because it allows us to be a smart consumer, which is a critical skill for a health care provider. We want to integrate the best available evidence with clinical decision making skills and patients' preferences to provide the best care possible for our patients. Due to personal experience with stroke and interest in neurorehabilitation, I was interested in the latest intervention technology for helping patients regain walking ability. Hence my clinical question is: Is robotic exoskeleton training more effective than conventional walking therapy to improve gait speed in chronic stroke patients?

Methods

The two main data bases used were PubMed and Physiotherapy Evidence Database (PEDro). PubMed was used initially as it contains over 26 million research citations, and a broader search base was desired. A personal library of studies was also built on PubMed as a starting point. Physiotherapy Evidence Database was used next due to its focus on PT intervention research. Since the clinical question is specific to intervention, a narrower search was beneficial at a later stage. PEDro is also useful for rating research studies on a 0-10 scale. Keywords used were: stroke, exoskeleton, gait/walking. Limits were placed on publication date (10 years) as exoskeletons are a relatively new technology, and robots are constantly evolving. If the population was not stroke patients, the study was excluded. If the outcome did not include gait speed, the study was excluded. If the interventions did not include robotic exoskeleton, and if there was no comparison intervention, the study was excluded. Total hits found before beginning to review articles was 12.

The article chosen for this appraisal was published this year in 2019 on Neurology. Authors include Arun Jayaraman, PT, PhD, Megan K. O'Brien, PhD, Sangeetha Madhavan, PT, PhD, and 9 more, however these three in particular contributed equally to their study and are considered co-first authors. Corresponding author Dr. Jayaraman is a clinician and faculty at the Department of Physical Therapy at Northwestern University. Participants were recruited from Shirley Ryan AbilityLab in Chicago, Willowbrook Outpatient and DayRehab Center and Northbrook Outpatient Center, both in Illinois.

This article was chosen because it was one of the few articles that included all the elements listed in the clinical question, including intervention, comparison intervention, population, and outcome. Also, this article was the most recently published (this year, 2019).

Results

Summary of the study

The objective of this study was to explore the effect of gait training with hip-assistive robotic exoskeleton vs traditional functional gait training on clinical outcomes and corticomotor excitability of three bilateral leg muscles in chronic stroke patients. This was a single-blind, randomized, parallel study in which fifty participants were equally divided into the Honda Stride Management Assist (SMA) exoskeleton group or intensity matched functional gait training group. A total of 18 sessions were delivered over 6-8 weeks and clinical outcomes as well as corticomotor excitability (CME) were obtained at 4 different time points: baseline, midpoint, completion of study, and at a three month follow-up. Gait speed was the primary outcome of interest and this measure improved for the SMA group by completion of intervention. SMA group had greater significant improvement in walking endurance and CME of involved rectus femoris compared to the functional group. Hence, the study concludes that gait training with SMA does in fact improve gait speed in chronic stroke patients (as hypothesized), and it may elicit greater improvements in walking endurance, balance and CME compared to conventional functional gait training.

Appraisal of the study introduction

Strengths

The introduction is clear and concise, and the authors do well at starting with a broader picture, "improving walking ability is a high-rated priority for individuals with stroke, and a central focus of physical therapy interventions", then narrowing down to their specific intervention, which is the Stride Management Assist (SMA) exoskeleton. The authors are quite thorough in their description of the SMA (where it was developed, how heavy it is, the general design, etc). Further, most of the sources seem to be primary sources from credible journals, such as the Journal of Neurological Physical Therapy, with an impact factor of 1.766 (not excellent, but established). The variables are outlined clearly, especially in the last sentence where a clear hypothesis is stated with both variables in the same sentence.

Weaknesses

One weakness of the introduction that it does not provide background information about strokes in general. For instance, it may have been beneficial to include the percentage of the world population who are affected by stroke each year, or how much we expect stroke incidence to increase in the future. Also, background information on the comparison treatment, functional gait training, are not provided. A potential weak literature may be number 10 in the references list, which was published in 1982 (more than 35 years ago), has only one author, and does not outline a clear method, and is not a RCT. Finally, since the authors are including corticomotor excitability (CME) as one of their dependent variables, they should include some basic background information on CME, such as what CME is.

<u>Appraisal of the study methods</u>

Strengths

The design of this study was a single-blind, parallel, randomized trial. This is a high level of research. The group assignments were not revealed to people enrolling individuals in the study because participants were de-identified and randomly assigned to an intervention group using a computer-generated 1:1 allocation. Further, outcome assessors were blinded to intervention assignment (SMA group did not wear exoskeleton during assessment). Another strength is that apart from the interventions, both groups were managed in the same way. Also, the authors do a good job describing the intervention clearly. They provide the duration, intensity scale (12-16 on Borg's or 75% age-predicted HR max), and different types of training.

Weaknesses

Although there were no attritions after the interventions began, data from many subjects were excluded in the analysis. Specifically, data from 20 subjects were excluded for transcranial magnetic stimulation analysis. This decreases reliability/validity of the study, because the sample size was significantly reduced especially for the latter analysis. Further, only 36 participants out of 50 qualified for follow-up, due to 14 participants being disqualified for receiving additional therapy. This could definitely reduce reliability/validity of the study especially because the study's primary objective was to assess the long-term outcome of SMA on traditional clinical measurements. Another weakness is that subjects were not masked to their group assignment. As far as intervention technique, it is missing minor details such as how to place the device on the patient, which would be useful if we were to repeat the procedure. Also, it does not provide a picture of the device on a patient, which would be useful to verify that the device is worn correctly if we were to repeat the experiment. With regards to instruments/outcome measures and their reliability, basic clinical assessments (10MWT, 6MWT, functional gait assessment, Berg balance scale, 5 times sit-to-stand-test, and fungl-meyer assessment) were not described. Further, patient reported measures (scales and questionnaires) were not described either. The reliability and validity of tools were not mentioned anywhere in the paper for any tools used. Further, the procedure of data collection are not described in detail.

Appraisal of the study results

Strengths

The results section is very organized (divided into 5 distinct parts) and addresses each research question. The authors report all the outcome measures presented in methods which were 12 clinical outcomes, all seen in figure 3, and the CME outcomes, present in the text. Overall the figures and tables are presented clearly. The threshold of p value is clearly shown. The statistically significant results are accurately presented and stated. The authors also include information regarding MCID and NNT and apply these to their results.

Weaknesses

There are two sources that are particularly outdated, from 1982 and 1988, however these sources refer to an Rating of Perceived Exertion (Borg's RPE) and a local regression technique respectively, both of which were probably established a long time ago and have been around for a while. Improvements can be made on addressing the clinical significance of application of the study. Further, confidence intervals were not used.

Discussion

This study is significant to current PT practice because first, stroke is a leading cause of acquired long-term disability worldwide. Second, most stroke survivors indicate walking ability as one of their top priorities for therapy objectives. Walking ability is a significant component in assessing discharge potential of patients. This creates a continuing demand for improved gait rehabilitation techniques. This study is fully relevant to the clinical question posed as it explores the effectiveness of powered robotic exoskeleton in improving gait ability.

I am in favor of using SMA exoskeleton as studies (including this one) have shown the benefits of using exoskeleton on improving clinical outcomes, and also because the use of exoskeletons significantly reduces the physical burden placed on PTs. If, however, a therapist is solely focused on increasing gait speed, the device is not necessary as there was no significant difference between SMA and functional gait groups on this outcome. Potential risk could be incorrect use of the robotic device. Further, exoskeletons are very expensive so there is a potential financial risk for clinics to acquire these devices. I believe the benefits outweigh the risks, as long as PTs are carefully trained to use the device. Affordability of the device could improve the argument in favor of using this intervention.

Overall, this research paper is of high quality, and I would be confident in using the intervention for future patients. However, I do wish that the study elaborated more on the exact steps to use the exoskeleton as well as provide a picture of a patient wearing the skeleton, to give future PTs a better idea of how to use the device effectively. In addition, I would make certain that there are 2 or more therapists who are thoroughly trained in the use of these devices to ensure safety.

In conclusion, the strengths of this study outweigh the weaknesses. The study's greatest weaknesses are: lack of information on strokes, functional gait and CME, high number of excluded data in analysis, lack of patient masking, lack of picture depicting patient in device, and lack of mentioning validity of assessment tools. In the big picture, these weaknesses are quite minor; thus, I am in favor of using robotic exoskeletons to improve gait measures in patients with chronic stroke.