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Does biofeedback increase gait velocity in children with cerebral palsy?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies Philadelphia College of Osteopathic Medicine Philadelphia, Pennsylvania

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ABSTRACT

Objective: The objective of this selective EBM review is to determine whether or not "Does biofeedback increase gait velocity in children with cerebral palsy (CP)?".

Study Design: A systematic review of three randomized control trials (RCTs) published between 2014 and 2019.

Data Sources: All three RCTs were found using PubMed. Each article was published in English in peer reviewed journals and selected based on their applicability to the clinical question, provide a new technique in CP rehabilitation, and include patient-oriented outcomes (POEMS).

Outcome Measured: The outcome measured was gait velocity before and after treatment using Tekscan software, 3D motion analysis system, and 10-meter walk test. The mean change from baseline was calculated once the treatment was received for both the control and study groups.

Results: In the RCT by Hussein et al., biofeedback increased gait velocity as compared to the control group (p = 0.03), indicated by a mean change from baseline of -9.6 cm/second in the study group versus -2.69 cm/second in the control group. In the RCT by Elnaggar, biofeedback increased gait velocity as compared to the control group (p = 0.042), indicated by a mean change from baseline of 6.235 m/minute in the study group versus 1.73 m/minute in the control group. In the RCT by Cho et al., biofeedback increased gait velocity as compared to the control group versus 0.5 m/second in the study group versus 0.2 m/second in the control group.

Conclusion: All three studies demonstrated that biofeedback significantly increased gait velocity in children with CP. This indicates that biofeedback is an effective treatment method for gait training in children with CP. Future studies should focus on expanding generalizability and ease of access to biofeedback options.

Key Words: biofeedback, cerebral palsy, gait

INTRODUCTION

Cerebral palsy (CP) is a movement disorder that is characterized by a non-progressive, chronic impairment of movement including muscle tone, strength, and/or coordination. CP is caused by abnormal development or damage to the brain while it is still developing, which can occur at any time from utero up through the first few years of life. There are four types of CP including spastic (most common), dyskinetic, ataxic, and mixed CP. CP is the most common childhood movement disorder affecting about 1 in 345 children in the United States.¹ The worldwide prevalence of CP is 1-4 per 1,000 live births.¹ As of 2010, less than 60% of children with CP could walk independently.¹ In 2003, the CDC estimated that the lifetime cost to care for an individual with CP is roughly 1 million dollars, which correlates to about 1.4 million dollars today.¹ Additionally, the healthcare costs for a child with CP is 10x higher than that of a child without CP.¹ Although there is not an exact number of healthcare visits accounted for specific to CP, it is understood that the treatment of CP involves an extensive care team including physical therapists, occupational therapists, speech and language pathologists, neurologists, and more.²

As it stands today, there is no cure for CP; however, there is a wide variety of management techniques utilized in this patient population such as physical, occupational and speech and language therapy. Additionally, mechanical devices are often utilized to promote mobility and function, for example, foot/leg orthotics, braces, crutches and splints.³ Most commonly as a last resort, anti-spasticity medications and interventions are employed such as muscle relaxers and botulinum neurotoxin injections.³ Many of these interventions come with adverse effects including prohibitive costs, negative cosmetic outcomes and poor long-term benefits. This culminates into the need for newer options for CP management; enter in biofeedback. Biofeedback is an alternative medical technique that can be used to control specific

aspects of one's body. Biofeedback has successfully been used in many different areas of medicine, for example, blood pressure control and pain management. Sensors are often used to measure bodily functions and the results are then displayed with suggestions or cues for the patient to change those functions. Most commonly, real time feedback is provided to the patient to promote reinforcement of the positive changes.⁴ In theory, biofeedback may be able to supplement and augment physical therapy and occupational therapy treatment to provide better mobility outcomes for patients with CP.

OBJECTIVE

The objective of this selective EBM review is to determine "Does biofeedback increase gait velocity in children with CP?".

METHODS

When beginning the search process for viable studies, it was important that each study meet certain criteria to allow for the clinical question to be appropriately answered. Specifically, the focus was aimed at children with CP and an intervention of gait training with biofeedback as compared to traditional gait training without biofeedback. Additionally, each study needed to include gait velocity as an outcome measured. Lastly, search results were limited to RCTs only.

Articles were selected based on their ability to appropriately answer the clinical question, provide a new technique in CP rehabilitation, and include patient-oriented outcomes (POEMS). To further narrow down the search results, key words were utilized including "biofeedback", "cerebral palsy", "gait" and "virtual reality". All studies were required to be published in peer reviewed journals in English. Although each RCT was found on PubMed, the search was initially widened to include PubMed, CINAHL plus, AMED, and Alt HealthWatch. Inclusion criteria was comprised of RCTs published in 2010 or later, whereas studies published prior to 2010 were

excluded. The statistics used consisted of mean change from baseline of gait velocity along with p-values representing the statistical significance. Demographics and characteristics of each study can be found in Table 1.

OUTCOME MEASURED

All studies measured gait velocity before and after treatment in both the study and control groups; however, velocity was calculated differently in each study. Hussein et al. utilized the Tekscan Walkway system, which is a digital mat with sensors to detect gait velocity in cm/second.⁵ When reporting change in velocity from pre- to post-treatment, Hussein et al. recorded an increase in velocity as a negative number. The RCT by Elnaggar employed a 3D motion analysis with cameras and markers to capture each patient's velocity in m/minute.⁶ Lastly, Cho et al. used the 10-meter walk test to calculate gait velocity in m/second.⁷ The 10-meter walk test allowed for each participant to be timed how long it would take to walk a total of 10 meters.⁷

RESULTS

Hussein et al. enrolled 30 children ages 4-6 with spastic diplegic CP and randomly and equally assigned them via computer program to either the control group or the study group.⁵ All participants received the treatment program including one hour of stretching and strength exercises and 30 minutes of gait training three times per week for two months.⁵ The control group's gait training consisted of walking for 30 minutes on an open environment using obstacles, steppers and balance boards, whereas, the study group's gait training utilized the Tekscan Walkway System as biofeedback.⁵ The Tekscan Walkway System allowed for the children to see how their foot was placed on the mat, which was projected up on a plasma screen in front of them in order to make adjustments as necessary for the next step.⁵ Although patients,

Study	Туре	# Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
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Hussein ⁵ (2019)	RCT	30	4-6	Patients diagnosed with diplegic CP from 4 -6 years old, spasticity grades 1 and 1+ according to modified Ashworth Scale, and gross motor function classification system level II and III	Children who had visual impairments, hearing damage, fixed deformities at lower limbs or inability to understand the task were excluded	N/A	Gait training with biofeedback vs traditional gait training
Elnaggar ⁶ (2014)	RCT	30	6-10	Diplegic children that have the ability to self- ambulate independently, 6-10 years of age, emotional and cognitive state enable the child's understanding and cooperation during evaluation and treatment, and free of fixed musculoskeletal deformities in their lower limbs	Children unable to self-ambulate independently or have fixed musculoskeletal deformities in their lower extremities	N/A	Gait training with biofeedback vs traditional treadmill gait training
Cho ⁷ (2016)	RCT	18	4-16	Diagnosis of spastic CP and below grade 2 on the Modified Ashworth Scale in the lower limbs; age 4-16 years; cognitive abilities enabling communication using only simple language; Gross Motor Function Classification System level I-III; ability to walk farther than 10 m for more than 2 minutes using a walker with ankle foot orthosis; no neurological disease other than CP; have not received an injection of anti-spastic medicine to reduce rigidity within the last 3 months; no history of epileptic seizure	Children with neurological disease other than CP, received an injection of anti-spastic medicine to reduce rigidity within the last 3 months, history of epileptic seizure.	0	Gait training with biofeedback (virtual reality) vs traditional treadmill gait training

Table 1. Demographics & Characteristics of Included Studies

clinicians and study workers were not blinded to the treatment groups, objective outcomes were measured.⁵ Change in gait velocity (cm/second) for both groups was observed at the end of the two month treatment program.⁵ Increases in velocity were recorded as a negative number.⁵ In the control group, there was a statistically significant increase in gait velocity (p = 0.0001), in cm/second, from the pretreatment mean of 37.2 ± 9.79 to the post-treatment mean of 39.89 ± 10.2 with the mean change from baseline of -2.69 cm/second.⁵ Similarly, in the study group there was a significant increase in gait velocity (p = 0.0001), in cm/second, from the pretreatment mean of 48.96 ± 12.53 with the mean change from baseline of -9.6 cm/second.⁵ When comparing the control versus the study group, biofeedback with The Tekscan Walkway System was superior to traditional gait training; there was a statistically significant increase in gait velocity (p = 0.03) of the study group over the control group with a mean difference of -9.07 cm/second.⁵ The above results are summarized in Table 2.

	Control Group	Study Group	Mean	р
	$(Mean \pm SD)$	$(Mean \pm SD)$	Difference	
Pre-treatment	37.2 ± 9.79	39.36 ± 14.7	-2.16	0.64
Post-treatment	39.89 ± 10.2	48.96 ± 12.53	-9.07	0.03
Mean Change	-2.69	-9.6		
from baseline				
р	0.0001	0.0001		

Table 2. Gait Velocity (cm/second) from Pre- to Post-Gait Training Treatment⁵

Elnaggar enrolled 30 children ages 6-10 with spastic diplegic CP and randomly assigned them to either the control group or the study group.⁶ All participants received the treatment program including 30 minutes of physical therapy exercises and 30 minutes of treadmill training three times per week for three months.⁶ The control group's gait training consisted of walking for 30 minutes on a treadmill without external cues, whereas, the study group's gait training utilized verbal cues from a therapist and a 3D motion analysis system as biofeedback.⁶ The system allowed for the children to see their foot projections on the screen in front of them in order to make adjustments as necessary for the next step.⁶ Gait velocity was recorded.⁶ Although patients, clinicians and study workers were not blinded to the treatment groups, objective outcomes were measured.⁶ Change in gait velocity (m/minute) for both groups was observed at the end of the three month treatment program.⁶ In the control group, there was a statistically significant increase in gait velocity (p = 0.003), in m/minute, from the pretreatment mean of 45.377 ± 4.812 to the post-treatment mean of 47.107 ± 3.987 with the mean change from baseline of 1.73 m/minute.⁶ Similarly, in the study group there was a significant increase in gait velocity (p = 0.001), in m/minute, from the pretreatment mean of 50.692 ± 5.167 with the mean change from baseline of 6.235 m/minute.⁶ When comparing the control versus the study group, biofeedback with was superior to traditional gait training. There was a statistically significant (p = 0.042) increase of gait velocity in the study group over the control group with a mean difference of 3.585 m/minute.⁶ The above results are summarized in Table 3.

	Control Group	Study Group	Mean	р
	$(Mean \pm SD)$	$(Mean \pm SD)$	Difference	
Pre-treatment	45.377 ± 4.812	44.457 ± 4.912	0.92	0.608
Post-treatment	47.107 ± 3.987	50.692 ± 5.167	3.585	0.042
Mean Change	1.730	6.235		
from baseline				
р	0.003	0.001		

Table 3. Gait Velocity (m/minute) from Pre- to Post-Gait Training Treatment⁶

Cho et al. enrolled 18 children ages 4-16 with spastic CP and randomly and equally assigned them to either the control group or the study group by lots.⁷ All participants received the treatment program including 30 minutes of physical therapy exercises and 30 minutes of gait training three times per week for eight weeks.⁷ The control group's gait training consisted of walking for 30 minutes on a treadmill without biofeedback, whereas, the study group's gait training utilized the Nintendo Wii virtual reality as biofeedback.⁷ The virtual reality environment

allowed for the participants to see a virtual representation of themselves a Wii character, which was projected up on a plasma screen in front of them.⁷ Participants received real time feedback as to how fast they were walking; the Wii character's speed would adjust based on the participant's speed, which allowed for them to make adjustments as necessary.⁷ The study evaluators were blinded to the group allocation and objective outcomes were measured.⁷ Change in gait velocity for both groups was observed at the end of the eight week treatment program.⁷ In the control group, there was a statistically significant increase in gait velocity (p = 0.001), in m/second, from the pre-treatment mean of 0.51 ± 0.4 to the post-treatment mean of 0.69 ± 0.4 with the mean change from baseline of 0.18 m/second.⁷ Similarly, in the study group there was a significant increase in gait velocity (p = 0.001), in m/second, from the pretreatment mean of 0.44 \pm 0.2 to the post-treatment mean of 0.89 \pm 0.2 with the mean change from baseline of 0.20 m/second.⁷ When comparing the control versus the study group, biofeedback with virtual reality was superior to traditional gait training; there was a statistically significant increase (p < 0.05) in gait velocity of the study group over the control group with a mean difference of 0.02 m/second.⁷ The above results are summarized in Table 4.

	Control Group	Study Group	Mean	р
	$(Mean \pm SD)$	$(Mean \pm SD)$	Difference	
Pre-treatment	0.51 ± 0.4	0.44 ± 0.2	0.07	0.639
Post-treatment	0.69 ± 0.4	0.89 ± 0.2	0.20	< 0.05
Mean Change	0.18	0.45		
from baseline				
р	0.001	0.001		

 Table 4. Gait Velocity (m/second) from Pre- to Post-Gait Training Treatment⁷

DISCUSSION

Cerebral palsy is a devastating movement disorder that affects many aspects of patients' lives, which has no known cure at this time. Although there are many management modalities for CP, the search is still on to discover a technique that provides long term effects without adverse outcomes or prohibitive costs. Biofeedback has been linked to successes in the control of other disorders; however, there is a limited amount of research regarding its benefits as it relates to CP. There are some potential limitations to biofeedback use, however. Intensive physical and occupational therapy is currently the gold standard management of CP; the addition of biofeedback into this regimen could mean longer rehabilitation session times, increase in costs due to the equipment necessary to appropriately gauge improvements in patient functioning, and longer commutes to the facilities that offer biofeedback.

This review focuses on the use of biofeedback as a treatment modality in patients with CP to increase gait velocity. All studies included in the review demonstrated a statistically significant increase in gait velocity when comparing pre- to post-treatment in both the control and study groups. More promising for the success of biofeedback over traditional gait training alone, there was also a significant increase in gait velocity of the study group over the control group in all three studies. All of this culminates to demonstrate that despite the success of current modalities, adding biofeedback may prove an even greater benefit for the treatment of CP.

Limitations of the included studies affect the validity of their results. Each study selected patients from either a hospital or outpatient clinic. This is important to note because the patients may have been at different baselines of rehabilitation. Elnaggar⁶ recruited patients with CP from King Khalid Hospital, which may correlate to recent hospital stays and thus indicating a potentially deconditioned state to begin the study. On the other hand, Hussein et al.⁵ and Cho et al.⁷ recruited patients from outpatient physical therapy clinics, demonstrating that the patients may have been conditioned prior to the start of the studies. Both situations could have skewed the results. Additionally, all three studies had a small sample size of patients with spastic CP, which prevents generalizability to the CP population. Although spastic CP is the most common

type of CP, there are other types of CP such as dyskinetic and ataxic CP, which were not represented in any of the three research studies making it difficult to determine whether biofeedback could be successful in all patients with CP.

On the other hand, it is important to note that differences between the Hussein, Elnaggar and Cho studies may altar the ability for extrapolation of validity to this systematic review and ultimately successes to the CP population. One important aspect to mention is the Hussein study's control group. Instead of a control group with traditional gait training as seen with Elnaggar and Cho, Hussein opted to use an open environment with obstacles, steppers and balance boards. This specific example draws some concern for the ability to fully trust Hussein's results. Lastly, Cho et al. had a study design fairly different from that of Hussein and Elnaggar. Cho's study utilized the Nintendo Wii virtual reality environment as a form of biofeedback as opposed to a formal biofeedback walkway system used by Hussein and Elnaggar. Again, this can skew trust in Cho et al.'s results when combining the data from all studies to determine success in the CP population.

CONCLUSION

The studies utilized in this systematic review demonstrated that the use of biofeedback in children with CP significantly increases gait velocity. This topic would benefit from additional research to further explore the success of biofeedback in patients with CP on a larger scale such as by including adults and patients with other types of CP to allow for stronger generalizability. In future studies, it would be valuable to test other methods of biofeedback that would be more easily attainable by patients, including smartphone applications that track gait velocity. This could limit prohibitive costs and travel time to the specific rehabilitation facilities that offer biofeedback. Additionally, for future systematic reviews, it is vital to streamline key aspects of

the research at hand such as in the control group design and in the biofeedback systems ultimately allowing for enhanced validity in the review. Overall, biofeedback is promising in the management of CP and should continue to be further studied.

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