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Original Article

Efficacy of robot-assisted gait training combined with botulinum toxin injections in cerebral palsy

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Abstract

Aim: Cerebral palsy (CP) is the most common neuromuscular disorder of the childhood for which various therapeutic modalities available, which range from conservative approach to surgery. In the present study, we aimed to evaluate the efficacy of robot assisted gait training in patients with cerebral palsy following botulinum toxin injections in the lower extremity.

Material and Methods: The study enrolled children (4 to 16 years of age) diagnosed with CP presenting to the Physical Therapy outpatient clinic who had level 1 to 4 walking difficulty associated with lower extremity spasticity according to the GMFCS (Gross Motor Function Classification System) and received botulinum toxin injections to the lower extremity within the previous month. CP patients received robot-assisted gait training five times a week over 3 weeks for a total of 15 sessions by two physiotherapists under the supervision of a physician. Study assessments included measurements of the range of motion (ROM) of the joints and the popliteal angle, GMFCS-88, Berg Balance Scale (BBS) and the and Pediatric Functional Independence Measure (WeeFIM) which were conducted before and after treatment.

Results: A total of 14 pediatric patients (8 girls, 6 boys) were included in the study. The mean age of the children was 9.93±3.54 years. A statistically significant reduction in the popliteal angle was found at post-treatment assessments compared to baseline. Berg Balance Scale, WeeFIM and GMFCS-88scores were significantly improved following treatment.

Conclusion: Robot-assisted gait training following botulinum toxin injections were found to provide marked improvements in motor functions, balance, spasticity and functional status in children with CP.

Keywords: Cerebral palsy; botulinum toxin; robot-assisted gait training

INTRODUCTION

Cerebral palsy (CP) is a permanent but often changing disorder of movement, posture and tonus caused by a non-progressive disease of the brain that has not yet completed its anatomical and physical development in the early stages of life. While clinical problems and impaired of cognition and sensory perception may have an impact on the disability level, CP is frequently accompanied by, spasticity and gait disturbance. It is the most common cause of complete motor impairment caused by a non-progressive brain lesion (1).

Over the years, conventional physiotherapy modalities (e.g. range of motion and stretching exercises, positioning) , occupational therapies, oral antispastic agents, chemical neurolysis, botulinum toxin injections, and surgical interventions (selective dorsal rhizotomy) have been used in the treatment of CP. Former studies have shown increased range of motion (ROM), reduced spasticity, improved functional and postural control, increased mobility and walking speed with the application of physical therapy methods in cerebral palsy (2). Administration of botulinum toxin to spastic muscles is a useful treatment as an adjunct to conventional physical therapy and increases the effectiveness of traditional methods. Botulinum toxin is a neurotoxin which is given

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by injections into the muscles in CP. Botulinum toxin results in reduced spasticity in the target tissue, increases the range of motion of the joint, prevents the development of contractures and facilitates performance of functional activities (3).

In recent years, robotic technology has been used increasingly for gait disorders in neurological diseases. There are studies in the literature involving robot-assisted gait training in different patient groups such as CP, cerebrovascular disease, spinal cord injury, Parkinson's disease and multiple sclerosis. Robot-assisted gait training (RAGT) provides a significant improvement in the gait function of patients with CP. RAGT is a safe method to assist standing and walking in pediatric CP patients (4,5). Studies have shown that robotic treatment improves upper and lower extremity functions in children with CP. The general consensus on the robotic treatment is that repetitive practice of activities would improve isolated movements and increase functional strength (5).

As an adjunct to treatment, botulinum toxin injections increase the efficacy of the treatment in patients with spasticity and have become an integral part of the management. With advances in technology, there has been a surge in the research on robot-assisted gait training. In the present study, we aimed to evaluate the efficacy of RAGT in patients with cerebral palsy following botulinum toxin injections in the lower extremity.

MATERIAL and METHODS

The study enrolled children (4 to 16 years of age) diagnosed with CP presenting to the Physical Therapy outpatient clinic who had level 1 to 4 walking difficulty associated with lower extremity spasticity according to the GMFCS (Gross Motor Function Classification System) and received botulinum toxin injections to the lower extremity within the previous month. Approval for the conduct of the study was obtained from the Ethics Committee for Clinical Research Trials of Erciyes University on August 9 , 2016. Informed consent was obtained from the parents/ legal representatives of the children before initiation of the study.

Children with grade 4 spasticity, contracture or rigidity in the lower extremity as assessed by the Modified Ashworth Scale, a difference in leg lengths greater than 2cm, children with hypotonic CP or drug-resistant epilepsy, children currently receiving intrathecal baclofen pump treatment, children with a scoliosis greater than 30 degrees, complicated osteoporosis (non-traumatic fracture), cardiovascular instability or GMFCS level 5 disability were excluded.

At our clinic, children with CP are given botulinum toxin injections into the muscles of lower extremity at a dose of 100 units diluted in 4 ml of normal saline using a 22 Gauge needle. A maximum of 200 units is applied per child. For children receiving botulinum toxin injections, information on the amount of toxin given and the administration site was retrieved retrospectively from their medical files. Pediatric CP patients received robot-assisted gait training five times a week over 3 weeks for a total of 15 sessions by two physiotherapists under the supervision of a physician. On average, each session lasted 30 minutes. Study assessments included measurements of the range of motion (ROM) of the joints and the popliteal angle, GMFCS-88, Berg Balance Scale (BBS) and the Pediatric Functional Independence Measure (WeeFIM) which was conducted before and after treatment.

Outcome Measurements

Popliteal angle: The popliteal angle is an assessment of the tone of the hamstring muscles. It is done one leg at a time. The thigh is flexed on the abdomen with one hand and then the other hand straightens the leg by pushing on the back of the ankle until there is firm resistance to the movement. The angle between the thigh and the leg is typically about 90 degrees (6).

Gross motor functional criteria- 88 (GMFCS-88): It is a measurement aimed at showing the gross motor function of the children aged 5months to 16 years. It consists of a total of 88 items, and these items are that 17 are of the Lying-Rolling section, 20 are in the Sitting section, 14 are in the Crawling-Kneeling section,13are in the standing section and 24 are in the Walking, Running, Jumping section (7).

Berg balance scale (BBS): The Berg balance scale is used to objectively determine a patient's ability (or inability) to safely balance during a series of predetermined tasks. It is a 14 item list with each item consisting of a five-point ordinal scale ranging from 0 to 4, with 0 indicating the lowest level of function and 4 the highest level of function. 14 items consist of sitting, standing up, standing, transferring, stepping and turning (8).

Pediatric functional independence measurement (WeeFIM): WeeFIM includes 18 items in six areas, namely self-care, sphincter control, transfers, locomotor, communication, social and cognitive. In these areas, each function is scored from1 to 7, depending on whether it receives help, whether it does on time, or whether an assistant device is needed (9).

Statistics

The data obtained were evaluated using the Statistical Package for Social Sciences (SPSS) 21.0 statistical package program. Descriptive statistics are presented as mean (±) standard deviation, median (min; max), and percentage.

Wilcoxon test was used to evaluate the outcome measurements at baseline and posttreatment. Comparison of outcome measurements according to

GMFCS levels Kruskal-Wallis test was used and Post-Hoc analyzing was performed for statistically significant values. Statistical significance was accepted as p< 0.05.

RESULTS

A total of 14 pediatric patients (8 girls, 6 boys) were included in the study. The mean age of the children was 9.93±3.54 years. Demographic characteristics of the patients are presented in Table 1.

Table 1. Demographic characteristics of participants

		n=14
Age		9.93±3.54
Gender	Female	8 (%57)
	Male	6 (%43)
GMFCS	Level 1	1(%/7)
	Level 2	3(%21)
	Level 3	4 (%29)
	Level 4	6 (%43)

A statistically significant reduction in the popliteal angle was found at post-treatment assessments compared to baseline. Significant improved was found Berg Balance Scale, WeeFIM , GMFCS-88 total scores ,GMFCS-88 standing and walking, running and jumping subscores compared to baseline. Baseline and post-treatment values of outcome measures are given in Table 2.

Table 2 Popliteal angle, WeeFIM, Berg Balance Scale and GMFCS-88 scores at baseline and post-treatment

	Baseline	Post-treatment	
(n-14)	Median (min-max)	Median (min-max)	P value
Popliteal Angle	30 (10-50)	20 (5-40)	<0.05
Pediatric functional independence measurement WeeFIM	90 (27-118)	93 (28-123)	<0.05
Berg Balance Scale	13.5 (0-51)	14.5 (0-54)	<0.05
Gross motor functional criteria- 88 GMFCS-88	138 (69-252)	150 (83-258)	<0.05
GMFCS-88 standing and walking subscores	9 (5-33)	15 (6-48)	<0.05
GMFCS-88 running and jumping subscores	13 (0-69)	19.5 (0-72)	<0.05

Comparison of patients based on the level of GMFCS showed a significant difference only in GMFCS-88 standing and walking, running and jumping subscores between level 2 and level 4 patients. Level 2 patients showed more significant improvement. Comparison of outcome measurements according to GMFCS levels are given in Table 3.

Table 3. Comparison of outcome measurements according to GMFCS levels

	Median of differences in baseline and post-treatment (Min, Max)				P value
	GMFCS Level 1	GMFCS Level 2	GMFCS Level 3	GMFCS Level 4	
Popliteal angle	5 (5-5)	5 (2-10)	7.5 (5-10)	10 (5-20)	>0.05
Pediatric functional independence measurement WeeFIM	5 (5-5)	5 (3-6)	7 (4-11)	3 (0- 6)	>0.05
Berg Balance Scale	3 (3-3)	7 (4- 8)	5.5 (2- 8)	2 (0- 4)	>0.05
GMFCS-88 total	6 (6- 6)	21(13-33)	15.5(12- 33)	13.5(3-33)	>0.05
GMFCS-88 standing and walking subscores	3 (3-3)	18 (8- 33)	5.5(4- 11)	1.5 (0-4)	<0.05 level 2 and4
GMFCS-88 standing and walking subscores	3 (3-3)	9 (7- 15)	6.5 (3-8)	2 (0-5)	<0.05 level 2 and 4

DISCUSSION

In the current study involving evaluation of the effectiveness of robotic rehabilitation in children with cerebral palsy, we observed a marked improvement in spasticity, balance, motor functions and functional ability.

CP is the most common neuromuscular disorder of the childhood for which various therapeutic modalities available, which range from conservative approach to surgery. These include mainly conventional physical therapy and rehabilitation methods. For years, conventional physical therapy has been used for the management of pediatric CP patients and is believed to be effective. Botulinum toxin injection enhances the effectiveness of conventional physical therapy and it has become an integral component of the physical therapy modalities. Several studies demonstrated the efficacy of botulinum toxin injections complemented with adjunctive conventional physical therapy. Vanessa et al.

compared the efficacy of conventional physical therapy in combination with multilevel Botulinum toxin injections (treatment group) versus daily physiotherapy (control group) and found greater improvement in gross motor functions in the treatment group (10).

With recent advances in technology, robot-assisted therapy emerged as a new alternative therapeutic option and robotic treatment is increasingly used for therapeutic purposes in various disorders (cerebral palsy, hemiplegia, paraplegia, multiple sclerosis…). Deficits in posture, movement and tonus are common in children with cerebral palsy. As part of the physical examination of CP, measurement of the popliteal angle informs the physician about the level of spasticity in the flexor muscles of the knee. Nagel et al. reported reduced spasticity in the hip flexors and knee flexors as assessed by the Ashworth scale following robot-assisted gait training in children with bilateral spastic. At the same time, they observed a mean reduction of 40 degrees in the popliteal angle with slow velocity movement and a mean reduction of 28 degrees with fast velocity movement (11). Consistently, we found decreased popliteal angle values post-treatment in the current study. In children with CP, postural control is limited due to damage to the developing central nervous system. Balance control has a key role in walking and other functional activities. Balance is a parameter that should be taken into account when treating children with CP. Many studies have shown the effects of physical therapy and rehabilitation methods on balance. Intensive balance training has been demonstrated to improve balance in spastic children (11). In a study investigating the impact of robotic therapy on balance; intervention group received robotic treatment and physiotherapy, while control group received physiotherapy alone. Statistically significant improvements were detected in balance parameters in the intervention group. Control group also showed some improvement but it was statistically non-significant (13). In the present study, significant improvement was found in Berg Balance Scale scores following treatment.

Physical therapy and rehabilitation applications hold an important place in the management of pediatric CP patients who often have deficits in gross motor functions. Studies on robotic rehabilitation have specifically focused on the standing and walking parameters of the GMFCS. Several studies reported greater improvements in standing, walking, running and jumping skills with the use of robot-assisted gait training as demonstrated by GMFCS (4,5,14). Additionally, patients at a higher level of gross motor functions (GMFCS levels 1 and 2) showed greater improvement in walking, running and jumping functions in comparison to GMFCS level 3-4 patients. In the present study, we also observed significant improvement in GMFCS-88 subscores, with much greater improvement in GMFCS level 2 patients. Few studies are available which examined the effects of robot-assisted therapies on functional independence. In a study by Smania et al CP patients were divided into two groups as robotic and control groups. While the treatment group received robot-assisted therapy together with conventional physical therapy methods, control group received only conventional physical therapy applications. Greater improvement was detected in the WeeFIM scores of the robotic therapy group compared to control group (15). In our study, we also observed significant improvement in post-treatment WeeFIM scores.

Prior research efforts have primarily focused on the efficacy of robot-assisted treatments on walking ability in CP. Unlike other studies, we evaluated the effects of robot-assisted gait training on balance; motor functions, spasticity and functional status individually. Limitations of our study include the small sample size and absence of a control group.

CONCLUSION

In conclusion, robot-assisted gait training following botulinum toxin injections were found to provide marked improvements in motor functions, balance, spasticity and functional status in children with CP. Pediatric CP patients may benefit from robot-assisted gait training when used as an adjunct to botulinum toxin injections.

Competing interests: The authors declare that they have no competing interest.

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Ethical approval: Approval for the conduct of the study was obtained from the Ethics Committee for Clinical Research Trials of Erciyes University on August 9 , 2016.

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