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Original Article

Evaluation of the effects of robot-assisted gait training on bowel function in children with cerebral palsy and the caregiver burden: A pilot study

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ABSTRACT

Objectives: The aim of this study was to investigate the effects of robot-assisted gait training (RAGT) on bowel function by measuring the frequency of evacuation, stool consistency, and severity of constipation in children with cerebral palsy (CP) and determining caregiver burden.

Patients and methods: This retrospective pilot study was conducted with 30 children (16 males, 14 females; mean age 8.8±3.2 years; range, 6 to 11 years) with CP between January 2019 and July 2019. Patients were equally divided into two groups: the RAGT group and the control group. Both groups underwent conventional physical therapy. The RAGT group underwent RAGT in addition to physical therapy. The results of the Bristol Stool Scale, the Constipation Assessment Scale, and the frequency of defecation before and after the study were recorded. Caregivers of children in both groups were asked to answer five questions regarding their burden at the beginning of the study and the end of the study.

Results: While a significant improvement was found in defecation frequency in the RAGT group ($p=0.01$), defecation frequency was not significantly improved in the control group ($p>0.999$). Bristol Stool Scale scores changed significantly within both groups ($p<0.05$). Constipation Assessment Scale scores significantly changed only in the RAGT group ($p=0.01$). A significant positive change in caregiver burden was observed in the RAGT group ($p<0.05$).

Conclusion: Robot-assisted gait training has positive effects on the frequency of defecation, stool consistency, and constipation severity in children with CP and caregiver burden.

Keywords: Caregiver burden, cerebral palsy, constipation, rehabilitation.

Cerebral palsy (CP) is defined as "permanent movement and posture disorders that cause activity limitation, which is due to a number of nonprogressive disorders occurring in the developing fetal or infant brain."[1] Children with CP have several comorbidities that affect daily activities and life quality.[2] Impairments related to the gastrointestinal system are widespread in severe neurodevelopmental disorders. Dysphagia, gastroesophageal reflux, eating pattern disorders, chronic constipation, and vomiting are probable problems of the gastrointestinal system in children with CP.[3,4]

Constipation is one of the common problems related to the gastrointestinal system in children with CP. It varies from 25 to 74% in different studies.[5,6] Constipation is defined as two bowel movements per week or two of the following on more than one of four occasions: straining, hard stools, and the feeling of incomplete defecation.[7] The management of constipation in children with CP includes both pharmacological and conservative treatments.[8]

Robot-assisted gait training (RAGT) is a novel treatment modality that can be utilized during

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rehabilitation for children with neurologic disorders. These systems are based on supported treadmill training and sensorimotor learning principles that are assisted by robotics. Sensory stimulation through visual and auditive feedback from various plays and an intensive repetitive stimulation of the different phases of gait are used for reacquiring functional gait.[9,10] With the help of these systems, a passive upright position is sustained, intestinal transit is eased, cardiovascular system functionality is reinforced, muscle strength is preserved, and respiratory and urinary infections are reduced.[1]

Recent research has investigated the positive effects of RAGT on gait. However, the effectiveness of RAGT on constipation in children with CP has not been investigated.[11] Hence, this pilot study was designed to explore the efficacy of RAGT on bowel function by measuring the frequency of evacuation, stool consistency, and the severity of constipation in children with CP and evaluating caregiver burden.

PATIENTS AND METHODS

This pilot study was carried out as a retrospective analysis of prospectively collected data in the physical therapy and rehabilitation clinic of the University of Health Sciences, Ankara Dışkapı Yıldırım Beyazıt Training and Research Hospital between January 2019 and July 2019. Thirty children (16 males, 14 females; mean age 8.8±3.2 years; range, 6 to 11 years) with cerebral palsy and Gross Motor Function Classification System (GMFCS) levels III and IV,[12,13] who have no communication problems according to the Communication Function Classification System (levels I-III) and whose upper leg length is >22 cm for suitability to RoboGait® (Bama Technology, Ankara, Türkiye), were included in this study. Children with mental retardation, respiratory dysfunction, severe hip dislocation, percutaneous endoscopic gastrostomy, a history of soft tissue or bone surgery in the last six months, baclofen pump, severe epilepsy, and GMFCS levels I, II, and V were excluded.

Procedures were performed in our outpatient clinic for children with CP. Detailed documentation of findings (e.g., symptoms, spasticity management, musculoskeletal problems, orthoses, concomitant problems like feeding, and constipation) was recorded. Fifteen of the children who had already completed the robotic rehabilitation sessions were included in the RAGT group. The control group consisted of the remaining 15 children at the end of the waiting list who did not attend RAGT sessions. As the unit had one RoboGait®, there was an outpatient waiting list for the children who were eligible for robotic rehabilitation. The sessions were scheduled by an experienced physiotherapy technician. All the participants attended routine conventional physical therapy (PT) sessions.

Robot-assisted gait training was performed with RoboGait®, which is a lower extremity robotic orthosis that positions the lower extremity joints in line with the physiological gait pattern. This system provides adjustable weight support and allows patients to walk on a treadmill.[14] Robot-assisted gait training sessions were conducted three times per week with a duration of 30 min for six weeks (Figure 1). Trained and experienced therapists supervised the participants during the sessions to monitor their progress and correct gait patterns and posture. The participants in the control group continued attending conventional PT sessions three times per week for six weeks and did not attend any RAGT sessions. The duration of the conventional PT sessions varied between 30 and 45 min. The conventional PT sessions included coordination, proprioception, balance, weight-bearing, balance, ambulatory training, and stretching and strengthening exercises.

Figure 1. Robot-assisted gait training with RoboGait®.

At the beginning of the study, the age, sex, CP type, and GMFCS levels of the participants were recorded from their documents. The results of the Bristol Stool Scale (BSS) and Constipation Assessment Scale (CAS) before and after the intervention were documented. In addition to these, the defecation frequencies of the participants were categorized into two separate groups in both RAGT and control groups according to whether the frequency of defecation was once in two to three days or once in a day.

The BSS scale, which consists of seven categories, was utilized to evaluate the shape of stools to indicate changes in bowel habits and to gather data on potential pathological entities. The shape of the stool is depicted with an image in each category of this scale. The first and second categories indicate constipation; the third, fourth, and fifth classes are appropriate for an ideal stool shape, whereas the sixth and seventh categories demonstrate diarrhea. This scale is considered to show the direct relationship between the type of stool and the intestinal transit.[15]

Constipation severity was evaluated with CAS. This scale is a valid and reliable self-rated tool that can be used with both adults and children to investigate the presence and severity of constipation.[16] Each question in this scale, which has a total of eight questions, is scored between 0 (no issues) and 2 (a severe issue), and the total score varies between 0 (no constipation) and -16 (severe constipation).

We wanted the caregivers of children in both groups to answer five questions using a 100 mm Visual Analog Scale regarding their caregiver burden both at the beginning and at the end of the study. The questions were as follows: *(i)* how burdened do you feel in the management of your child's defecation; *(ii)* how physically fatigued do you feel due to the management of your child's defecation; *(iii)* how physically fatigued do you feel due to the management of your child's diaper change; *(iv)* how much time do you spend on diaper change; *(v)* how much pain or discomfort does your child feel during defecation?

Statistical analysis

Data were analyzed using IBM SPSS version 20.0 software (IBM Corp., Armonk, NY, USA). Normality of distributed variables was investigated using visual (histograms and probability plots) and analytical methods (Shapiro-Wilk test). The data were expressed as the frequency (%) for nominal and categorical variables, median (interquartile range) for nonnormally distributed continuous and ordinal variables, and mean ± standard deviation (SD) for normally distributed continuous variables. The Mann-Whitney U test was employed to compare ordinal and nonnormally distributed continuous variables. The Pearson chi-square test or Fisher exact test were used to compare nominal variables. The Wilcoxon test for BSS and CAS and the McNemar test for defecation frequency were used to compare after and before the protocol within groups. The Mann-Whitney U test was utilized to compare the changes in BSS, CAS, and caregiver burden from the beginning of the study to the end of the study between the two groups. The findings were assessed at a confidence interval of 95%, and statistical significance was accepted as $p<0.05$.

RESULTS

The groups were well-matched in terms of age, sex, GMFS level, CAS score, BSS, and evacuation frequency ($p>0.05$, Table 1). While a significant improvement was found in defecation frequency in the RAGT group ($p=0.01$), defecation frequency was not significantly improved in the control group ($p>0.999$, Figure 2).

Bristol Stool Scale scores changed significantly within both groups ($p=0.02$, RAGT group; $p=0.04$, Control group; Table 2). Constipation Assessment Scale scores significantly changed only in the RAGT group ($p=0.01$, Table 2). The change of BSS and CAS from the beginning of the study to the end of the study were similar between the groups ($p=0.19$, $p=0.35$, respectively). There was no significant difference in change of pain during defecation, load due to management of defecation, physical fatigue due to management defecation, physical fatigue due to diaper change, time of diaper change, and defecation time from the beginning of the study to the end of the study between the two groups ($p>0.05$, Table 3). Within-group comparisons demonstrated a significant positive change in load due to the management of defecation, physical fatigue due to management of defecation, and time of diaper change in the RAGT group ($p=0.02$, $p=0.03$, and $p=0.02$, respectively); however, this finding was not demonstrated in the control group ($p>0.05$, Table 3).

DISCUSSION

This pilot study was the first to analyze the effect of RAGT on bowel function and the caregiver burden of patients with CP. The findings of this study have

TABLE 1
Comparison of baseline characteristics between the groups

	RAGT group				Control group				
	n	%	Median	Min-Max	n	%	Median	Min-Max	*p*
Age (year)									0.20*
Sex									>0.99**
Males	8	53.3			8	53.3			
Females	7	46.7			7	46.7			
GMFS									0.15*
Grade 3	2	13.3							
Grade 4	13	86.7			15	100			
Constipation Assessment Scale			10	4-14			8	6-14	>0.99*
Bristol Stool Scale			3	1-4			3	2-4	0.96*
Defecation frequency									>0.99**
Once in two or three days	11	73.3			10	66.7			
Once a day or more	4	26.7			5	33.3			

RAGT: Robot-Assisted Gait Training; GMFS: Gross Motor Function Scale; CAS: Constipation assessment scale; BSS: Bristol Stool Scale; *: Mann-Whitney U test; **: Fisher exact test.

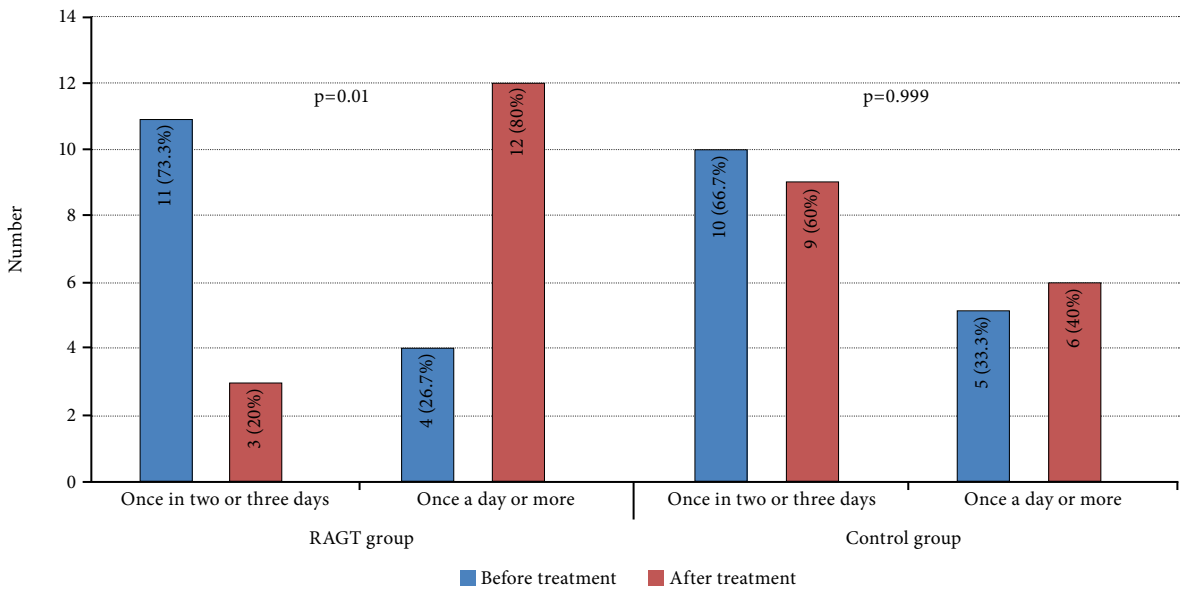

Figure 2. Changes in defecation frequency in RAGT and control groups.
RAGT: Robot-Assisted Gait Training.

TABLE 2
Within-group comparisons of BSC and CAS scores before and after treatment

	RAGT group							Control group						
	Baseline			After treatment				Baseline			After treatment			
	Median	Q1/Q3	Mean	Median	Q1/Q3	Mean	*p**	Median	Q1/Q3	Mean	Median	Q1/Q3	Mean	*p**
BSS	3	2-3	2.61	3	3-4	3.14	**0.02**	3	2-3	2.61	3	2-3	2.87	**0.04**
CAS	10	4-14	9.41	7	4-14	7.87	**0.01**	8	6-14	9.61	8	5-13	9.00	0.07

BSS: Bristol Stool Scale; CAS: Constipation Assessment Scale; RAGT: Robot-Assisted Gait Training; Q: Interquartile range; *: The difference between after and before therapy within groups, Wilcoxon signed-rank test; **: The difference between RAGT group and control group after treatment compared to before treatment, Mann-Whitney U test; Bold values show statistically significant p<0.05.

TABLE 3
Changes in caregiver burden between and within the groups

	RAGT group							Control group						
	Baseline			After treatment				Baseline			After treatment			
	Median	Q1/Q3	Mean	Median	Q1/Q3	Mean	p^*	Median	Q1/Q3	Mean	Median	Q1/Q3	Mean	p^*
Pain during evacuation (VAS)	0	0-30	14.01	0	0-0	9.34	0.11	20	10-60	29.34	20	10-50	27.34	0.54
Load of management of evacuation (VAS 0-100 mm)	10	10-40	33.34	10	10-30	31.34	**0.02**	30	20-50	33.34	30	10-50	31.34	0.11
Physical fatigue due to management evacuation (VAS 0-100 mm)	20	10-50	24.01	10	10-30	22.67	**0.03**	30	20-50	24.01	30	20-50	22.67	0.11
Physical fatigue due to diaper change (VAS 0-100 mm)	10	0-30	24.01	10	0-30	22.67	0.18	20	10-50	24.01	20	10-30	22.67	0.57
Time of diaper change (VAS 0-100 mm)	10	0-50	24.01	10	0-30	22.01	**0.02**	20	10-50	24.01	20	10-30	22.01	0.07

RAGT: Robot-Assisted Gait Training; Q: Interquartile range; VAS: Visual analog scale; *: The difference between after and before therapy within groups, Wilcoxon signed-rank test; **: The difference between RAGT group and control group after treatment compared to before treatment, Mann-Whitney U test; Bold values demonstrate statistical significance.

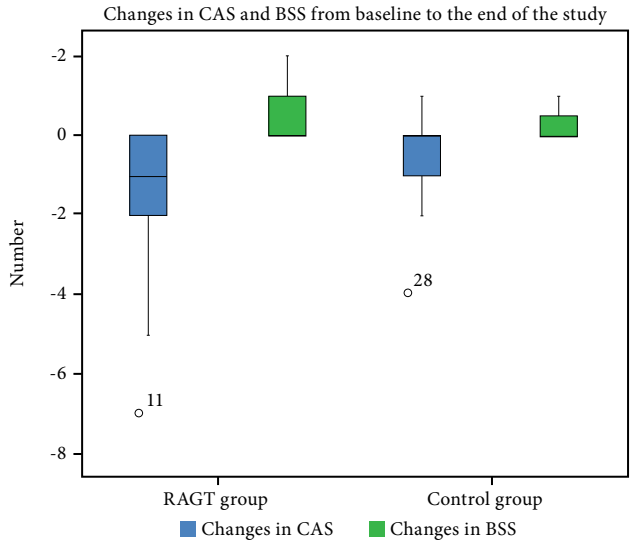

Figure 3. Comparison of the changes in CAS and BSS from baseline to the end of the study.

BSS: Bristol Stool Scale; CAS: Constipation Assessment Scale; RAGT: Robot-Assisted Gait Training.

shown that defecation frequency, stool consistency, and constipation severity significantly improved as a result of combining the RAGT with conventional PT in children with CP. In the control group, only stool consistency changed significantly. The results revealed a significant reduction in the caregiver burden due to bowel management, defecation, physical fatigue, and time spent on diaper change in the RAGT group.

Children with CP may have motor impairments, spasticity, contractures, and walking inabilities. In addition, they have a higher risk for secondary problems like constipation.[7,17] Constipation can be due to the damage to the central nervous system, which affects the autonomic and enteric nervous systems.[17] The management of constipation in children who have neurologic impairments can be more difficult than in healthy children. Therefore, feasible and effective treatment programs should be planned.[18]

In recent studies, the common primary outcome has been the effect of RAGT on ambulation in patients with physical disabilities.[11,19] Weight-bearing therapies can help improve pulmonary, gastrointestinal, and renal functions in addition to bone density while preventing contractures and deformities.[7] However, the effects of RAGT, which allows weight-bearing in an upright position on bowel functions, have not been studied.

Different authors studied the effect of connective tissue manipulation, Kinesio taping, stretching exercises, and reflexology on constipation in children with CP.[17,18,20] In a recent study, the constipation severity and the frequency of defecation improved after stretching exercises, demonstrating the positive effects of stretching exercises on constipation.[17] Orhan et al.[18] investigated the effect of Kinesio taping and connective tissue manipulation in children with CP suffering from chronic constipation. They showed that Kinesio taping and connective tissue manipulation are effective treatment methods for the frequency of defecation, defecation duration, stool consistency, abdominal pain, and the quality of life in children with CP.[18] Muscle activation with exercise has beneficial effects on neuromusculoskeletal and movement-related functions, urinary and gastrointestinal functions, endurance, flexibility, general well-being, activities, and participation in people with physical disabilities.[2] In our study, conventional PT was applied to the participants in both groups for six weeks. A significant improvement in stool consistency was shown in the control group in the present study.

Innowalk is another device that helps patients with dynamic standing. The results showed a benefit of Innowalk on lower extremity joints' range of motion, quality of life, and bowel function.[2] In a case study, have shown that abdominal pain disappeared, and medication use for bowel symptoms decreased after the Innowalk treatment.[2] It was thought to be related to increased voluntary trunk movements due to Innowalk.

Eisenberg et al.[7] found positive results with Hart Walker on constipation compared to the control group at the end of six months follow-up. Hart Walker allows weight-bearing exercise. The beneficial effects of Hart Walker on bowel function were based on stepping activity while standing or increasing upright position.

In the present study, we have found that both RAGT and conventional PT improved stool consistency, but only RAGT had a significant effect on the frequency of defecation. Accordingly, using technologies to maintain verticalization and mobilization for longer periods may also improve bowel functions in children with CP. The shorter duration of RAGT treatment in our study can be an explanation for our results. More improvement in bowel functions might be determined with a longer treatment duration of RAGT.

Rivi et al.[8] developed a scale to assess the caregiver burden associated with defecation management of children. They investigated the caregivers' daily load due to the management of their child's defecation with a four-category rating scale. At the same time, they investigated the time spent on managing the defecation with this scale, as well as the financial cost and the discomfort caused to caregivers. In addition, the physical fatigue of caregivers due to the management of defecation and diaper change was evaluated with a six-point scale by Rivi et al.[8] Before their study, they used this scale on the caregivers of their children with CP. After the child used the standing frame for four weeks, a 1-point decrease was found in caregivers' physical fatigue due to management of defecation, and a 2-point decrease was found in their physical fatigue due to diaper change. However, they found that the daily load of the caregivers due to the management of defecation minimally changed. After the child started to use the standing frame, the discomfort due to constipation completely disappeared.

We decided to collect data regarding the caregiver burden due to defecation management by five questions as in the questionnaire used by Rivi et al.[8] Since there is no valid and reliable scale for measuring caregiver burden due to the defecation management in children with CP. According to the analysis of the answers, the caregiver burden due to the management of defecation, physical fatigue due to the management of defecation, and time spent on diaper change significantly decreased after the RAGT sessions.

The main limitations of our study are its nonrandomized design and the low number of participants. Randomized controlled studies involving a larger number of participants may be helpful in showing the effectiveness of RAGT on bowel function. Another limitation of our study is the deficiency of spasticity evaluation. Spasticity affects both caregiver burden and constipation, and we think that future studies that also evaluate spasticity will provide more insight into the factors contributing to caregiver burden. The fourth limitation involves the treatment duration and follow-up period of our study. A longer period of RAGT might have a better effect on bowel functions. The last limitation of our study is that we used a five-question scale for investigating the caregiver burden as there is no valid and reliable scale for caregiver burden due to defecation management.

In conclusion, the results of this pilot study verify the positive effects of RAGT on the frequency of defecation, stool consistency, constipation severity, and the caregiver burden in patients with CP. In the future, we suggest increasing the number of participants (in both experimental and control groups) and conducting an experimental study to assess the effectiveness of the RAGT on bowel functions of children with CP and the caregiver burden.

Ethics Committee Approval: The study protocol was approved by the Dışkapı Training and Research Hospital Ethics Committee (date: 05.08.2019, no: 69/14). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from the parents and/or legal guardians of the patients.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Idea/concept, design, materials: D.C., E.Ü.A.; Control/supervision: D.C., N.A., E.Ü.A.; Data collection and/or processing: D.C., N.A.; Analysis and/or interpretation: D.C.; Literature review: D.C., N.T., Ö.Z.K.; Writing the article: D.C., N.T.; Critical review: D.C., E.Ü.A.; References and fundings: D.C.

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