ORIGINAL ARTICLE

https://doi.org/10.1590/1806-9282.20211260

Seating system for scoliosis in nonambulatory children with cerebral palsy: a randomized controlled trial

Merve Damla Korkmaz[1*], Murat Korkmaz[2], Nalan Capan[3], Goktug Sanli[4], Yasar Tatar[5], Ayse Resa Aydin[3]

SUMMARY

OBJECTIVE: This study aimed to investigate the effect of an adaptive seating system on pelvic obliquity and spinal coronal/sagittal balance in children with nonambulatory cerebral palsy and scoliosis.

METHODS: This was a single-blind, prospective, randomized interventional study. Nonambulatory children aged 6–15 years with cerebral palsy and scoliosis were included. The seating system was used for 4 h/day, and exercises were performed 3 days/week for 12 weeks. The Cobb angle, spinopelvic parameters, pelvic obliquity, Reimer's migration index, and Sitting Assessment Scale were measured before and after treatments.

RESULTS: A total of 29 participants were randomized into two groups, namely, the seating system+exercise group (SSE-group; n=15) and the exercise group (E-group; n=14). There was no significant change in Cobb angle and Reimer's migration index for both hips in SSE-group, but there was a significant increase in E-group (p=0.002, 0.049, and 0.003, respectively). The sagittal vertical axis, pelvic incidence, and pelvic obliquity decreased in SSE-group. However, there was no difference in the other sagittal parameters and Sitting Assessment Scale-total scores among groups.

CONCLUSION: The adaptive seating system was found to be superior in reducing the progression of Cobb angle and hip subluxation/dislocation, decreasing pelvic obliquity, and improving the sagittal balance of the spine/pelvis compared with exercise therapy.

KEYWORDS: Cerebral palsy. Sitting. Scoliosis. Spine. Pelvis.

INTRODUCTION

Cerebral palsy (CP) is the most common cause of serious pediatric disabilities. Children with CP have different levels of activity limitations[1]. According to the Surveillance of Cerebral Palsy in Europe, approximately 40% of children with CP are classified into Gross Motor Function Classification System (GMFCS) levels IV–V, which are nonambulatory[2]. These patients are at risk of spinal deformity, especially scoliosis[3], hip subluxation/dislocation, and musculoskeletal deformities[4,5].

It is considered that seating is a fundamental position for function and health in CP[6]. Seating systems are one of the nonoperative modalities for neuromuscular scoliosis and pelvic obliquity (PO)[4]. Since the 1960s, many types of seating systems, such as seat inserts, three-point trunk supports, and modular seating systems, have been used to improve postural control and sitting posture[4,5]. The correction of PO is also aimed in these systems to reduce the progression of spinal curvature[3].

According to the literature, the spinal balance is also very important to maintain posture[7,8]. Evaluating spinopelvic parameters and Cobb angles (CAs) radiographically reveals the effect of treatments more clearly. There are very few studies showing the effect of seating systems on the spinal stability/balance, and these studies have low methodological quality[5].

The purpose of this study was to demonstrate the effects of a custom-molded adaptive seating system (ASS) on PO and the coronal and sagittal spinal balance in nonambulatory children aged 6–15 years with CP and scoliosis.

METHODS

Participants

Children with CP and scoliosis aged 6–15 years who were admitted to the Pediatric Rehabilitation Outpatient Clinic were recruited in this study. The inclusion criteria were as follows: being classified as GMFCS levels IV–V CP, having mild-to-moderate scoliosis (between 10º and 40º), and the absence of severe contracture in the lower extremity to prevent

[1]University of Health Sciences, Kanuni Sultan Suleyman Training and Research Hospital, Department of Physical Medicine and Rehabilitation – Istanbul, Turkey.
[2]Istanbul University, Istanbul Faculty of Medicine, Department of Orthopedics and Traumatology – Istanbul, Turkey.
[3]Istanbul University, Istanbul Faculty of Medicine, Department of Physical Medicine and Rehabilitation – Istanbul, Turkey.
[4]Marmara University, Faculty of Sports Sciences – Istanbul, Turkey.
[5]Marmara University, Faculty of Medicine, Department of Physical Medicine and Rehabilitation – Istanbul, Turkey.
*Corresponding author: mervedml@gmail.com
Conflicts of interest: the authors declare there is no conflicts of interest. Funding: none.
Received on December 10, 2021. Accepted on February 12, 2022.

sitting. The exclusion criteria were as follows: having a rigid deformity in the spine and/or pelvis, previous history of the spine and/or hip surgery, the use any other seating devices and/or trunk orthoses within 6 months, having severe scoliosis (CA >40º), and history of uncontrolled epileptic seizures.

The study protocol was approved by the Clinical Research Ethical Board in conformity with the Declaration of Helsinki. All participants and their parents were informed about the study. This study was registered at https://clinicaltrials.gov.

Study design

This study was designed as a single-blind, prospective, randomized controlled 12-week interventional trial, which was conducted between April 2016 and March 2019.

The participants who met the inclusion criteria were randomized into two groups according to the order of admission to the department using computer-generated random numbers: the ASS and exercise group (SSE-group) and the exercise-only group (E-group).

All treatments and initial evaluations were performed by the same investigator. However, after treatment, evaluations and radiologic measurements were performed by a different investigator who had at least 5 years' experience and was blinded to the treatments.

Intervention

All participants received general exercises for spinal mobilization, stretching of back muscles (for convex side), strengthening of the back (for concave side), and abdominal muscles, passively. In the initial evaluation, these basic spinal correction exercises were taught practically to the parents and participants in a 1-h training session. An exercise diary was also given, and controls were made weekly to ensure the accuracy and continuity of the exercise therapy. The program was performed 3 days/week, with 10 repetitions for each exercise in a set for 12 weeks. The home exercise program was created because the participants had difficulty coming to the hospital 3 days/week.

In addition to the exercises, in the SSE-group, a custom-molded ASS was used for 4 h/day. The ASS included custom-designed "seating elevations," ranging from 1 to 2.5 cm. These elevations were used to equalize the pelvis of participants with PO. The height of the elevation was adjusted by measuring the horizontal PO angles on the pelvic radiographs. "A thoracic support" with pads at different levels was also used to maintain the upright posture and spinal alignment. "A head support" was added if necessary. "A hip block" was used to keep the hips in the correct position (Figure 1). The usage time of the ASS was checked via weekly phone calls and at each follow-up examination.

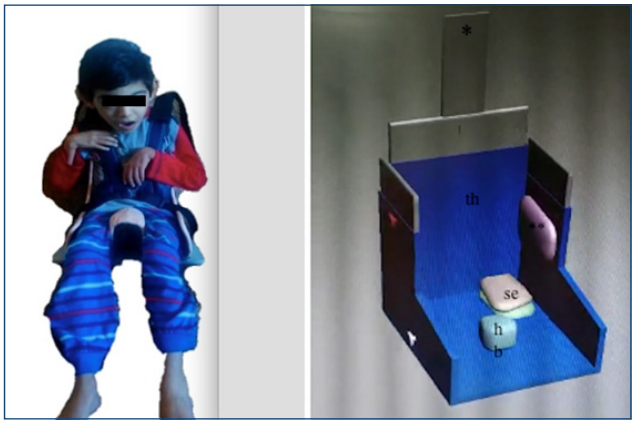

Figure 1. The seating system with a thoracic support (th), adjustable lateral supports (**), adjustable sitting elevation (se), a hip block (hb), and head support (*) if necessary.

Outcome measures

The demographic and clinical characteristics were all recorded at the initial examination.

The primary outcomes such as CA, sagittal spinopelvic parameters (i.e., thoracic kyphosis [TK] angle, lumbar lordosis [LL] angle, the sagittal vertical axis [SVA], pelvic tilt [PT], pelvic incidence [PI], and sacral slope [SS]), and PO angles were measured using the Surgimap® program. All radiographs were taken in sitting position.

The secondary outcomes were Reimer's migration index (RMI) for hip displacement and the Sitting Assessment Scale (SAS)[9] for evaluating sitting functional control. The SAS evaluation was not filmed because the parents of participants did not give consent. Instead, an assistant was included in the study who supervised the examination.

All evaluations and measures were performed before and after treatment.

Statistical analysis

Statistical analysis was performed using the IBM SPSS software version 23.0 (Statistics for MacOs). The normality of distribution was determined using histograms and the Shapiro-Wilk test. For inter-group analysis, the independent samples t-test or the Mann-Whitney U test was used, and for within-group analysis, Wilcoxon signed-rank test or the paired-samples t-test was used depending on the distribution analysis.

For the sample size, the confidence interval was 95%, and $p<0.05$ was considered statistically significant.

RESULTS

A total of 56 participants aged 6–15 years with nonambulatory CP and scoliosis who presented to the Outpatient Clinic

were evaluated for eligibility. Of these, 32 participants met the inclusion criteria. Two participants refused to participate in the study due to the distance from their city of residence. The remaining 30 children participated in the study. One participant dropped out of the study because of not attending follow-up examinations. Finally, the study was completed with 29 participants. The demographic and clinical characteristics of the participants are shown in Table 1.

The mean age of the study population was 10.24±2.72 years. There was no significant difference between the groups in terms of age, sex, age of menarche and puberty, GMFCS levels, Risser signs, and Tanner stages. No adverse effects were identified in either groups.

Inter-group analysis

Upon comparison of the two groups, there was a statistical difference in terms of CA (p=0.001), SVA (p=0.033), PI (p=0.037), PO (p=0.002), and RMI for both hips (p=0.026 and p=0.001, respectively). No statistical differences were identified in terms of TK, LL, PT, SS, and SAS-total scores (Table 2); only hand/

Table 1. Demographic and clinical characteristics of the participants.

Variable	SSE-group (n=15)	E-group (n=14)	p-value
Age (year)	9.67 (0.55)	10.86 (0.56)	0.084
Sex *(male/female)*	10/5	7/7	0.3
Type of CP			
Spastic	14	13	
Dyskinetic	1	1	
Tanner stages			0.51
Stage 1	9	5	
Stage 2	3	3	
Stage 3	2	3	
Stage 4	1	3	
Stage 5	0	0	
In puberty	3	7	
GMFCS levels			0.591
Level IV	4	2	
Level V	11	12	
Risser sign			0.51
Level 0	11	7	
Level 1	2	2	
Level 2	2	3	
Level 3	–	2	

SSE-group: seating system with exercise group, E-group: exercise group, CP: cerebral palsy, GMFCS: Gross Motor Functional Classification System.

Table 2. Effects of treatments on outcome measures at initial evaluation and after 12 weeks.

	SSE-group (n=15)	E-group (n=14)	p-value [b]
	Mean (SD)	Mean (SD)	
Cobb angle (°)			
BT	23.77 (12.98)	26.31 (9.99)	0.001*
PT	21.52 (11.64)	30.46 (12.10)	
p-value [a]	0.088	0.002	
Pelvic obliquity (°)			
BT	6.46 (3.15)	7.39 (4.28)	0.002*
AT	4.39 (2.34)	9.74 (5.49)	
p-value [a]	0.013	0.074	
Thoracic kyphosis (°)			
BT	33.75 (11.95)	41.07 (9.97)	0.354
AT	36.91 (14.47)	40.94 (10.98)	
p-value [a]	0.307	0.975	
Lumbar lordosis (°)			
BT	36.25 (9.90)	36.16 (9.43)	0.847
AT	40.43 (13.59)	37.90 (8.21)	
p-value [a]	0.691	0.451	
Sagittal vertical axis (mm)			
BT	10.93 (7,46)	13.48 (6.58)	0.033*
AT	8.02 (7,13)	15.26 (8.89)	
p-value [a]	0.016	0.331	
Pelvic tilt (°)			
BT	20.99 (13.62)	13.37 (7.86)	0.747
AT	18.69 (11.8)	13.5 (8.87)	
p-value [a]	0.910	0.826	
Sacral slope (°)			
BT	31.04 (14.93)	31.84 (11.4)	0.270
AT	27.16 (12.39)	33.1 (12.31)	
p-value [a]	0.100	0.802	
Pelvic incidence (°)			
BT	52.4 (11.9)	45.22 (11.34)	0.037*
AT	45.46 (10.33)	46.6 (5.97)	
p-value [a]	0.011	1.000	
Reimer's migration index (%)			
Right hip			
BT	26.27 (11.20)	22.85 (7.65)	0.026*
AT	24.80 (10.28)	28.29 (8.65)	
p-value [a]	0.345	0.049	
Left hip			
BT	39.80 (22,28)	32.43 (9.70)	0.001*
AT	37.00 (24,19)	40.28 (9.42)	
p-value [a]	0.310	0.003	

Continue...

Table 2. Continuation.

	SSE-group (n=15)	E-group (n=14)	p-value [b]
	Mean (SD)	Mean (SD)	
Sitting Assessment Scale			
Head control			
BT	2.9 (1.1)	2.1 (0.8)	0.561
AT	3.0 (1.0)	2.1 (0.8)	
p-value[a]	0.317	0.317	
Trunk control			
BT	1.9 (0.9)	1.5 (0.7)	0.384
AT	3.0 (1.1)	1.8 (0.9)	
p-value[a]	0.008	0.046	
Foot control			
BT	1.5 (0.6)	1.1 (0.4)	0.642
AT	1.7 (1.0)	1.3 (0.5)	
p-value[a]	0.102	0.157	
Arm control			
BT	2.2 (0.8)	1.6 (0.6)	0.030*
AT	2.7 (0.9)	1.7 (0.7)	
p-value[a]	0.005	0.157	
Hand control			
BT	1.6 (0.7)	1.3 (0.6)	0.003*
AT	2.5 (1.0)	1.4 (0.6)	
p-value[a]	0.006	0.317	
Total score			
BT	10.1 (3.3)	7.6 (2.7)	0.072
AT	12.2 (4.4)	8.3 (2.9)	
p-value[a]	0.002	0.026	

SSE-group, seating system with exercise group; E-group, exercise group; SD, standard deviation; BT, before treatment; AT, after treatment. *p<0.05, statistically significant difference. [a]p-value by Mann-Whitney U test or independent t-test. [b]p-value by Wilcoxon signed-rank test or paired samples t-test.

arm scores were significantly different among groups (p=0.003 and 0.030, respectively).

Intra-group analysis

The mean values of the CA and RMI for both hips were significantly increased in the E-group after treatment (p=0.002, 0.049, and 0.003, respectively). However, there was no significant difference in the SSE-group (Table 2).

In the SSE-group, there was a significant decrease in the mean values of SVA, PI, and PO (p=0.016, 0.011, and 0.013, respectively), whereas no significant differences were identified in the E-group. The remaining spinopelvic parameters were not statistically significant within each group (Table 2).

Sitting Assessment Scale-trunk, arm, hand, and total scores in the SSE-group and trunk and total scores in the E-group were significantly increased (Table 2).

DISCUSSION

The treatment of scoliosis in CP remains very challenging due to associated comorbidities[10]. It is known that surgical treatment is required in severe cases. Surgery for neuromuscular scoliosis has the highest mortality and morbidity rates. However, conservative treatment methods are very limited[11]. In this study, it was aimed to create a nonoperative treatment method for neuromuscular scoliosis, so the mid-term effects of an ASS on the spine and pelvis were assessed.

In several studies, different types of ASSs have been used to improve postural control and sitting posture in neuromuscular scoliosis[12-14]. However, few studies have evaluated the effects on the coronal spinal balance. Holmes et al.[15] evaluated the effects of three alternative arrangements of lateral support pads on spinal coronal alignment and achieved the most correction in coronal plane with a three-point force system. In this study, supporting both the trunk and the pelvis with the ASS reduced the CA progression. The participants in our study spend most of their daily lives lying or sitting in an inclined position. This result may have been achieved due to sitting in an upright position.

The spine maintains a mechanical balance on sagittal alignment with minimum energy consumption. This balance is achieved by the harmonious relationship of spine and pelvic anatomy[16]. In a study that compared spinopelvic parameters between patients with CP and healthy participants, the patients with CP had lower PT and greater SS, LL, and TK than healthy participants[7]. It can be said that the evaluation of sagittal spinopelvic parameters would be beneficial for the treatment of scoliosis in CP. Hayden et al.[17] found that pelvic motion caused a significant change in sagittal parameters. In our study, maintaining the PO and upright sitting posture improved sagittal balance.

Opinions about whether the PI angle is a dynamic or static parameter are conflicting[8,18,19]. It was stated that the PI increased during skeletal growth and became fixed after skeletal maturity occurred[8]. Recently, some studies reported that the PI was a dynamic parameter that could change with pelvic positions[18,19]. In our study, a significant decrease in PI was observed. This may be due to the incomplete skeletal maturity of the participants; spinal balance will be preserved in children who use the ASS at an early age and mild-moderate scoliotic period. SVA is a good parameter for analyzing spinal sagittal balance[20]. In our

study, the decrease in SVA in the SSE-group can be explained by sitting in an upright position. Vekerdy et al.[12] showed that there was no significant change in TK and LL, which play an important role in sagittal balance, after using a seating device. Similarly, there was no difference in both parameters in our study.

Pelvic obliquity is one of the potential factors that cause spinal asymmetry during the spinal growth, especially in nonambulatory CP[21]. In an experimental study, it was found that a trunk support had no significant effect on PO in nonambulatory children with CP and scoliosis[15]. In this study, using the ASS, which also maintained the pelvic levels, decreased PO. This result is noteworthy for future studies because it contributes to the relationship between the correction of PO and scoliotic curvatures.

As GMFCS levels increase, the incidence of hip displacement increases[22], resulting in gait abnormalities and impaired sitting balance[23]. Positive results were obtained in several studies that evaluated the effect of ASSs on hip dislocation[13,14]. In our study, ASS prevented progression of hip dislocation by maintaining the hip position.

Seated postural control is very important for the functionality in CP[6]. Considering the natural history of scoliosis in CP, it is possible to have a postural collapse in the absence of sitting balance[24]. It was found that a seating system had no effect on postural control[13]. Similarly, the ASS had no significant effect on postural control in our study. It can be suggested that the 12-week treatment period was not sufficient for maintaining postural control. Otherwise, the system provided significant improvement in holding or grasping objects compared with exercise therapy alone. Cimolin et al. observed that trunk-supported sitting systems improved the voluntary upper extremity function in severe CP[25]. This can be explained by the fact that ASS provided the conditions for nonambulatory children to use their hands to reach any objects.

To the best of our knowledge, this is the first randomized controlled study to demonstrate the effect of an ASS on the sagittal balance and PO in children with nonambulatory CP and scoliosis. Blinding the assessors, close monitoring of treatment adherence, and having a control group can be considered the strengths of this study. The result that only 4-h sitting in an upright position with maintained pelvic levels improved spinal alignment in CP is notable. It is important to present an alternative method to surgery for the treatment of neuromuscular scoliosis.

This study has some limitations. First, the participants could be selected only in CP with GMFCS level V. Second, the short follow-up period can be counted as a limitation.

CONCLUSIONS

This study demonstrated the positive effects of an ASS on the spinal sagittal/coronal balance and PO in nonambulatory children with CP and scoliosis. However, no effect was found on postural control.

ETHICAL APPROVAL

The study protocol was approved by the Clinical Research Ethical Board of Istanbul University Istanbul Faculty of Medicine (approval no: 2016/72) in conformity with the Declaration of Helsinki. The study was registered at https://clinicaltrials.gov (ID number: NCT03862625).

AUTHORS' CONTRIBUTIONS

MDK: Conceptualization, Data curation, Formal Analysis, Writing – original draft. **MK**: Data curation, Formal Analysis, Writing – review & editing. **NC**: Data curation, Writing – review & editing. **GS**: Data curation, Formal Analysis. **YT**: Conceptualization, Data curation, Formal Analysis. **ARA**: Conceptualization, Data curation, Writing – review & editing.

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