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Methodology for Study of the Effect of Cyclic Ergo Meter Exercise on Improving Gait Parameters in Ambulatory Spina Bifida Children

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Study Design
Randomized Control Trial.

Study Center
Subjects will be taken from GB Pant Hospital Delhi, Camps organized in various clinics, Deepak Memorial Hospital Delhi.

Subjects
70 spina bifida patient (35 in experimental group and 35 in control group.),

Inclusion Criteria
Ambulatory spina bifida children, Age above 4 years, Modified ashworth scale 1+, Full rom in Knee & Ankle.

Exclusion Criteria
Several orthopedic deformities which may interfere the patient in performing the cyclic ergometer exercises, Significant limb contracture, Severe cognitive and perceptual defect.

Method of Sampling
Convenience sampling.

Instrumentation
Cycle ergo meter, Stop watch, Tape measure, Marking pen, Leg press exerciser etc

Protocol

A sample of convenience of 70 children took part in this study these subjects are randomly divided in two groups, which received different exercises interventions

Group 1 consisting of 35 subjects received ergometery exercises [38] which consist of exercise at 25 RPM, (baseline level)) for 10 min, 40RPM for 10 min, 55 RPM for 10 min and 60 RPM for 10 min. A braking weight of 2 kg was used and hence the workload was 50, 80, 110, 120 W respectively followed by 10 minutes of passive joint mobilization and stretching exercises.

While, Group 2 consisting of 35 subjects received conventional exercises [34] which consists of passive joint mobilization and stretching of the lower limb muscles, strengthening exercises, and balance and gait exercises as shown in detail below.

Conventional training consisted of the repetition of three different sets of exercises:

1. Passive joint mobilization and stretching of the lower limb muscles with the patient lying on physiotherapy mat in the supine position.
2. Strengthening exercises, including leg-press exercises and sit-to stand and stand-to-sit exercises. In the first session, the correct performance of the leg-press exercise required strict supervision by the physiotherapist, the participants lie in the supine position and were asked to slowly push their feet against the physiotherapist's chest and to slowly bend them back again; in the subsequent sessions, these exercises were performed by using a leg-press machine with resistance specifically adapted for the child's ability;
3. Balance and gait exercises: The balance exercises were carried out with the participant sitting on a bench and in the standing position, with a front support or against a wall. Gait exercises consisted of guided ground walking (e.g., side stepping) with the assistance of the physiotherapist.

The exercise will be given in to 3 sets for both groups, each set of exercises lasted for 50 minutes 3 days a week for duration of 4 weeks for both groups

During the entire sessions, the physiotherapist stood near the children to ensure safety and prevent potential falls.

Demographic data of the subject was collected in the demographic collection form. This included history like Name, Age, Gender, Height, Weight, Limb length, and Spasticity level according to the modified Ashworth scale were obtained. Following this, the assessment of gait parameters i.e. cadence, velocity, stride length and step length was done after taking the pre assessment of the above, the intervention programme was applied for each group.

Procedure

After achieving consent of patient, the pre & post assessment in both the groups is done. 70 spina bifida cases are allocated in 2 groups of 35each from population

The subjects were invited to participate in this study. If they fulfilled the inclusion and exclusion criteria, informed consent was obtained from those willing to participate. Following this, the subjects were given verbal instructions regarding the exercise.

Demographic details and history like Name, Age, Gender, Height, Weight, Limb length and spasticity level according to the modified Ashworth scale were obtained. Following this, the assessment of gait parameters i.e. cadence, velocity, stride length and step length was done. The subjects were asked to walk over distance of 10 meters on the paper walkway.

Foot prints were taken with the help of oil paint applied on the sole of the patients. The subject was asked to move and told not to step outside the margin of the paper. This walking trail was released on a paper walkway in a well-lit environment at a self selected speed and wearing socks. Oil paint method was obtained footprints. Both the acceleration and deceleration phases of gait were excluded for data analysis. This is initial and final distance of 2 meters was excluded. Walking time in second was noted with the help of stopwatch. Stride length was calculated by measuring the distance from heel strike of one extremity to heel strike of same extremity. Step length was calculated by measuring the distance from heel strike of one extremity to heel strike of opposite extremity. Velocity was calculated by dividing the distance traversed by the time required to complete the distance. It was measured in centimeters/ seconds. Cadence was measured as the number as the number of steps taken by patients per unit of time.

Three trials were taken for each assessment and mean for each outcome measure was calculated. After this, the subject was asked to perform the exercise protocol. Group A was given ergometery exercise together with conventional exercise as describe in protocol and group B was given only conventional exercise for a period of 4 weeks, three times a week, for 50minutes. Following this, gait parameters were again calculated as described above.

Outcome Measures

Data will be collected by using the following 3-measurement scale:

1. Functional Ambulation Profile [1, 25].
2. Quantitative gait evaluation scale [26].Gait parameters to be assessed:
    a. Velocity
    b. Cadence
    c. Stride Length
    d. Step Length.

3. Modified Ashworth Scale [1].

Data Analysis

Statistics were performed using the SPSS software 12.5 version .An independent sample t-test was used to analyze the difference between the performances of the subjects in the two groups (1 and 2) after the intervention.

Paired t-test was used to examine the changes in dependent variables from the baseline to after the completion of the procedure in each group.

Table 1: Comparison age between group 1 and group 2.

	GROUP-1	**GROUP-2**
MEAN	12.66	12.60
S.D	3.33	3.13
t-value	.06	.06
sig	.955	.955

Level of significance p<0.05

Table 2: Comparison of stride length between GROUP 1 and GROUP 2 before and after performance of exercise protocol.

PRSTR	MEAN	S.D.	t-value	Sig.
GROUP 1	64.43	2.75	.109	.742^{NS}
GROUP 2	64.49	2.21		

PSSTR	MEAN	S.D.	t-value	Sig.
GROUP 1	74.16	6.59	7.84	.000
GROUP 2	65.50	.2.91		

Level of significance p<0.05
NS - non significant
PRSTR- Pre assessment of stride length
PSSTR- Post assessment of stride length
GROUP 1 - Experimental group
GROUP 2 - Control group

Table 3: Comparison of step length between GROUP 1 and GROUP 2 before and after performance of exercise protocol.

PRSTEP	MEAN	S.D.	t-value	Sig.
GROUP 1	27.06	1.81	.826	.414^{NS}
GROUP 2	27.15	1.81		

Level of significance p<0.05

PSSTEP	MEAN	S.D.	t-value	Sig.
GROUP 1	36.17	4.8	7.53	.000
GROUP 2	28.48	3.1		

Level of significance p<0.05
NS - non significant
PRSTEP- Pre assessment of step length
PSSTEP- Post assessment of step length
GROUP 1 - Experimental group
GROUP 2 - Control group

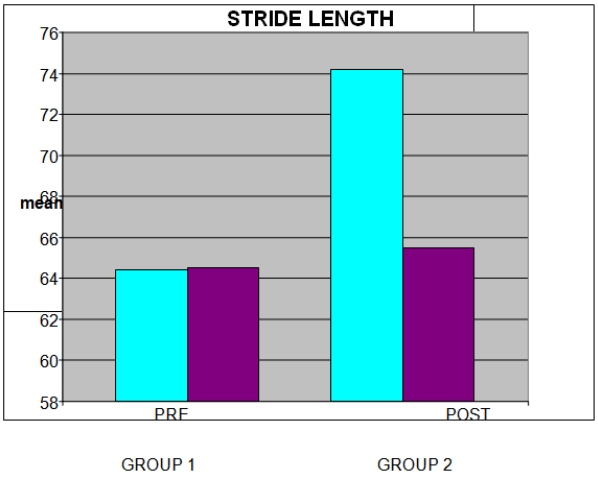
Table 4: Comparison of cadence between GROUP 1 and GROUP 2 before and after performance of exercise protocol.

PRCAD	MEAN	S.D.	t-value	Sig.
GROUP 1	88.48	1.33	.4.47	.651 NS
GROUP 2	88.62	1.26		

PSCAD	MEAN	S.D.	t-value	Sig.
GROUP 1	97.51	2.03	18.0	.000
GROUP 2	90.06	1.33		

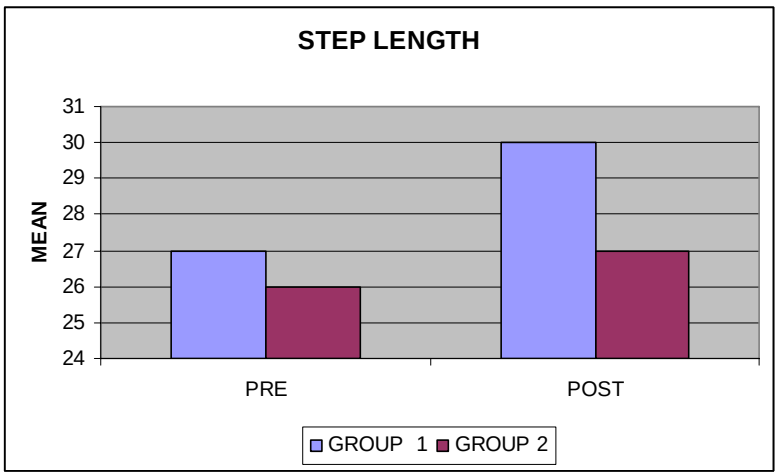
Level of significance $p<0.05$
NS - non significant
PRCAD- Pre assessment of cadence
PSCAD- Post assessment of cadence
GROUP 1 - Experimental group
GROUP 2 - Control group

Graph Comparison of stride length before and after exercise protocol between group-1 & group-2



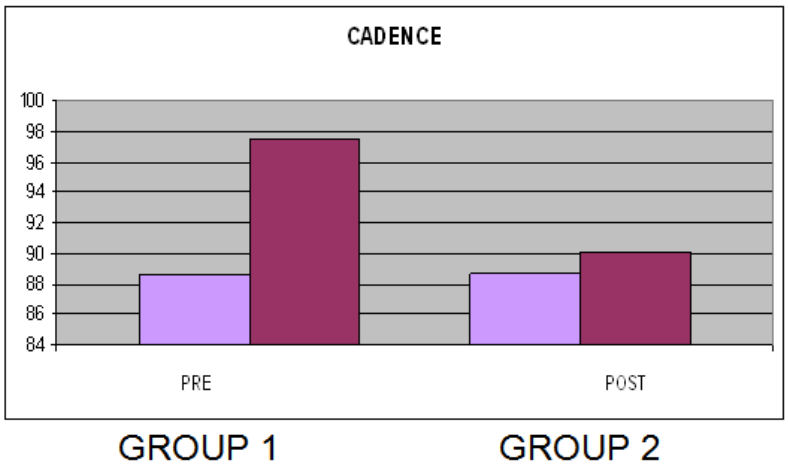
PRSTR- Pre assessment of stride length
PSSTR- Post assessment of stride length`
GROUP 1 - Experimental group
GROUP 2 - Control group

Graph Comparison of step length before and after exercise protocol between group-1 & group-2



PRSTEP- Pre assessment of step length
PSSTEP- Post assessment of step length
GROUP 1 - Experimental group
GROUP 2 - Control group

Graph Comparison of Cadence before and after exercise protocol between group 1 & group 2.



PRCAD- Pre assessment of cadence
PSCAD- Post assessment of cadence
GROUP 1 - Experimental group
GROUP 2 - Control group

Results

This paper deals with the results obtained after the statistical analysis. The study consisted of two groups, group 1(experimental) and group 2(control). Group 1 consisted of 35 subjects and group-2 consisted of 35 subjects. An unpaired t-test was used to find out the difference between the two groups and paired t-test for difference within the two groups.

There is no significant difference between age of group 1 and group 2 (table 1)

Comparison of gait parameters between two groups before and after performance of exercise protocol

Stride Length

There was no significant difference in stride length between group-1(64.43±2.75) & group 2 (64.49±2.21), t value 0.109, p-value .742 before performance (table 2).

There was a significant difference in stride length between group-1(74.16±6.59) & group 2 (65.50±.2.91), t value 7.84, p-value .000 after performance (table 2).

Step Length

There was no significant difference in step length between group-1(27.06±1.81) & group 2 (27.15±1.81), t value .826, p-value .414 before performance (table 3).

There was a significant difference in step length between group-1(36.17±4.8) & group 2 (28.48±3.1), t value 7.53, p-value .000 after performance (table 3).

Discussion

Our results demonstrate that repetitive ergometer training can significantly improve gait parameters in ambulatory spina bifida children. Improvements were seen in proximal Lower limb gait kinematics and in spatiotemporal parameters (gait speed and step length). The results obtained displayed that the magnitude of treatment effect was small to medium among the primary outcomes, further supporting the value of our experimental approach. No changes were seen in disability. There was no adverse event that led to a missed training session. No joint pain or muscle spasms were reported during or after the ergometery training program. Our study showed that the children in the experimental group significantly improved their gait. There are several reasons for this effect of treatment. First, children showed significant post treatment changes due to increased muscle endurance. Another possible explanation for the improvement in gait velocity may have been the increased muscle strength present after training. [26] It has been demonstrated that muscle weakness is a primary limiting factor in ambulation in children with spina bifida Although muscle strength was not specifically tested in this study, previous studies have shown that adult stroke patients trained with the GT I machine significantly increased their performance on the Motricity Index Test (lower limb section). [13] This effect on muscle strength is further confirmed by the fact that trained patients in previous studies usually experience a feeling of muscle fatigue after treatment, indicating that training on the ergo meter not only acts as a passive guide for movements but also requires active involvement of the lower limb muscles. A second main result of the present study demonstrates that the

children in the experimental group had improved gait endurance after training, however control group has not showed any significant changes in gait parameters. This improvement could have resulted from the previously described effects on gait kinematics and strength. In a study of patients with spina bifida, Benecke et al reported three advantages of using a bicycle ergo meter as a research device for improving gait parameters. First, nearly all people know how to cycle and do so in a very consistent, stereotyped fashion. Second, most patients, even those who are not fully ambulatory, can pedal on an ergo meter at zero or light resistance. Finally, because the active ROM at the hip or knee is greater for cycling than for walking, the effect of stretch on spastic muscles can be magnified somewhat for analysis. We can cite additional advantages of the ergo meter as a training device for patients with spina bifida .Secondly, an ergo meter with a heavy flywheel imposes a symmetry of timing and movement on the patient. The gait generating circuitry in the spinal cord presumably functions symmetrically, and the symmetrical movement pattern imposed by the ergo meter may allow this circuitry to orchestrate more effectively the muscles of the affected leg, facilitating and inhibiting them in a more nearly normal temporal rhythm. These advantages for retraining can be realized only if the patient can learn to use the muscles of the affected leg effectively while pedaling.

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