

Original Research Article

Effect of baclofen on physiotherapy in the management of spastic cerebral palsy via gross motor function measure

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ABSTRACT

Background: Cerebral palsy is the most common cause of physical disability in children. The gross motor function measure-66 (GMFM-66) is an observational clinical measure designed to evaluate gross motor function in children with cerebral palsy (CP). The aim of this study was to explore pediatric physiotherapists' experiences with the gross motor capacity with CP by implementing a short-term intervention.

Methods: This study was performed in the Department of Anatomy and Department of Pediatrics, University Hospital, Banaras Hindu University, Varanasi and Kiran Society, Varanasi. Patients aged between 2 years to 14 years of both sexes satisfying the inclusion and exclusion criteria were randomly enrolled into two groups; Group A included 60 patients who received only physiotherapy and Group B included 60 patients who received baclofen along with physiotherapy. Ethical clearance was obtained from the concerned authority. Data management and statistical analysis were performed using MS excel.

Results: Percentage of spastic diplegia were 20.0% and 16.6% and percentage of spastic quadriplegia were 31.6% and 26.6% in group A and group B respectively. Before treatment mean score of GMFM for group A was increased to after 3 months of treatment and which further increased to after 6 months of treatment when compared to group B as their baseline mean score of GMFM was after 3 months of treatment and it increased after 6 months of treatment.

Conclusions: The findings suggest the GMFM to be a useful and reliable instrument for assessing motor function and treatment outcome in CP.

Keywords: Baclofen, Cerebral palsy, GMFM, Physiotherapy

INTRODUCTION

Cerebral palsy (CP) was first defined by William Little in 1862 and initially was called Little's disease. It was described as a disorder that seemed to strike children in the first year of life, affected developmental skill progression, and did not recover over time. Little related the disorder as a deficiency of oxygen at the birth. After that, Sigmund Freud suggested that CP might be rooted in the brain's growth in the womb and related aberrant development to

factors influencing the developing fetus.¹ Asphyxia at the birth was thought to be the reason of CP until the 1980s, but today researches have revealed that this etiology to be less likely and only one of many with potential to result in CP.^{2,3} Recently, the maximum widely accepted consensus description utilized for both clinical and research purposes is the one put forward by Rosenbaum et al, "cerebral palsy describes a group of permanent disorders of movement and posture, causing activity limitations, that are accredited to non-progressive disturbances that occurred in the

developing fetal or infant brain. Alongside the motor impairments, sensation, perception, cognition, communication, behavior, epilepsy and musculo-skeletal problems are also attend to cerebral palsy".⁴ The most widely-used test battery that measures the functional motor level in order to regulate the motor development level of children with CP is the gross motor function measurement (GMFM). Through GMFM, physiotherapists can define the motor function level of the child; obtain aid in requiring the targets of the treatment, follow-up the post-treatment growth and present objective information regarding the child to relevant colleagues, other inter-discipliner experts and families. The purpose is to determine the capacity and variation. It is comprised of sections of supine-facedown positions and turning, sitting, crawling and standing on the knees, standing on the feet, walking and running and jumping.⁵ The gross motor function classification system (GMFCS) is a classification system developed for children with CP. The GMFCS has been defined by Palisano et al based on the activities the child can perform from sitting to walking. It is a practical system that can be used in clinics for the rehabilitation team to classify a child with CP, detect the efficiency of the requests and follow-up on the patient in inter-intra discipliner applications. Primarily, children with CP aged below 12 were separated into five levels by considering their independency in gross motor functions such as walking, sitting, mobilization and transfer activities and tools-equipment, tools that assist in walking. As motor functions of children change according to age, functions have been defined as under 2-years old, between 2-4 years old, between 4-6 years old and between 6-12 years old for each level. In order to contain the age ranges of between 12-15 and 15-18 years old in 200.⁶ The aim of this study was to explore pediatric physiotherapists' experiences with the gross motor capacity with CP by implementing a short-term intervention.

METHODS

This study was conducted in the Department of Anatomy and Department of Pediatric, Banaras Hindu University. All the spastic cerebral palsy patients seeking treatment in outpatient Department of Pediatrics, Sir Sundar Lal, Hospital, Banaras Hindu University and Kiran Society, Varanasi were the reference population from December 2017 to May 2018. From reference population, patients enrolled in the study who met the inclusion and exclusion criteria.

Inclusion criteria

Patients aged between 2 years to 14 years of both sexes; with disorder in posture apparently of cerebral origin started before two years of age, presence of spasticity related with or characterized by increased tone, exaggerated reflexes, clonus or extensor plantar response, and delayed miles stones of development which was improving over time were included as study population.

Exclusion criteria

Those with mix type of cerebral palsy; receiving systemic anti-spasticity medications or had received phenol and/or botulinum toxin type A injections; past surgical intervention that might interfere with; neurodegenerative disorders, ankle joint movement inborn errors of metabolism such as galactosemia, chromosomal abnormality such as Down syndrome, and presence of co morbidity such as epilepsy were excluded from the study.

Complete history and clinical examination was done for all enrolled patients. The written informed consent was taken from parents after explaining possible side effects.

Gross motor capacity

The GMFM was developed to determine changes in motor function in children with CP. The GMFM categorized into five gross motor function dimensions: A (lying and rolling), B (sitting), C (crawling and kneeling), D (standing), and E (walking, running, and jumping). Each item was scored on a four-point scale, similar to the Likert scale, ranging from 0 (does not initiate) to 3 (completes). The GMFM-66 was developed using Rasch analysis of the GMFM-88, whereby 22 of the original 88 items deleted to improve reliability and validity. Of the 22 items deleted, 13 were from the lying and rolling dimension, 5 were from the sitting dimension and 4 were from the kneeling and crawling dimension. The GMFM-66 represents the unidimensional construct of gross motor ability according to task difficulty and thus is recommended for research purposes when comparing changes in gross motor function over time in children with CP. However, the GMFM-66 is much less useful when scoring children with a severe disability.⁷⁻⁹

Measurement method

Classification of gross motor functional classification system into five levels: GMFSC-level I, the ability to walk/climb stairs without restriction, level II, can walk/climb stairs with minimal support (e.g., stair railing) over short distances and use a hand-held or wheeled mobility device for longer distances, level III, can walk using a handheld mobility device, with a wheeled device required for longer distances and stair climbing with assistance, level IV, minimal walking, mostly using mobility that requires power or physical assistance, and level V, transported in a manual wheelchair at all times with structures in place to support the head and trunk and protect/restrain arms and legs.¹⁰

Treatment Interventions

Intervention was completed by giving oral baclofen with physiotherapy to reduce spasticity, and uniform intensive rehabilitation protocol was applied which includes sitting balance in specialized sitting chair, prone lying position, range of motion exercise, stretching exercise, activities of

daily living (ADL) training. The patients were followed 4 weekly till 24th weeks. Compliance check was done by confirming from guardian and of empty bottles.

Group A was given physiotherapy 1 hour daily for 5 days a week.

Physiotherapy was taught once and done in residence with supportive exercise chart under supervision of guardian.

Group B received oral baclofen with physiotherapy corresponding to approximately 0.3 mg/kg a day in two divided doses has given for 24 weeks.¹¹

Ethical clearance

Ethical clearance has been obtained from the concerned authority to conduct the research work.

Statistical analysis

Descriptive statistics including standard deviation (SD) and mean were obtained for each quantitative variable. Data management and statistical analysis was performed using MS excel. Test statistics was used to analysis the data.

RESULTS

A total of 120 patients were enrolled in the study and were divided in to two treatment groups of 60 each. One group (group A) received only physiotherapy while the other group (group B) received physiotherapy along with oral baclofen. The results of the two treatment protocols were analyzed after 6 months of therapy. The age, sex, weight and height of the patients enrolled are shown in Table 1.

Table 1 depicts that the gender distribution, mean age, weight and height were comparable in the two treatment groups. Out of total female children, 53.3% belong to

group A and 43.3% in group B. Almost similar age group, weight and height of children were in both groups. There were no any significance differences between group A and group B of characteristics.

Table 1: Comparison of age sex, weight and height between two groups.

Characteristic	Group A (n=60)	Group B (n=60)	P value, test of significance
Gender			
Female	32 (53.3%)	26 (43.3%)	t=1.20,
Male	28 (46.6%)	34 (56.6%)	p=0.27
Age (years)	7.3±3.2	6.8±1.4	t =0.722, p=0.47
Weight (kg)	21.7±7.7	20.7±8.6	t =0.617, p=0.54
Height (cm)	116.6±19.5	112.5±20.5	t =1.12, p=0.28

Table 2: Clinical characteristics of the treatment groups (n=120).

Clinical form of CP	Group A (n=60) N (%)	Group B (n=60) N (%)
Spastic diplegia	20 (33.3)	18 (30.0)
spastic quadriplegia	28 (46.6)	26 (43.3)
spastic hemiplegic	12 (20.0)	16 (26.6)

Table 2 illustrates that the clinical characteristics such as spastic diplegia, spastic quadriplegia and spastic hemiplegic, of the treatment groups. Out of total study subject percentage of spastic diplegia were 33.3% and 30.0% in group A and group B respectively. Spastic diplegia affects mostly the legs and sometimes the arm. Percentage of spastic quadriplegia were 46.6% and 43.3% in group A and group B respectively. Poor coordination of facial muscles can also cause speech/language delays.

Table 3: The children were fairly evenly distributed among the 5 levels of the GMFCS.

GMFCS	Group A			Group B		
	Pre-treatment	3 months	6 months	Pre-treatment	3 months	6 months
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Level I	9 (15.0)	12 (20.0)	15 (25.0)	10 (16.6)	15 (25.0)	16 (26.6)
Level II	16 (26.6)	14 (23.3)	13 (21.6)	12 (20.0)	11 (18.3)	13 (21.6)
Level III	18 (30.0)	16 (26.6)	15 (25.0)	20 (33.3)	18 (30.0)	14 (23.3)
Level IV	8 (13.3)	10 (16.6)	10 (16.6)	8 (13.3)	10 (16.6)	12 (20.0)
Level V	9 (15.0)	8 (13.3)	7 (11.6)	10 (16.6)	6 (10.0)	5 (8.33)

Table 3 shows that the gross motor function of the children was classified on the GMFCS at the first study assessment as follows, 9 (15.0%) were classified at level I, 16 (26.6%) were classified at level II, 18 (30.0%) were classified at level III, 8 (13.3%) were classified at level IV, and 9 (15%)

were classified at level V in group A (pretreatment). On the other hand, in group B (pretreatment) 10 (16.60%) were classified at level I, 12 (20.0%) were classified at level II, 20 (33.3%) were classified at level III, 8 (13.3%) were classified at level IV, and 10 (16.6%) were classified at level V.

Table 4: GMFM scores for evaluation of gross motor function.

Scores of GMFM-66	Pre-treatment	3 months	6 months
Group A	67.6±18.2	70.3±18.3	73.0±18.3
Group B	66.8±19.5	69.9±19.2	74.4±19.0

Table 4 shows that the GMFM Scores for evaluation of gross motor function. In which, data analysis revealed that the before treatment mean score of GMFM for group A (67.6±18.2) was increase to (70.3±18.3) after 3 months of treatment and which further increased to (73.0±18.3) after 6 months of treatment when compared to group B as their baseline mean score of GMFM (66.8±19.5) was (69.9±19.2) after 3 months of treatment and it increased after 6months of treatment to (74.4±19.0).

DISCUSSION

The purpose of this study was to examine whether children with cerebral palsy receiving functional physical therapy had greater improvements in motor abilities compared with a reference group of children who received therapy based on the principle of normalization of the quality of movement. Both basic gross motor abilities in a standardized environment (measured with the GMFM). In present study, female children, 53.3% belongs to group A and 43.3% in group B. Almost similar age group, weight and height of children were in both groups. Percentage of spastic diplegia were 33.3% and 30.0% and percentage of spastic quadriplegia were 46.6% and 43.3% in group A and group B respectively. Similar study conducted by Kim (2018) included 24 study participants (17 boys, 7 girls, average age, 42.71 months) receiving intensive short-term treatment, 14 were diagnosed with CP spastic quadriplegia and 10 with spastic diplegia.¹² In present study, 9 (15.0%) were classified at level I, 26.6% were classified at level II, 30.0% in 1st group. In 2nd group 10 (16.6.0%) were classified at level I, 20.0% were classified at level II, 33.3% were classified at level III, 13.3% were classified at level IV, and 16.6% were classified at level V. Furthermore, in gross motor function level, most of the children in IR group with level 5 and 4 gross motor function at baseline changed to level 4 and 3 respectively. Likewise a substantial proportion of children in the baclofen + IR group changed from level 5 gross motor function to level 4 and a few to level 3 and level 2.¹³ Present study revealed that the before treatment mean score of GMFM for group A was increased to after 3 months of treatment and which further increased to after 6 months of treatment when compared to group B as their baseline mean score of GMFM was after 3 months of treatment and it increased after 6 months of treatment. In the light of some studies this study attributes similar results, a study conducted by Lowing et al support this study with same findings.¹⁴ Another study by Ahl et al evaluated the effect of functional training for children with cerebral palsy (CP). The outcome measures used were goal attainment scaling, gross motor function measure, pediatric evaluation of

disability inventory (functional skills and caregiver assistance scales), measure of processes of care, and a questionnaire.

The intervention was carried out in the context of daily life settings result shows that gross motor function and performance of daily activities, including social function, improved significantly.¹⁵

CONCLUSION

The intervention was carried out in the context of daily life situations, outcome shows that gross motor function and performance of daily activities, including other functions, considerably improved. The findings suggest the GMFM to be a useful and reliable instrument for assessing motor function and treatment outcome in CP.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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