



## Original Research Article

## Effect of baclofen on physiotherapy in the management of spastic cerebral palsy

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## ARTICLE INFO

## Article history:

Received 07-06-2020

Accepted 01-07-2020

Available online 18-08-2020

## Keywords:

Spastic cerebral palsy

Baclofen

Physiotherapy

## ABSTRACT

**Introduction :** A description of Cerebral Palsy (CP) is, a group of stable disorders of the development of movement and posture, causing activity limitations that are attributed to no progressive disturbances that happened in the developing fetal or infant brain.

**Objective:** To evaluate the role of oral Baclofen on Physiotherapy in reducing spasticity of cerebral palsy.

**Materials and 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. Spasticity parameters were evaluated using modified Ashworth scale, physical rating scale like knee recurvatum, angle for crouch gait and foot contact. All patients were followed up at 4 weeks interval and were evaluated after of 24 weeks. Ethical clearance was obtained from the concerned authority. Data management and statistical analysis were performed using MS excel.

**Results:** Physiotherapy was highly effective in reducing tone in spastic cerebral palsy. Similar was the observation when baclofen was added to physiotherapy regimen. However, when compared, the efficacy of baclofen along with physiotherapy was far superior as compared to physiotherapy alone. However, none of the treatment modalities has significant effect on knee recurvatum.

**Conclusion:** Addition of baclofen to physiotherapy regimen is superior to physiotherapy alone for reducing muscle tone and improving the joint angle stiffness as well as gait.

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## 1. Introduction

Cerebral palsy (CP) is heterogeneous with different clinical types, comorbidities, brain imaging patterns, causes, and now also heterogeneous underlying genetic variants. Few are solely due to severe hypoxia or ischemia at birth.<sup>1</sup> Cerebral palsy incidence is 1.5-2.5 per 1000 live births<sup>2,3</sup> and contributes as the most common cause of the chronic childhood disabilities.<sup>4</sup> Most common type of CP is spastic type contributing 70 - 80% of all cases.<sup>5</sup> Spasticity can reason for discomfort, stiffness, pain and difficulty in performing physical activities such as washing, dressing,

transfers, walking and picking up objects.<sup>6</sup> Spasticity can be managed by physical therapy, oral medications, tone inhibiting casts, focal injections and by surgery. Treatment of spasticity with oral medicines can be useful only in selected patients where a generalized reduction in body tone is needed. Baclofen, Tizanidine, Diazepam and Dantrolene are currently permitted for use in patients with spasticity. Medication plan should be devised seeking a balance between improved function, patient satisfaction and possible side effects.<sup>7</sup> Baclofen is the oldest and most commonly prescribed drugs in cases of spastic CP. Baclofen has Gaba Amino Butyric Acid (GABA) mediated action. Baclofen is an agonist that has presynaptic and postsynaptic effects on monosynaptic and polysynaptic

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pathways by binding to GABA B receptors. The most common adverse reaction is transient drowsiness, others are dizziness and weakness. Baclofen should be tapered gradually at higher doses to prevent withdrawal symptoms like hallucinations, seizures and increased spasticity. AAN recommends: There is insufficient evidence to support or refute the use of oral baclofen for the treatment of spasticity or to improve motor function in children with CP.<sup>8</sup> There are several studies expressing usefulness of Physiotherapy and Baclofen in CP. However, there are very few studies comparing effectiveness of Physiotherapy and Baclofen in spastic CP. The purpose of the study is to compare result of oral Baclofen and Physiotherapy in spastic cerebral palsy in reducing spasticity in cerebral palsy.

## 2. Materials and Methods

This study was performed in the Department of Anatomy and Department of Pediatrics, Banaras Hindu University. All the spastic cerebral palsy patients seeking treatment in outpatient department of Pediatrics, University Hospital, Banaras Hindu University and Kiran Society, Varanasi were enrolled in the study. Patients aged between 2 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 milestones of development which is improving over time were included as study population. Those with mixed 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. Patients were first assessed with Modified Ashworth Scale (MAS) based on muscle tone to determine the extent of spasticity. Then Physician Rating Scale was done to measure joint angle (crouch) specially by standard Goniometer, 46 knee recurvatum, foot contact. 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.

### 2.1. Treatment Interventions

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 0.3mg/kg a day in two divided doses has given for 24 weeks.<sup>9</sup>

### 2.2. Ethical clearance

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

### 2.3. 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.

## 3. 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 analysed after 6 months of therapy.

The age, sex, weight and height of the patients enrolled are shown in Table 1 .

The gender distribution, mean age, weight and height were comparable in the two treatment groups.

Effect of physiotherapy on spasticity parameters of cerebral palsy are depicted in Table 2.

There was significant improvement of spasticity after 6 months of physiotherapy as evaluated by modified Ashworth scale, angle for crouch gait, and foot contact. Though there was improvement in the physical rating scale in terms of knee recurvatum, it was not statistically significant.

Effect of combined physiotherapy and oral Baclofen on spasticity parameters of cerebral palsy are shown in Table 3.

There was also significant improvement of spasticity after 6 months of combined physiotherapy and oral Baclofen as evaluated by modified Ashworth scale, angle for crouch gait, and foot contact. Though there was improvement in the physical rating scale in terms of knee recurvatum, it was not statistically significant.

Illustrates the pretherapy spasticity parameters of the treatment groups. The Modified Ashworth Scale (MAS) grade, the physician rating scale in terms of knee

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

Characteristic	Group A (n=60)	Group B (n=60)	Test of significance, P value
Gender			
F	32(53.3%)	26(43.3%)	t =1.20,
M	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:** Effect of physiotherapy on spasticity parameters of cerebral palsy

	Pre therapy Number (%)	Post therapy Number (%)	Chi square value, P value
<b>Modified Ashworth scale</b>			
0-1	0(0)	02 (03.3)	78.4, 0.000
2-3	10(16.7)	56 (93.4)	
4-5	50 (83.3)	02 (03.3)	
<b>Physical rating scale</b>			
<b>Knee*</b>			
Recurvatum >5	4(6.7)	0(0.0)	4.44, 0.109
Recurvatum <0-5	4(6.7)	6(10.0)	
No Recurvatum	52(86.6)	54(90.0)	
<b>Angle for crouch gait</b>			
Severe	20(33.3)	0(0.0)	26.1, 0.000
Moderate	32(53.3)	40(66.7)	
Mild	6(10.0)	14(23.3)	
None	2(3.4)	6(10.0)	
<b>Foot contact</b>			
Toe	50(83.3)	0(0.0)	88.3, 0.000
Toe-heel	10(16.7)	38(63.3)	
Flat	0(0.0)	22(36.7)	
Heel-toe	0(0.0)	0(0.0)	

**Table 3:** Effect of combined physiotherapy and oral Baclofen on spasticity parameters of cerebral palsy

	Pre therapy Number (%)	Post therapy Number (%)	Chi square value , P value
<b>Modified Ashworth scale</b>			
0-1	0(0)	46(76.7)	93.1, 0.000
2-3	8(13.3)	12(20.0)	
4-5	52(86.6)	2(3.3)	
<b>Physical rating scale</b>			
<b>Knee*</b>			
Recurvatum >5	2(3.4)	0(0.0)	2.04, 0.361
Recurvatum <0-5	8(13.3)	8(13.3)	
No Recurvatum	50(83.3)	52(86.7)	
<b>Angle for crouch gait</b>			
Severe	14(23.3)	0(0.0)	42.0, 0.000
Moderate	28(46.7)	8(13.3)	
Mild	14(23.3)	44(73.4)	
None	4(6.7)	8(13.3)	
<b>Foot contact</b>			
Toe	48(80.0)	0(0.0)	94.5, 0.000
Toe-heel	10(16.7)	8(13.3)	
Flat	2(3.3)	48(80.0)	
Heel-toe	0(0.0)	4(6.7)	

**Table 4:** Comparison of baseline spasticity parameters of the treatment groups.

Baseline Characteristic	Group A Number (%)	Group B Number (%)	Chi square value , P value
<b>Modified Ashworth scale</b>			
0-1	0(0)	0(0)	
2-3	10(16.7)	8(13.3)	2.89, 0.23
4-5	50 (83.3)	52(86.6)	
<b>Physical rating scale</b>			
<b>Knee*</b>			
Recurvatum >5	4(6.7)	2(3.4)	
Recurvatum <0-5	4(6.7)	8(13.3)	2.04, 0.36
No Recurvatum	52(86.6)	50(83.3)	
<b>Angle for crouch gait</b>			
Severe	20(33.3)	14(23.3)	
Moderate	32(53.3)	28(46.7)	5.19, 0.15
Mild	6(10.0)	14(23.3)	
None	2(3.4)	4(6.7)	
<b>Foot contact</b>			
Toe	50(83.3)	48(80.0)	
Toe-heel	10(16.7)	10(16.7)	2.04, 0.36
Flat	0(0.0)	2(3.3)	
Heel-toe	0(0.0)	0(0.0)	

recurvatum, the angle for crouch gait and foot contact were comparable in both treatment groups as there were no statistical difference in the values of two groups.

Comparison of the outcome of the treatment groups are shown in Table 5 . There were significant differences in Modified Ashworth scale, Angle for crouch gait and Foot contact in the Group B receiving both physiotherapy and oral baclofen as compared to physiotherapy alone. Physical rating scale in terms of knee recurvatum was comparable.

The patients receiving baclofen experienced side effects like drowsiness in 18 (30%), increased frequency of urination in 10 (16.6%), weakness in 8 (13.3%), headache, constipation and paresthesia in 4 (6.6%) each. Two (3.3%) each experienced nausea, urticaria, ataxia and behavioural changes.

#### 4. Discussion

The study was conducted using the most commonly used oral antispastic drugs i.e. Baclofen and Physiotherapy in patients with spastic CP. The result of physiotherapy and oral Baclofen with physiotherapy was compared in patients with spastic CP in terms of diminution of spasticity, progress in range of motion and adverse effect profile. In present study, 120 children with cerebral palsy were divided into two groups (60 physiotherapy and another 60 baclofen with physiotherapy group). At the baseline assessment baclofen with physiotherapy group; 8(13.3%) were MAS grade 3, 36(60.0%) grade 4, 16(26.7%) grade 5. After 6 months, spasticity was significantly decreased; 46(76.7%) children pointed MAS grade 0-1, 12(20.0%) were grade 2-3 and 2(3.3%) grade 4-5. In physiotherapy group; 10(16.7%) were MAS grade 3, 44(73.3%) grade 4, 6(10.0%) grade

5. After 6 months, spasticity also significantly decreased in this group; 2(3.3%) children pointed MAS grade 0-1, 56(93.3%) were grade 2-3 and 2(3.3%) grade 4-5. In this study we obtained that baclofen with physiotherapy group furnish better response in reducing spasticity compared to in the physiotherapy group, regarding physician ratings scale, majority of the severe and moderate angle for crouch gait at baseline in physiotherapy group transformed to moderate and mild angle respectively. However, the baclofen with physiotherapy group received more development, with most of the severe and moderate angle for crouch gait at baseline changed to mild a few to none. In addition, this study confirmed that both Physiotherapy and oral Baclofen with physiotherapy are highly effective agents to combat spasticity in CP. Statistically considerable progress was seen in the mean MAS score at in both the groups. A study on Baclofen in 23 patients with spasticity of spinal origin showed significant improvement in terms of mean change in MAS as compared to placebo.<sup>10</sup> A controlled trial of Baclofen showed significant improvement in spasticity in a group of 20 cerebral palsy patients. Baclofen study found significant improvement in active range of motion as compared to placebo.<sup>11</sup> A double-blind, randomized cross-over pilot study of oral baclofen versus placebo on fifteen children with spastic or spastic/dystonic quadriplegia scored significantly better on the Goal Attainment Scale with baclofen compared with placebo.<sup>12</sup> Furthermore, Changes in knee recurvatum in both groups were not significant. During determining crouch, the patient in the physiotherapy group had at baseline 33.3% severe and 53.3% moderate angle at baseline. But baclofen with physiotherapy baseline scores were 23.3% and 46.6% respectively. Physiotherapy group also show improvement

**Table 5:** Comparison of the outcome of the treatment groups.

Spasticity parameters	Group A Number (%)	Group B Number (%)	Chi square value, P value
<b>Modified Ashworth scale</b>			
0 – 1	2(3.3)	46(76.7)	69.0, 0.00
2 – 3	56(93.4)	12(20.0)	
4 – 5	2(3.3)	2(3.3)	
<b>Physical rating scale</b>			
<b>Knee</b>			
Recurvatum >5	0(0.0)	0(0.0)	0.323, 0.57
Recurvatum <0-5	6(10.0)	8(13.3)	
No Recurvatum	54(90.0)	52(86.7)	
<b>Angle for crouch gait</b>			
Severe	0(0.0)	0(0.0)	34.0, 0.00
Moderate	40(66.7)	8(13.3)	
Mild	14(23.3)	44(73.4)	
None	6(10.0)	8(13.3)	
<b>Foot contact</b>			
Toe	0(0.0)	0(0.0)	33.2 , 0.00
Toe-heel	38(63.3)	8(13.3)	
Flat	22(36.7)	48(80.0)	
heel-toe	0(0.0)	4(6.7)	

in angle for crouch but baclofen with physiotherapy group change more significantly. In present study maximum children having foot contact with their toes at baseline in physiotherapy group changed to toe-heel contact 38(63.3%) or flat foot 22(36.7%). The children of the baclofen with physiotherapy group also demonstrated a similar change. The change was more noted in the baclofen with physiotherapy group. these finding are similar to Amin et al.<sup>13</sup> Baclofen has been weakly studied in spasticity of cerebral origin with most studies evaluating efficacy in treating spasticity of spinal cord origin. While no studies on the use of baclofen to treat children was found, it is still commonly recommended as a treatment option for children with spasticity.<sup>14,15</sup> Blocks of intensive therapy can be an alternative to regular dosage of physiotherapy, however, until further studies are conducted, the physiotherapy intervention, intensity, and frequency should be tailored to meet the needs of each individual infant and family.<sup>16</sup> Analytical findings of this study showed that combined baclofen and intensive rehabilitation is more beneficial to decrease stiffness and spasm and thereby improving movement in a young child with cerebral palsy.

## 5. Conclusion

The study exhibited that elementary abilities and self-care enhanced after physiotherapy with baclofen is effective for reducing generalized spasticity regarding muscle tone and joint angle stiffness and gait improvement in cerebral palsy patients over physiotherapy.

## 6. Source of Funding

None.

## 7. Conflict of Interest

None.

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**Cite this article:** Ali T, Mohanty C, Prasad R, Das BK. **Effect of baclofen on physiotherapy in the management of spastic cerebral palsy.** *IP J Paediatr Nurs Sci* 2020;3(2):49-54.

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