Original Article

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Role of Baclofen in Combination with Intensive Rehabilitation in Spastic Cerebral Palsy

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Abstract

Background: The treatment of cerebral palsy is multifactorial. **Objective:** In this study we find out the combined efficacy of baclofen and intensive rehabilitation in the treatment of spastic cerebral palsy. **Methodology:** This observational study was conducted over 30 patients in Dhaka Medical College Hospital from January 2011 to December 2011.The patient satisfying the inclusion and exclusion criteria was randomly enrolled in this study. They received Baclofen orally two times daily according to the body weight regularly in combination with intensive rehabilitation 1 hour daily five times a week for 24 weeks. All patients were followed up at 4 weeks interval and were evaluated for a total of 24 weeks. **Result:** Combination of Baclofen and intensive rehabilitation is effective in reducing tone in spastic cerebral palsy by using Modified Ashworth scale ($p<0.05$). Combination of Baclofen and intensive rehabilitation is also effective in joint angle improvement in spastic cerebral palsy measured by physician rating scale crouch ($p<0.05$) and foot contact, ($p<0.05$) and also improvement in gross motor function ($p <0.05$). **Conclusion:** For reduction of generalized spasticity regarding muscle tone, range of motion of the joint and improvement of gait in cerebral palsy patients, combination of Baclofen and intensive rehabilitation may be used. [J Natl Inst Neurosci Bangladesh 2015;1(1):18-21]

Keywords: Referral pattern, psychiatry, neurology

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Introduction

Neurological illness has been found associated with Cerebral Palsy (CP) describes a group of permanent disorders of the development of movement and posture, causing activity limitations that are attributed to non-progressive disturbances that occurred in the developing fetal or infant brain. The motor disorders of cerebral palsy are often accompanied by disturbances of sensation, perception, cognition, communication, and behavior; by epilepsy, and by secondary musculoskeletal problems[1]. In a majority of cases, the predominant motor abnormality is spasticity[2].

Cerebral palsy is the most common childhood disability with a prevalence of 1.5 to 3 per 1000 live births[3,4]. However, in a study at Physical Medicine & Rehabilitation Department of BSMMU 1.72% patients were diagnosed as CP[5]. Spastic cerebral palsy is the most common type, accounting for 75% of cases which affects a large proportion of this population[6]. Spasticity is one of the common features of cerebral palsy as it contributes to limitations in body structure and function, leading to deformity[7]. Treating the spasticity component of the movement disorder might enable improvement in the performance, participation, and

satisfaction in everyday activities of these children[6]. Treatment of spastic cerebral palsy includes physiotherapy along with antispastic medication. Available drugs that are used to treat spasticity include benzodiazepines, baclofen, alpha-adrenergic agonists (tizanidine, clonidine), dantrolene sodium, and gabapentine[8]. Baclofen is a GABA agonist that is used to reduce muscle tone. Intensive rehabilitation may be defined as 1 hourly intervention, 5 days a week, as opposed to a therapy sessions once a week or once every second week[9]. It consists of neurodevelopmental treatment (NDT), therapeutic exercises (TEs) and activities of daily living (ADL) training[10]. The aim of this study was to find out the efficacy of oral baclofen in combination with intensive rehabilitation in reducing spasticity in cerebral palsy.

Methodology

This observational study was done in the Department of Physical Medicine & Rehabilitation, Dhaka Medical College Hospital and Department of Pediatrics, Dhaka Medical College Hospital. The total duration of study was from January 2011 to December 2011. All the spastic cerebral palsy patients seeking treatment in outpatient department of Physical Medicine & Rehabilitation and Pediatrics, Dhaka medical college hospital were the reference population. From reference population, patients enrolled in the study who met the inclusion and exclusion criteria. Patients aged between 12 months to 12 years of both sexes; with disorder in the development of movement and posture presumably of cerebral origin started before 2 years of age, presence of spasticity associated with or characterized by increased tone reflexes, clonus or extensor plantar response, and delayed miles stones 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 ankle joint movement; neurodegenerative disorders, chromosomal abnormality such as Down syndrome, inborn errors of metabolism such as galactosemia and presence of comorbidity such as epilepsy were excluded from the study. Complete history and clinical examination were done for all enrolled patients. After taking written informed consent they were finally selected for the study. Intensive rehabilitation 1 hour daily for 5 days a week and oral baclofen corresponding to approximately 0.3mg/kg a day in two divided doses was given for 24 weeks. Patients were first assessed with Modified Asworth Scale (MAS)39 based on muscle tone to determine the extent of spasticity. Then Physician Rating Scale40 to measure joint angle (crouch) specially by standard goniometer, 46 knee recurvatum, foot contact and overall functional status by Gross Motor Functional Classification System[11]. Then intervention was done by giving oral baclofen with intensive rehabilitation to reduce spasticity and uniform intensive rehabilitation protocol was applied which includes prone lying position, sitting balance in specialized sitting chair, range of motion exercise, stretching exercise, activities of daily living (ADL) training. After 4 weeks (1st follow up) during the continuation of drugs, patients were again assessed by principal investigator using before mentioned 3 scales and adverse effect of oral baclofen was recorded in followup sheet. After 8 weeks (2nd follow up) were again assessed by principal investigator using before mentioned 3 scales and adverse effect of oral baclofen was recorded in followup sheet. Then followup assessment was done every 4 weekly at 12th week, 16th week, 20th week and lastly 24th week with continuing the drugs using same scales by principal investigator. Intensive rehabilitation was given by an experienced physiotherapist at the department of Physical Medicine & Rehabilitation, Dhaka Medical College Hospital, Dhaka. After group allocation, baclofen was given according to following dose schedule. Oral baclofen was started with a very low dose (corresponding to approximately 0.3mg/kg a day) in two divided doses. One hour intensive physiotherapy was done daily for 5 days a week. Activities included in each session were body alignment weight transfer in various positions, bimanual activities and facilitation sequences of movements. Ethical clearance has been obtained from the concerned authority to conduct the research work of study subjects. Data were collected through a pretested structured questionnaire. Data were processed and analyzed using SPSS (statistical package for social science) version 17. Test statistics used to analysis the data were chi square Test and student T test. The level of significance was set 0.05 and p-value of less than 0.05 was considered significant.

Results

A total of 30 patients were recruited to yield 21 male and 9 female. Mean age (months) was 37.4 ± 4.9. Mean weight was 13.0 ± 2.5 (Table 1).

Discussion

In this study, 30 children with cerebral palsy were enrolled. At the baseline evaluation 4(13.3%) were Modified Asworth Scale grade 3, 18(60.0%) grade 4, 8(26.7%) grade 5. After 6 months, spasticity was significantly reduced; 23(76.7%) children showed Modified Asworth Scale grade 0-1 , 6(20.0%) were grade 2-3 and 1(3.3%) grade 4-5. Regarding Physician ratings scale, most of the severe and moderate

Table 1: Demographic characteristics

Variables	Values
Age	37.4 ± 4.9
Weight	13.0 ± 2.5
Gender	
• Male	21 (70%)
• Female	9 (30%)

angle for crouch gait at baseline in experienced more improvement, with most of the severe and moderate angle for crouch gait at baseline changed to mild a few to none (p<0.001). Changes in knee recurvatum were not significant as very few children had knee recurvatum >5 or <0-5 (p=0.688). During measuring crouch, the patient's baseline scores were 24% and 52% respectively and at 1st month scores were 0% and 52%. change more significantly. In this study most of the children having foot contact with their toes at baseline change (80% of the children at baseline had foot contact with their toes, but at 6 months of evaluation 80% showing flat foot). The change was more (p<0.001). In gross motor function level, most of the children changed from level 5 gross motor function to level 4 and a few to level 3 and level 2 (p<0.001) which indicate better improvement in activities in daily life.

Table 2: Modified Asworth Scale

Level	Pretreatment score	Level	Score after 3 month	Score after 6 month	Chi Square test P value
3	4 (13.3%)	0-1	21 (70.0%)	23 (76.7%)	P <0.00001 S
4	18 (60%)	2-3	9 (30.0%)	6 (20.0%)	(P < 0.05)
5	8 (26.7%)	4-5	0	1 (3.3%)	

Table 3: Physician Rating Scale

Physical rating scale	Pre treatment	3 Month after treatment	6 Month after treatment	Chi Square test; P value
Knee				
Recurvatum >5	1 (3.3)	0(0.0)	0(0.0)	X2= 2.1802
Recurvatum <0-5	4 (13.3)	5 (16.7)	4 (13.3)	P = 0.702 NS
No Recurvatum	25 (83.3)	25(83.3)	26 (86.7)	(P < 0.05)
Angle for crouch gait				
Severe	6 (24.0)	2 (8.0)	1 (4.0)	X2= 10.47
Moderate	13 (52.0)	21 (84.0)	22 (88.0)	P = 0.033 S
Mild	6 (24.0)	2 (8.0)	2 (8.0)	(P < 0.05)
None	0(0.0)	0(0.0)	0(0.0)	
Foot contact				
Toe	24 (80.0)	0(0.0)	4 (13.3)	X2= 92.64
Toe-heel	5 (16.7)	6 (20.0)	24 (80.0)	P <0.00001 S
Flat	1 (3.3)	23(76.7)	2 (6.7)	(P < 0.05)
Occasional heel-toe	0(0.0)	1(3.3)	0(0.0)	

*Figure within parenthesis indicates percentage.

In a study Intermittent versus continuous physiotherapy in children with cerebral palsy- Christiansen et al[14] reported that GMFM-66 score increased significantly in both intermittent and continuous group. Baclofen has been poorly studied in spasticity of cerebral origin with most studies evaluating efficacy in treating spasticity of spinal cord origin. Although 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[15-16]. Baclofen is stable in liquid form, but can only be given enterally (except if given intrathecally). Baclofen cannot be given intravenously and is not absorbed rectally[17]. Children can have similar withdrawal symptoms as in adults, which includes hallucinations and seizure[18]. The usually starting dose is 2.5mg a day and titrated up every 3-5 days to a maximum of 20-60mg. per day[19]. In a study of infants receiving physical therapy, Scherzer et al noted improvement in broadly defined motor and social skills and in the patient's ability to address the children's daily needs, but could not separate the influences of age, therapy and cognitive level[13].

In the study in Norway to assess the effects of intensive physiotherapy in cerebral palsy. A single-subject design was used. Intervention consisted of two 4-week periods of daily

Table 4: Gross Motor Functional Classification System

Gross Motor Function	Pre treatment	3 Month after treatment	6 Month after treatment	Chi Square test; P value
Level1	0(0.0)	0(0.0)	1(3.3)	X2= 14.14
Level2	1(3.3%)	1(3.3)	1(3.3)	P =0.028 S
Level3	0(0.0)	0(0.0)	0(0.0)	(P < 0.05)
Level4	3(10.0%)	6(20.0)	14(46.7)	
Level5	26(86.7%)	23(76.7)	14(46.7)	

physiotherapy, interrupted by 8 weeks of physiotherapy as usual. The children were assessed every 4th week using the Gross Motor Function Measure. Results were visually analyzed, and statistical significance of Gross Motor Function Measure-66 scores was established with the 2 SD band method. Compliance was high. All infants showed gross motor progress compared with baseline, but separating effect of daily physiotherapy from physiotherapy as usual was inconclusive. Parents preferred the intensive treatment alternative. Blocks of intensive therapy can be an alternative to regular dosage of physiotherapy, but until further studies are conducted, the physiotherapy intervention, intensity, and frequency should be tailored to meet the needs of each individual infant and family[20]. 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.

Conclusion

Analytical results of this study shows that basic motor abilities and self-care improved after intensive physiotherapy with baclofen is effective for reducing generalized spasticity regarding muscle tone and joint angle stiffness and gait improvement in cerebral palsy patients.

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