



ISSN : 2350-0743

www.ijramr.com



International Journal of Recent Advances in Multidisciplinary Research

Vol. 03, Issue 12, pp.2075-2078, December, 2016

RESEARCH ARTICLE

SIDDHA MEDICINES AND METHODOLOGIES ON DYNAMIC GAIT INDEX OF CEREBRAL PALSY CHILDREN

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ARTICLE INFO

Article History:

Received 17th September, 2016

Received in revised form

24th October, 2016

Accepted 06th November, 2016

Published online 30th December, 2016

Keywords:

Cerebral Palsy,
Brahmi Nei,
Vasavu Ennai,
Dynamic Gait Index.

ABSTRACT

The Objective of the study is to determine the effect of Brahmi Nei with massage and varmam on dynamic gait index of children with spastic cerebral palsy. Among the 250 children 210 Spastic CP satisfied the inclusion criteria and were divided in to three groups (N=70 Nos). Group –I treated as an active control, Group –II received Brahmi Nei, Group - III received Brahmi Nei along with external therapies such as massage with Vasavu ennai and Varmam twice a day. Experimental period was 90 days and dynamic gait index was recorded 0th day and followed by every 30th day. Group III had improved dynamic gait index in which are compared with other two groups. Finally, it can be concluded that Brahmi Nei along with Vasavu ennai massage and Varmam has a clinical efficacy on gait in cerebral palsy children.

INTRODUCTION

Cerebral palsy (CP) is described as “a group of disorders of the movement and posture, 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 spasticity and rigidity leads to gait imbalance.” The prevalence of cerebral palsy is estimated to be 1.5- 3 per 1000 live births, with variations possibly differences in ascertainment and classification (Andersen, G. L et.al 2008, Blair, E. 2010). During the last years, focus of care for children with cerebral palsy has shifted from a main emphasis on motor function, towards participation and minimizing limitations of activity, in line with the World Health Organization (WHO) framework; the International Classification of Functioning, Disability and Health (ICF). Throughout the years a large number of treatment options have been available for spasticity to improve gait children with cerebral palsy. Today the ultimate aim with therapy is to promote activity and participation in everyday life according to the child’s and family’s priorities. Oral Baclofen, Tizanidine, Dantrolene, Diazepam and Gabapentin are widely used for spasticity.

Not all children with spasticity benefit from this treatment to improve gait index (Orsnes GB, 2000) the incidence of adverse drug effects (drowsiness, sedation and muscle weakness) were high. Children with localized or multifocal spasticity injections have benefit of Botulinum toxins Lim (EC-H, Seet RCS. 2008) formation of antibodies against has been demonstrated (Muller K, et.al 2009) Neurosurgery such as rhizotomy and orthopaedic surgery (tendon lengthening and soft tissue releases) may be the options (Ward AB, 2009). In view of all of the above, an immediate and urgent need exists to look for an alternative form of therapy such as natural products. In India, Siddha system of medicine owes its origin to medicinal ideas and practices of a class of Tamil sages. It has bio pharma products such as herbs, minerals, metals and salts all have been used for pediatric population. The purpose of this research work is to develop recommendations on “best practices” related primarily to the evaluate Siddha methodologies and Medicines. Different treatment modalities can improve the quality of life to the cerebral palsy children to improve gait index and these can include Siddha medicines included Brahmi Nei (TNSMB, 1995) as internal medicine, Vasuvu Ennai (SHP, 1995)) for thokkanam (Massage) and Varama therapy (Kannan Rajaram, 2008 R.Thiyagarajan 1985) and as external, all of which have been used in the Siddha system of medicine for many centuries either singly or in various combination. In order to limit this issue, efforts were undertaken to study the result of the use of a combination of these therapy.

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MATERIALS AND METHODS

Preparation of Experimental Formulations

Brahmi Nei as internal medicine and Vasavu Ennai for thokkanam (Massage) were identified for this study. Raw drugs to prepare the products were purchased from the market and fresh plants were collected from wild sources. The raw materials have got authentication from Department of Medicinal Botany, National Institute of Siddha, and Chennai.

Birahmi Nei

Birahmi Nei was prepared as described as in the sashtrich Siddha literature. Briefly, it was prepared by adding paste of *Zingifer officinale* Linn., (Dried Rhizome) *Piper longum* Linn. (Dry fruit), *Alpenia officinarum* Linn. (Dried Rhizome), *Feronia elephantum* Linn.(seed), Induppu, *Caryota urens* Linn.(pal jaggery), *Gurkuma aromatic* Linn.(Rhizome) each 14gms, in freshly prepared *Bacopa monniera* Linn.(5.44kg), *Acorus calamus* Linn.(1.36 kg), *Alpenia galanga* Linn.(1.36kg), and in vessel having Cow's milk (5.44kg), Cow's Ghee,(2.72 kg). Above mixture was heated and filtered after acquiring completion test. In this way, Birami Nei was prepared.

The boiling was stopped and the oil was filtered using a washed and dried white filter cloth when chikku patham was attained. In this way, Vasavu Ennai was prepared.

Clinical Study

The present study was a prospective, open label, non-randomized, outpatient and inpatient based, single centered drug trial conducted in the department of Kuzhanthai Maruthuvam (Pediatric), National institute of Siddha, Chennai. It was conducted during 2011 to December 2016 after obtaining approval from the Institute Ethics Committee (NIS/IEC/2011/3/48). Single batch of Brahmi Nei and Vasavu ennai were prepared for the entire study. The first 250 children with spastic cerebral palsy were screened during the study period. Children of either sex between the age group of 3 to 12yrs, who were diagnosed with spastic cerebral palsy, were identified to include the study. Other type of cerebral palsies and along with seizure disorder, Spinal deformities, impaired vision Autistic Spectrum Disorders, ADD/ADHD (Hyper activity), Mental Retardation, Visual Impairments and Blindness, Hearing Loss and Deafness, Down Syndrome, Spina Bifida, Traumatic Brain Injury were excluded from the study. 210 children satisfied the inclusion criteria and were willing to participate in the study, signed the informed consent.

Table 1. Changes in gait level surface and gait speed

	Gait Level Surface			Change in Gait Speed		
	Group I	Group II	Group III	Group I	Group II	Group III
	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD
Day 0	1.46 ± 0.50	1.57 ±0.65	1.51 ±0.50	1.49 ±0.50	1.53 ±0.63	1.60 ±0.65
Day 30	1.51 ±0.53	1.46 ±0.50	1.91 ±0.58	1.50 ±0.50	1.44 ±0.53	1.91 ±0.61
Day 60	1.59 ±0.55	1.41 ±0.52	2.04 ±0.60	1.47 ±0.53	1.37 ±0.54	2.00 ±0.68
Day 90	1.64 ±0.70	1.39 ±0.49	2.06 ±0.72	1.46 ±0.56	1.43 ±0.53	2.14 ±0.84

Table 2. Changes in Step over obstacle and Step around the obstacle

	Step Over Obstacle			Step around the Obstacle		
	Group I	Group II	Group III	Group I	Group II	Group III
	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD
Day 0	1.50 ±0.53	1.73 ±0.66	1.73 ±0.72	1.47 ±0.50	1.57 ±0.65	1.71 ±0.68
Day 30	1.41 ±0.50	1.53 ±0.56	2.00 ±0.68	1.36 ±0.51	1.40 ±0.49	1.91 ±0.58
Day 60	1.51 ±0.50	1.50 ±0.56	2.09 ±0.74	1.47 ±0.53	1.33 ±0.47	2.00 ±0.72
Day 90	1.37 ±0.59	1.41 ±0.50	2.51 ±0.90	1.46 ±0.58	1.40 ±0.52	2.16 ±0.86

Gait changes in the different clinical groups at 90 days of treatment. The number of children in each group is given within parentheses. Values are given as mean ± S.D for 70 children in each group. Values not sharing a common superscript letter differ significantly at $p < 0.05$ (DMRT).

Vasavu Ennai

Vasavu Ennai also was prepared as described as in the sashtrich Siddha literature. Briefly, it was prepared by adding paste of *Hemidesmus indicus* Linn.(100gms), in freshly prepared juice of *Citrus aurantifolia* Linn., *Aloe barbadensis* Linn., in vessel having *Cocos nucifera* Linn oil and *Ricinus communis* Linn., oil each one litre. Above mixture was heated and filtered after acquiring completion test and boiled in medium flame with continuous stirring and monitoring of paakam.

The parents of children who were enrolled was informed about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable for them. Children were divided in to three groups (N=70 Nos). Group –I treated as an active control received regular OPD medicines, Group –II received internal medicine Brahmi Nei (3 yrs to 5 yrs - 8 ml, 6 yrs to 9 yrs - 10 ml, 10 yrs to 12 yrs - 12 ml) twice a day. Group - III received internal medicine Brahmi Nei along with external therapies such as massage with Vasavu ennai and

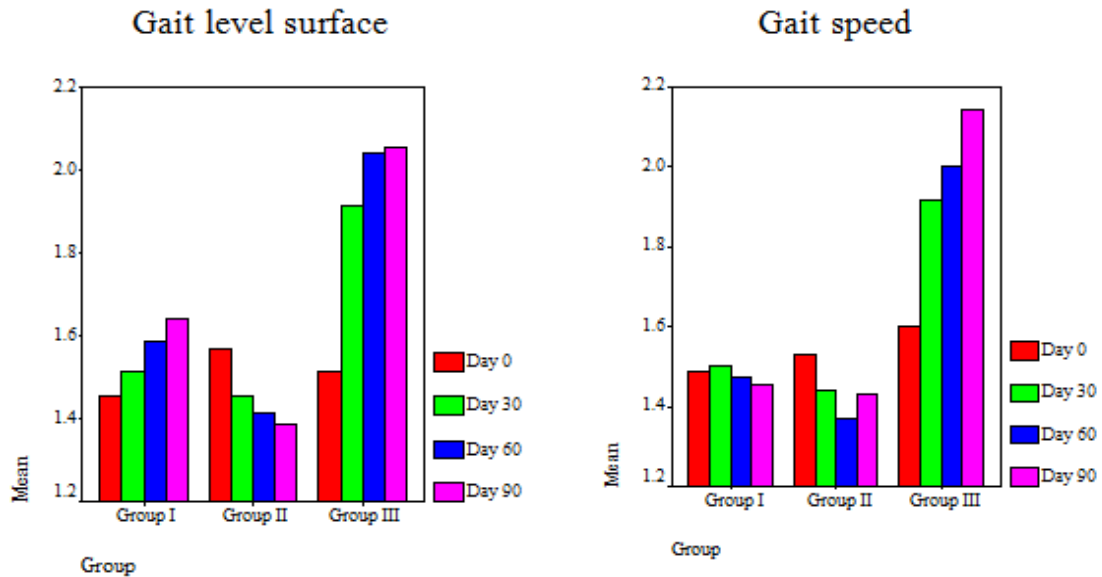


Fig.1. Changes in gait level surface and gait speed

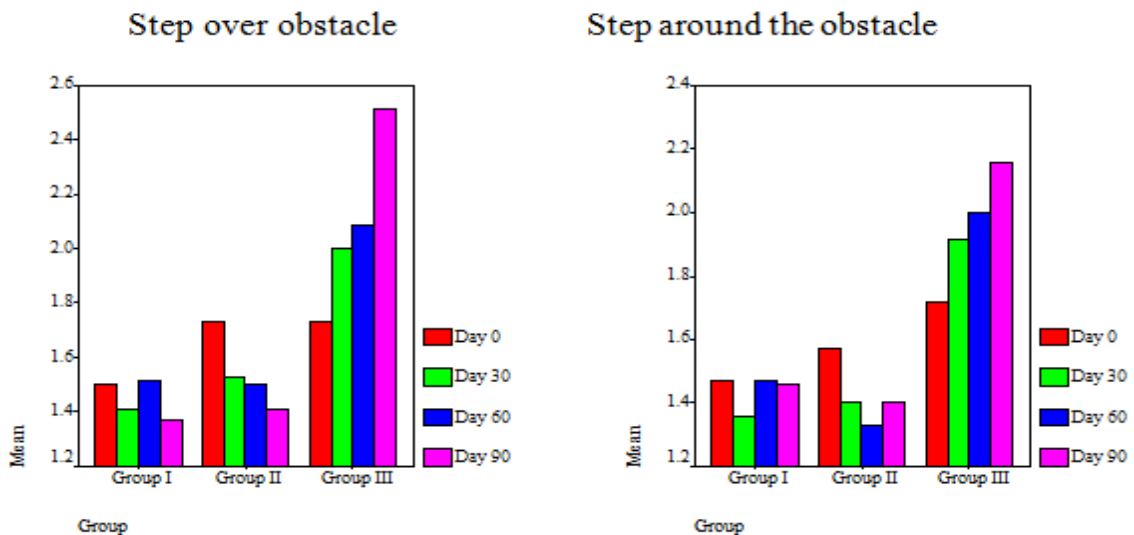


Fig. 2. Changes in Step over obstacle and Step around the obstacle

Varmam (Kondai kolli, Natchathira kaalam, Thilartha varmam, Pidari kaalam) twice a day. Experimental period was 90 days and spasticity was recorded 0th day and followed by every 30th day. Experimental formulations were assigned to each subject and regular study drug reconciliation was performed to document the drug assigned, consumed, and remaining are logged on the drug reconciliation form with sign & date.

Assessment of Dynamic Gait Index

In this assessment, tone refers to the readiness of gait. There are four summary items i.e Gait level surface, Change in gait speed, Step over obstacle, Step around obstacles *Gait level surface* 4 - walks 20', no assistive devices, good speed, no evidence for imbalance, normal gait pattern. 3- Mild impairment: walks 20', uses assistive devices, slower speed, mild gait deviations. 2 - Moderate impairment: walks 20', slow speed, abnormal gait patters, evidence for imbalance. 1 - Severe impairment: cannot walk 20' without assistance, severe gait deviations or imbalance.

Change in gait speed 4- Able to smoothly change walking speed without loss of balance or gait deviation. Shows significant difference in walking speeds between normal, fast and slow paces. 3- Is able to change speed but demonstrates mild gait deviations, or no gait deviations but unable to achieve a significant change in velocity, or uses as assistive device. 2- Makes only minor adjustments to walking speed, or accomplishes a change in speed with significant gait deviations, or changes speed but loses balance but is able to recover and continue walking. 1- Cannot change speeds or loss balance and has to reach for a wall or be caught. *Step over obstacle.* 4- Is able to step over box without changing gait speed; no evidence for imbalance. 3- Is able to step over shoe box, but must slow down and adjust steps to clear box safely. 2- Is able to step over box but must stop, then step over. May require verbal cueing. 1-Cannot perform without assistance. *Step around obstacles.* 4- Is able to walk safely around cones safely without changing gait speed; no evidence of imbalance. 3- Is able to step around both cones, but must slow down and adjust steps to clear cones. 2- Is able to clear cones but must

significantly slow speed to accomplish task, or requires verbal cueing. 1- Unable to clear cones, walks into one or both cones, or requires physical assistance.

Statistical Analysis

All of the analyses were performed using the SPSS statistical software, version 20.0. The results are expressed as mean values \pm SD. Statistical significance was tested by means of analysis of variance (ANOVA), paired students t-test for within-group comparison and the independent student t-test was used for comparisons between the two therapy groups and the group means were compared by Duncan's Multiple Range Test (DMRT). Values were considered statistically significant when at $p < 0.05$ (Duncan BD, 1957)

RESULTS AND DISCUSSION

While the Group II of children showed no significant increase in gait, children of Group I and Group III showed significant improve in dynamic gait index. However, there was no significant difference in gait changes in group II. This study indicating that the combined therapy of internal medicine and external medicine had superior action as far as improve in dynamic gait index is concerned. We observed that the single internal medicine with Brahmi nei had no significant action as far as gait is concerned. There were significant difference in Group I and Group III. In Siddha literature CP is under the Vadha disease therefore, the therapeutic management is considered to be internal medicine, (Thokkanam) massaging and varmam. Since Brahmi primary use is to enhance cognitive function, research has been focused on the mechanism behind these properties. The triterpenoid, saponins and their bacosides are responsible for increase the muscle tone through enhance nerve impulse transmission. The bacosides aid in repair of damaged neurons by enhancing kinase activity, neuronal synthesis, and restoration of synaptic activity, and ultimately nerve impulse transmission and boosting the synthesis of new protein in the brain (Singh HK and Dhawan BN 1997). Massage with Vasavu ennai which soothe the sensory nerve endings, they produce a hyperemic effect causing the arterioles dilate in musculature, and reduce stiffness (Shailaja U et.al 2013). Massage is considered to enhance muscle relaxation (Nordschow M and Bierman W,1967) reduce muscle tension (Dubrosky V, 1982) and soreness (Tiidus P and Shoemaker J, 1995) and post- sequently, improve performance (Rinder A, 1995) . Massage is also thought to provide a soothing, sedative, invigorating feeling and can give the comfort (Tiidus P, 1997). Varma therapy is one of the method of treatment is prevalent in southern parts of Tamilnadu and Kerala. The stimulation of particular points in human body in appropriate pressure gives relief from the spasm.

Conclusion

Finally, it can be concluded that Brahmi Nei along with Vasavu ennai massage and Varmam has a definitive action as well as clinical efficacy on dynamic gait index in cerebral palsy children in contrast to that seen in regular OPD treatment and Brahmi nei.

The effects of internal and external therapies may be due individual drugs' multipronged action. Further study is required for scientific validation to prove its clinical efficacy in multicentre clinical study.

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