Medicine



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ABSTRACT

Asst.Professor, Sri Sairam Institute of Technology, Chennai, Tamil Nadu The Objective of the study is to determine the effect of Brahmi Nei with massage and varmam on spasticity 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 spasticity was recorded 0th day and followed by every 30th day. Group III had decreased spasticity in different group of muscles 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 spasticity in cerebral palsy children.

KEYWORDS : Cerebral palsy, Brahmi Nei, Vasavu ennai, Spaticity

1.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." The prevalence of cerebral palsy is estimated to be 1.5-3 per 1000 live births, with variations possibly differences in ascertainment and classification ^{1,2} 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 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 treatment³, the incidence of adverse drug effects (drowsiness, sedation and muscle weakness) were high. Children with localized or multifocal spasticity injections have benefit of Botulinum toxins4 formation of antibodies against has been demonstrated⁵. Neurosurgery such as rhizotomy and orthopaedic surgery (tendon lengthening and soft tissue releases) may be the options⁶. 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 disabled children and these can include Siddha bio pharma products included Brahmi Nei7 as internal medicine, Vasuvu Ennai 8 for thokkanam (Massage) and Varama therapy 9,10 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.

2.Materials and Methods

2.1 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 sasthric 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, Caryyota 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.

Vasavu Ennai

Vasavu Ennai also was prepared as described as in the sasthric 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 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.

2.2 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. 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 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.

2.3 Assessment of Spasticity

The most commonly used definition of spasticity is described by Lance (1980) i.e "Spasticity is a motor disorder characterized by a velocity-dependent increase in tonic stretch reflexes (muscle tone) with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex, as one component of the upper motor neuron syndrome"¹¹. Several methods have been developed and used to assess spasticity. The most commonly used test in clinical practice is the MAS -B^{12,13}. The test is based on the assessment of resistance to passive stretch of muscle group at one non specified velocity in Gastrocnemous and Soleus, Hip adductors, Thigh flexors and extensors, Triceps and biceps, Shoulder girdle and trunk muscles, Forearm flexors and extensors.

0 - No increase in muscle tone

1 - Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension

1+ - Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM

2 - More marked increase in muscle tone through most of the ROM, affected part(s) easily moved

- 3 Considerable increase in muscle tone, passive movement difficult
- 4 Affected part(s) rigid in flexion or extension

2.4 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 < 0.05¹⁴.

3. Results and Discussion

Table-1. Spasticity changes Gastrocnemous and Soleus, Hip adductors, Thigh flexors and extensors muscles

	Gastrocnemous and Soleus			Hip adductors			Thigh flexors and extensors		
	Gr. I	Gr. II	Gr. III	Gr. I	Gr. II	Gr. III	Gr. I	Gr. II	Gr. III
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
Day 0	3.59±	3.69±	3.60±	3.84±	3.81±	3.41±	4.00±	4.00±	3.61±
	1.03	1.08	1.03	0.88	0.95	0.96	0.90	0.83	1.00
Day	3.51±	3.50±	3.21±	3.79±	3.93±	2.89±	4.16±	4.10±	2.90±
30	0.88	.94	.95	.96	.89	0.86	0.79	0.78	0.85
Day	2.96±	3.50±	2.91±	3.57±	3.60±	2.29±	3.94±	3.86±	2.30±
60	1.06	1.02	1.07	0.89	0.87	0.90	0.76	0.79	.92
Day	3.00±	3.39±	2.46±	3.49±	3.47±	2.09±	3.93±	3.73±	2.04±
90	1.09	1.13	1.22	0.93	0.90	0.86	0.84	0.80	0.92

Table -2 Spasticity changes Triceps and biceps, Shoulder girdle and trunk muscles, Forearm flexors and extensors muscles

	Triceps and biceps			Shoulder girdle and trunk muscles			Forearm flexors and extensors		
	Gr. I	Gr. II	Gr. III	Gr. I	Gr. II	Gr. III	Gr. I	Gr. II	Gr. III
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
Day 0	3.84±	3.81±	3.41±	3.84±	3.81±	3.41±	3.84±	3.81±	3.40±
	0.88	0.95	0.96	0.88	0.95	0.96	0.88	0.95	0.95
Day	3.79±	3.93±	2.89±	3.79±	3.76±	2.61±	3.79±	3.99±	2.90±
30	0.96	0.89	0.86	0.96	0.95	0.91	0.96	0.81	0.82
Day	3.57±	3.60±	2.29±	3.69±	3.56±	2.26±	3.47±	3.80±	2.30±
60	0.89	0.87	0.90	0.83	0.90	0.86	0.86	0.84	0.73
Day	3.49±	3.47±	2.09±	3.66±	3.49±	2.07±	3.46±	3.73±	1.87±
90	0.93	0.90	0.86	0.85	0.85	0.89	0.91	0.93	0.70

Spasticity 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 \pm S.D for 70 children in each group. Values not sharing a common superscript letter differ significantly at p < 0.05 (DMRT).

Fig-1. Spasticity changes Gastrocnemous and Soleus, Hip adductors













While the Group II of children showed no significant reduce in spasticity, children of Group I and Group III showed significant reduction in spasticity all group of muscles. However, there was no significant difference in spasticity changes in group II. This study indicating that the combined therapy of internal medicine and external medicine had superior action as far as reduction in spasticity is concerned. We observed that the single internal medicine with Brahmi nei had no significant action as far as reduction in spasticity is concerned. There were significant decrease 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 ¹⁵. Massage with Vasavu ennai which soothe the sensory nerve endings, they produce a hyperemic effect causing the arterioles dilate in musculature, and reduce stiffness ¹⁶. Massage is considered to enhance muscle relaxation,¹⁷ reduce muscle tension¹⁸ and soreness,¹⁹ and post- sequently, improve performance 20 . Massage is also thought to provide a soothing, sedative, invigorating feeling and can give the comfort ²¹. 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.

4. 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 spasticity 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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