



Exploratory Study on the Ayurvedic Therapeutic Management of Cerebral Palsy in Children at a Tertiary Care Hospital of Karnataka, India

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ABSTRACT

Cerebral palsy (CP) is the leading cause of childhood disability affecting cognitive function and developments in approximately 1.5 to 3 cases per 1000 live births. Based on Ayurvedic therapeutic principles, CP patients were subjected to *Abhyanga* (massage) with *Moorchita Tila Taila* (processed sesame oil) and *Svedana* (fomentation) with *Shastikashali Pinda Sveda* (fomentation with bolus of drugs prepared with boiled rice). Study group received *Mustadi Rajayapana Basti* (enema with herbal decoction) and *Baladi Yoga* (a poly-herbo-mineral formulation), while the placebo group received *Godhuma Vati* (tablet prepared with wheat powder) and saline water as enema. Treatment with *Mustadi Rajayapana Basti* and *Baladi Yoga* improved the activities of daily life by 8.79%, gross motor functions by 19.76%, and fine motor functions 15.05%, and mental functions like memory retention got improved by 15.43%. The placebo group showed an improvement of 0.21% in daily life activities, 2.8% in gross motor, and 2.4% in fine motor functions. *Mustadi Rajayapana Basti* and *Baladi Yoga* proved to be more supportive in improving the motor activities and gross behavioral pattern. Further clinical trials are required to evaluate and validate the maximum effect of the combination therapy in a large sample with repetition of the courses for longer duration.

Keywords: *Abhyanga, Baladi Yoga, Cerebral palsy, Moorchita Tila Taila, Mustadi Rajayapana Basti, Shastikashali Pinda Sveda*

INTRODUCTION

Cerebral palsy (CP) describes a group of disorders of the development of movement and posture that cause activity limitation, which are attributed to non-progressive disturbances that occur in the developing fetal or infant brain. The motor disorders of CP are often accompanied by disturbances of sensation, cognition,

communication, perception, and/or behavior, and/or by a seizure disorder.^[1] Incidence of CP ranges from 1.5 to 3 cases per 1000 live births.^[2] The incidence is higher in males than in females; the Surveillance of Cerebral Palsy in Europe (SCPE) reports male to female ratio of 1.33:1.00.^[3] The United Cerebral Palsy Foundation states that there are 800,000 children and adults in the United States with CP. The Centers for Disease Control estimates

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DOI: 10.4103/2225-4110.124345

that about 10,000 babies are born each year with CP.^[4] Despite the non-progressive character of CP, some children deteriorate in mobility-related activities during childhood.^[5] Spasticity is a disabling clinical symptom that is prevalent in those with CP.^[6] The primary problems associated with spasticity are loss of balance, strength, and selective motor control of the muscles, and increased muscle tone which leads to problems such as fixed contractures and bony deformities that cause severe motor dysfunction in patients.^[7-10] Perinatal asphyxia accounts for between 6% and 8% of CP. Prenatal causes are responsible for approximately 75% of all CP cases, although it is impossible to determine the nature and the exact timing of the damage. Postnatal acquired CP ranges in incidence from 10% to 18%.^[11]

Management of CP focuses on helping the individual to maximize his or her potential by providing physical therapy to facilitate motor development and to enhance independence in motor skills, self-care, play, and leisure activities.^[12] Current interventions for CP include: Physical therapy to prevent the weakening or deterioration of muscles and for motor development; braces or orthotic devices to stretch spastic muscles, which can disrupt balance and normal motor development; occupational therapy to help develop daily living skills, such as feeding, dressing, or using the bathroom; speech therapy to help develop communication and language skills; behavioral therapy to promote socially appropriate behaviors; and surgery to treat severe cases of contractures of muscles that cause movement problems or placing a feeding tube in severe cases of swallowing problems and malnutrition.^[13]

CP cannot be correlated with any single disease or condition mentioned in Ayurveda, as it is a multifactorial disease. However, considering the classification and the respective features of the types, CP may be stated as *Janma Bala Pravritta Vyadhi* (congenital disorder). In some cases, it may also be due to the derangement of *Doshas* (bodily humors). Consequently, CP may also be considered as *Shiro Marmabhighata Vata Vyadhi* (diseases caused due to injury to head), as *Marmaghata* (injury to vital organs) is one of the causes of *Vata Vikara* (disease of *Vata*, i.e. body humor). Ayurvedic classics have mentioned that derangement of bodily humors and/or injury to vital organs during formative stage, fetal life, delivery, and neonatal period produces symptoms like loss of activities, stammering, dumbness, and weakness, including mental derangement due to impairment of motor and sensory activities. The therapeutic management is done according to *Vata Vikara* (disease of *Vata*, i.e. body humor) where the main line of treatment is considered to be application of medicated enema and internal administration of drugs.^[14,15]

Incidence of CP has not declined despite the medical advances made in neonatal management and obstetric care. On the contrary, with a decline in infant mortality rate, there has actually been an increase in the incidence and severity of CP.^[16] Defining the goals of CP treatment is one of the main issues in its management. These goals, which should be individualized for each patient, are to reduce the muscle tone, increase the range of motion of the joints, improve the function of upper and lower extremities, delay the need for surgery, and predict surgical results.^[2] The few available treatments to reduce generalized spasticity are associated with a high incidence of adverse effects and complications. There is

an urgent need for studies to establish the efficacy of the current therapies and to find additional safe and effective treatments to help children affected by generalized spasticity due to CP. None of the oral medications used to treat spasticity in children has been adequately tested for safety and efficacy. There are minimal or no data regarding the pharmacokinetics or appropriate dosing parameters to treat children.^[17] These critical questions deserve serious research efforts. Currently there is no cure for CP.^[18] Few answers can be found in various indigenous systems of medicines being used globally. Indian Systems of Medicine, including Ayurveda, Unani, and Siddha, have been in use since time immemorial and are time tested. The present study was conducted with a goal to improve physical activity, capacity of mobility, social participation, and health-related quality of life in children with CP by means of Ayurvedic intervention using a combination of massage therapy, fomentation, and Ayurvedic drug administration through enema and oral route, i.e. *Rajayapana Basti* and *Baladi Yoga*.

MATERIALS AND METHODS

Design

This study had a double-arm pre-test and post-test design.

Participants

Patients presenting with CP were enrolled from Kaumarabhritya (Ayurvedic Pediatrics) out-patient department and in-patient department of SDM College of Ayurveda and Hospital, Hassan, irrespective of their sex, caste, religion, etc., Institutional ethical committee approved the protocol and written informed consent was obtained from the parents before any study-related procedures were performed. The inclusion criteria were: (a) Patients diagnosed with CP; (b) patients of both sexes belonging to the age group of 2-10 years. The exclusion criteria taken into account were: (a) presence of uncontrolled seizures and (b) systemic diseases such as renal or cardiac disorders.

Study drugs

1. *Mustadi Rajayapana Basti*: *Musta* (*Cyperus rotundas* Linn.), *Usheera* [*Vetiveria zizanioides* (Linn.) Nash], *Patha* (*Cissampelos pareira* Linn.), *Amrita* [*Tinospora cordifolia* (Thunb.) Miers], *Tikta* (*Picrorhiza kurroa* Royle ex Benth), *Aragwadha* (*Cassia fistula* Linn.), *Bala* (*Sida cordifolia* Linn.), *Rasna* (*Alpinia officinarum* Hance), *Punarnava* (*Boerhavia diffusa* Linn.), *Manjistha* (*Rubia cordifolia* Linn. sensu Hook. f.), *Brihati* (*Solanum indicum* Linn.), *Gokshura* (*Tribulus terrestris* Linn.), *Shalamparni* [*Desmodium gangeticum* (Linn.) DC.], *Prisniparni* [*Uraria picta* (Jacq.) DC.], *Kantakari* (*Solanum xanthocarpum* Schrad. and Wendl.), *Madanaphala* [*Randia dumetorum* (Retz.) Poiret], *Trayaman* (*Gentiana kurroo* Royle), *Satapuspā* (*Anethum sowa* Kurz.), *Yastimadhu* (*Glycyrrhiza glabra* Linn.), *Priyangu* (*Callicarpa macrophylla* Vahl.), *Kutaja* (*Holarrhena antidysenterica* Wall.), *Daruharidra* (*Berberis aristata* DC.), *Saidhava* *Lavana* (Himalayan pink rock salt), *Madhu* (honey), *Ghrita* (butter oil), *Ksheera* (cow's milk), *Mamsa rasa* (goat meat soup).
2. *Baladi Yoga*: *Bala* (*Sida cordifolia* Linn.), *Prasarani* (*Paederia foetida* Linn.), *Eranda Mula* (*Ricinus communis* Linn.),

Ashwagandha (*Withania somnifera* Dunal), Lashuna (*Alium sativum* L.), Kumari [*Aloe vera* (L.) Burm. f.], Mandukaparni [*Centella asiatica* (Linn.) Urban], Shuddha Rasaka [purified zinc carbonate ($ZnCO_3$)], Shuddha Mandura [purified iron silicate (Fe_2SiO_4)], Abhraka Bhasma [purified powdered talc, Biotite Calx].

3. *Godhuma Vati* (placebo): Wheat powder processed and prepared in tablet form.

4. Sterilized saline water (placebo).

Raw drugs were procured from SDM Pharmacy, Udupi and were authenticated at Department of Dravyaguna and Vaisajya Kalpana, SDM College of Ayurveda and Hospital, Hassan.

Observation-based assessment criteria

Assessment of the participants was made according to the assessment criteria shown in Table 1, which were developed by the authors and a precise version can be found elsewhere.^[15] However, the present work presents the augmented version of the assessment criteria.

Intervention

A total of 123 patients were registered within the study period of 24 months. The patients were randomly divided into two groups as follows: 61 patients in the study group, and 62 patients in control group who received placebo. Out of 123 participants, 100 completed the study and 23 participants discontinued and

Table 1. Assessment criteria for cerebral palsy patients

		Grade
Daily activities		
Eating	Totally dependent	
Drinking	Can do with physical support	0
Brushing	Can do with verbal prompting	1
Bathing	Can do independently	2
Toileting		3
Gross motor		
Crawls a distance of 5ft or more	Cannot do at all	0
Sitting	Can do with support	1
Standing	Can do without support	2
Walk for minimum 5-10 steps	Can do independently	3
Claps hands		
Fine motor		
Puts small object into a container	Not does at all	0
Throws ball in any direction	Does with help	1
Uses thumb and index finger	Does independently	2
Retains two 1-inch cubes in one hand for 30 s		
Folds paper and inserts into envelope		
Language		
Ability to understand verbal commands	No response	0
	Turns face but not understanding	1
	Understands but not acting accordingly	2
	Understands and acts accordingly	3
Speech	No speech and sound	0
	Pronounces sound without meaning	1
	Pronounces some words with meaning	2
	Cannot make well-formed sentences	3
	Can speak well-formed sentences	4
Performance		
Making a triangle between three points	Cannot draw at all	0
	Can meet two points, not triangle	1
	Can draw a triangle	2
Mental status		
Happiness	Never laughs or enjoys in social events	0
	Occasionally laughs or enjoys in social events	1
	Normally laughs or enjoys in social events	2
Memory (after showing five familiar objects)	Cannot recollect any one of the objects shown	0
	Can recollect some of the objects, but forgets the order	1
	Can recollect five objects in the same order	2

could not be followed up. Thus, 60 participants in the study group and 40 participants in the control group were followed up in this study. For 8 days, all the patients were given *Abhyanga* (total body massage) with *Moorchita Tila Taila* (processed sesame oil), followed by *Svedana* (fomentation) with *Shastikashali Pinda Sveda*. After that, *Basti* (enema) was administered according to the following regimen.

Group A – Study group (*Mustadi Rajayapana Basti* and *Baladi Yoga*): *Mustadi Rajayapana Basti* was administered once daily in the morning in empty stomach. After completion of *Basti* (enema) procedure, the patients were administered the powder of *Baladi Yoga* orally in a dose of 1 g/day in two divided doses with ghee and honey before food for consecutive 60 days.

Group B – Control group [*Basti* with saline water and *Godhuma Vati* (wheat powder)]: *Basti* was administered with saline water once daily in the morning in empty stomach. Thereafter, the participants were given one *Godhuma Vati* of 1 g in two divided doses for 60 days.

The participants were administered *Basti* in empty stomach to facilitate absorption of the drugs and bypass the first-pass metabolism. The dose was administered as per the classical reference mentioned in Charaka Samhita (*Siddhi Sthana* 3:31-32) and is shown in Table 2.

RESULTS

Sex wise distribution of the participants showed that group A consisted of 61.7% males and 38.3% females and group B consisted of 57.5% males and 42.5% females. Age wise distribution of the participants is shown in Table 3. Religion followed by the participants showed that 97% of the study participants belonged to Hindu religion, and 56% of the participants were from rural

Table 2. Dosage of *Basti* (enema) according to age

Age (years)	Dose of <i>Basti</i> classical (<i>Pala</i>)	Dose of <i>Basti</i> equivalent in metric system (ml)
1	1	48
2	2	96
3	3	144
4	4	192
5	5	240
6	6	288
7	7	336
8	8	384
9	9	432
10	10	480

Pala = 48ml

Table 3. Age wise distribution of study subjects (N=100)

Age group (years)	Group A (study group)		Group B (control group)		Total	
	No. of patients	%	No. of patients	%	No. of patients	%
2-4	36	60	23	57.5	59	59
5-7	21	35	14	35	35	35
8-10	03	05	03	7.5	06	06

habitat. Occupation of the earning parents showed that 43% were primarily farmers, 27% had some kind of business setup, and 30% were service holders. It was noted that 31% of subjects belonged to joint family. In this series, an interesting fact came up, which was that 36% parents of the patients gave the history of consanguinity and 24% mothers have had early marriage and conception before the age of 18 years.

The pre-conception status of the mothers showed on enquiry that 8% mothers of the patients had the history of spontaneous abortion, 2% mothers had undergone D and C operations, 2% used intrauterine contraceptive devices (IUCD), and 33% mothers had the history of using oral contraceptives. Accordingly, it was found that 45% mothers suffered from one or the other disease; of these, 18% mothers had anemia, 12% had pre-eclampsia, and 9% had pregnancy-induced hypertension (PIH). However, 55% mothers remained healthy. Antenatal check-up (ANC) reports showed that mothers of 52% children did not follow the ANC advices properly, while 36% properly followed them. On the other hand, the mothers of remaining 12% children did not attend ANC. Thirteen percent mothers delivered by Lower Uterine Cesarean Section and 6% delivered by instrumental application. Eighty-one percent of the study subjects delivered within hospital setup. Among the 100 patients, 55 were pre-term infants. At the time of birth, 47% of the subjects had birth asphyxia and 44% were low-birth-weight babies with 44% subjected to incubation, while 43% subjects were born with abnormal head circumference. Effects of the intervention on daily activities and on the gross and fine motor functions assessed in both the groups, study and control, are shown in Tables 4-6, respectively.

Significant improvement was observed in the study group regarding ability to understand verbal commands and intellect, speech, memory, and happiness, which is shown in Table 7. Overall improvement of 13.66% was seen in patients undergoing treatment with *Mustadi Rajayapana Basti* and *Baladi Yoga*, compared to 2.21% improvement seen in the control group.

DISCUSSION

The results of the present study showed that *Mustadi Rajayapana Basti* along with *Baladi Yoga* provided mild improvement in 93.44% patients of the study group, with the outcome measures being mental status, fine and gross motor functions, and daily life activities. While in the placebo control group, *Basti* was administered maintaining all the procedures, except that in the place of *Mustadi Rajayapana Basti*, only saline water was applied. In place of *Baladi Yoga*, *Godhuma Vati* (wheat powder) was administered as placebo. These findings reveal that the beneficial effects observed were due to the medication also and not only due to the *Basti* (enema) procedure. The attendance of reasonable number of CP patients may be because 36% parents gave a history of consanguinity while 45% of the mothers were having some kind of complications before child birth. Early child birth was noticeable in 24% mothers. Studies worldwide have revealed that risk factors like pre-existing diseases in mothers during delivery, birth asphyxia, gestational age, and low birth weight are associated with CP in children.^[11] CP is a *Vata Vyadhi*; therefore, the therapies

Table 4. Effect of treatment (drugs and placebo) with regard to assessment of daily activities in both the groups in this study (N=100)

Parameter	Study group			Control group		
	% improvement in relation to the pre-interventional status	SD (±)	P value	% improvement in relation to the pre-interventional status	SD (±)	P value
Eating	10.76	0.43	<0.001	1.04	0.02	>0.10
Drinking	10.60	0.43	<0.001	0.00	0.00	>0.05
Brushing	9.15	0.42	<0.001	0.00	0.00	>0.05
Bathing	7.23	0.39	<0.001	0.00	0.00	>0.05
Toileting	6.25	0.38	<0.01	0.00	0.00	>0.05

SD: Standard deviation

Table 5. Effect of treatment (drugs and placebo) on the gross motor functions in both the groups in this study (N=100)

Parameter	Study group			Control group		
	% improvement in relation to the pre-interventional status	SD (±)	P value	% improvement in relation to the pre-interventional status	SD (±)	P value
Crawling	28.00	0.50	<0.001	5.00	0.26	>0.05
Sitting	30.85	0.50	<0.001	4.00	0.27	>0.05
Standing	15.00	0.46	<0.001	0.00	0.00	>0.05
Walking	09.52	0.42	<0.001	1.00	0.16	>0.10
Clapping hands	15.46	0.44	<0.001	4.00	0.27	>0.05

SD: Standard deviation

Table 6. Effect of treatment (drugs and placebo) on the fine motor functions in both the groups in this study (N=100)

Parameter	Study group			Control group		
	% improvement in relation to the pre-interventional status	SD (±)	P value	% improvement in relation to the pre-interventional status	SD (±)	P value
Puts small objects in a container	14.60	0.415	<0.001	2.00	0.158	>0.10
Throws ball in all directions	21.05	0.446	<0.001	6.00	0.350	>0.10
Uses thumb and index finger	11.36	0.376	<0.001	0.00	0.226	>0.05
Retains two 1-inch cubes in one hand	17.78	0.446	<0.001	4.00	0.221	>0.10
Folds paper and inserts into envelope	10.48	0.390	<0.001	0.00	0.000	>0.05

SD: Standard deviation

Table 7. Effect of treatment (drugs and placebo) on the mental status in both the groups in this study (N=100)

Parameter	Study group			Control group		
	% improvement in relation to the pre-interventional status	SD (±)	P value	% improvement in relation to the pre-interventional status	SD (±)	P value
Ability to understand verbal command and intellect	13.27	0.415	<0.001	1.00	0.158	>0.10
Speech	10.43	0.403	<0.001	2.00	0.221	>0.10
Performance	11.11	0.403	<0.001	3.00	0.221	>0.10
Memory	8.74	0.360	<0.01	3.00	0.221	>0.10
Happiness	21.05	0.450	<0.001	2.00	0.158	>0.10

SD: Standard deviation

having *Brimhana* (stoutening therapy) and *Balya* (strengthening) properties were selected for this thereby resulting in more circulation. Also, the venous and lymphatic return is assisted, increasing the strength (or immunity) of the body. It relieves pain in the joints, reduces emaciation of the study. *Abhyanga* and *Shastikashali Pinda Sveda* soothe the sensory nerve endings, thereby causing

relaxation. They produce a hyperemic effect causing the arterioles to dilate, limbs, and make the body strong with well-developed musculature. *Abhyanga* causes movements of the muscles, thereby accelerating the blood supply, which in turn helps in relieving the muscular fatigue and reduces stiffness. *Mustadi Rajayapana Basti* and *Baladi Yoga* have *Rasayana* (rejuvenator) effect in the body,

as *Charaka* had stated: *Rasayana* (rejuvenation therapy) *Indriya Balam Param* (increases the strength of sensory and motor organs), *Visham Avisham Bhavati Gatre* (removes toxins from the body parts), *Medha Smriti Karam* (promotes intellect and memory).^[14] In this study, the role of Ayurvedic management has shown some hope for improving the quality of life among CP patients.

A study from USA showed that the massage therapy reduced spasticity and arm hypertonic muscle tone and improved fine and gross motor functioning in children with CP. Improved immune function has been reported in one massage study,^[19] showing increased number and activity of natural killer cells, which have the potential to destroy viral cells.^[20] Massage therapy has been shown to decrease stress hormone (cortisol) levels.^[21] Several studies have reported that massage leads to enhanced alertness, as shown by increased cognitive scores in preschool children.^[22] A study from Norway showed improvement in basic motor abilities and self-care and mobility in young children with CP after they were given goal-directed activity focused physiotherapy involving their local environment.^[23] Treatment with botulinum toxin type A (BTX-A) has been a well-established option in the interdisciplinary management of spasticity since the late 1980s, providing focal reductions in muscle tone in CP patients. A study from Turkey highlighted that single multilevel BTX-A injection reduces spasticity and improves motor function in children with CP.^[2] Studies showed that for generalized spasticity, diazepam is probably effective in reducing spasticity, but there are insufficient data on its effect on motor function and its side-effect profile. Tizanidine is possibly effective, but there are insufficient data on its effect on motor function and its side-effect profile. There are insufficient data on the use of dantrolene, oral baclofen, and intrathecal baclofen, and toxicity has been frequently reported.^[17] A survey in the USA showed 56% of the families of children with CP using Complementary and Alternative Medicine which included massage therapy and aqua therapy as the most common.^[24] Recent years have also seen the development of multiple intensive therapy or educationally based programs which provide some benefits due to their strong focus on activity and independence, but also raise some concerns. These include the fact that they have failed to demonstrate superior effectiveness over other approaches. Despite their significantly greater time intensity, they fail to identify the “active” ingredients, making it unclear to determine which aspects of the programs are effective and which are not.^[25]

Cure for CP is not yet available.^[18] Throughout the lifespan of patients, the motor disability persists and interacts with normal developmental processes, altering its presentations and complications. The present mode of care in CP includes regular physical therapy, followed by medical and surgical interventions if needed, mostly in early childhood through pre-adolescence. A long list of treatments has shown to improve motor outcomes, but very few definite practical guidelines exist for the management of CP due to limited scientific evidence to support holistic intervention approaches. Consequently, approach toward CP patients varies among clinicians, health care settings, and geographic areas with regard to the different types and modes of treatments prescribed, the timing and the range of treatment intensity, or frequency of interventions. Since CP is not a single disease entity with a known

causal pathway, but in fact a heterogeneous group of disorders with etiological differences, brain injury patterns, and associated health complications, the choice and response to intervention is further complicated. Documentations reveal that the developmental patterns of children with CP are very slow, especially in physical and cognitive disability. So, it is better to expect immediate short-term effects of intervention rather than long-term effects in reality. Instrument sensitivity to detect small changes in motor ability is another setback while studying the effects of treatment of motor problems resulting from CP. Even minor improvements have the potential of becoming major practical and psychological significance for children with CP and their families.^[26] When Ayurvedic therapeutic principles were applied to CP patients, the patients showed signs of improvement, but in a very slow manner. Traditional Ayurvedic procedures have been used effectively since ages and were implemented for treating diseases related to congenital anomalies. However, knowledge-based evidences need to be validated in a scientific way.

The increasing trend of Complementary and Alternative Medicine is reflective of the high interest in new and different therapies that has always been present among families of children with CP. The observations of this study are encouraging with rays of hope bestowed upon by the age-old system of medicine of Ayurveda for the crippled children to have meaningful and improved quality of life. It is hoped that it will stimulate the research workers in the field to take up more such studies, so that new horizon may open up for children suffering from CP who are otherwise leading a long miserable life for no fault of their own. Further clinical trials must be carried out to evaluate and validate the maximum effect of *Rajayapana Basti* and *Baladi Yoga* combination, used in the present study, on a large sample with repetition of the courses for longer duration. Also, there is a need to find if by starting treatment in the early stage, i.e. immediately after cerebral injury and diagnosis, one can expect better improvement. Ayurveda with its immense treasure can deliver different modalities of treatment regarding CP. So, we have to explore these areas keeping in mind that a multi-dimensional approach with evidence-based personalized medicine will lead the road toward success.

ACKNOWLEDGMENTS

Authors offer their thanks to all the staffs of Kaumarabhritya Department of SDM College of Ayurveda and Hospital and the CP patients and their parents who participated in this study.

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