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EFFICACY OF SAMVARDHANA GHRITA AND YOGA BASTI IN THE MANAGEMENT OF CEREBRAL PALSY: A RANDOMIZED OPEN-LABEL CLINICAL STUDY

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ABSTRACT
Cerebral palsy (CP) is a diagnostic term used to describe a group of permanent disorders of movement and posture causing activity limitation, that are attributed to non-progressive disturbances in the in the developing foetal or infant brain. According to WHO (World Health Organization) approximation, in India estimated incidence of Cerebral Palsy is around 3/ 1000 live births. Study was carried out in 18 patients, 9 in Group A and 9 in Group B. In Group A (Yoga Basti + *Samvardhana Ghrita*), *Samvardhana Ghrita* was given as internal medication for 62 days along with three courses of Panchakarma procedures i.e. *Udvartana*, *Abhyanga*, *Swedana* and *Yoga Basti* with the interval of 16 days between two courses. In Group B, only *Samvardhana Ghrita* was given as internal medication for 62 days to compare the efficacy of *Samvardhana Ghrita* in both groups. Group A is effective to improve growth (length, weight, CC), development (sitting, standing, fine motor, language and personal & social), spasticity and power of four limbs, in patients. Group B is more effective to improve head holding and MUAC with compared to group A.

KEYWORDS: *Abhyanga*, Spasticity, *Swedana*, *Udvartana*, *Yoga Basti*.

INTRODUCTION
CP is an umbrella term encompassing a group of non-progressive, non-contagious condition that causes motor impairment by abnormalities in movement, posture and tone.[1] In short, it is a group of symptoms occurring due to involvement of musculature, sense organs (i.e. Vision, Hearing, Speech etc.) and mind including intelligence at variable extent. It can be caused by any of prenatal, natal and post natal factors and main eventual pathology is any type of injury to the developing brain.

All the sophisticated technology and highly expensive and complicated therapies of medical research field have failed to find definite cure for the disease.

There is no exact correlation found for CP in Ayurvedic literature. While observing the etiology and clinical features, the predominance of *Vata* is obvious and put this disease entity nearer to *Vata* dominant conditions or *Vata Vyadhi*. While considering pathophysiology and management of Spastic CP it can be taken as *Avarana Janya Vata Vyadhi*. Causative factors like inappropriate *Ritu*, *Kshetra*, *Ambu* and *Bija*[2] *Dauhrida Avamanana*[3] (negligence of urges during *Dauhrida* - stage of pregnant women), presence of *Garbhopaghatkarbhavas*[4] incompatible *Garbha Vriddhikarabhava*[5] and improper following of *Garbhini Paricharya*[6] may have undesirable effect on the fetus in utero.[7] More over *Akala Pravahana* during labour, *Shiromarmabhighata*, defect in *Prana Pratyagamana* process, *Ulbaka*, *Nabhi Nadi Vikara*, *Graha Roga*, improper *Shishu Paricharya* etc may play role as causative factor, before, during and after birth. These hamper normal growth and development of child and cause many diseases, deformities and even death. It gives an idea about some factors or events that give rise to the occurrence of these co-morbid conditions.

MATERIALS AND METHODS
Inclusion criteria
1. Children with spastic CP of 1 to 10 years of both sex
2. Children with developmental disability of both physical and mental (Delayed milestones)

Exclusion criteria
1. Children's age < 1 and > 10 years.

2. Children with major congenital disorder and with other types of CP.
3. Children with other disease status viz. diabetes, acute infection etc.

Groups

- **Group A**
  - ✓ *Udvartana* with *Yava* and *Kulattha* (20 min) for 5 days
  - ✓ *Abhyanga* with *Bala Taila* (20 min) + *Nadi Sweda* (20 min) for 5 days
    Vasti: (8 days *Yoga vasti* + 16 days interval + 8 days *Yoga vasti* + 16 days interval + 8 days *Yoga vasti*)
  - ✓ Internal medication of *Samvardhana Ghrita* for 62 days along with the procedures except the days in which *Basti* were given.

- **Group B**
  - ✓ Only Internal medication of *Samvardhana Ghrita* for 62 days

❖ **Posology**

- **Dose of *Samvardhana Ghrita*** was determined by using reference of *Sharngdhara Samhita, Purva Khanda* 6/14-17 unit of measurement i.e. *Masha* into grams. It is mentioned in Table no.1.

Anupana **:** *Madhu*
Duration **:** 62 Days
Follow up **:** 2 months

Dose of *basti dravya* is given as per the reference of *Charaka Samhita Siddhi Sthana* 3/31-32, which is given in the table no.2. These doses are mentioned for *Aasthapana Basti*. *Anuvasana* should be given ¼ of the quantity of *Asthapana Basti.*

Criteria for assessment

Assessment criteria include CDC grading for motor milestones, suitable scoring pattern was prepared for Fine Motor, Language and Personal and Social milestones, Ashworth Scale to assess spasticity, Muscle Power grading, Manual Ability Classification System (MACS) to assess the function of upper limb, Gross Motor Functions Classification System (GMFCS) and Activities of Daily Living score (ADL) was taken as assessment criteria to observe the effect of therapy.

Assessment of overall effect of therapy

The total effect of therapy was assessed considering overall improvement in sign and symptoms.
Maximum Improvement: > 75% improvement
Moderate Improvement: > 50% to 75% improvement
Mild Improvement: > 25% to 50% improvement
No Improvement: ≤ 25% improvement

Statistical analysis

Statistical analysis was done by using student paired‘t’ test and comparison of both the group was done by student unpaired ‘t’ test.

OBSERVATION AND RESULTS

Maximum number of patients i.e. 55.55% was below 4 year of age. It shows the parental concern regarding requirement of an early intervention to the disease and particularly pursuing the knowledge of Ayurvedic treatment in managing. Greater number of male patients i.e. 66.67% was registered in this study which supports the higher prevalence of CP in male. The reported incidence of CP by the Surveillance of Cerebral Palsy in Europe (SCPE) is higher in males than in females and it is 1.33: 1.[8] As per maternal antenatal history observed; trauma was found in 5.88%, Hypertension and mental stress in 17.65%, use of any medicine in 5.88%, prolonged labour and infection in 11.76%. Hypertension is found in 17.65% of mother during gestational period. In antenatal history mental stress was found in 17.65 % of mothers. Observation on mode of delivery was found that normal home delivery was observed in 27.77%, normal hospital delivery in 44.44%, LSCS in 16.67%, Forceps and Vacuum assisted in 5.56% patients. In this present study CP developed in the patient though greater number of mother (72.21%) having normal delivery. Mode of delivery did not show any direct correlation with the incidence of CP. To establish this relation with CP, may be large sample size study is needed. Term of gestation at the time of birth was preterm in 16.67% whereas full term in maximum number i.e. 83.33%. Stromberg B. et al. has concluded that prematurity is one of the two most important risk factors for CP universally.[9] Observation of this study supports above reference and also suggests the possible incidence of CP even in full term infant. In Birth weight; 33.33% were belonged to LBW (< 2.5 Kg) whereas 61.11% had Normal birth weight (≥2.5 Kg). while 5.56% had VLBW (< 1.5 kg). Among 18 patients of Spastic CP, Quadriplegic were 77.78% and Hemiplegic were 16.67%. Dyskinetic were 5.56%. Total 18 patients of CP, Moderate and Severe types according to severity of the condition were observed in 44.44% and 55.56% patients respectively. Comparative effect of Group A with that of Group B on developmental milestones, anthropometrical parameter, motor system components parameter documented in table no.1,2 and 3 respectively. The result of the present study was assessed as Maximum, Moderate, Mild and No improvement on the basis of improvement in assessment criteria. Assessment parameters were examined and evaluated before starting the treatment and after completing the treatment. Results documented in table no.4.

DISCUSSION

Group A (*Yoga Basti* + *Samvardhana Ghrita*) has shown significant results ($p < 0.05$) on head holding, sitting, standing and fine motor milestones, language whereas personal & social milestone shows insignificant result ($p > 0.05$). Group B (*Samvardhana Ghrita*) has shown significant results ($p < 0.05$) in the parameters of Language. Rest all parameter has shown insignificant ($p > 0.05$) result. Delayed development of gross and fine motor function may be due to problem in normal

function of *Vata* (*Pravartaka Cheshtanamucchavchanam*). To achieve results in developmental disorders, function of *Vata* (normal physiology) should come to normalcy. Here in both the groups, *Samvardhana Ghrita* might have worked on CNS by crossing BBB (*Majja Dhara Kala*) because of its lipophylic property, thus stimulating higher mental functions (*Medha, Smruti* and *Buddhi*). *Udvartana* had given a well platform for further procedures like *Abhyanga, Swedana* and *Basti* by removing *Avarana* and *Srotorodha*. *Abhyanga* and *Swedana* caused *Dosha Gati* from *Shakha* to *Koshtha*, which helped in removing vitiated *Dosha* through *Basti*. *Basti* helped to accomplish the effect of *Shodhana*. Combined effect of total therapeutic measures, *Avarana* was removed, *Mastulunga Majja* got nourishment, *Vata* came to normalcy and hence proper development of milestones was achieved. Language is more of the function of *Udana Vayu (Vaka Pravrutti Prayatnorja)*, which is normally at *Uraha Pradesha*,[10] insignificant result in this study suggests that *Basti* along with other Panchakarma procedures do not show complete correction in the function of vitiated *Udana Vayu* within study period. As this disease entity comes under *Asadhya vyadhi*, the study period may not be enough to show effect on language. Individualistic *Dosha* oriented practices like *Aushadha Grahana Kala* (*Sayam Bhojana Pashchat* for *Udana Vayu*)[11] *Swasthana Dosha Chikitsa* etc might give better results in this aspect. Personal & social development is more of the function of *Prana Vayu*[12] (*Buddhi, Endriya, Chitta Dhruka*). Insignificant result in this milestone suggests that the treatment protocol did not show effect to the persistent damaged *Murdha*. This milestone starts to develop in early infantile age, so the correction of this milestone requires early and prolonged intervention.

Group A has shown significant results ($p < 0.05$) in anthropometrical parameters like length and weight, while insignificant results ($p > 0.05$) was observed in parameters like CC (Chest circumference), MAC (Mid arm circumference) and HC (Head circumference).

Group B has shown significant result ($p < 0.05$) in anthropometrical parameter like weight. While length, MAC, CC and HC showed insignificant results ($p > 0.05$).

Growth is achieved by nourishment of *Rasadi Dhatus*. Here in both the group, *Samvardhana Ghrita* might caused *Brimhana* by *Snigdha* and *Guru* Guna, *Udvartana* opened the minutes channels and improved blood and lymphatic circulation, *Abhyanga* provided nourishment by its property like *Snigdha, Mrudu, Bahala, Picchila* which are told as *Brimhana Dravya* property by *Charaka* in *Langhana Brimhaniya Adhyaya*. Swedana caused excretion of *Mala* (waste metabolites). *Snigdha Basti* (*Anuvasana* with *Bala Taila*) is also told to be have *Brimhana* effect. Hence considering all aspects, growth parameters shows improvement in this study.

Group A has shown significant result by, increasing power in left lower limb, GMFCS and ADL score. Whereas rest limb muscle power-tone, MACS shown statistical insignificant result.

In Group B, all parameter has shown statistical insignificant ($p > 0.05$) result.

Spasticity is characterized by increased resistance by passive stretch, velocity dependent and asymmetric about joints (i.e. greater in flexor muscle at the elbow and the extensor muscle at the knee).[13] This may happen due to *Avarana* of *Vata*, wherein, due to *Avarana*, *Vayu* cannot perform its normal function i.e. normal movement of joints (*Pravartaka Cheshtanam*). Initially *Udvartana* helped in reduction of vitiated *kapha* by its *Ruksha* and *Srotoshodhana* property. Once *avarana* is removed the aim of treatment is to pacify vitiated *vata*. *Vayu* resides in *Sparshnendriya* which is located in *tvacha*, *Abhyanaga* is quoted as *Tvachya*, so *Abhyanga* might work directly on *Vata* to bring it back to normalcy. Basti acts on CNS (especially extra pyramidal area) by stimulating ENS, there are many evidences for relation between CNS and ENS.

Yoga Basti is unique combination of *Asthapana* and *Anuvasana Basti*; also included in *Panchakarma Chikitsa*. *Anuvasana Basti* has well known *Vata* pacifying effect through *Snigdha, Guru Guna*. So development in Gross and Fine motor milestone were better observed in Group A.

Yoga Basti has shown significant result in length, weight, it may be due to administration of *Anuvasana Basti*, which increases anabolism by its *Brimhana* property. *Samvardhana Ghrita* has shown significant result in weight, it shows that *Ghrita* improves *Dhatu Poshana* and in turn improves growth of child.

Here both group shows similar kind of result, Group A has shown significant improvement in language, both lower limb muscle power, left lower limb tone, right upper limb MACS in comparison to Group B, rest of parameters like length, weight, MAC, HC, CC, GMFCS, ADL shown statistical insignificant difference between both groups for the improvement.

In both the group improvement in consistency of food intake and relief in constipation shows good results, this may be due to the correction of vitiated *Samana* and *Apana Vayu* by *Snigdha* and *Guru Guna* of *Samvardhana Ghrita.*

In majority of patients irrespective of group A and B, effect was found near to the 10 to 15%. As this disorder is incurable, this percentage of improvement also helps patient to improve quality of life. Treatment of this kind

of condition is just like a pyramid, if researchers are able to make small improvement in earlier age than it will reflect its major benefit in later age in the form of developing skills. Previously it was believed that neurons do not repair or rejuvenate after any injury, but the new concept of neuroplasticity says that CNS have the ability to repair their neurons by axonal sprouting to take over the function of damaged neurons. This improvement in patients also supports the concept of Neuroplasticity. So it is quite irrational to say 'no improvement' (<25%) by following standard criteria for assessing total effect of therapy. Improvement in the clinical sign and symptoms of Spastic CP shows the efficacy of Ayurvedic treatment measures.

CONCLUSION

Group A *(Yoga Basti + Samvardhana Ghrita)* is effective to improve growth (length, weight, CC), development (sitting, standing, fine motor, language and personal & social), spasticity and power of four limbs, in patients. Group B *(Samvardhana Ghrita)* is more effective to improve head holding and MUAC with compared to group A. Total effect of therapy shows results in range of 10 to 15% relief which comes under no improvement (<25%) as per the standard criteria for total effect of therapy, but even this noticeable improvement in neurological disorder is significant in a large way. The efficacy of intervention and prognosis of the disease gets adversely proportionate with the advancement of age.

Tables

Table 1: On developmental milestones.

Features	% of relief		Mean difference	't'	P
	Group A	Group B			
Head holding	30	33.35	0.08	2.051	> 0.05
Sitting	27	4.8	1.1	6.6	> 0.05
Standing	21.28	10.71	0.75	- 0.75	> 0.05
Fine motor	24.39	0	1.25	0.25	> 0.05
Language	27.5	7.99	1.04	3.65	**< 0.05***
Personal and Social	8.33	3.85	0.21	0.43	> 0.05

n=15 *Significant

Table 2: On anthropometrical parameter.

Features	% of relief		Mean difference	't'	P
	Group A	Group B			
Length	0.53	0.17	0.36	0.53	>0.05
Weight	2.98	0.94	0.23	1.22	>0.05
MAC	0.42	1.53	-0.15	- 1.02	>0.05
HC	0.27	0	0.13	1	>0.05
CC	0.99	0	0.5	1.87	>0.05

n=15 *Significant

Table 3: On motor system components parameter.

Features	% of relief		Mean difference	't'	P
	Group A	Group B			
Muscle power – lt upper	8.7	0	0.25	1.53	>0.05
Rt upper	4.76	0	0.13	1	>0.05
Lt lower	24	4.77	0.58	3.58	**< 0.05***
Rt lower	21.74	5.57	0.46	2.42	**< 0.05***
Modified ashworth scale – lt upper	14.29	5.01	0.33	0.87	>0.05
Rt upper	10.71	5.89	0.2	0.43	>0.05
Lt lower	15.63	4	0.46	2.42	**< 0.05***
Rt lower	9.09	0	0.25	1	>0.05
Macs – lt. Upper	4.54	0	0.125	0.55	>0.05
Rt. Upper	17.39	0	0.5	2.65	**< 0.05***
Gmfcs	8.7	0	0.25	1.53	>0.05
Adl	21.88	0	0.88	1.53	>0.05

n=15 *Significant

Table 4: Showing groupwise clinical improvement of 15 patients.

Assessment of Result	Group A		Group B		Total	
	No.	%	No.	%	No.	%
Maximum improvement	0	0%	0	0%	0	0%
Moderate improvement	0	0%	0	0%	0	0%
Mild improvement	0	0%	0	0%	0	0%
No improvement	8	100%	7	100%	15	100%

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