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Randomized Clinical Trial to Evaluate the Efficacy of *Ashtamangal Ghrita* Oral and *Nasya* in the Management of Cerebral Palsy

Research Article

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Abstract

Background: Cerebral palsy is one of the most common childhood disabilities, which hinder the development of a child, causing extensive suffering to affected children and their families. According to world health organization about 10% of population have some form of disabilities. Cerebral Palsy can be compared with *Vatavyadhi* (neurological disorder) manifested in various form like *sarvangavata* (quadri-plegia), *pakshaghata* (hemiparesis), *ekangavata*(monoplegia), *pangu and khanja* (motor disorder), *kampavata, jadatva* (mental retadation), *mukatva* (dumbness) etc. Objective: To evaluate the efficacy of *Ashtamangal ghrita*, in the form of oral medication and as *nasya* in the management of cerebral palsy. Material and Methods: Total 24 Children with physical and mental developmental disabilities of of age group 01 to 10 years of either sex were randomly divided into two groups, group A received *Ashtamangal ghrita* (orally) - 1 ml/kg body weight in two divided doses for 3 months and Group B received *Pratimarsh Nasya* with *Ashtamangal ghrita* – 2 drops in each nostril 2 times a day for 3 months. Assessments were done on the basis of 5 point grading score of Clinical symptoms of Cerebral Palsy as per standard classification scale for CP, i.e, motor functions were assessed on the basis of CDC Grading Scale for Motor milestones and Teacher's drooling test. Follow up visit was on every 15th day. Result: Overall effect of therapy shows that there was 34.79% improvement in group A & 37.74% improvement in group B. Results were slightly superior in group B than group A in most of the parameters. Although intergroup comparison of both groups was not-significant or there were no differences in both groups statistically. Group A was slightly superior than group B in following parameters –Head holding, sitting, teacher drooling scale and spasticity. In all the other parameters group B was slightly superior. Conclusion: Clinical efficacy of both *Ashtamangal ghrita* orally and as *nasya* on various parameters of Cerebral Palsy showed that both were effective, safe and comparable.

Key Words: *Ashtamangal ghrita,* Cerebral Palsy, *Nasya,* Motor milestones.

Introduction

Cerebral palsy (CP) is one of the most common childhood disabilities, which hinder the development of a child, causing extensive suffering to affected children and their families. Cerebral palsy is caused by non – progressive damage to brain before, during or after birth. It is not a single entity but a term given to wide variety of neuromotor impairments, secondary to a lesion in the developing brain. It includes heterogeneous clinical states of unpredictable etiology and severity ranging from minor to total handicap (1). Motor disorders of CP often accompany disturbances of sensation, perception, communication, cognition, and behavior. Cerebral palsy can be classified into - Spastic, Hypotonic (ataxic), Extrapyramidal, Cerebellar involvement & mixed type. Spastic CP is the most common form (65%) (2). The prevalence of cerebral palsy in children is 2/1000 live births (3). According to world health organization about 10% of population have some form of disabilities (4). Cerebral Palsy is rendered incurable although several advances and researches in the management are going on in various parts of globe to improve the physical, mental and functional status of the CP child. Cerebral palsy cannot be co-related with any single disease entity in Ayurveda. Cerebral Palsy can be compared with *Vatavyadhi*(neurological disorder) which may manifest itself in various form like *pakshaghata* (hemiparesis), *sarvangavata* (quadri-plegia), *ekangavata*(monoplegia), *pangu and khanja* (locomotor disorder), *kampavata, jadatva* (mental retardation), *mukatva* (dumbness) etc. CP can be stated as *Janma Bala Pravritta Vyadhi* (congenital disorder). Also, CP can be considered as *Shrio marmabhighataja Vata Vyadhi* (disease caused due to the injury of head). (5,6) Features of cerebral palsy can also be correlated with *Skanda graha* in which *hata- ekpaksh* (complete or partial loss of motor activity of one half of the body), *mukha vakrata* (facial palsy), *lalasrav* (excessive salivation) etc. are the main symptoms (7). Other factors like inappropriate *ritu* (ovulation cycle), *kshetra* (uterus), *ambu* (amniotic fluid and fetal nutrition) and *bija* (sperm and ovum) (8), *dauhrida-avamanana*

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(neglect of urges of pregnant women) (9), incompatible *garbhavriddhi-karabhava* (normal requisite for growth and development of fetus) (10,11) and improper *garbhinipariacharya* (antenatal regimen) (12) may be contributory causing undesirable effects on fetus hindering it's normal growth and development, thereby leading to many disorders, deformities and even death.

Materials and Methods

Protocol of Clinical Study

- **Consent –** Written and informed consent of study subjects was taken before inclusion in the trial.
- **IEC approval** - Approval for clinical trial on human being was obtained from institutional ethical committee of S.A.C. & Hospital, Lucknow, U.P. (No.IEC /AYM/ 072 -2017). The study was registered in Clinical trial registry of India (CTRI registration no.- CTRI/2018/06/014415).
- **Proforma** - Proforma incorporating detailed profile of study subjects with chief complaints, history of present illness, sign & symptoms and assessment was prepared.

Following materials and methods have been adopted for conducting present trial-

- **Type of study-** Randomized, two groups comparative clinical trial.

Selection of cases and group allocation-

- **Age-** 1-10 years
- **Sample size-** Total 31 patients were selected from OPD and IPD of *Kaumarabhritya* department of State Ayurvedic College and Hospital, Lucknow & randomly allocated in two groups- 15 patients in group A & 16 patients in group B. During trial 7 patients were dropout- 3 patients from group A & 4 patients from group B, so complete study was on 24 patients.

- **Group A**- *Ashtamangal ghrita* (orally) - 1 ml/kg body weight in two divided doses for 3 months.
- **Group B**- *Pratimarsh Nasya* with *Ashtamangal ghrita* – 2 drops in each nostril 2 times a day for 3 months.

Shashtikashali pinda sweda for 20 days daily for 30 minutes on whole body was given in both groups, temperature of the pottali was lukewarm & tolerable to the child, after 10 days interval course was repeated. Such 3 cycles were done.

Preparation of Trial Drug

Ashtamangal ghrita was mentioned in *bala roga prakarana* in *Yoga Ratnakara.*The crude drugs present in '*Ashtamangal Ghrita'* were *Vacha (Acorus calamus* Linn.*), Brahmi (Bacopa monnieri* Linn.*), Kushta (Saussurea lappa* Clarke*), Piper (Piper longum* Linn.*), Sariva (Hemidesus indicus* Linn.*), and Sarshap (Brassica compestris* Linn.*) in equal proportion along with* Saindhava (sodium chloride) and Go-Ghrita. *Ashtamangal ghrita* was prepared according to *sneha kalpana* procedure described in *Sharangdhara Samhita*. In both the groups the used drug was *Ashtamangal ghrita* but there was difference in preparation. For nasya purpose, *mridu paka* of *ghrita* was done & for oral *madhyam paka* of *ghrita* was done.

- **Dose deciding criteria -** Dose of *Ashtamangal ghrita* orally-Dose of *Ashtamangal ghrita* was decided on basis of classical reference as mentioned in *Sharangadhar Samhita Sneha kalpana adhyaya* 9/1, dose being 1 Pala i.e. 48 grams (approx 50 ml) then dividing by average adult body weight 50 kg (general rule to get pediatric dose as per kg body weight) so the dose of *ghrita was* 1ml/kg body weight in two divided doses. *Pratimarsh Nasya-* Sushruta and *Vagbhat* have explained the dose in the form of *bindus* (drops). Thus, dose of *Pratimarsh nasya* was 2 drops in each nostril for 2 times in a day.
- **Duration of trial -** It was a trial of 90 days. The clinical assessment of patients was carried out during the trial 1st on 30th day, 2nd on 60th day and 3rd on 90th day and then after trial.
- **Criteria to be adopted -** For conducting the trial following criteria has been adopted-
- **Inclusion criteria -** Children with CP aged 1 year to 10 years of either sex, with physical and mental developmental disabilities (Delayed milestones) along with already diagnosed cases of CP are included in the study.
- **Exclusion criteria -** Children of CP with major congenital disorder & other disease status viz. Juvenile DM, Acute infections, severe systemic illness etc. or children with any progressive neurologic anomalies or Muscular dystrophy are excluded from the study
- **Discontinuation criteria -** Parents/guardians not willing to continue treatment or patients who develop life threatening complications during treatment.

Assessment criteria

Grading of Clinical symptoms of Cerebral Palsy depending on severity was done on 0-5 point grading score pattern as per standard classification scale for CP, i.e, CDC Grading Scale for Motor milestones- Head Holding, Sitting, Standing, Fine motor and Language. Also grading done for performance (Making triangle between three points) Mental status (Happiness) Memory (After showing 5 familiar objects) and for drooling ,Teacher's drooling scale.

Side effect evaluation criteria- Clinical criteria were adopted to rule out possible side effects of the study drug. It included the documentation of information related to change in appetite, sleep, abdominal features, drowsiness, pain, irritability etc.

- **Statistical analysis –** Observations documented during study were analyzed and findings were evaluated by using statistical analysis to establish efficacy. Wilcoxon Test, Mann Whitney Test and t-test, were used for the statistical analysis.
- **Drug compliance-** If there is more than or equal to 80% compliance, the participant would be continued in the trial.

The compliance need to be assessed at each visit during follow up by counting the no. of empty container/bottles/sachets returned and approximate quantity consumed by the patient.

Patient information and consent

Prior to trial, the principal investigator had given the patient verbal and written information about the trial in the form the participant/guardian/parent (s) can read and understand. A voluntary, signed witnessed informed consent was obtained from the participant prior to any clinical trial.

Observations

Demographic Observation

Distribution according to age shows that maximum number of patients in both groups were 55 % between age 1-4 years of age group, out of which in group A 74% were of age group 1-4 years ,in group B 38% were of age group 1-4 years. Distribution according to sex shows the male predominance in group A 67% and in group B – 63%. Overall observation shows male predominance. Distribution according to socio-economic status shows that maximum patients were of lower-middle class -60% in group A and 69% in group B. distribution according to immunization status shows that in group A -67% patients had incomplete immunization status and in group B -56% patients were properly immunized.

Clinical Observation

Distribution according to history of infectious disease shows that in group A -13.33% patients had history of chickenpox and 6.66% patients had history of other infection and in 80% patients there were no history of infection. In group B 19% patients had history of infection and in maximum patients-81% had no history of infection. Distribution according to age of weaning shows that the total 19% patients have the age of weaning at 6 month of age in both the groups. Delayed age of weaning was 39 % at 1 year of age and 23% at 2 year of age. Distribution according to tone shows that in group A maximum patients 60% were of hypertonic and in group B maximum patients were hypotonic. In group B 19% patients were of normal tone. Distribution according to involuntary movements shows that in 47 % in group A there were no involuntary movements, seizures were found in 33% in group A and 38 % in group B, Dystonia were found in 13% in group A and 6 % in group B, Athetosis were found in 7% in group A and 13 % in group B. Distribution according to gait shows that in group A maximum 80% patients were diplegic and in group B maximum patients 44 % were unable to walk followed by diplegic gait in 38% patients. Distribution according to type of motor deficit shows that in group A maximum patients 80 % were diplegic, 20 % quadriplegic. In group B 44% patients were quadriplegic, 38 % diplegic, 19% patients were hemiplegic. Distribution according to past history shows that in group A 13 % patients were showing past history of high grade fever, 13% neonatal jaundice, 7% showing inconsolable cry. In group B 13 % patients were showing past history of convulsions, 6 % patients showing pneumonia, 6% patients showing diarrhoea, 6% showing septicaemia. Distribution according to antenatal history shows that in group A 20 % cases were showing antenatal history of hypothyroidism,7 % cases showing high grade fever & 7% cases fever with rash. In group B 23 % cases were showing antenatal history of hypothyroidism, 6% bad obstetric history, 6% high grade fever, 3% cases dehydration, fever with rash & jaundice. Distribution according to natal history shows that most of the cases were showing prolonged 2nd stage of labour, LSCS, leaking or bleeding PV, history of instrumentation, decreased fetal movement. Distribution according to post natal history shows that most of the cases were showing LBW, delayed cry, IUGR, preterm, fever, neonatal jaundice, septicaemia. Distribution according to reflexes shows that in group A 33% were showing diminished reflexes, 27% exaggerated,7 % cases can't be assessed due to hyperactivity and 33 % cases were normal. In group B 35% cases were showing diminished reflexes, 29% exaggerated, 29% were normal & in 3% cases reflexes were absent.

Therapeutic Observations - Milestones

Table No.1 : Effect of Treatment on Head Holding in both the Groups

Head holding	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	2.83	2.17	-	-	-	3.75	1.96	-	-	-
Day 30	2.83	2.17	0.00	0.00	1.000	3.75	1.96	0.00	0.00	1.000
Day 60	2.83	2.17	0.00	0.00	1.000	4.00	1.65	6.67	-1.73	0.083
AT	3.25	1.86	14.71	-2.24	**0.025**	4.25	1.22	13.33	-1.86	0.063
AF	3.25	1.86	14.71	-2.24	**0.025**	4.25	1.22	13.33	-1.86	0.063

Table No.2 : Effect of Treatment on Sitting in both the Groups

Sitting	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	1.58	1.73	-	-	-	2.42	1.98	-	-	-
Day 30	1.67	1.72	5.26	-1.00	0.317	2.58	1.78	6.90	-1.41	0.157
Day 60	1.92	1.62	21.05	-2.00	**0.046**	2.92	1.78	20.69	-2.45	**0.014**
AT	2.33	1.56	47.37	-3.00	**0.003**	3.50	1.57	44.83	-2.92	**0.004**
AF	2.33	1.56	47.37	-3.00	**0.003**	3.50	1.57	44.83	-2.92	**0.004**

In group A significant improvement were found from BT to Day 60 (21.05%, p=0.046), AT (47.37%, p=0.003) and AF (47.37%, p=0.003). In group B significant improvement were found from BT to Day 60 (20.69%, 0.014), AT (44.83, p=0.004) and AF (44.83%, p=0.004). Group A showed slightly superior results than group B.

Table No. 3: *Effect of Treatment on Standing in both the Groups*

Standing	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	1.08	1.44	-	-	-	1.50	1.73	-	-	-
Day 30	1.17	1.40	7.69	-1.00	0.317	1.58	1.68	5.56	-1.00	0.317
Day 60	1.25	1.42	15.38	-1.00	0.317	2.08	1.51	38.89	-2.65	**0.008**
AT	1.75	1.36	61.54	-2.53	**0.011**	2.50	1.24	66.67	-2.97	**0.003**
AF	1.75	1.36	61.54	-2.53	**0.011**	2.50	1.24	66.67	-2.97	**0.003**

In group A significant improvement were found from BT to AT (61.54%, p=0.011) and AF (61.54%, p=0.011). In group B significant improvement were found from BT to Day 60 (38.89%, 0.008), AT (66.67, p=0.003) and AF (66.37%, p=0.003). Group B showed superior results than group A.

Table No.4 : Effect of Treatment on Fine motor in both the Groups

Fine motor						Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	1.83	1.34	-	-	-	1.92	1.56	-	-	-
Day 30	1.83	1.34	0.00	0.00	1.000	2.00	1.48	4.35	-1.00	0.317
Day 60	1.83	1.34	0.00	0.00	1.000	2.42	1.31	26.09	-2.45	**0.014**
AT	2.67	1.07	45.45	-3.16	**0.002**	3.00	1.21	56.52	-2.92	**0.004**
AF	2.67	1.07	45.45	-3.16	**0.002**	3.00	1.21	56.52	-2.92	**0.004**

In group A significant improvement were found from BT to AT (45.45%, p=0.002) and AF (45.45%, p=0.002). In group B significant improvement were found from BT to Day 60 (26.09%, 0.014), AT (56.52, p=0.004) and AF (56.52%, p=0.004). Group B showed slightly superior results than group A.

Table No. 5: Effect of Treatment on Personal/social in both the Groups

Personal/ social	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	3.08	1.78	-	-	-	3.50	1.98	-	-	-
Day 30	3.08	1.78	0.00	0.00	1.000	3.67	1.83	4.76	-1.41	0.157
Day 60	3.17	1.64	2.70	-1.00	0.317	4.00	1.60	14.29	-2.45	**0.014**
AT	3.75	1.48	21.62	-2.83	**0.005**	4.50	1.38	28.57	-2.64	**0.008**
AF	3.75	1.48	21.62	-2.83	**0.005**	4.50	1.38	28.57	-2.64	**0.008**

In group A significant improvement were found from BT to AT (21.62%, p=0.005) and AF (21.62%, p=0.005). In group B significant improvement were found from BT to Day 60 (14.29%, 0.014), AT (28.57%, p=0.008) and AF (28.57%, p=0.008). Group B showed slightly superior results than group A.

Table No. 6: Effect of Treatment on Mental status in both the Groups

Mental status	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	1.08	0.67	-	-	-	1.25	0.87	-	-	-
Day 30	1.08	0.67	0.00	0.00	1.000	1.42	0.79	13.33	-1.41	0.157
Day 60	1.17	0.72	7.69	-1.00	0.317	1.58	0.67	26.67	-2.00	**0.046**
AT	1.42	0.67	30.77	-2.00	**0.046**	1.67	0.65	33.33	-2.24	**0.025**
AF	1.42	0.67	30.77	-2.00	**0.046**	1.67	0.65	33.33	-2.24	**0.025**

In group A significant improvement were found from BT to AT (30.77%, p=0.046) and AF (30.77%, p=0.046). In group B significant improvement were found from BT to Day 60 (26.67%, 0.046), AT (33.33%, p=0.025) and AF (33.33%, p=0.025). Group B showed slightly superior results than group A.

Table No.7: Effect of Treatment on Language in both the Groups

Language	Group A	Group B								
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	1.92	1.38	-	-	-	2.83	1.80	-	-	-
Day 30	1.92	1.38	0.00	0.00	1.000	2.83	1.80	0.00	0.00	1.000

Day 60	1.92	1.38	0.00	0.00	1.000	3.00	1.65	5.88	-1.41	0.157
AT	2.33	1.07	21.74	-2.24	**0.025**	3.33	1.56	17.65	-2.45	**0.014**
AF	2.33	1.07	21.74	-2.24	**0.025**	3.33	1.56	17.65	-2.45	**0.014**

In group A significant improvement were found from BT to AT (21.74%, p=0.025) and AF (21.74%, p=0.025). In group B significant improvement were found from BT to AT (17.65%, p=0.014) and AF (17.65%, p=0.014). Group B showed slightly superior results than group A.

Table No.8 : Effect of Treatment on Performance in both the Groups

Performance	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	0.25	0.62	-	-	-	0.33	0.78	-	-	-
Day 30	0.25	0.62	0.00	0.00	1.000	0.33	0.78	0.00	0.00	1.000
Day 60	0.25	0.62	0.00	0.00	1.000	0.83	0.83	150.00	-2.12	0.034
AT	0.50	0.80	100.00	-1.73	0.083	1.00	0.74	200.00	-2.53	0.011
AF	0.50	0.80	100.00	-1.73	0.083	1.00	0.74	200.00	-2.53	0.011

In group A no significant improvement was found from BT to any follow up and AF as well (p>0.05). In group B significant improvement were found from BT to Day 60 (150%, p=0.034), AT (200%, p=0.011) and AF (200%, p=0.011). Group B showed superior results than group A.

Table No.9 : Effect of Treatment on Memory in both the Groups

Memory	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	0.33	0.89	-	-	-	1.00	1.71	-	-	-
Day 30	0.33	0.89	0.00	0.00	1.000	1.00	1.71	0.00	0.00	1.000
Day 60	0.33	0.89	0.00	0.00	1.000	1.08	1.68	8.33	-1.00	0.317
AT	0.42	1.00	25.00	-1.00	0.317	1.25	1.66	25.00	-1.73	0.083
AF	0.42	1.00	25.00	-1.00	0.317	1.25	1.66	25.00	-1.73	0.083

In group A & B both, no significant improvement was found from BT to any follow up and AT as well (p>0.05).

Table No.10 : Effect of Treatment on Teacher drooling scale in both the Groups

Teacher drooling scale	Group A					Group B				
	Mean	SD	% imp	z-value	p-value	Mean	SD	% imp	z-value	p-value
BT	1.00	1.13	-	-	-	0.92	1.08	-	-	-
Day 30	0.75	0.87	25.00	-1.73	0.083	0.83	1.03	9.09	-1.00	0.317
Day 60	0.67	0.78	33.33	-1.63	0.102	0.58	0.67	36.36	-1.63	0.102
AT	0.17	0.39	83.33	-2.46	**0.014**	0.25	0.45	72.73	-2.27	**0.023**
AF	0.17	0.39	83.33	-2.46	**0.014**	0.25	0.45	72.73	-2.27	**0.023**

In group A significant improvement were found from BT to AT (83.33%, p=0.014) and AF (83.33%, p=0.014). In group B significant improvement were found from BT to AT (72.73%, p=0.023) and AF (72.73%, p=0.023). Group A showed slightly superior results than group B.

Table No.11 : Intergroup Comparison of Milestone Parameters between the groups

Milestones		Group A		Group B		Mann Whitney Test	
		Mean	SD	Mean	SD	U-value	p-value
Head holding	BT	2.83	2.17	3.75	1.96	54.00	0.319
	Day 30	2.83	2.17	3.75	1.96	54.00	0.319
	Day 60	2.83	2.17	4.00	1.65	49.00	0.198
	AT	3.25	1.86	4.25	1.22	51.00	0.242
	AF	3.25	1.86	4.25	1.22	51.00	0.242
Sitting	BT	1.58	1.73	2.42	1.98	54.50	0.319
	Day 30	1.67	1.72	2.58	1.78	49.00	0.198
	Day 60	1.92	1.62	2.92	1.78	49.00	0.198
	AT	2.33	1.56	3.50	1.57	41.00	0.078
	AF	2.33	1.56	3.50	1.57	41.00	0.078

Standing	BT	1.08	1.44	1.50	1.73	61.50	0.551
	Day 30	1.17	1.40	1.58	1.68	61.50	0.551
	Day 60	1.25	1.42	2.08	1.51	44.00	0.114
	AT	1.75	1.36	2.50	1.24	47.00	0.160
	AF	1.75	1.36	2.50	1.24	47.00	0.160
Fine motor	BT	1.83	1.34	1.92	1.56	70.00	0.932
	Day 30	1.83	1.34	2.00	1.48	71.00	0.977
	Day 60	1.83	1.34	2.42	1.31	52.50	0.266
	AT	2.67	1.07	3.00	1.21	63.00	0.630
	AF	2.67	1.07	3.00	1.21	63.00	0.630
Personal/ Social	BT	3.08	1.78	3.50	1.98	62.00	0.590
	Day 30	3.08	1.78	3.67	1.83	59.00	0.478
	Day 60	3.17	1.64	4.00	1.60	51.00	0.242
	AT	3.75	1.48	4.50	1.38	51.50	0.242
	AF	3.75	1.48	4.50	1.38	51.50	0.242
Mental status	BT	1.08	0.67	1.25	0.87	65.50	0.713
	Day 30	1.08	0.67	1.42	0.79	56.00	0.378
	Day 60	1.17	0.72	1.58	0.67	52.00	0.266
	AT	1.42	0.67	1.67	0.65	55.50	0.347
	AF	1.42	0.67	1.67	0.65	55.50	0.347
Language	BT	1.92	1.38	2.83	1.80	52.00	0.266
	Day 30	1.92	1.38	2.83	1.80	52.00	0.266
	Day 60	1.92	1.38	3.00	1.65	45.00	0.128
	AT	2.33	1.07	3.33	1.56	46.50	0.143
	AF	2.33	1.07	3.33	1.56	46.50	0.143
Performance	BT	0.25	0.62	0.33	0.78	71.00	0.977
	Day 30	0.25	0.62	0.33	0.78	71.00	0.977
	Day 60	0.25	0.62	0.83	0.83	42.50	0.089
	AT	0.50	0.80	1.00	0.74	45.00	0.128
	AF	0.50	0.80	1.00	0.74	45.00	0.128
Memory	BT	0.33	0.89	1.00	1.71	58.50	0.443
	Day 30	0.33	0.89	1.00	1.71	58.50	0.443
	Day 60	0.33	0.89	1.08	1.68	53.00	0.291
	AT	0.42	1.00	1.25	1.66	48.50	0.178
	AF	0.42	1.00	1.25	1.66	48.50	0.178
Teacher drooling scale	BT	1.00	1.13	0.92	1.08	68.50	0.843
	Day 30	0.75	0.87	0.83	1.03	70.50	0.932
	Day 60	0.67	0.78	0.58	0.67	69.00	0.887
	AT	0.17	0.39	0.25	0.45	66.00	0.755
	AF	0.17	0.39	0.25	0.45	66.00	0.755

No significant difference was found in any milestone parameter between the groups at any time in follow ups.

Discussion on Therapeutic Observations and Results

In Ayurveda symptoms of cerebral palsy can be correlated with *vata vyadhi*. As we know that main function of *vata* is "*pravartakschchestanamucchvachanam*". (functions related to nervous system), whenever the *vata* gets vitiated, the normal functions of *vata* derange. (Ch.Su.12)Delayed development of gross and fine motor function may be due to a problem in normal function of *Vata*. Hence, to achieve results in developmental disorders, function of *Vata* (normal physiology) should come to normal. Here, *Ashtamangal Ghrita* might have worked on central nervous system (CNS) by crossing BBB (Blood Brain Barrier-*Majja Dhara Kala*) because of its lipophilic property, thus stimulating higher mental functions (*Medha, Smriti* and *Buddhi*). *Abhyanga* and *Swedana* caused *Dosha gati* from *Shakha* to *Koshtha*. Thus by the combined effect of total therapeutic measures, *Majja* got nourishment, *Vata* came to normalcy, and hence the proper development of milestones were achieved.

Significant improvement was found in both the groups in spasticity. 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). Spasm was reduced significantly, which may be due to *Shamana* of *Vata Guna* like *Chala* and *Shita* by virtue of *Ashtamangal Ghrita*, *Abhyanga* and *Sweda*. *Abhyanga* & *shashtikashalipinda sweda also* act by increasing blood circulation. This facilitating transdermal drug absorption & receiving beneficial effects of respective drugs. *Shashtika shali* is *snigdha, sthira, balavardhaka. Bala, go dugdha & dashmoola* are *snigdha, rasayana, balya* & *vatahara*. Thus by virtue of these properties of drugs & increased blood circulation spasticity was decreased & tissue extensibility increased facilitating ease of motion.

Significant improvement were found on Language in both the Groups although Group B shows

slightly superior results than group A. Language is more of the function of *Udana Vayu*, which is normally situated at *Uraha Pradesha(chest region)(14)*, showed significant result in this study in both groups. As this disease entity comes under *chronic problem*, the study period may not be enough to show the complete correction of language.

Effect of Treatments on Teacher drooling scale showed significant improvement in both the Groups. Group A showed slightly superior results than group B. Saliva production is almost completely controlled by the autonomic nervous system both sympathetic & parasympathetic. In CP primary functions such as lip closure, intra oral tongue suction & swallowing may be disturbed as a result of neurodevelopmental delay. On the basis of overall pharmacological activity of *Ashtamangal ghrita* it has medhya & *vatahara* properties. Besides these it also has neuroprotective activity. Due to all these properties of drug there was significant improvement in brain functions & thus showing improvement in excessive salivation.

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.(15) This improvement in patients also supports the concept of Neuroplasticity.

The rationality behind taking *ghrita* as a base is to extract or hold lipid soluble active fraction from the ingredients used. When it taken internally it enters into the systemic circulation & can easily cross the blood brain barrier, thereby strengthens or stimulate the CNS. On evaluation of ayurvedic pharmacodynamics properties of *Ashtamangal ghrita's* ingredients, the predominant *ayurvedic* pharmacodynamic properties of *Ashtamangal ghrita* were *madhura, katu, tikta rasa, guru, snigdha & laghu guna, madhura & katu vipaka, ushna & sheeta veerya, tridosha shamak, medhya prabahv & jathragni deepak.*

Madhura rasa is *sarvadhatuvardhaka, brihmana, jeevniya, preenan, sthairykaran. Madhura* rasa is formed by *prithvi & jala mahabhuta*. The *panchbhautika composition* of *mamsa* dhatu is also *jala & prithvi*. This by the principle of *samanyam vriddhikaranam, madhura rasa* helps in nourishment of *mamsa dhatu*. Due to *sarvadhatu vardhaka guna* it provides support & proper nourishment to neurons. Its *ksheenakshata sandhankara* guna helps in regenerating damaged neurons. *Katu rasa* is *indriyouttejaka* (to stimulate sensory/motor organs to perceive their subjects), *agnideepak* (secretion of hormones in synaptic vesicles), *marganavivrunoti* (to create new pathway for proper functioning and replacement of damaged neurons). *Tikta rasa* also has *sthirikarana* property (provides strength to muscles & tissues). *Guru & Snigdha* guna are *vatahara* & provide nourishment to the body. *Ushna veerya* acts by *vatahara* property & also increases blood circulation in brain while *sheeta veerya* with *stambhana & sthirikarana* property may restrict the excessive neuronal discharge seen in case of convulsions. *Madhura vipaka* has *vatahara* property & its *panchbhautika* composition is *prithvi* and *jala*. Thus, same as *madhura rasa* it also acts by the principle of *samanyam vriddhikaranam* & helps in nourishment of *mamsa dhatu.*

Comparison of the results shows that *Nasya* of *ashtamangal Ghrita*was found better than oral administration. *Nasya* is specifically designed route for *shirorogas*. It has very significant role on diseases of *murdha, netra, shrotra, kantha,* etc. Central nervous system consists of the brain and spinal cord. It integrates different kinds of sensory information, emotions, thoughts and memories. It is protected blood brain barrier and blood C.S.F. barrier. C.N.S. diseases have a great challenge for entry of medicine into brain tissue. The capillary endothelial cells in the brain have tight junctions. Blood brain barrier (B.B.B.) protects brain cells from harmful substances and pathogens by preventing passage of many substances from blood to brain tissue. It permits certain substances to enter C.S.F. but exclude others. Both these barriers are lipoidal & limit the entry of non-lipid soluble drugs. In *nasya*, there is direct entry of medicine into C.N.S. According to *ayurved*, nose is entrance for head. Drugs administered through nose spreads over *Shrungatak marma* (Cavernous sinus) as well as channels within head, nose, throat and removes vitiated doshas. Nasya is the best treatment for *shirorogas* as it goes faster to target organ and bypass the first metabolism. There is close relationship between nose and brain which is also accepted by modern science. Anatomical & physiological study of nose shows that nasal mucosa (olfactory mucosa) is the only site which directly connects brain & external environment. Drug administered through nose gets absorbed through three ways –through nasal mucosa and vascular pathway.

By these routes drug have direct entry into C.N.S. and crosses the BBB. As the study drug, *Ashtamangal ghrita* was in lipid form, it also facilitated drug absorption. This also facilitated the absorption of medicine through mucous membrane and capillaries. According to pharmaceutical research, lipid soluble drugs diffuse by dissolving in lipoid matrix of membrane. Lipid soluble drugs pass readily across the whole surface of the capillary endothelium. In *nasya*, recommended position of patient is given as supine with head tilted. Due to this, drug molecules come in closer contact with olfactory mucosa which is the alleyway for medicine.(16)

Conclusion

Cerebral palsy includes a group of non-progressive and non-contagious disorders causing physical disability mainly in the various areas of body movement. Currently there is no cure for CP. But use of ayurvedic management can reduce the muscle tone, increases the range of motion of the joints, improves the function of upper and lower extremities, delays the need for surgery & thus improving the life style & activities of daily life.

In the present clinical trial significant results were found in all the parameters except memory in both

groups i.e. oral administration of *Ashtamangal ghrita* in group A & *nasya* of *Ashtamangal ghrita* in group B. Quality of life was improved in most of the patients in both groups due to reduction in spasticity & improved power. Overall effect of therapy shows that there was 34.79% improvement in group A & 37.74% improvement in group B. Results were slightly superior in group B than group A in most of the parameters. In group B *nasya* of *Ashtamangal ghrita* and *Shastikashali pinda sweda* were used. Although most of the parameters in group B show slightly superior result than group A but intergroup comparison of both groups was not-significant or there were no differences in both groups statistically..Group A was slightly superior than group B in following parameters –Head holding, sitting and teacher's drooling scale. Except these parameters, in all the other parameters group B was slightly superior than group A. There were no any significant mean changes in all the parameters after 1 month of follow up period without intervention of treatment which shows the persistent effect of the therapy in both the groups. No untoward effects of any drug or procedure were noticed during or after the trial.

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