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Clinical response of *Abhaya Ghrita* and procedure based therapy on Gross Motor Functions in children with Cerebral Palsy : An Open Label, Randomized Clinical Trial

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ABSTRACT

Introduction - Cerebral Palsy (CP) being the leading cause of disability in children is a symptom complex, which has worldwide incidence of 2.1/1000 live births, and for India it is 3/1000 live births. In Ayurveda, the cerebral palsy can be correlated with various conditions due to *Vata* predominance. There is no satisfactory criterion in managing this condition is developed till date. The present study is planned with *Abhaya Ghrita* and procedure based therapy to provide possible improvement in gross motor function of children with cerebral palsy and thereby improving their quality of life. **Material and Methods** - A Trial was conducted at a tertiary health care setting to evaluate the clinical efficacy of Ayurvedic Intervention (*Abhaya Ghrita* and procedure based therapy *Udvardana, Sarvanga Abhyanga, Nadi Sweda* and *Matra Basti*). Diagnosed children of cerebral palsy, aged 1-12 years of either gender were selected. The scale gross motor function manual (GMFM) and Cerebral Palsy quality of life (CP-QOL) were used for assessment. **Results** - Total 20 patients were registered in the present study. 70% patients were below 8 years of age with clear male predominance comprised of 85% of the total sample size. As per the birth history of the patients 15% were preterm, home delivery was present in 20%. 45% and 10% were Low birth weight (LBW) and Very Low birth weight (VLBW) after birth respectively. History of delayed cry was present in 80% cases. 45% required Hospitalization and 65% were subjected to Resuscitation and need of incubator just after birth was present in 25% patients. **Discussion** - Gross Motor Function scale has shown significant improvement in motor activities like lying and rolling, sitting and total score with $p < 0.001$, on crawling and kneeling and standing with $p < 0.01$ and on walking and running with $p < 0.02$. The CP-QOL has also shown significant results on health and family and friends component. **Conclusion** - Thus, it may be concluded that the Ayurveda approach including internal intake of *Abhaya Ghrita* & procedure based therapy is effective in improving the gross motor function and quality of life of children with cerebral palsy.

Key words: *Abhaya Ghrita, Cerebral Palsy, Gross Motor Functions Manual (GMFM), Quality of Life (QOL).*

INTRODUCTION

According to WHO (World Health Organization) 15% of the world's and 3.8% of India's adult population is estimated to have some form of disability.^[1-2] Cerebral Palsy (CP) is being the leading and the most common

chronic cause of disability and it is responsible for impaired health related quality of life of children and their care giver.^[3-5] It is a non-progressive neuro-motor disorder caused by consequences of damage to the developing brain at various stages of life during prenatal, natal and postnatal period. With reference to the prevalence of this disorder, more than 15 million people world wide and more than 25 lakh people in India^[6] are living with this disability. Worldwide incidence of Cerebral Palsy is 2.1/1000 live births^[7] and for India it is 3/1000 live births.^[8] In those born at term rates are lower at 1 per 1000 live births.^[9] The incidence of cerebral palsy in India has remained constant over the last 20 years despite of increasing survival rate of low birth weight babies. Rates appear to be similar in both the developing and developed world,^[9] more often occurring in poorer people.^[10] The incidence rate is higher in males than

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in females; in Europe it is 1.3 times more common in males.^[11] The degree of impairment of QOL is correlated with the severity of the condition.^[12]

There is no successful management protocol developed for CP till date, and the whole world is in search of one; the condition can be managed with early intervention. Long term medication with multiple alternatives i.e. Medication, Physiotherapy, Speech therapy, Occupational therapy, Counselling and Surgery, with supportive aids under timely observation of a specialist may be helpful for the rehabilitation towards independent life. Therefore, multidisciplinary approach is desired for the management of CP.^[13] In Ayurveda, the various conditions presenting the sign and symptoms of CP can be correlated with *Vata* predominant diseases. The *Panchakarma* procedure based therapy has been used since long time in improving and managing *Vata* predominant conditions in classics.

Thus, the present study was aimed to observe the efficacy of Ayurveda interventions by improvement in gross motor functions and the quality of life of children with cerebral palsy with the intention of providing some benefit in present condition and minimizing the disability.

MATERIALS AND METHODS

Materials

A Trial was conducted in the clinical settings of a Ayurveda tertiary health care hospital, New Delhi. The complete trial was of 3 months. One course of treatment was for 17 days, total 3 course of treatment, with an interval of 15 days between each course [Table 1]. Initial screening and the consent was obtained from the parents of the children. A case record form (CRF) was prepared and was maintained for all registered patients through-out the study.

Study design

A single group interventional clinical trial with total 20 patients.

Inclusion Criteria

Children diagnosed with Cerebral Palsy (CP), aged 1-12 years of either gender were selected after

obtaining written informed consent from their parents.

Exclusion Criteria

Children with progressive neurological disorder, systemic acute or chronic illness, congenital disorders, fixed contractures, severe intractable epilepsy and children who had received Botox or had undergone Phenol injection or intra-theal Baclofen medication in last 1 year were excluded from the study.

Table 1: Showing Plan of treatment of the study

Name of the Procedure	Drugs used	Form	No. of Days
<i>Udvardana</i>	<i>Tila Pinyaka</i>	<i>Churna</i>	3
<i>Sarvanga Abhyanga</i>	<i>Ksheerbala Taila</i>	<i>Taila</i>	14
<i>Nadi Swedana</i>	<i>Vatahara Patra Kwatha</i>	<i>Kwatha</i>	14
<i>Matra Basti</i>	<i>Ksheerbala Taila</i>	<i>Taila</i>	7
Oral administration	<i>Abhaya Ghrita</i>	<i>Ghrita</i>	90

Evaluation and Assessment of study outcomes was done using Gross motor function manual (GMFM) scale,^[14] and CP-Quality of life scale (CP-QOL).^[15]

Procedures

Udvardana^[16-17]

A type of body massage that uses a paste made of ground grains to cleanse the skin, improve circulation and help weight loss. It was done with *Tila Pinyaka Churna*^[18] i.e., powder of Sesame oil cake (*Sesamum indicum* Linn.) for 10-15 minutes, starting from the lower limbs up to the upper limb and trunk.

Abhyanga^[19]

Abhyanga is a procedure of anointing oil on the body for the purpose of bringing stability and to normalize the *Vata*. *Sarvanga Abhyanga* (Full body massage) was done with *Ksheerbala Taila*^[20] for 10-20 minutes, starting from the lower limbs upto the upper limb and trunk, Followed by *Nadi Sweda*.

Nadi Sweda^[21]

The process of induction of sweating with the help of steam, generated from medicated herbal decoctions. It was done with *Vatahara Patra Kwatha* like *Eranda (Ricinus communis)*, *Nirgundi (Vitex negundo)* etc. for 5-10 minutes, after *Sarvanga Abhyanga*.

Matra Basti^[19, 22]

Administration of medication through ano-rectal route by inserting the catheter 4 *Angula* inside the anal sphincter is known as *Basti*. The milder form of *Basti* i.e. *Matra Basti* with *Ksheerbala Taila*^[20] once daily (from the 8th day) after *Sarvanga Abhyanga* and *Nadi Sweda* was given in the present study. All the Procedures were done as per the standard operative procedures (SOP) of *Panchakarma*.^[19]

Internal medication

Abhaya Ghrita^[23] was given orally twice daily during morning and evening (before meal) with *Anupana* of *Ushnajala* (Luke warm water). The dose of *Abhaya Ghrita* and *Matra Basti* was prescribed as per the age of children according to *Sharangadhara Samhita*.^[24-25] [Table 2,3]

Ethical clearance and Registration - The trial was ethically approved by IEC before starting actual clinical study and was registered in CTRI with - IEC No.: AIIA/2017/PG-12 and CTRI Registration No.: CTRI/2018/05/013889.

Statistical Analysis was done using student’s Paired ‘t’ test with the help of SPSS software.

Table 2: Showing Dose of Abhaya Ghrita

SN	Age (years)	Dose/day
1.	1-3	1 -3 gm. in divided doses
2.	3- 6	3 -6 gm. in divided doses
3.	6- 9	6 -9 gm. in divided doses
4.	9-12	9 -12 gm. in divided doses

Table 3: Showing Dose of Matra Basti

SN	Age (in yrs)	Dose of <i>Matra Basti</i> (in <i>Pala</i>)	Dose (in ml) approx.
1.	1-5	2- 5	10
2.	5-10	5-10	20
3.	>10	>10	30

OBSERVATIONS AND RESULTS

General observations - Total 17 patients completed the study with 3 drop outs. 35% patients were from poor socio-economic status. Only 30% fathers and 25% of mothers of the patients were educated above the inter-school (12th).70% were from nuclear family. Positive Family history of CP was present in one case [Fig.1 and 2].

Fig. 1: Showing Age wise distribution of study participants

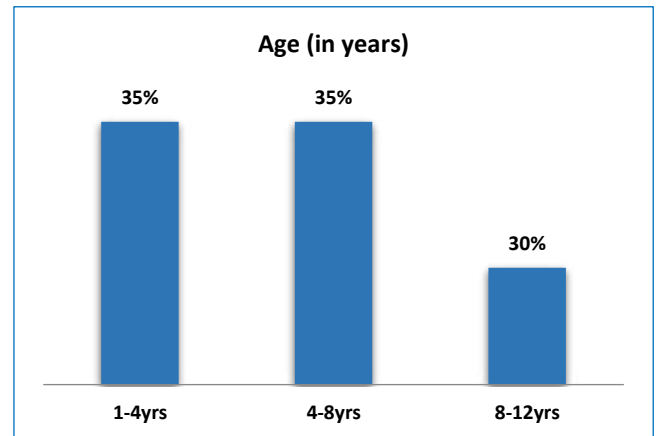
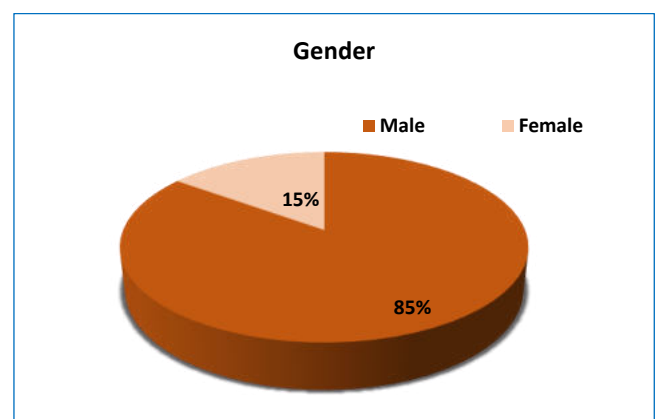


Fig. 2: Showing Gender wise distribution of study participants



Antenatal history - Positive poor Antenatal history with hyperemesis in 30% cases, chronic illness in 5%, and abortion in 20% cases was observed and history of intake of certain medications during pregnancy was found in 20% cases. Maternal age below 20 years in 35% and above 30 years in 15% cases. 50% mothers were primigravida for the affected child.

Birth history - 15% patients were preterm, normal delivery and home delivery was observed in 80% and 20% cases respectively. 45% and 10% of the total sample size were Low birth weight (LBW) and Very Low birth weight (VLBW). 45% required Hospitalization, 65% were subjected to Resuscitation and 25% required Incubator just after the birth. Delay in cry (<5 min.) was present in 31.25% and >5 min. was present in 18.75% cases [Fig.3].

Fig. 3: Showing Status of cry after birth wise distribution of the patients

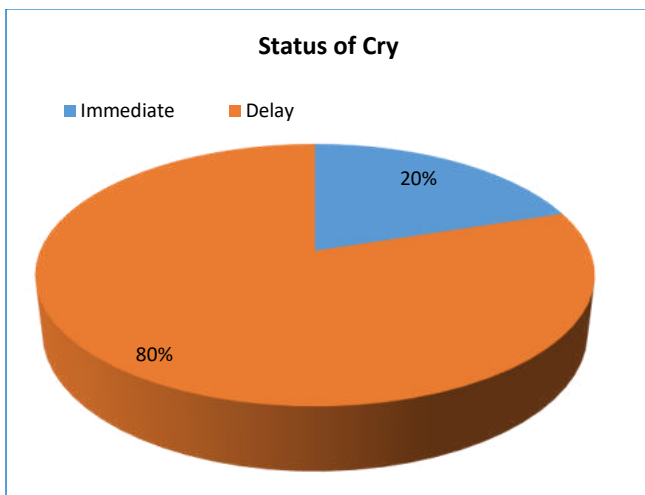


Table 4: Showing Natal History of the patients

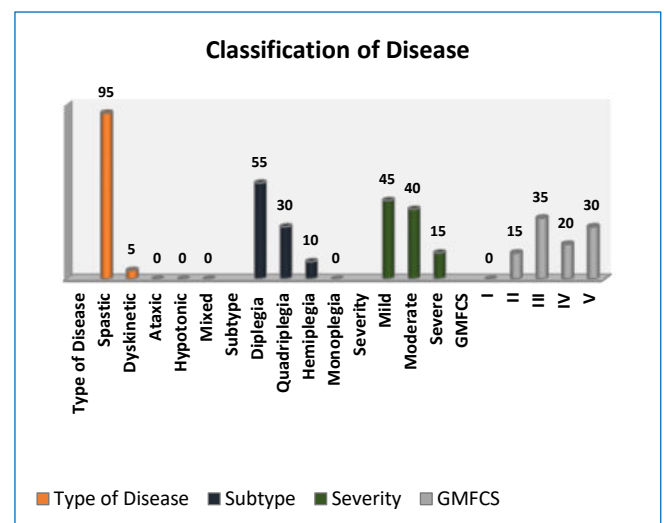
Natal History of	Present in (%)
Prolonged labour	40%
Foetal distress	50%
Meconium aspiration	10%
Neonatal jaundice	15%
Convulsions	55%

Table 5: Post-natal History of the patients

History of	Present in (%)
RRTI	40%
Recurrent fever	30%
Seizures	15%
Other illness	25%
Feeding difficulties	85%
Excessive salivation	70%
Constipation	65%

Poor appetite (45%), disturbed sleep (20%), *Vishama Agni* (poor digestive power) in 50% and *Krura Koshta* (constipated bowel) 60% was present. 70% *Vata-Kaphaja Prakriti*, 20% *Pitta-Kapha* and 10% *Vata-Pittaja Prakriti* were present. Classifications were made based on type of disease, subtype, severity and as per assessment with - [Fig.4].

Fig.4: Showing Classification of type of disease and severity and GMFCS wise distribution



RESULTS

On Gross Motor Function Manual Scale (GMFM) - The GMFM score has shown significant results at all the domains. More than 50% of relief was observed in crawling and kneeling (81.44%) and standing (74.37%) [Table 6].

Table 6: Showing Effect of therapy on GMFM Scale (n=17)

Assessment parameters	Mean score		SD +/-	t	P value	% of relief
	BT	AT				
Lying & Rolling	29.18	37.82	14.15±1.08	6.16	<0.001*	29.61
Sitting	30.05	41.29	20.30±1.8.11	4.74	<0.001*	37.40
Crawling & Kneeling	7.65	13.88	11.66±1.3.80	3.66	<0.01*	81.44
Standing	6.75	11.77	10.27±1.3.68	3.65	<0.01*	74.37
Walking & Running	6.7	13.41	11.17±1.9.44	2.74	<0.02*	100
Total score	28.79	44.99	24.64±2.7.21	6.11	<0.001*	56.27

* - Highly significant, ** - Significant, *** - Not Significant

Quality of Life Scale (QOL) - This has been observed that significant results (p<0.01) in assessment parameter of Quality of life scale at Family and friends, health and finals score, and pain and bother with (p<0.05) are present [Table 7].

Table 7: Showing Effect of therapy on QOL Scale (n=17)

Assessment parameters	Mean score		SD +/-	t	P value	% of relief
	BT	AT				
Family & Friends	68.35	78.24	27.27±25.87	3.39	<0.01*	14.47
Participation	11.0	12.53	9.27±10.30	0.88	>0.10**	13.91
Communication	15.24	15.59	6.40±5.91	0.51	>0.10**	2.30
Health	59.29	70.47	18.6±17.72	3.09	<0.01*	18.86
Special	2.65	2.82	3.79±6.2	0.1	>0.10*	6.42

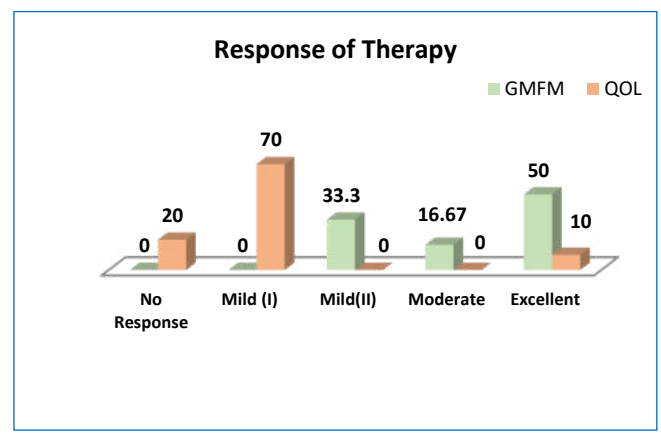
equipment				3	**	
Pain & Bother	18.88	14.71	6.13±6.59	2.49	<0.05*	77.91
Final questions	21.12	21.41	8.97±9.80	0.15	>0.10**	1.37
Access	23.53	26.24	14.77±15.11	0.90	>0.10**	11.52
Your health	23.71	27.53	7.09±8.50	1.50	>0.10**	16.12
Final Score	242.12	271.18	62.55±60.91	3.80	<0.01**	12.0

* - Highly significant, ** - Significant, *** - Not Significant

Overall effect and response of therapy

The Overall clinical improvement in this study was observed 78.03% on gross motor function scale and 17.49% on quality of life scale [Fig.5].

Fig. 5: Showing Response of the Therapy



DISCUSSION

Cerebral Palsy, being the leading cause of disability in children is the matter of concern due to their vulnerability for deficiencies in health care services.^[3] Disabled persons experience greater vulnerability to secondary conditions like co-morbidity, age-related conditions, engaging in health risk behaviours and higher rates of premature death.^[26]

The procedure based therapy includes various *Panchakarma* procedures which have proven beneficial effect on children with cerebral palsy. *Vata*

get pacified by *Snehana*, *Swedana*, *Basti* and other measures having *Snigdha* and *Ushna* property. According to concepts of Ayurveda, *Sneha* diffuses in the body through the minute hair follicles of skin and is assimilated by *Bhrajaka Pitta*. *Ksheerbala Taila* contains *Kshira* which is *Brimhana* and *Balya* in nature and *Taila* itself provides *Snigdha* and strength to the body by acting as *Vata Shamaka* agents without disturbing *Pitta* and *Kapha*. Thus, *Abhyanaga* with *Ksheerbala Taila* carried out in this study controls the vitiated *Vata*, which is the main factor in the pathogenesis of CP and has provided relief in the symptoms.

As regards to pharmacodynamics of *Abhaya Ghrita*, it contains drugs of *Tikta*, *Katu*, *Madhura Rasa*, *Ushna Veerya* and *Katu Vipaka* properties with *Laghuta*, *Tikshnata* and *Snigdha*. *Ushna Veerya* (50%) and *Katu Vipaka* (62.5%) drugs are *Pittavardhaka* in nature, and can be considered as *Medhya* due to *Prakrita Karma* (normal physiological function) of *Pitta*.^[27] With mild involvement of *Sheeta Veerya* (37.5%) drugs and *Anushna-Sheeta Veerya*, it is helpful in maintaining the equilibrium as well as also responsible to increase *Dhriti*, as *Prakrita Karma* (normal physiological function) of *Kapha*.^[27] *Ghrita* preparations are nootropic in nature with memory enhancer, anti-amnesic, anti-oxidant properties^[28] along with a distinctive property of *Samskarasya Anuvartana*^[29] (acquires the qualities of other drugs and does not lose its own properties). Thus, for the diseases condition like CP which involves various parts of the body as per extent and severity of the causative factor, *Abhaya Ghrita* with its *Medhya* and *Rasayana* properties is used as a carrier for better absorption and bioavailability of drugs in CNS^[30] and has provided strength to the nerves and muscles.

In children with CP the hallmark is a deficit in motor control and the challenge is not merely to accelerate motor task acquisition but to enrich the repertoire and coordination of the movements involved in that task. The scale GMFM has been used to evaluate the ability and the level of difficulty in performing functions in a child with CP. Thus, it is able to identify the impairments in motor skills and thus helpful in

evaluating the improvement after the therapy. In this study, GMFM scale has shown significant results in improving the gross motor functions of children with CP, the overall clinical improvement (78.03%), can be considered as good for the diseased condition like CP. Also the therapy is helpful in improving the quality of life of CP children at milder extent with overall effect in 17.49% cases.

Poor socio-economic status, education status of the parents, Positive family history, abortions, pre-terms specifically below 32weeks, Low Birth weight and small for gestational age and other Neonatal factors like birth asphyxia, seizure, meconium aspiration, neonatal jaundice are risk factors for CP.^[31-33] Positive poor maternal antenatal history due to various causes may be associated with placental dysfunction disorders, high incidence of LBW, SGA, premature births and increased emotional stress due to dehydration, nutritional deficiencies and other factors among the mothers.^[34] Age of the mother and parity (≥ 3) is directly related with higher incidence of CP.^[35] Mode and place of delivery also play important role in causing CP.^[36] Intra-partum hypoxic conditions in around 10% of the cases causing CP depend on the place of delivery.^[37] Spastic CP (95%), specifically spastic diplegia (55%) is the most common type of cerebral palsy among all and it is contributed to around 70-80% of all cases.^[38] Duration of resuscitation is also associated with abnormal motor movements and the physiological classification of CP. Need of Resuscitation for more than 15 minutes of duration is associated with severe CP, whereas resuscitation for less than 15 minutes or for an unknown time is associated with quadriplegia.^[39] CP can be diagnosed typically between the ages of 18-24 months (up to 2 years);^[40] however the appearance of symptoms is much based on the severity of the disease. Parents are the first to suspect the delay in achieving age related milestones of their child.^[41] 70% of the patients below 8 years of age in the present study show increased awareness among the parents [Fig.1]. Male predominance (85%) in CP may be due to the role of hormones, cerebral structure and genetic polymorphism of the males as compared to

females^[42] [Fig.2]. Motor functions and manual abilities are also more affected in males than females.^[43] Feeding problems are the most common complaint in patients with CP; approx. 30-80% disabled individuals are suffering from feeding difficulties.^[44] Further more a family with CP child needs more manpower for the care of disable and dependent child. Mothers in a nuclear family (70%) have to cope-up with this situation and this issue is found raising stress level of mother of a child with CP, and its impact on quality of life of parents.^[45]

CONCLUSION

Vata as major contributing factor for CP, the measures which pacify *Vata* are used in the present study. The use of *Abhyantara* and *Bahya Snehana* in the form of oral administration *Abhaya Ghrita* and *Ksheerbala Taila* for *Abhyanga* and *Matra Basti* were done to alleviate *Vata*, there by, reduction in stiffness and improvement in the gross motor functions by *Balya* and *Brimhana* of the body has been achieved. Thus, it can be concluded that the procedure based Ayurveda management approach is effective in improving the gross motor function of children with cerebral palsy and also beneficial in improving the quality of life.

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