CLINICAL STUDY ON THE EFFICACY OF SAMVARDHANA GHrita ORALLY AND BY MATRABASTI IN MOTOR DISABILITIES OF CEREBRAL PALSY IN CHILDREN
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ABSTRACT
Objective of the study was to assess the efficacy of Samvardhana ghrita orally and by Matrabasti in motor disabilities of cerebral palsy in children. Study was carried out in the IPD of Dept. of Kaumarabhritya, SDM College of Ayurveda & Hospital, Hassan, Karnataka, India. 40 children satisfying diagnostic criteria and age 2-10 years were included & randomly distributed into two groups of 20 patients each. Group A (Samvardhana ghrita orally) treated with 5 gms of Samvardhana ghrita with Madhu as anupana twice daily for 48 days. In Group B (Samvardhana ghrita as matrabasti), 20 ml of Samvardhana ghrita was administered through basti after local abhyanga with Moorchita Taila and local Swedana with NadiSwedha method. For oral and matrabasti route, Group A and B shown improvements in language and performance (61.11%, 46.15%), speech (66.66%, 56.25%) and performance of skill (57.89%, 76.45%), in fine motor functions such as puts small object in container (58.88%, 66.66%), throws ball in all direction (38.23%, 60.00%), uses thumb and index finger (34.21%, 68.75%), retain 2 one inch cube in fist (34.21%, 55.58%), folds paper inserts into envelope (66.66%, 38.88%), in gross motor functions such as in crawling (31.85%, 48.00%), sitting (55.55%, 57.89%), standing (36.36%, 61.90%), walking (34.61%, 44.00%) and claps hands (44.44%, 63.41%) respectively. Both oral administration and basti route of samvardhana ghrita have promising result in managing motor disabilities of cerebral palsy in children.

Keywords: Samvardhana ghrita, Motor disabilities, Cerebral palsy

INTRODUCTION
Cerebral palsy is the second commonest cause of the disability in children next to Poliomyelitis.1 Cerebral palsy is a static encephalopathy that may be defined as a non-progressive disorder of posture and movement often associated with epilepsy and abnormalities in speech, vision and intellect resulting from a defect or lesion of the developing brain.2 The prevalence of cerebral palsy among children is 2 per 1000 live births.3-5 There are 25 lakhs cerebral palsy affected children in India.6 The health organisation (W.H.O.) estimates that about 10% of the population have some form of disability.7 Statistics from different source indicates that 3.8% of the population has some form of disability in India.8 Nearly 15-20% of total physical handicapped children suffer from cerebral palsy.9 Cerebral palsy is considered as ‘Bala Samvardhana Vikara’, based on the lakshanas such as Pangu (lame), Mooka (dumb), Ashruthi (deaf), Jada (mental retardation) where the chief dosha involved is vata. Hence all such were treated with line of treatment of vata vikara.10 The study drug Samvardhana ghrita comprises of Khadira, Prishnaparni, Arjuna Twak, Saindava, Balamoola, Atibalamoola and Kebuka kanda.11

MATERIALS AND METHODS
Objective: To assess the efficacy of Samvardhana ghrita orally and by Matrabasti in motor disabilities of cerebral palsy in children.

Source of Data: Patients were selected successively from the in-patient department of Kaumarabhritya, Shri Dharmasthala Manjunatheshwar College of Ayurveda and Hospital, Hassan, Karnataka, India. Ethics clearance was obtained from Institutional Ethic committee of SDM College of Ayurveda and Hospital, Hassan (IEC No. SDMAH/IEC/10/2002-dated 28-03-2002).

Method of Collection of Data
Inclusion criteria
The patients of cerebral palsy with mild to moderate physical disability within 2 to 10 years of age group were selected.

Exclusion criteria
Patients of cerebral palsy below 2 years and above 10 years with severe physical disability were excluded.

Plan of the study
Children for the present study were selected from the OPD and IPD of Kaumarabhritya Department of SDM College of Ayurveda & Hospital, Hassan, Karnataka, India.

Research design
Selected 40 patients of Cerebral palsy between 2 years to 10 years of age were taken for clinical trial in two different groups.

Group A: In this group 20 patients of Bala samvardhana vikriti /cerebral palsy were treated with 5 gms of Samvardhana Ghrita with Madhu as anupana twice daily
for 48 days. The effect of treatment was assessed after 48 days.

**Group B:** 20 patients of Samvardhanavikriti were included in this group. 20 ml of Samvardhana ghrita was administered as Matra Basti after local Abhyanga with Moorchita Taila and local Swedana with Nadi sweda method. This treatment was continued for 48 days. The observation and results were recorded periodically on 48 days of treatment.

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Botanical Name</th>
<th>Part Used</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Khadira</td>
<td>Acacia catechu</td>
<td>Twak</td>
<td>Churna</td>
</tr>
<tr>
<td>Prishnaparni</td>
<td>Uraria picta</td>
<td>Mula</td>
<td>Churna</td>
</tr>
<tr>
<td>Arjuna</td>
<td>Terminalia arjuna</td>
<td>Twak</td>
<td>Churna</td>
</tr>
<tr>
<td>Sandhava</td>
<td>Rock salt</td>
<td></td>
<td>Churna</td>
</tr>
<tr>
<td>Bala</td>
<td>Sida cardifolia</td>
<td>Mula</td>
<td>Churna</td>
</tr>
<tr>
<td>Atibala</td>
<td>Abutilon indicum</td>
<td>Mula</td>
<td>Churna</td>
</tr>
<tr>
<td>Kebuka</td>
<td>Costus speciosus</td>
<td>Kanda</td>
<td>Churna</td>
</tr>
<tr>
<td>Ksheera</td>
<td>Cow’s milk</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ghrita</td>
<td>Cow’s ghee</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Method of Preparation of Samvardhana ghrita**

Ingredients with Sanskrit and botanical name, form and proportion are detailed in Table 1. Raw drugs were obtained from SDM Pharmacy, Udupi and authenticated in Department of Dravyaguna, Shri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan. The medicine was prepared in teaching pharmacy, Shri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan. Drugs such as Khadira (Acacia catechu), Prishnaparni (Uraria picta), Arjuna Twak (Terminalia arjuna), Saindava (Rock salt), Balamoola (Sida cardifolia), Atibalamoola (Abutilon indicum), Kebuka Kanda (Costus speciosus) (each 2.250kg) taken and pulverised into coarse powder, chaaruthavasheshka kwatha of the coarse powder was prepared by adding 80 litres of water. The above seven drugs (each 750gms) taken and pulvred into medium fine powder as kalka. Ghrita (20 kg) was taken in a vessel and boiled along with kwatha kalka and milk (20 kg) till it attains the Ghrita siddha lakshana. Then it was filtered and cooled. After that it was preserved in air tight, properly labelled bottle of 200 ml each.

**Laboratory Investigations:** Investigations like Haemoglobin, Total leukocyte count, Differential leukocyte count, and Erythrocyte sedimentation rate were done before and after treatment.

**Assessment Criteria**
The assessment criteria has been shown in Table 2.

**OBSERVATION**

Age wise distribution of registered subjects shows that 65% (n=26) were in 2-4 year age group, 25% (n=10) were in 4-6 year age group, 2.5% (n=1) were in 6-8 year age group and 7.5% (n=3) in 8-10 year age group. Sex wise distribution showed that 72.5% (n=29) were males and 27.5% (n=11) were females. Greater number of male patients supports the higher prevalence in male i.e.1.33:1, which was reported by Surveillance of Cerebral Palsy in Europe (SCPE). The religion based distribution showed that 87.5% (n=35) of the children were Hindus and 12.5% (n=5) were Muslims. The socio-economic status based distribution showed that 25% (n=10) belonged to poor socioeconomic status, 62.5% (n=25) belonged to middle class, and 12.5% (n=5) were from upper class. Dolk H, Pattenden S et al has found that less health consciousness, unhygienic environment and deficiency in proper antenatal and obstetrical care in low economic group, are probably due to higher incidence of cerebral palsy. 50% (n=20) were having the history of Consanguinity. Distribution on care and concern by parents showed that 10% (n=4) were getting minimum care, 65% (n=26) were getting moderate care and 25% (n=10) were getting maximum care. Distribution on pre-conceptional status of mother showed that 5% (n=2) had spontaneous abortion, others were having history of spontaneous abortion, 12.5% (n=5) done D&C, 30% (n=12) used I.U.C.D, 7.5% (n=3) used oral contraceptives, 5% (n=2) were elderly Primigravida, 15% (n=6) were early primipara and 25% (n=10) were without any above complaints. Observation on mother’s health status during pregnancy showed that 25% (n=10) mothers were healthy, 20% (n=8) were unhealthy with malnutrition, 20% (n=8) were anemic, 35% (n=14) were with different disease of pregnancy. Observation on Garbini (Antenatal care) of the mother showed that 15% (n=6) had taken proper ANC, 60% (n=24) had taken improper and 25% (n=10) were not undergone ANC. Observation of maturity at birth showed that 25% (n=10) patients were full term, 70% (n=28) were premature and 5% (n=2) were post mature. Observation on mode of delivery of the mother showed that 67.5% (n=27) were delivered normally, 17.5% (n=7) were by L.S.C.S and 15% (n=6) by Instrumental application. As earlier reported data obstetric events predisposing to birth trauma include instrumental delivery and vacuum extraction.

Observation of birth weight of patients showed that 75% (n=30) were having history of normal birth weight, 12.5% (n=5) were small for gestation period, 12.5% (n=5) were large for gestation period. Observation on history of infantile illness of the patients showed that 12.5% (n=5) were with history of Neonatal jaundice, 15% (n=6) with the meningo encephalitis, 12.5% (n=1) with primary complex, 7.5% (n=3) with Gastro-enteritis, 57.5% (n=23) with miscellaneous history and 5% (n=2) with no specific history. Observation on breast feeding of the patients showed that 75% (n=30) were breast fed, 15% (n=6) had improper breast feeding, 10% (n=4) had no breast feeding. Observation on history of weaning period of patients showed that 37.5% (n=15) patients done early weaning and 62.5% (n=25) done late weaning. Observation on immunization status of patients showed that 82.5% (n=33) had taken full course of immunization in proper time, 15% (n=6) were taken but not in proper course and 2.5% (n=1) not taken at all. Distribution of patients according to the types of cerebral palsy showed that 10 patients were of spastic hemiplegic, 25 were of spastic diplegic, 4 were of spastic quadriplegic and 1 patient remained unclassifiable.
RESULTS

Language and Performance

The effect of therapy on ability to understand was 61.11% and 46.15% respectively in both Samvardhana ghrita oral group and Samvardhana ghrita Basti group which was significant at the level of (p<0.001). The effect of therapy on speech showed 66.66% and 56.25% improvement respectively in S.G oral group and S.G Basti group which was significant at the level of (p<0.001). The performance skill was improved by 57.89% and 76.45% in S.G oral group and S.G Basti group respectively which was also significant at the level of (p<0.001). The comparison of the effect of therapy on language and performance for both oral and Basti group is shown in Graph 1.

Effect of therapy in fine Motor function

The effect of therapy on fine motor function of the Samvardhana ghrita oral group showed improvement of 58.88%, 38.23%, 34.21 %, 34.21 %, 66.66% in characteristics like puts small object in a container, throws ball in all direction, uses thumb and index finger, retain 2 one inch cube in fist, folds paper inserts into envelope respectively and with significance of all at p<0.001 except first character. The effect of therapy on fine motor functions like puts small objects in container, throws ball in all direction, uses thumb and index finger, retain 2 one inch cube in first fold paper and inserts in the envelope with improvement of 66.66%, 60.0%, 68.75%, 55.58%, 38.88% respectively in Samvardhana ghrita Basti group and all are significant at the level of p<0.001. The comparison of the effect of therapy on fine motor function for both oral and Basti group is shown in Graph 2.

Table 2: Showing assessment criteria of cerebral palsy

<table>
<thead>
<tr>
<th>Sl.</th>
<th>Gross motor</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>i. Crawls a distance of 5ft or more</td>
<td>Not at all does</td>
</tr>
<tr>
<td></td>
<td>ii. Sitting</td>
<td>Can do with support</td>
</tr>
<tr>
<td></td>
<td>iii. Standing</td>
<td>Can do without support</td>
</tr>
<tr>
<td></td>
<td>iv. Walk for minimum 5-10 steps</td>
<td>Can do independently</td>
</tr>
<tr>
<td></td>
<td>v. Claps hands</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Fine motor</td>
<td>Grade</td>
</tr>
<tr>
<td></td>
<td>i. Puts small object in to a container</td>
<td>Not does at all</td>
</tr>
<tr>
<td></td>
<td>ii. Throws ball in any direction</td>
<td>Does with help</td>
</tr>
<tr>
<td></td>
<td>iii. Uses thumb and index figure</td>
<td>Does independently</td>
</tr>
<tr>
<td></td>
<td>iv. Retains two one inch cubes in one hand for 30 seconds</td>
<td></td>
</tr>
<tr>
<td></td>
<td>v. Folds paper and insert in to envelope</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Language</td>
<td>Grade</td>
</tr>
<tr>
<td></td>
<td>A. Ability to understand for verbal commands</td>
<td>No response</td>
</tr>
<tr>
<td></td>
<td>B. Speech</td>
<td></td>
</tr>
<tr>
<td></td>
<td>i. No speech and sound</td>
<td>Pronounce sound without meaning</td>
</tr>
<tr>
<td></td>
<td>ii. Pronounce some words with meaning</td>
<td>Making not well formed sentences</td>
</tr>
<tr>
<td></td>
<td>iii. Making not well formed sentences</td>
<td>Well formed sentences</td>
</tr>
<tr>
<td>4.</td>
<td>Performance</td>
<td>Grade</td>
</tr>
<tr>
<td></td>
<td>Making a triangle between three points</td>
<td>Cannot draw at all</td>
</tr>
<tr>
<td></td>
<td>Can meet 2 points, not triangle</td>
<td>Can draw triangle</td>
</tr>
</tbody>
</table>

Graph 1: Comparing the effect of therapies on language and performance group
Gross Motor Assessment
Samvardhana ghrita oral group provided significance of $p<0.001$ in all the characteristics of gross motor with improvement of 31.85%, 55.55%, 36.36%, 34.61%, 44.44% in crawling, sitting, standing, walking and claps hands respectively. The effect of therapy on gross motor with characteristics like crawling, sitting, standing, walking, claps hands shows improvement of 48.00%, 57.89%, 61.90%, 44.00%, 63.41% respectively in Samvardhana ghrita basti group with significance of $p<0.001$ in all characteristics. The comparison of the effect of therapy on gross motor function for both oral and Basti group is shown in Graph 3.

DISCUSSION
Discussion on effect of therapy
The language and performance of the patients were assessed before and after treatment. The effect of therapy in ability to understand is found comparatively higher in oral group (66.66 %) than Basti group (56.25%). Probably since the Samvardhana Ghrita is explained in Lehana Adhyaya, the assimilation of the drug properties may be better when given through oral route. The effect of therapy in performance skill was better in Basti group (76.45 %) than oral group (57.89 %). The performance skill test done in patients was an overall assessment of motor activity and co-ordination skills. Probably “Basti” group showed better result due to the improved inherent action of alleviation of vata by Basti. All the above results are statistically significant with ($p<0.001$).

The fine motor functions were assessed under different characteristic and have showed comparatively better improvement in Basti group. The fine motor functions were assessed under different characteristic and have showed comparatively better improvement in Basti group. All the results were statistically highly significant. General motor functions were also assessed before treatment and after treatment under the headings of crawling, sitting, standing, walking and claps hands. The effect of therapy was better in Basti group. Moreover the effect of therapy in walking and sitting were comparatively promising in Basti group. Basti may be importing ‘Adhakaya bala’ by correcting
vata at its own ashaya. The brumhana effect of Basti may have improved the general motor activity. The fine and gross motor functions were comparatively higher by Basti therapy than oral. This may be the effect of Basti as a procedure than medicine.

An overall assessment of therapy shows that both oral administration and Basti route of Samvardhana Ghrita have promising result in the management of Samvardhana vikaras like cerebral palsy. Among the different parameters evaluated in the present study fine and gross motor functions were comparatively better improved in Basti group than oral group. The difference in the improvement was markedly notable. Vata is explained as “tantrayantradhara” which explains the structural and functional integrity of the body. When Basti is administered it may be helping to improve this integrity of the tantra and yantra by inherent action of Basti karma (ie, action of karma at Pakvashya) and the therapeutic effect of Samvardhana Ghrita. Moreover the majority of the selected patients were ‘Pangu’ (Spastic diplegia) in which the shtanasamshraya of the vyadhis is in kaatesthana. Basti may be acting in the major all vataasthasan from the pakvashaya like kati and sakthi. In the oral route such an inherent action of specific to any karma is not attributable. So a sound conclusion is not possible in this aspect. Further studies may be conducted to assess the efficacy of medication in different route. A fair result may be obtained by conduction of research in large number of patients at multi-centre.

**Probable mode of action of Samvardhana Ghrita**

The development disorders or Samvardhana vikaras mainly arouse with the pathologies like shoshanabhisahaya, dhatuksaya and masthiyagathatha. These pathologies can be conveniently restored to near normalcy with the administration of Samvardhana ghrita. Almost all drugs of Samvardhana Ghrita induce Samprapti vighatanam and restore health progress in the said pathology. Khadira is having tikta-kashaya rasa which is vata pittahara in action. Prishnipam is having madhura-tikta rasa, snigdha guna, ushna veerya and madhura vipaka which is tridoshahara in action. Arjuna is kashaya in rasa which will act as pittahara drug. Balamoola is madhura in rasa, snigdha and pichila guna and madhura vipaka, hence function as vata pittahara drug.

It is brumhana and balya also. Atibala is having madhura rasa, snigdha guna and madhura vipaka, and thus acts as vatapittahara along with its balya and brumhana effect. Kekuba kanda is tikta-kashaya in rasa, acting as pittahara. On whole, Samvardhana ghrita is having kashaya, madhura and lavana rasa and madhura vipaka which are opposite to the properties of vata. Vata is the main causative factor and hence with the use of this ghrita probable correction takes place at vitiated vata level and thereby improving in these parameters and clinical signs and symptoms of cerebral palsy. However the Guru-smigdha guna, Brumhana, medhya, hridaya and tridosha shamaka properties also influence vayu for the best prognosis.

**CONCLUSION**

Oral route is found to be more effective in improving the language and performance while Basti group had showed better improvement in gross and fine motor development. It may be concluded from the clinical study that Samvardhana ghrita is effective in management of Samvardhana Vikriti both orally and by Basti root and hence the said drug is useful in the management of cerebral palsy in children.

**REFERENCES**
