WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.074
Volume 7, Issue 17, 1435-1443. Research Article ISSN 2277– 7105

CLINICAL EVALUATION OF A SIDDHA PREPARATION BRAHMI NEI (INTERNAL MEDICINE) AND KOLLU PODI THIMIRTHAL (EXTERNAL) IN THE TREATMENT OF SIRASTHAMBAVAATHAM (CEREBRAL PALSY) – A PILOT STUDY

G. Ridhambaradevi*[1], R. Vinodini[1], M. Meenakshi Sundaram[2] and V. Banumathi[3]

[1]PG Scholar, Department of Kuzhandhai Maruthuvam, National Institute of Siddha, Chennai-47.

[2]Associate Professor, Department of Kuzhandhai Maruthuvam, National Institute of Siddha, Chennai-47.

[3]Director, National Institute of Siddha, Chennai-47.

Article Received on
14 August 2018,
Revised on 05 Sept. 2018,
Accepted on 26 Sept. 2018,
DOI: 10.20959/wjpr201817-13484

***Corresponding Author**
G. Ridhambaradevi
PG Scholar, Department of Kuzhandhai Maruthuvam, National Institute of Siddha, Chennai-47.

ABSTRACT

Introduction: In Siddha system of medicine, Sirasthambavaatham is a disease which is correlated with Cerebral palsy that was managed by various neuroprotective medicines and external therapies like varmam, thokkanam, nasiyam, otradam with the help of medicated oils and powders. Cerebral palsy is defined as non-progressive disorder of posture and movement often associated with seizure and abnormalities of speech, vision and intellect resulting from a defect or lesion of the developing brain. In National Institute of Siddha, Chennai about 75% of children visited Kuzhanthai maruthuvam OPD on 2013 – 2014 for the management of Sirathambavatham which inspired us to undergo research on that topic. ***Objective*:** The objective of the study is to analyse the efficacy the drug Brahmi nei and Kollu podi thimirthal in the management of Sirasthambavatham (Cerebral palsy). ***Method:*** The pilot study was conducted at the Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram Sanatorium, Chennai-47. Ten children were recruited in the study, those meeting with inclusion and exclusion criteria. They were treated with Brahmi nei twice a day and Kollu podi thimirthal for 28 days. Grading of spasticity was recorded before and after treatment with the help of Modified As worth scale. ***Result*:** There is significant reduction in spasticity of the muscles for all the 10 children included in this study. Paired‘t’ test was performed for determining the statistical significance between before

and after treatment. ***Conclusion:*** It can be concluded that Brahmi nei along with Kollu podi thimirthal (massage) has a definitive action on spasticity in cerebral palsy children.

KEYWORDS: Sirasthambavatham, Cerebral palsy, Special children, Modified Asworth scale, Powder massage, Siddha medicine.

1. INTRODUCTION

Well-being of humans is not designed in heaven but by us and the atmosphere around us. Dramatic life style modifications have introduced lots of harmful effects in the form disease to the society. Health of an individual depends not only on his physical state but also on his mental state. To make the body and the mind in perfect shape, people are in a quest for a natural remedy which will be rendered by our traditional system. The medicines used in Siddha system are prepared from herbals, minerals and animals which will not cause any side effects on proper usage. In the materialized world, people have started to look back at their traditional science in which the natural atmosphere dwells. One such traditional system is Siddha system of medicine which is one of the oldest traditional systems in the world. Our Siddha system stabilizes the mind and improves the well-being of the people. Nowadays not only the body of the human being gets affected by disease but also the Mind due to various activates being followed. So it is very obvious that the society is looking for system which provides holistic approach for curing disease and it will be provided by our Siddha system. Siddha system of medicine, which was preferred and practiced by Siddhar's, who are the forerunners of indigenous medical science. The Siddhar's are persons who practiced meditations, pranayamas and other yogic practices, so that they have attained Siddhi and supernatural powers, and also to cure the sufferings.

According to the siddha system the paediatric life stages are classified into10 stages. They are Kaapu paruvam (0-3Months), sengeerai (3-5 months), Thaal (5-7 months), sappani (7-9 months), mutham (9-11 months), varugai (11-13 months), ambulli (13-15 months) these 7 stages are common for male and female child. After this period siruparai (15-17 months), sitril (17-19 months), siruther (19-21 months) are mentioned for male children and kazhangu (15-17 months), ammanai (17-19 months), oosal (19-21 months) are mentioned for female children. There are many diseases commonly affecting the children from the time of conception to Adolescence. One among them is *Sirakambavatham,*[1] also known as *Sirasthambavatham.* In this disease commonly nervous system is being involved and in later

stages it makes discomfort, disability and inability to the individual. Clinical features of Sirasthambavatham are as follows;

தம்பமாய் உதிரகண்ட நரம்பிற் புக்கித்
தலையோடு சரீரமெலாந் தாக்கிப் புக்கும்
கம்பமாய் காதிரண்டு மிகவுங் கேளா
கையோடு காலிரண்டும் வசக்கே டாகும்
நிம்பமாய் நினைவுதான் கலங்கிக் காணும்
நெடுமூச்சுங் கொட்டாவி நித்திரை யாகும்
சிம்பமாய் தலைநடுங்கிக் கனப்பு முண்டாஞ்
சிரக்கம்ப வாதமென்றே செப்ப லாமே.

- யூகி வைத்திய சிந்தாமணி [1]

Description

In Yugi vaithiya chinthamani the symptoms of Sirasthambavatham are described as follows; Motor disability, postural and coordination disturbances, hearing disorder, contractures, spasticity of the limbs, mental, behavioural disorders, panting respiration, yawning, sleep disorders, delayed neck holding, frequent infection with fever.[1]

Sirasthambavatham is correlated with spastic form of Cerebral palsy (Spastic CP, Spastic Quadriplegia, Spastic Diplegia, and Spastic Hemiplegia). Cerebral palsy is a common cause of childhood disability. It is defined as a group of non-progressive but often changing motor impairment syndromes secondary to lesions or anomalies of brain arising in early stages of its development.[2]

Hence the author is interested to try an effective remedy to the suffering children and evaluate this disease with the modern aspect with the application of basic principles of Siddha and also with the supporting modern parameters.

2. MATERIALS AND METHOD

2.1 Preparation of Experimental Formulations

Brahmi Nei as internal medicine and Black gram (Kollu) powder for podi thimirthal (Powder massage) were identified for this study. Raw drugs to prepare the medicine were purchased

and got authentication from Department of Medicinal Botany, National Institute of Siddha, Chennai.

2.1.1. Brahmi Nei

Brahmi Nei was prepared as described as in the sasthric Siddha literature. Zingiber officinale Linn. (Dried Rhizome), Piper longum Linn. (Dry fruit), Phyllanthus emblica Linn. (Dry fruit), Operculina turpethum Linn. (Dried root), Feronia elephantum Linn.(seed), Induppu, Caryyota urens Linn. (Palm jaggery), Curcuma aromatic Linn. (Rhizome) each 14gms are finely powdered and ground with cow's milk to get a texture of paste. The paste is added to the juice of freshly prepared Bacopa monniera Linn. (5.44kg), Acorus calamus Linn.(1.36 kg), Alpenia galanga Linn.(1.36kg), Cow's milk (5.44kg) and Cow's Ghee,(2.72 kg) in the vessel. Above mixture was heated and filtered after obtaining in the texture of ghee. In this way, Brahmi Nei was prepared.[3]

2.1.2. Kollu Podi

Podi thimirthal[4] is one of the 32 types of external therapies in Siddha literature. In Sirasthambavatham Kollu podi (Black gram powder) was used for podi thimirthal procedure.

2.2. Clinical Study

The present study was a prospective, open label, non-randomized, trail conducted in the Department of Kuzhandhai maruthuvam (Paediatric), National Institute of Siddha, Chennai. It was conducted during 2016 – 2017 after obtaining approval from the Institutional Ethical Committee of National Institute of Siddha (NIS/IEC/10/2016-17/30 - 20.05.2016). The trial has been registered in Clinical trial registry of India (CTRI/2018/04/013283). Before enrolment into the study, children satisfied the inclusion criteria and were willing to participate in the study, signed the informed consent. The parents of children who were enrolled was informed about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable for them.

A total of 10 children of either sex between 2 – 12 years of age, Patients who are diagnosed as Sirasthambavatham (Spastic form of cerebral palsy) were included in the study. Children with seizure, flaccidity, ataxic cerebral palsy and any other serious illness were excluded from this study. Recruited patient were subjected to

- ✓ Day 1 : Oil bath with CHUKKU THYLAM
- ✓ Day 2 : Purgation with MANTHA ENNAI (5 – 10 ml)

- ✓ Day 3 : Rest
- ✓ Day 4- 25: Internal medicine - BRAHMI NEI (Twice a day)
  External therapy - KOLLU PODI THIMIRTHAL (Dialy).

The trial drug was given by the investigator and monitored in the Inpatient department and outpatient department of Kuzhanthai maruthuvam, National Institute of Siddha, chennai. Spasticity was recorded before and after treatment with the help of Modified Asworth scale.

Assessment of Spasticity – Modified Ashworth scale

Several methods have been developed and used to assess spasticity. The most commonly used test in clinical practice is the Ashworth scale.[5] The test is based on the assessment of resistance to passive stretch of muscle group at one non specified velocity in Gastrocnemius and Soleus, Hip adductors, Thigh flexors and extensors, Triceps and biceps, Shoulder girdle and trunk muscles, Forearm flexors and extensors. The Modified Ashworth Scale measures resistance during passive soft tissue stretching and is used as a simple measure of spasticity.[6] Scoring taken from Bohannon and Smith, 1987.

- ✓ (0) - No increase in muscle tone.
- ✓ (1) - Slight increase in tone with a catch and release or minimal resistance at end of ROM when the affected parts is moved in flexion or extension.
- ✓ 1+ (2) - As 2 but with minimal resistance through range following catch.
- ✓ (3) - More marked increase tone through ROM but affected parts easily moved.
- ✓ (4) - Considerable increase in tone, passive movement difficult.
- ✓ (5) - Affected part rigid in flexion or extension.

2.3 Study outcome

Study outcome was defined as Reduction in stiffness of muscles.

2.4 Statistical Analysis

All collected data were entered into MS Excel software using different columns as variables and rows as patients, SPSS software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. The quantity variables were expressed as Mean ± Standard Deviation and qualitative data as percentage. A probability value of <0.05 was considered to indicate as statistical significance. Paired ‘t’ test was performed for determining the significance between before and after treatment. In my study statistical analysis was done for Modified ASWORTH score.

3. RESULTS

- ❖ In this clinical study, 40% of cases were between 2 to 5 years of age, 30% of cases were between 6 to 9 years of age and 30% were under 10 to 12 years of age. (Figure 1)
- ❖ According to sex, 60% of cases were male child and 40% of cases were female child. (Figure 2)
- ❖ Based on the Modified Asworth Scale;
- ✓ Out of 10 children, before treatment one child reported with Grade 1+ who got improved to Grade 0 after treatment.
- ✓ Out of 5 children reported with Grade 3 before treatment, one child improved to Grade 1, 3 of them improved to Grade 1+ and one child got improved to Grade 2 after treatment.
- ✓ Out of 4 children reported with Grade 4 before treatment got improved to Grade 3 after treatment.(Table 1 , Figure 3)
- ❖ Separate score will be given to each grade which is helpful to analyse the result statistically. (Table 1)

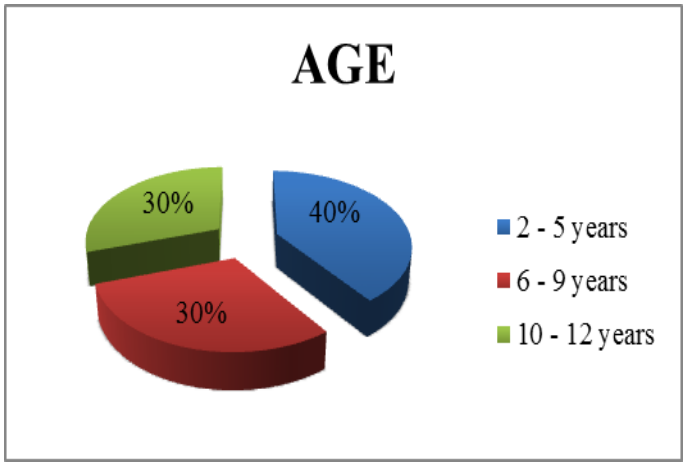

Figure 1: Distribution of age.

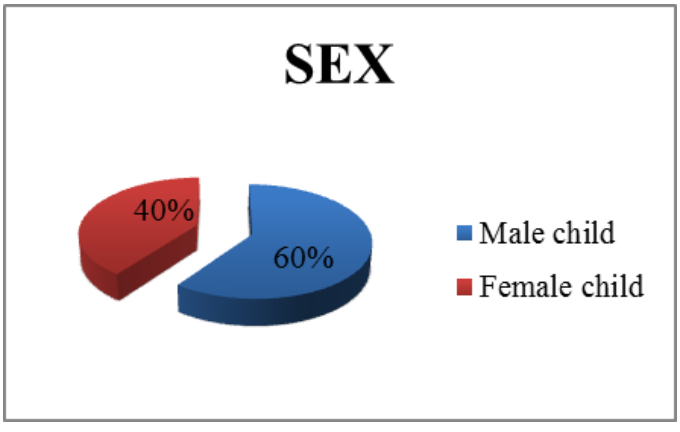

Figure 2: Distribution of sex.

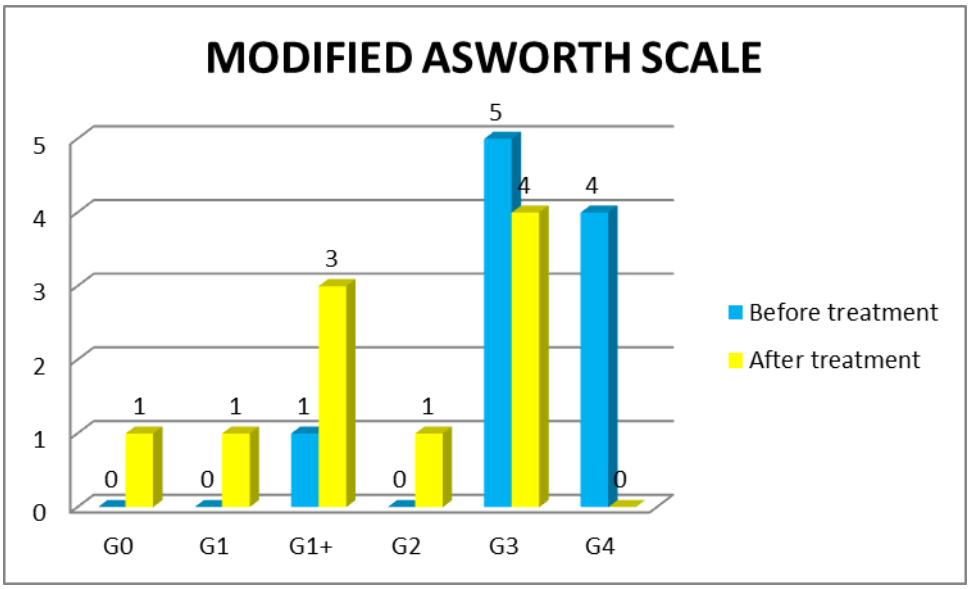

Figure 3: Modified Asworth scale.

Table 1: Patient Details With Clinical Assessment.

Sl.no	IP / OP no	Age / Sex	Socioeconomic status	ASWORTH Scale			
				Before treatment		After treatment	
				Grade	Score	Grade	Score
1	2024	7 / MC	Poor	G3	4	G1+	2
2	2017	8.5 / FC	Middle lower	G3	4	G2	3
3	2042	4.5 / FC	Poor	G3	4	G1	1
4	2079	4.6 / MC	Middle upper	G4	5	G3	4
5	2074	5 / MC	Poor	G3	4	G1+	2
6	2081	12 / MC	Poor	G4	5	G3	4
7	2105	12 / MC	Middle upper	G4	5	G3	4
8	2092	7 / FC	Middle lower	G1+	2	G0	0
9	2184	12 / FC	Middle lower	G4	5	G3	4
10	I96961	3 / MC	Middle lower	G3	4	G1+	2

Paired Sample Statistics

Modified ASWORTH Score

Table 2: Distribution of Mean and Standard Deviation of before and after treatment is as follows.

Modified ASWORTH Score	Mean ± Standard Deviation	t Value	p Value
Before treatment	4.2 ± 0.91	7.3	P < 0.0001
After treatment	2.6 ± 1.4		

The Mean Standard Deviation of Modified ASWORTH Score before and after treatment was 4.2 ± 0.91 and 2.6 ± 1.4 respectively which is **statistically significant (p < 0.0001)**.

The analysis reveals that there is 38% reduction in spasticity of cerebral palsy children when compared to before treatment.

4. DISCUSSION

In this study we assessed the drug Brahmi nei and Kollu podi thimirthal in Cerebral palsy child on the level of spasticity by Modified Asworth scale. Based on the result of the study there is a significant reduction in spasticity of the muscles for all the 10 children included in this study. Also the statistical analysis reveals that there is 38% reduction in spasticity of cerebral palsy children when compared to before treatment with significant p value ($p < 0.0001$).

As per Siddha literature, Vatham acts as the king governing all the vital functions of the body. It's the humour that owes its importance to the creature of the life, next come the Pitham responsible for the existence of life, and Kabham brings the end to the life. When Vatham the force of creation itself get deranged at birth, Pitham and Kapham also get deranged which is reflected as Sirakambavatham. The trial drug is aimed to normalize the Vatham, which in turn stabilises the decreased pitham and normalize the increased kapham thus bringing the three humours static.

Brahmi nei is chosen for this trial because, the cognition facilitating activity of Brahmi extract is attributed to saponins, Bacoside A and Bacoside B which are effective in much lower doses in various models studied included tests for conditioned taste aversion and conditioned shock avoidance.[7][8] Laboratory studies on rats indicate that extracts of Brahmi improve memory capacity. Some studies in mice suggest that ingestion of Bacopa for a 12 week period can significantly improve cognitive ability by accelerating the rate of learning and enhanced memory.[9] The triterpenoid, saponins and their bacosides are responsible for increase the muscle tone through enhance nerve impulse transmission.[10] Powder massage with Kollu podi which soothe the sensory nerve endings, produce a hyperaemic effect causing the arterioles dilate in musculature and reduces stiffness.[11]

5. CONCLUSION

In 28 days of treatment there was 38% of reduction in spasticity statistically which is truly a good progress. Hence it can be concluded that Brahmi Nei along with Kollu podi thimirthal (massage) has a definitive action on spasticity in cerebral palsy children and helping the child to attain his potential and lead an independent life. The effects of internal and external

therapies may be due to individual drugs' multipronged action. Further study is required for scientific validation to prove its clinical efficacy in multicentre clinical study.

6. REFERENCES

1. Kuppusamy.K.N. Siddha Maruthuvam Pothu. Published by Indian System of Medicine and Homeopathy. 2012; 599.
2. Parthasarathy.A. IAP Textbook of Pediatrics. Published by Jaypee Brothers Medical Publishers (P) Ltd. 4th edition. 2009.
3. Kuppusamy.K.N, Uthamaraayan.K.S. Siddha Vaithiya Thirattu. Published by Indian System of Medicine and Homeopathy. 2009.
4. Thirunarayanan.T, Sudha.R. External therapies of Siddha. Published by Centre for traditional medicine and research. 251.
5. Ashworth B. Preliminary trial of carisoprodol in multiple sclerosis. Practitioner 1964; 192: 540542.
6. Ansari, NN; Naghdi, S; Arab, TK; Jalaie, S. "The interrater and intrarater reliability of the Modified Ashworth Scale in the assessment of muscle spasticity: limb and muscle group effect". Neuro Rehabilitation. 2008; 23 3): 231–7. PMID 18560139.
7. Kirtikar KR, Basu BD. Indian Medicinal Plants part II. Allahabad. Indian press, 1918; 930.
8. Warrier PK, Nambiar VPK. Indian Medicinal Plants. Orient Longman, Chennai, India. 1996; 235-239.
9. Rameshwari R. et al, Pharmacological actions of Bacopa monnieri - A review. International Journal of Pharmacy and Industrial Research, 2013; 3(02): [158 – 167].
10. Singh HK, Dhawan BN Neuropsychopharmacological effects of the Ayurvedic nootropic Bacopa monniera Linn (Brahmi). Indian J. Pharmachol, 1997; 29: S359– S365.
11. Shailaja U, Rao PN, Arun Raj GR. Clinical study on the efficacy of Samvardhana Ghrita orally and by Matrabasti in motor disabilities of Cerebral Palsy in children. Int J Res Ayurveda Pharm, 2013; 4: 373-7.