



**IJAYUSH**  
*International Journal of AYUSH*  
AYURVEDA, YOGA, UNANI, SIDDHA AND HOMEOPATHY  
<http://internationaljournal.org.in/journal/index.php/ijayush/>

International Journal  
Panacea  
Research library  
ISSN: 2349 7025

Original Research Article

Volume 9 Issue 4

Oct – Dec 2020

## CLINICAL EVALUATION OF THE SIDDHA MEDICINE ALONG WITH PODITHIMIRTHAL THERAPEUTIC MANAGEMENT IN CEREBRAL PALSY CHILDREN

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### ABSTRACT:

Cerebral refers to the cerebrum – a major portion of human brain, which is the affected area of the brain in this disease condition and Palsy means paralysis which refers to weakness. Thus CP is defined as a disorder of movement and posture due to non-progressive damage to the developing brain. In our siddha classical pediatric book, the symptoms of Siravatham are nearly correlated with Cerebral palsy. The prevalence of cerebral palsy is estimated to be 1.5-3 per 1000 live births. CP Childrens reporting at Dep of Kuzhandhai maruthuvam OPD of Ayothidoss pandithar hospital, National institute of Siddha were taken as sample for this study. The total sample size was 30. Treated with internal medicine Kurunthotti Kudineer and external Medicated powder massage (Kollu podithimirthal), Followed by Vasavu ennai massage (Thokkanam), Total treatment period was 90 days. Clinical assessment was recorded on 0<sup>th</sup> day and followed by every 30<sup>th</sup> days by using assessment Scales. Finally, it can be concluded that internal medicine along with external therapy has a clinical efficacy on spasticity in cerebral palsy children.

**Keywords:** Cerebral palsy, Siravatham, Kurunthotti Kudineer, Kollu Podithimirthal, Vasavu ennai thokkanam.

## 1. INTRODUCTION

Siddha system of medicine is vast ocean of internal and external medicines. In Siddha, diagnosis is based on three humours. In our siddha classical pediatric book, the definition for *Siravatham* has been described as “Siravatham Enbathu Thalai Nadukkam, Kaium Kaalum Asaithidathu, Nadakka Siramam, Mulai Unnathu”<sup>(1)</sup>. The symptoms of Siravatham are nearly co-related with Cerebral palsy<sup>(2)</sup>. The prevalence of cerebral palsy is estimated to be 1.5-3 per 1000 live births<sup>(3)</sup>. About all, spastic cerebral palsy is common in children and its range is 61%. Oral Baclofen Botulinum toxin injections are widely used for cerebral palsy. Not all patients benefit from this treatment. However, this drug was shown to have undesirable other effects such as sedation, respiration problems and muscular weakness, dry mouth and hallucinations. A meta-analysis concluded that effect of oral antispastic drugs is small and evaluation of the effect on children quality of life is lacking from the studies.

It is in the context that I have undertaken a review of the Siddha formulation which could help management of CP. There has been much discussion about the role of Siddha System of Medicine in the evaluation, management and treatment of Cerebral Palsy children. The purpose of this project is to develop recommendations on “best practices” related primarily to evaluate Siddha methodologies and medicines. Different treatment modalities can improve the quality of life to the disabled children and these can include for reduced spasticity (muscle tone). The external therapies such as Thokkanam<sup>(4)</sup> and Podithimirthal<sup>(5)</sup> are to reduce the spasticity of muscle.

Thus, the aim and objectives of the present study were to test the efficacy of the Siddha medicines/methodologies in cerebral palsy children. The drugs chosen for this dissertation includes Kurunthotti Kudineer<sup>(6)</sup> as Internal medicine, Kollu Podithimirthal<sup>(5)</sup> (Powder Massage) followed by Vasuvu Ennai<sup>(7)</sup> Thokkanam (Oil Massage) therapy as external, all of which have been used in the Siddha system of medicine, either singly or in various combination. From those, the author has selected the above medicines to study its safety and efficacy and hopes it will give fruitful results.

## 2. Materials and Methods:

Kurunthotti Kudineer as internal medicine and Kollu Podithimirthal followed by Vasavu Ennai thokkanam (Massage) external was identified for this study. Raw drugs to prepare the products were purchased from the market and fresh plants were collected from wild sources. The raw materials have got authentication from Department of Medicinal Botany, National Institute of Siddha and Chennai. Purification of raw drugs and preparation of trial drug was done at Gunapadam Laboratory, Department of Gunapadam, NIS Chennai.

### 2.1 Internal medicine (Kurunthotti Kudineer):

S.no	Name	Botanical name	Part used	Quantity
1	Kurunthotti veer	Sida Rhomphoidus Linn <sup>(8)</sup>	Root	20.4 gm
2	Thazhuthazhai veer	Clerodendrum Phlomidis Linn <sup>(8)</sup>	Root	10.2 gm
3	Mazhil	Mimusop Elengi Linn <sup>(8)</sup>	Flower	20.4 gm
4	Naagaram	Zingiber officinalae Linn <sup>(8)</sup>	Dried Rhisome	5.1 gm
5	Maruvu	Majorana hortensis Linn <sup>(8)</sup>	Full plant	15.3 gm
6	Devatharam	Cedrus Deodara Linn <sup>(8)</sup>	Wood	10.2 gm

**Table 1**

### Purification Kurunthotti Kudineer raw drugs<sup>(9)</sup>:

Raw drugs are purified as mentioned in Sikitcha Ratna Deepam Sarakku Suthi Muraigal.

### Preparation of Kurunthotti Kudineer:

All purified drugs are coarsely powdered and kept in a clean glass container. The prepared medicine also authenticated by the concerned head of the department for its completeness.

**Dosage :** 2 to 4 years - 15 ml (bds), 5 to 7 years - 20 ml (bds)

### **Indication:**

Kurunthotti Kudineer pacifies the aggravated Vathadosha [Siravatham] which was given to these Childrens.

### **2.2 External Medicine I- Kollu Podithimirthal**

**Karuppu Kollu** – *Macrotyloma uniflorum* are

Ingredients mentioned above are made as a coarse powder.

### **2.3 External medicine II- Vasavu ennai**

Take 1.3 litre (1Padi) of castor oil, gingelly oil, cows' ghee in a bronze vessel and add (1Padi) lemon juice keep it under sunlight and stir. Take 50 gm of yellow wax get into small pieces, 30 gm powder of vellai kungiliyam (*Shorea Rubesta*) is melted in the container and mixed with content in bronze vessel and well grinded kept under the sunlight. Water dried completely after preserve in container.

### **2.4 Clinical Study:**

Our National Institute of Siddha OPD, majority of cases are approaching Kuzhandhai Maruthuvam department daily with the Symptoms of Siravatham. Hence it was proposed to study about the disease. A Protocol was prepared and submitted before IEC of National Institute of Siddha. The IEC approval was obtained No: NIS/IEC/2016/11-23/14-10-2016. The trial was registered in Clinical trial Registry of India with Reg. No. CTRI/ 2018/04/ 013322.

Children with spastic reporting at pediatric OPD of Ayothidoss pandithar hospital, National institute of Siddha were taken as sample for this study. The study was conducted during the period of January 2016 to December 2018. More than 100 children reporting with symptoms of cerebral palsy were screened during the study period. Children of either sex between the age group of 2 to 7 years, who were diagnosed as spastic cerebral palsy, were include in this study. The total sample size was 30. Other type of cerebral palsies was excluded from the study. Parents of the children those who enrolled were informed about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them. Signed the informed consent obtained. Treated with internal medicine Kurunthotti Kudineer (Medicated herbal decoction) and external medicated powder massage (Kollu podithimirthal), Followed by Vasavu ennai massage

(Thokkanam), Total treatment period was 90 days. Clinical assessment was recorded on 0<sup>th</sup> day and followed by every 30th days by using assessment Scales.

### Medications/Methodologies, Dose and Procedure for clinical trial

S.No	Medicine/Methodology	Dose	Procedure
1.	Kurunthotti Kudineer Internal (Twice a Day)	2yrs to 4 yrs - 15 ml 5yrs to 7yrs - 20 ml	Oral Administration
2.	Kollu Podithimirthal - External (Once a Day)- 45 days		
	Followed by		
3.	Vasvu Ennai Thokkanam - External (Once a Day)- 45 days. Procedure as per the Siddha literature external therapy.		

Table 2

### 2.6 Clinical assessment Parameters:

The assessment was done based on improvement in-

1. **For Muscle Spasticity** - Modified Ashworth Scale (MAS) <sup>(10)</sup>,  
Modified Tardieu Scale (MTS) <sup>(10)</sup>.
2. **For Motor Function** - Gross Motor Function Classification System  
For cerebral palsy (GMFCS) <sup>(11)</sup>,
3. **For Muscle Power** – MRCG <sup>(12)</sup> Scale for Muscle Power.
4. **For Gait analysis:** Dynamic Gait Index (DGI) <sup>(13)</sup>
5. **For Posture Assessment:** Posture Assessment Scale (PAS) <sup>(14)</sup>
6. **For Functional Performance:** Disability Assessment Scale (DAS) <sup>(15)</sup>.

### 3. RESULTS AND OBSERVATIONS:

30 Patients with confirmed diagnosis of with satisfying the inclusion criteria were enrolled after obtaining written informed consent and were to receive Kurunthotti Kudineer with External therapy Kollu podithimirthal and Vasavu ennai massage.

The criteria were family history, sex predominance, age distribution, occupation, dietary habits and incidence of the disease with reference to thinai, seasonal variation, clinical manifestations and assessment of the improvement in the prognosis of the disease with the trial drug. Total treatment period was 90 days. Clinical assessments were recorded on 0<sup>th</sup> day and followed by every 30<sup>th</sup> days.

The major objective of the work described in this study was to elucidate combination of internal medicine along with external therapies such as routine OPD&IPD advice in children. In clinical analysis we observed motor function like spasticity, muscle tone, Gross motor function analysis, and Gait analysis showed significant improvement in childrens. But the results had shown significantly differed each other. However, children had shown significant improvement in all clinical parameters in children.

**Table-1 Effect of Treatment on Clinical Assessment Criteria**

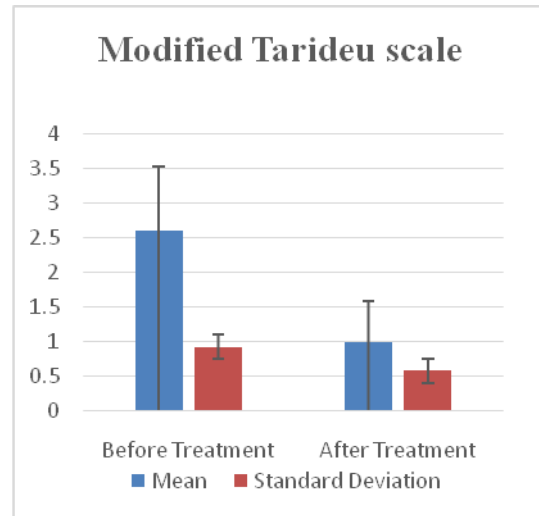
Scales	MAS	MTS	MRC	GMFCS	DAS	PAS	DGI	Total
Value	Mean Score $\pm$ Standard Deviation							
<b>Before Treatment</b>	2.60 $\pm$ 1.003	2.60 $\pm$ 1.003	3.20 $\pm$ 1.349	3.20 $\pm$ 1.349	2.433 $\pm$ 0.681	3.20 $\pm$ 1.349	2.433 $\pm$ 0.681	17.06 $\pm$ 4.848
<b>After Treatment</b>	0.93 $\pm$ 0.583	0.93 $\pm$ 0.583	1.333 $\pm$ 0.994	1.333 $\pm$ 0.994	1.133 $\pm$ 0.568	1.333 $\pm$ 0.994	1.133 $\pm$ 0.568	10.73 $\pm$ 3.453

\*\* Highly significant

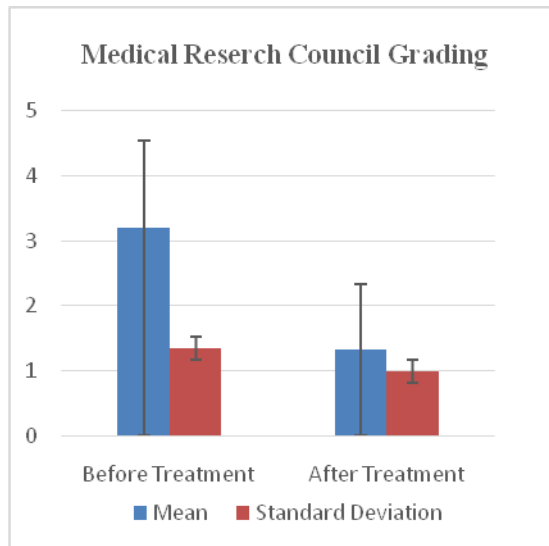
Statistical analysis reveals that there has been a highly significant ( $P < 0.0001$ ) reduction in MAS, MTS, MRCC, GMFCS, PAS, DGI, DAS scales after treatment indicating the improvement in children doing their daily activities.



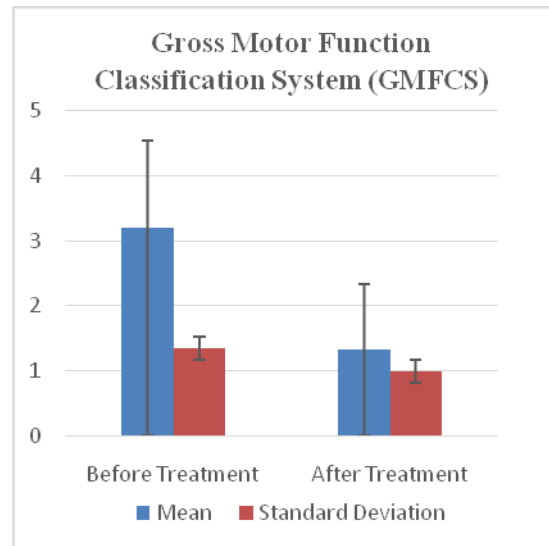
**Fig1** MAS for spasticity for UL and LL has shown highly significant ( $p < 0.0001$ ).



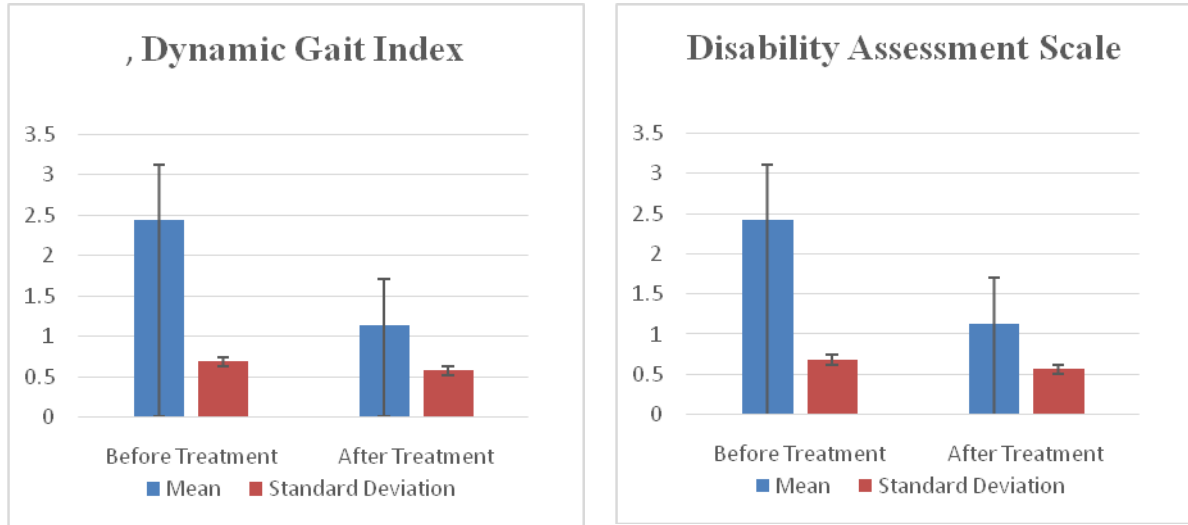
**Fig2** MTS for spasticity for UL and LL has shown highly significant ( $p < 0.0001$ ).



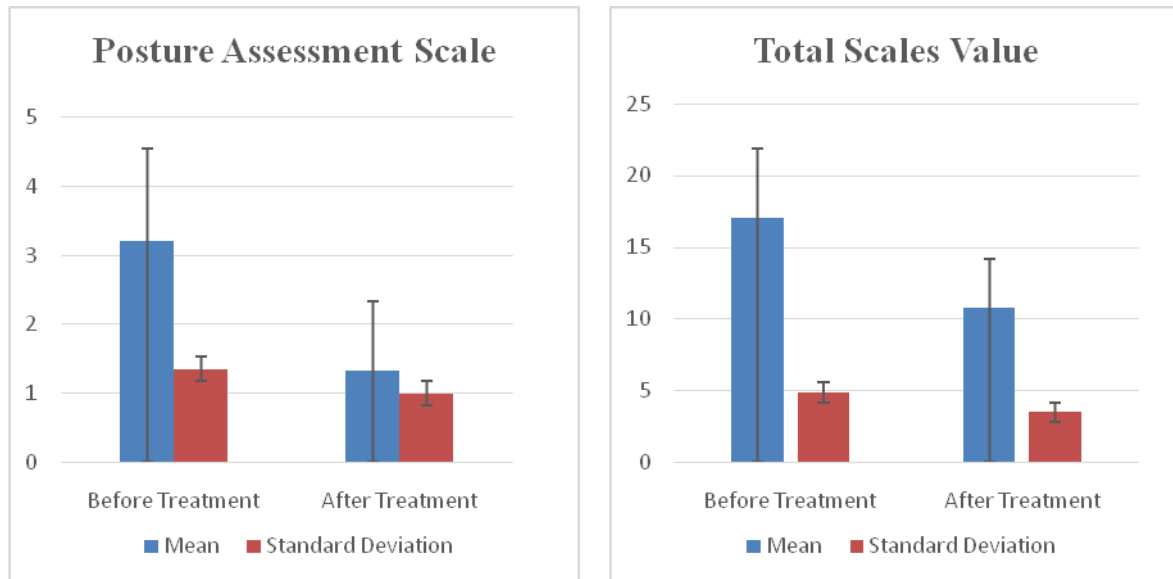
**Fig 3** MRC scale for muscle power for all limbs has shown significant results ( $p < 0.0001$ ).



**Fig4** (GMFCS) scale for motor function all Limbs has shown significant results ( $p < 0.0001$ ).



**Fig5** DGI scale for gait analysis for Lower limbs **Fig6** DAS scale for Functional Performance has shown highly significant ( $p < 0.0001$ ). has shown highly significant ( $p < 0.0001$ ).



**Fig7** PAS scale for Functional Performance has shown highly significant ( $p < 0.0001$ ).

**Fig 8** Total scale for Functional Performance has shown highly significant ( $p < 0.0001$ ).

**0<sup>th</sup> Day**



**Fig 9: Came with difficult to Sit, Stand, Walk Without support. Lying in bed only.**

**30<sup>th</sup> Day**



**Fig 10: After Treatment Stand with support.**

**60<sup>th</sup> Day**



**Fig 11: After 60 days treatment stand without support.**

**90<sup>th</sup> Day**



**Fig 11: After 90 days treatment sit without support.**

#### 4. DISCUSSION:

“Siravatham” is a functional Cerebral palsy. It is defined as persistent but not unchanging disorder of movement and posture due to a defect or lesion of the developing brain. In our Siddha classical pediatric book, the definition for Siravatham has been described as “Siravatham enbathu thalai nadukkam, kaium kaalum asaithidathu, nadakka siramam, mulai unnathu”. The symptoms of Siravatham are nearly co-related with Cerebral palsy. The prevalence of cerebral palsy is estimated to be 1.5-3 per 1000 live births.

However, modern drugs can be said to partially fulfil desirable requirements in some extent.

Oral Baclofen, Botulinum toxin injections are widely used for cerebral palsy. Not all patients benefit from this treatment. However, this drug was shown to have undesirable other effects such as sedation, respiration problems and muscular weakness, dry mouth and hallucinations.

Siddha literature suggested the use of compositions such as Kurunthotti Kudineer, Kollu Podithimirthal and Vasavu ennai Thokkanam (Massage) external therapies. The history of usage of these formulations and procedures are very old. However, combinations of internal and external therapies have been reported successfully. In this view, the study was undertaken to evaluate the combined therapy for the management of cerebral palsy. This study made quantitative measure of different clinical parameters. Efforts have been made to reduce the Spasticity, Muscle tone, stiffness in the joints. Through the use of Siddha medicines in cerebral palsy children. The outcomes of the three treatments were compared at intervals of up to 90 days.

Additionally, analytical standardization, Acute and 14 days repeated oral toxicity studies of internal medicine Kurunthotti Kudineer were also been studied. With these above objectives, a detailed study plan was undertaken as detailed earlier with materials and methods described.

Kurunthotti Kudineer pacifies the aggravated vatha dosha which was given to these patients for 90 days. Ephedrine which is the main alkaloid present in Sida Rhomphoidus strengthens and tones the muscles and acts as energy enhancer<sup>(16)</sup>. Thazhuthazhai is

indicated for Vatha diseases<sup>(17)</sup>. Traditionally the heartwood of *Cedrus deodara* plant was used to enhance cerebral function, balance the mind, body connection, nervous system and strengthen the brain. It was reported to possess CNS depressant and neuroleptic activity<sup>(18)</sup>.

*Mimusops elengi* is effect of alcoholic extract of flower was evaluated for congestive enhancing activity, Tonic, astringent which cures biliousness, diseases of the gums and teeth<sup>(19)</sup>. *Zingiberine officinale* is indicated for Vatha diseases<sup>(20)</sup>, Some active components of ginger are reported to stimulate digestion, absorption, relieve constipation and flatulence by increasing muscular activity in the digestive tract<sup>(21)</sup>. Linalool, Limonene which is the main alkaloid present in *Majorana hortensis* strengthens and tones the muscles<sup>(22)</sup>.

Kollu podithimirthal which is given to these children pacified the aggravated Kaba dosha. Horse gram powder improves mobility of joints and reduces spasticity. Massage with Vasavu ennai which soothe the sensory nerve endings, they produce a hyper emic effect causing the arterioles dilate in musculature and reduce stiffness. Experimental period was 90 days and the clinical parameters such as spasticity, muscle tone; stiffness in the joints and to improve the gait was recorded 0<sup>th</sup> day and followed by every 30<sup>th</sup> day. Subsequently, all children were examined by the physician at every visit and every day during the trial. Use of any other therapy that does not interfere with the study drug will also be permitted. Patients were allowed to continue with their ongoing lifestyle and diet. Information about study subjects were kept confidential and managed. Statistical analysis reveals that there has been a highly significant ( $P < 0.0001$ ) reduction in MAS, MTS, MRCC, GMFCS, PAS, DGI, DAS scale after treatment indicating the improvement in children doing their daily activities. Statistical analysis reveals that there has been a significant reduction in total scales after treatment indicating the improvement in children doing their daily activities.

## 5. CONCLUSION:

In Siddha literature CP is under the Vatha disease therefore, the therapeutic management is Kurunthotti kudineer (Internal medicine), Kollu podithimirthal and Vasavu ennai massage (Thokkanam) massaging. The trial drug was treated to the children. Kurunthotti Kudineer

primary use is to enhance cognitive function. Research has been focused on the mechanism behind these properties. Kollu Podithimirthal which is given to these Children is for pacifying the aggravated Kaba dosha. Podithimirthal with horse gram powder improves mobility of joints and reduces spasticity, Massage with Vasavu ennai which soothe the sensory nerve endings, they produce a hyperaemic effect causing the arterioles dilate in musculature and reduce stiffness. However, children had shown significant improvement in all clinical parameters in children.

## **6. ACKNOWLEDGEMENTS:**

My sincere thanks to the Director, SRO& HOD & the faculties of Post graduate Kuzhandhai Maruthuvam department, National Institute of Siddha, Tambaram Sanatorium, Chennai-47.

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