AYU

Clinical Research

Clinical study on the efficacy of *Chandra Kalka* with *Mahadalu Anupanaya* in the management of *Pakshaghata* (Hemiplegia)

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Abstract

Hemiplegia is a highly prevalent disease and can be correlated with *Pakshaghata*, a disease described in *Ayurveda*. In Sri-Lankan traditional system of medicine, *Chandra Kalka* with *Mahadalu Anupanaya* are used successfully in the management of early stage of *Pakshaghata* and mentioned in *Vatika Prakaranaya*, a book on traditional medicine. So far, no scientific studies have been performed to evaluate the efficacy of *Chandra Kalka* with *Mahadalu Anupanaya*. This study was conducted at Kurunegala Ayurvedic Base Hospital, Sri-Lanka. Thirty patients were selected and randomly divided into two groups. The first group consisted of twenty five patients and treated with one pill of (250 mg) *Chandra Kalka* with 40 ml of *Mahadalu Anupanaya* three times a day for fourteen days as an internal therapy. Second group consisted of five patients who were treated with placebo in single blind method. The response to the treatment was recorded and therapeutic effect was evaluated through symptomatic relief of the patients. In the group of patients treated with the above drugs, statistically significant reduction was observed in symptoms such as slurring of speech, swallowing difficulties, fasciculation of tongue, and mouth deviation. In view of this observation and results obtained in this study, it is concluded that the above drug is a very effective traditional preparation that could be used in early stage of management of *Pakshaghata*, providing speedily and positive effects with a powerful action in controlling symptoms of *Pakshaghata*.

Key words: Hemiplegia, *Mahadalu anupanaya*, *Chandra Kalka*, *Pakshaghata*

Introduction

The term *Pakshaghata* literally means paralysis of one half of the body where "*paksha*" denotes the right half of the body or the left half of the body and "*Aghata*" or "paralysis" denotes the impairment of *Karmendriya*, *Gyanendriyas* and *Manas*.

Gyanendriyas are considered as part of the *Sangnavaha srotas* (sensory system) and *Karmendriya* are considered as part of the *Cheshtavaha srotas* (motor system) and *Manas* is supposed to control and guide the both, *Gyanendriya* and *Karmendriyas*. *Pakshaghata* is a *Vatavyadhi* of *Nanatmaja* variety according to *Charaka*,[1] but *Acharya Sushruta* categorized *Pakshaghata* under *Mahavatavyadhi*.[2] *Vata Dosha* gets vitiated due to the indulgence of various diet and regimen then *Dosha* would

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accumulate in *Rikta Srotas* (vacant channels) in the body and produces *Pakshaghata*. The clinical features are *Vaksanga* (slurring of speech), *Sandhi-Bandha Shaithilya* (weakness of muscles), *Vaktradavakra* (mouth deviation), *Sphoorana* of *Jihva* (fasciculation of the tongue), *Cheshta Nirvuthi* (impairment of motor function), and *Chetanansha* (loss of consciousness).[2] *Pakshaghata* can be correlated with hemiplegia. According to the modern medicine, hemiplegia is a disease with paralysis of one side of the body. The term "hemiplegia" consists of two words "hemi" and "plege". "Hemi" means half and "plege" means a blow, or stroke. Paralysis or palsy literally means to relax, implies a total or partial loss of either motion or sensation or of both in one or more or all parts of the body and also palsy is defined as loss or impairment of voluntary muscular power. Clinical features are described as slurring of speech, mouth deviation, fasciculation of the tongue, swallowing difficulties, abnormal reflexes, and weakness of muscles.[3]

Traditional physicians of Sri-Lanka use *Chandra Kalka* with *Mahadalu Anupanaya* which describes management of early stage of *Pakshaghata* to purify vitiated *Dosha* and expel vitiated *Dosha* accumulated in *Srotas*. *Chandra Kalka* with *Mahadalu*

Anupanaya is one of the traditional treatments used by traditional physicians with success[4] (hemiplega).

Aims and objectives

In management of *Pakshaghata*, traditional physicians of Sri-Lanka use *Chandra Kalka* with *Mahadalu Anupanaya* success. But so far, no scientific studies have been reported on the efficacy of *Chandra Kalka* with *Mahadalu Anupanaya*, hence the present study was carried out to scientifically evaluate the efficacy of *Chandra Kalka* with *Mahadalu Anupanaya* in *Pakshaghata*.

Materials and Methods

Preparation of Trial drugs

Preparation of Chandrakalka

The herbs enlisted in Table 1 were cleaned, dried and ground into coarse powders separately. The 10 g of each of these powders were accurately weighed and mixed with 40 ml of sesame oil and kept for 24 h in a closed container made out of clay. Then this mixture was ground into fine paste by adding 35 ml of sesame oil. Afterwards, this mixture was ground with 75 ml of Bee's honey till it turned into a paste (*Kalka* form). Weight of the final product was 285 g. Pills weighing 250 mg were prepared from this *Kalka*. *Chandra Kalka* pills weighing 250 mg were used in this study as the research drugs [Table 1].

Preparation of Mahadalu Anupanaya

Each ingredient enlisted in Table 2 was pounded separately, mixed together and weighed. The final weight of the mixture was 2400 g. This mixture was divided into three equal parts, each part weighing 800 g. Then three bundles were prepared with mixture using a piece of cotton cloth. These bundles were heated using steam of water on low fire, and removed from steam when the aroma started to emit. Then 15 ml of water was added and squeezed. The final volume of the *Swarasa* (extracted juice) obtained from three bundles was 125 ml. Then 120 ml of *Swarasa* was measured and this volume was used in the research by adding *Anupanaya*. The 1.5 g of paste of *S. album*, paste of kernel of *Strychonos potatorum* (Family: Fabaceae; Sinhala name: *Ingini*), and sugar, 2.5 ml of Bee's honey, juice of *C. aurantium* and breast milk, and 1.25 ml of ghee, were added to the aforesaid extract as *Anupanaya*.

Preparation of internal placebo

Internal placebo was prepared by adding two drops of Green coloring (Delmege brand ELP) to 120 ml of boiled and cooled water (in proportion).

Table 1: Preparation of *Chandrakalkas*

Local name	Sanskrit name	Botanical name (Latin name)	Family	Part used	Proportion (g)
Higurupiyalli	*Chandramula*	*Hedychium spicatum*	Zingiberaceae	Rhizome	10
Inguru	*Nagara*	*Zingiber officinale*	Zingiberaceae	Rhizome	10
Heenarata	*Rasna*	*Alpinia galanga*	Zingiberaceae	Rhizome	10
Kaladuru ala	*Mustaka*	*Cyperus rotundus*	Raninculaceae	Tuber	10
Kaluduru	*Karave*	*Cumimum cyminum*	Apiaceae	Seed	10
Valagashal	*Vidanga*	*Embellica ribes*	Myrsinaceae	Seed	10
Sududuru	*Jeeraka*	*Nigella sativa*	Raninculaceae	Seed	10
Heenensal	*Pala*	*Elettaria cardamomum*	Zingiberacea	Seed	10
Nelli	*Amalaki*	*Phyllanthus embellica*	Phyllanthaceae	Seeded fruit	10
Shathapushpa	*Madurika*	*Anethem graveolenes*	Apiaceae	Seed	10
Asamodagam	*Ajamoda*	*Trachyspermum roxburghianm*	Umbelliferae	Seed	10
Kothamalli	*Dhanyaka*	*Coriandrum sativum*	Apiaceae	Seed	10
Kelida	*Kutaja*	*Holarrhena antidysenterica*	Apocynaceae	Seed	10
Suvada kottam	*Suvadahota*	*Saussurea lappa*	Asteraceae	Root	10
Sarana mul	*Punarnava*	*Boerhavia diffusa*	Nyctaginaceae	Root	10
Katukarosasana	*Katurohini*	*Picrorrhiza kurrooa*	Scrophulariaceae	Root	10
Athividayam	*Ativisha*	*Aconitum heterophyllum*	Raninculaceae	Root	10
Bulu	*Bibhitaki*	*Terminalia bellirica*	Combretaceae	Pericarp	10
Aralu	*Haritaki*	*Terminalia chebula*	Combretaceae	Pericarp	10
Thippili	*Pippali*	*Piper longum*	Piperaceae	Fruits	10
Valthibbatu	*Kudawulli*	*Solanum trilobatum*	Solanaceae	Fruits	10
Sadikka	*Jathipala*	*Myristica fragrans*	Myristicaceae	Nut meg	10
Vasavasi	*Jathipala*	*Myristica fragrans*	Myristicaceae	Aril	10
Nika	*Nirgundi*	*Vitex negundo*	Verbenaceae	Leaves	10
Upulkolla	*Kamala*	*Nelumbo nucifera*	Nelumbonaceae	Leaves	10
Sandalwood	*Chandana*	*Santalum album*	Santalaceae	Heart wood	10
Valmi	*Madhuyashti*	*Glycyrrihiza glabra*	Fabaceae	Heart wood	10
Devadara	*Suradaru*	*Cedlus deodara*	Pinaceae	Heart wood	10
Karabunati	*Lavanga*	*Syzygium aromaticum*	Myristicaceae	Flower bud	10

Table 2: Preparation of *Mahadalu Anupanaya*

Local name	Sanskrit name	Botanical name	Family	Used part	Proportion (g)
Dhei	*Nimbu*	*Citrus limon*	Rutaceae	Tender leave	240
Orange	-	*Citrus aurantium*	Rutaceae	Tender leave	240
Nika	*Nirgundi*	*Vitex negundo*	Verbenaceae	Tender leave	240
Elabatu	*Bruhati*	*Solanum melongena*	Solanaceae	Tender leave	240
Yakinaran	*Atavejambera*	*Athlantic zelanica*	Rutaceae	Tender leave	240
Heennaran	*Naranga*	*Critus arurantifolia*	Rutaceae	Tender leave	240
Vanapala	*Vasa*	*Adathoda vasica*	Acanthaceae	Tender leave	240
Olida	*Gunja*	*Abrus precatorius*	Fabaceae	Tender leave	240
Kuppamaniya	*Mukthavarsi*	*Acalypha indica*	Euphorbiaceae	Tender leave	240
Kuburu	*Putikaranja*	*Caesalpinia bondue*	Fabaceae	Tender leave	240
Kuburu seed	*Putikaranja*	*Caesalpinia bondue*	Fabaceae	Kernel	240
Garlic	*Rasona*	*Alium sativam*	Amaryllidaceae	Bulb	60

Selection of patients

Thirty patients fulfilling the inclusion criteria were enrolled in this study from Ayurvedic Base Hospital, Kurunegala. Detailed medical history was taken and physical examination was done in detail according to both modern and Ayurvedic clinical methods. Patients of either sex aged less than 75 years, patients who were associated with clinical features of *Sandhi-Bandha Shaithilya* (weakness of muscles), *Vaksanga* (slurring of speech), *Vaktradavakra* (mouth deviation), *Sphoorana* of *Jihva* (fasciculation of the tongue), and swallowing difficulties, the patients who are suffering from disease less than one month were included in this study.

Patients over 75 years of age, patients who were suffering from diabetes mellitus, hypertension, paraplegia (*Adarangaghata*), monoplegia (*Akangaghata*), quadriplegia (*Sarvangaghata*), and the patients who are suffering from hemiplegia more than one month were excluded from the study.

Clinical study

Enrolled patients fulfilling the criteria were randomly divided into two groups. The first group consisted of twenty five patients and treated with one pill of (250 mg) *Chandra Kalkaya* with 40 ml of *Mahadalu Anupanaya* three times a day for 14 days as an internal therapy. Second group consisted of five patients and treated with internal placebo treatment. They were given 40 ml of placebo three times a day for 14 days. The parameters of assessment were essentially based on symptomatic relief and were measured by using a graded scale.

Assessment criteria

The assessment was done on the basis of improvement in signs and symptoms. Assessment of the clinical symptoms was done depending on the severity according to the scoring pattern.

1. *Vaksanga* (slurring of speech)
   Complete *vaksanga* - 3
   Pronouncing with great efforts - 2
   Pronouncing with less efforts - 1
   Normal speech (whistling) - 0
2. *Vaktrardavakra* (mouth deviation)
   Complete *Mukavakrata* - 3
   Half *Mukavakrata* - 2
   Mild *Mukavakrata* - 1
   Normal - 0
3. *Sphurana* (fasciculation of the tongue)

Constant and/or all over the tongue - 3
50% of the tongue - 2
25% of the tongue - 1
No *sphurana* - 0
4. *Bala* (muscle power)
   No contraction (complete paralysis) - 0
   Flicker of contraction - 1
   Active movement when gravity eliminated - 2
   Active movement against gravity and resistance - 3
   Normal - 4
5. Muscle tone
   Decreased (hypotonea) - 0
   Normal - 1
   Increased (hypertonia) - 2
6. Reflexes (bicep and knee joint)
   Exaggeration - 3
   Diminish - 2
   Normal - 1
   Absent - 0
7. Swallowing difficulties
   Swallowing liquid only - 3
   Swallowing semi-solid - 2
   Swallowing solid - 1
   Normal - 0

Overall assessment of therapy

Total effect of the therapy was assessed on the following grounds.

Complete remission - More than 75% relief in signs and symptoms

Marked improvement - Between 51% and 75% improvement in signs and symptoms

Improved - Between 25% and 50% achievement

Unchanged - No improvement in signs and symptoms

Statistical analysis

Statistical comparisons were made using Kruskall–Wallis test and *student t* paired test, using the statistical package Minitab 12.1 for windows. *P value* < 0.05 was considered as significant effect.

Observations and Results

In this study, maximum number of patients were belonged to

Table 3: Percentage of symptomatic relief at the end of the treatment

Symptoms	*Mahadalu Anupana* with *Chandra Kalka*				Internal placebo		
	Completely relieved (%)	Partially relieved %		Unchanged (%)	Completely relieved (%)	Partially relieved (%)	Unchanged (%)
		Marked improvement	Improved				
Vaksanga (slurring of speech)	64	20	04	12	00	01	99
Swallowing difficulties	44	34	10	12	00	00	100
Sphoorana of *Jihva* (fasciculation of tongue)	52	20	04	24	00	00	100
Vaktradavakra (mouth deviation)	68	16	04	12	00	01	99
Muscle power (power of arm, forearm, muscles)	20	24	40	16	00	00	100
Muscle power (power of thigh, leg muscles)	16	12	40	32	00	00	100
Exaggeration of knee jerk	00	16	20	64	00	00	100
Exaggeration of bicep reflexes	00	08	20	72	00	00	100
Muscle tone	00	00	15	85	00	00	100

Table 4: Effect of therapy on clinical features (treated group *n* = 25)

Clinical features	Mean score		*t*	*P*
	BT	AT		
Mouth deviation	2.520	0.520	9.61	<0.002
Fasciculation of tongue	1.840	0.680	4.92	<0.040
Swallowing difficulties	2.840	0.720	8.07	<0.003
Slurring of speech	2.040	0.520	9.24	<0.001
Muscle power (power of arm, forearm, muscles)	1.520	2.080	4.30	<0.042
Muscle power (power of thigh, leg muscles)	1.520	2.080	3.93	<0.045
Exaggeration of knee jerk	1.000	0.640	3.67	>0.115
Exaggeration of bicep reflexes	1.000	0.720	3.06	<0.035
Muscle tone	1.000	0.635	3.57	>0.110

Table 5: Overall effect of therapy

Effect	TG group		PG group	
	No. of patients	Percentage	No. of patients	Percentage
Complete remission	04	16	00	00
Marked improvement	14	56	00	00
Improved	07	28	00	00
Unchanged	00	00	00	00

50-60 years of age group. The 70% patients were non-vegetarians. According to this study, it was also revealed that 50% patients were frequently feeling stress (tension), 33% excessive thinkers, and 17% were sorrowful persons. In the group of patients treated with *Mahadalu Anupanaya* with *Chandra Kalka*, statistically significant reduction was observed in symptoms such as slurring of speech, swallowing difficulties, fasciculation of tongue, and mouth deviation. In patients suffering from slurring of speech, 64% patients were completely relieved and the relief is highly statistically significant ($P < 0.001$). In the treated group, 68%-44% patients relieved in symptoms like mouth deviation, swallowing difficulties, and fasciculation of tongue, the effect was statistically significant at the level of $P < 0.002$, $P < 0.003$, and $P < 0.040$ respectively. The 64%-52% patients partially relieved by the symptoms like weakness of muscles of the arm, forearm, thigh and leg and the relief is less significant at the level of $P < 0.042$ and $P < 0.045$ respectively. Though the slight reduction of exaggeration of the knee jerk and muscle

tone were observed, but statistically insignificant. Among the group treated with internal placebo, no statistically significant reduction was noted after treatment [Tables 3-5].

Discussion

The word meaning "*Anupana*" is considered as "a fluid vehicle for medicine". Activity of *Chandra Kalkaya* is activated, or catalyzed, or accelerated by combination of *Anupana*. *Mahadalu Anupana* enchances the action of *Chandra Kalkaya*, the potentiator has its own action similar to that of *Chandra Kalka*. Sri-Lankan traditional physicians are in the opinion of that the combined action of *Chandra Kalka* with *Mahadalu Anupana* is greater than that of single therapies. *Dalu Beheth* (*Swarasa*/ *Anupana*/Vehicals) especially act in the three "*Marma*" (vital organs) of the body. Brain is the one of the three *Marmas* and it was mainly affected in the diseases of *Pakshaghata*.[5]

In Ayurvedic classics, it is mentioned that the *Margavarodha*, *Marmabhighata*, and *Dhatukshaya* lead to the *Pakshaghata*. Further, it is also mentioned the involvement of *Sira Snayu* and *Dhamani* in the pathogenesis of *Pakshaghata*. According to the authentic books, *Avarodha* (obstruction) is usually due to *Kapha* (secretion), or *Aama* (half digested food end product).[6] *Chandra Kalka*

with *Mahadalu Anupana,* the drugs used in this study, have the properties of *Vata-Kapha shamaka, Amapachaka, Srotoshodhaka*; hence these medicines are used in the treatment of *Pakshaghata* by traditional physicians. The main symptoms produced by affecting *Nadi* and *Vata vaha srotas* are slurring of speech, mouth deviation, fasciculation of tongue, and swallowing difficulties, showed 64%, 68%, 52%, 44% relief after the treatment respectively. Ingredients of *Chandra Kalka* and *Mahadalu Anupana* have properties of *Nadi Balakaraka* and *Nadi Uttejaka* (stimulate nerve system). It was observed that the muscle tone and power of the arms and legs were recovered to some extent after the treatment, but it was statistically insignificant. Majority of the ingredients of *Chandra kalka* and *Mahadalu Anupanaya* have the properties of *Srotas Shodhana* (channel purifier) and *Aama Pachana* (to increase digestion). As a result of these properties, vitiated channels become purified when treated with these drugs. In this study, treatment was carried for two weeks, 16% patients had complete remission and 56% showed marked improvement. If this treatment carried on for a longer period, result may be better. In view of these observations and results obtained in this study, it is concluded that *Mahadalu Anupanya* with *Chandra Kalkaya* is a very effective traditional preparation that could be used in management of *Pakshaghata*, providing speedily and positive effects with a powerful action in controlling symptoms of *Pakshaghata.*

Conclusion

From this data, it can be concluded that treated group has provided better relief in most of the signs and symptoms of the disease. Also better relief was observed in slurring of speech, mouth deviation, fasciculation of tongue, and swallowing difficulties, at the significant level. It can be suggested that *Mahadalu Anupana* and *Chandra Kalka* could provide a better treatment modality in management of early stage of *Pakshaghata* (hemiplegia). No adverse effect was found in TG group during clinical study According to the observations and results of this clinical study, it is concluded that *Mahadalu Anupana* and *Chandra Kalka* are very effective traditional Sri-Lankan preparations that could be used in the management of early stage of *Pakshaghata* (hemiplegia).

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