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 the 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 Natamaja variety according to Charaka,[¹] but Acharya Sushruta categorized Pakshaghata under Mahavratavyadhi.[²] Vata Dosha gets vitiated due to the indulgence of various diet and regimen then Dosha would accumulate in Rikta Srotas (vacant channels) in the body and produces Pakshaghata. The clinical features are Vaktsanga (slurring of speech), Sandhi-Bandha Shaithihya (weakness of muscles, Vaktravaktra (mouth deviation), Sphoorana of Jihva (fasciculation of the tongue), Cheshta Nirvuthi (impairment of motor function), and Chetanansha (loss of consciousness). 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]

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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\% (hemiplegia).

**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 Strychnos potatorum (Family: Apocynaceae; 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     | Chhandramula      | 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             |
| Kaladuru          | Karave            | Cuminum cyminum            | Apiaceae        | Seed      | 10             |
| Valagashal        | Vidanga           | Embelica ribes              | Myrsinaceae     | Seed      | 10             |
| Sududuru          | Jeeraka           | Nigella sativa              | Raninculaceae   | Seed      | 10             |
| Heenensal         | Pala              | Elettaria cardamomum        | Zingiberaceae   | Seed      | 10             |
| Nelli             | Amalaki           | Phyllanthus embellica       | Phyllanthaceae  | Seed fruit| 10             |
| Shathapushpa      | Madurika          | Anethem graveolens          | 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 belliaca         | Combretaceae    | Pericarp  | 10             |
| Aralu             | Haritaki          | Terminalia chebula          | Combretaceae    | Pericarp  | 10             |
| Thippili          | Pippali           | Piper longum                | Piperaceae      | Fruits    | 10             |
| Valthbibatuk      | Kudawulli         | Solanum trifolatum         | 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       | Glycyrrhiza glabra          | Fabaceae        | Heart wood| 10             |
| Devadara          | Suradaru          | Cedlus deodora              | Pinaceae        | Heart wood| 10             |
| Karabunati        | Lavanga           | Syzygium aromaticum         | Myristicaceae   | Flower bud| 10             |
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), Vaktrardavakra (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 Anupanaya with Chandra Kalka | Internal placebo |
|-------------------------------|--------------------------------------|-----------------|
|                              | Completely relieved (%) | Partly relieved (%) | Marked improvement (%) | Unchanged (%) | Completely relieved (%) | Partly relieved (%) | Unchanged (%) |
| Vakslanga (slurring of speech) | 64 20 04 | 12 00 01 99 |
| Swallowing difficulties       | 44 34 12 | 00 00 100 |
| Sphoorana of Jihva (fasciculation of tongue) | 52 20 04 | 24 00 00 100 |
| Vakradadavakra (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      | 9.61 | <0.002 |
| Fasciculation of tongue   | 1.840      | 4.92 | <0.040 |
| Swallowing difficulties   | 2.840      | 8.07 | <0.003 |
| Slurring of speech        | 2.040      | 9.24 | <0.001 |
| Muscle power (power of arm, forearm, muscles) | 1.520 | 4.30 | <0.042 |
| Muscle power (power of thigh, leg muscles) | 1.520 | 3.93 | <0.045 |
| Exaggeration of knee jerk | 1.000      | 3.67 | >0.115 |
| Exaggeration of bicep reflexes | 1.000 | 3.06 | <0.035 |
| Muscle tone               | 1.000      | 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 Anupanaya enhances 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 Anupanaya is greater than that of single therapies. Dalu Beheth (Swaras/Anupana/Vehicles) especially act in the three “Murmas” (vital organs) of the body. Brain is the one of the three Murmas and it was mainly affected in the diseases of Pakshaghata.[5]

In Ayurvedic classics, it is mentioned that the Margavarotha, Marmabhighata, and Dhatuskhsaya lead to the Pakshaghata. Further, it is also mentioned the involvement of Sira Snaya and Dhamani in the pathogenesis of Pakshaghata. According to the authentic books, Anuradha (obstruction) is usually due to Kapha (secretion), or Aama (half digested food end product).[6] Chandra Kalka
with Mahadalu Anupanaya, 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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