Clinical Research

A Clinical trial of Sri Lankan traditional decoction of Pitawakka Navaya in treatment of Kaphaja Shirsha Shoola (chronic sinusitis)

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Abstract

Authentic Ayurvedic texts mention eleven types of Shiro Roga (diseases in head). Kaphaja Shirsha Shoola, which occurs due to vitiation of Kapha and Vata Dosha, is one of them. Chronic sinusitis is a chronic inflammation of sinuses. It can be correlated with Kaphaja Shirsha Shoola. Decoction of Pitawakka Navaya consists of nine ingredients. They are Bhoomyamalaka, Haritaki, Bharangi, Chavya, Pippali, Salarka, Guduchi, Shunthi and Maricha. These herbs, which pacify vitiated Vata Dosha and Kapha Dosha, are used by traditional physicians in Sri Lanka to treat Kaphaja Shirsha Shoola (chronic sinusitis). However, no scientific studies have been conducted to evaluate the efficacy of Pitawakka Navaya in treatment of Kaphaja Shirsha Shoola. Hence, this clinical study has been conducted to evaluate its efficacy. Sixty patients suffering from Kaphaja Shirsha Shoola were selected and examined. These patients were randomly divided into two groups of thirty patients each. First group was treated with 120 ml of decoction of Pitawakka Navaya twice a day for fourteen days. The second group was treated with 120 ml of placebo twice a day for fourteen days. After treatment, most of the patients’ symptoms were completely or partially relieved. In less than 10% of patients, some symptoms were unchanged or aggravated. It is observed that traditional decoction Pitawakka Navaya is beneficial for Kaphaja Shirsha Shoola (chronic sinusitis).

Key words: Chronic sinusitis, decoction of Pitawakka Navaya, Kaphaja Shirsha Shoola

Introduction

In authentic Ayurvedic texts, it is mentioned that there are eleven types of Shiro Roga (diseases in head). Kaphaja Shirsha Shoola is a disease which occurs in the Urdhjavajathrugatha Pradesha (area above the clavicle). The clinical features of Kaphaja Shirsha Shoola are Guru (heaviness of the head), Prathishtabdha (fullness of head), Himam (coldness of the head), Shiroadhibita (headache), Shuna Akshikuta (swelling around the eyes), Shuna Vadanam (swelling in the face), Shuna Nasa (swelling of the nose), Suptha (numbness), Tandra (drowsiness), Alasya (lassitude), Arochaka (anorexia), Sthimita (rigidity in head), Shiranispandatha (veins not pulsating), Karn Kandu (itching inside the ears), Ruknanda Ahanya Adikacanishi (mild pain during daytime and severe at night) and Anthak Kaphalipatham (feeling of having a coating of phlegm inside the head).[1-3]

Kaphaja Shirsha Shoola can be correlated with chronic sinusitis. Chronic sinusitis is one of the most commonly diagnosed chronic illnesses in the United States, affecting 30 million to 40 million Americans each year. When sinusitis lasts longer than twelve weeks, then this condition is known as chronic sinusitis.

Chronically inflammation of the sinus mucosa is a common ailment in which the maxillary sinus is mostly involved. Chronic sinusitis is usually the result of incompletely resolved acute sinusitis. Clinical features of chronic sinusitis are nasal obstruction, nasal discharge, tendency to clear one’s throat frequently, abnormalities of smell, epistaxis, dryness of throat, sore throat, headache, sense of tiredness, low grade fever, feeling of being unwell, gastro intestinal discomfort, chronic bronchitis, excoriation of skin of nasal mucosa and tenderness of the sinuses.[7]

Pitawakka Navaya is a decoction used by Sri Lankan traditional physicians in treatment of Kaphaja Shirsha Shoola (chronic sinusitis). This name was given because this decoction contains nine ingredients, namely Bhoomyamalaka, Haritaki, Bharangi, Chavya, Salarka, Pippali, Guduchi, Shunthi, and Maricha. But so far no scientific studies have been conducted to evaluate the efficacy of Pitawakka Navaya in Kaphaja Shirsha Shoola (chronic sinusitis). Hence, it was decided to conduct this clinical study in order to evaluate its efficacy.
Table 1: Percentage of symptomatic relief during treatment of *Kaphaja Shirsha Shoola* (chronic sinusitis) with decoction of *Pitawakka Navaya*

| Symptoms                                      | Control group | Treated group |
|-----------------------------------------------|---------------|---------------|
|                                               | Partial relief (%) | Complete relief (%) | Unchanged (%) | Agg erad (%) | Partial relief (%) | Complete relief (%) | Unchanged (%) | Agg erad (%) |
| Guru (heaviness of head)                      | 44.00         | 38             | 00            | 62          | 00            | 53.33       | 43.70        | 37.5         | 12.5         | 6.3          |
| Prathishtabdha (fullness of the head)         | 30.66         | 40             | 00            | 60          | 00            | 36.66       | 27.3         | 45.4         | 27.3         | 00           |
| Shiroabhitapa (headache)                      | 43.33         | 25             | 00            | 65          | 10            | 56.66       | 23.52        | 41.2         | 23.52        | 11.8         |
| Shuna Akshikuta (swelling around the eyes)    | 33            | 00             | 15            | 85          | 00            | 26.66       | 37.5         | 37.5         | 25           | 00           |
| Shuna Vadanum (swelling in the face)          | 13            | 00             | 15            | 85          | 00            | 16.66       | 40.00        | 60.00        | 00           | 00           |
| Shuna Nasa (swelling of the nose)             | 33            | 00             | 15            | 85          | 00            | 26.66       | 37.5         | 37.5         | 25           | 00           |
| Tanda (drowsiness)                            | 44.00         | 22             | 00            | 78          | 00            | 53.33       | 31.25        | 31.25        | 37.5         | 00           |
| Alasya (lassitude)                            | 37.77         | 20             | 10            | 70          | 00            | 43.33       | 46.1         | 30.8         | 23.1         | 00           |
| Arochaka (anorexia)                           | 23            | 15             | 10            | 70          | 00            | 16.66       | 60.00        | 40.00        | 00           | 00           |
| Sthimitha (rigidity of head)                  | 30            | 00             | 10            | 90          | 00            | 23.33       | 42.85        | 42.85        | 14.3         | 00           |
| Karna Kandu (itching inside the ears)         | 35.88         | 15             | 15            | 70          | 00            | 33.33       | 40.00        | 50.00        | 10.00        | 00           |
| Ruknanda Ahanaya Adikanishi (Mild pain during day and severe pain at night) | 30            | 5              | 00            | 90          | 05            | 23.33       | 00           | 28.6         | 57.1         | 14.3         |
| Anthak Kaphaliptham (feeling of having a coating of phlegm inside the head) | 20.44         | 10             | 00            | 90          | 00            | 23.33       | 28.6         | 71.4         | 00           | 00           |
| Nasal obstruction                             | 36.77         | 10             | 00            | 90          | 00            | 50.00       | 40.00        | 53.33        | 6.66         | 00           |
| Nasal discharge                               | 50.25         | 00             | 00            | 100         | 00            | 56.66       | 35.3         | 47.00        | 11.8         | 5.9          |
| Tendency to clear one’s throat frequently     | 16.22         | 20             | 00            | 80          | 00            | 56.66       | 18.2         | 54.5         | 27.3         | 00           |
| Abnormalities of smell                        | 15.12         | 00             | 00            | 100         | 00            | 16.66       | 40.00        | 60.00        | 00           | 00           |
| Epistaxis                                     | 8.55          | 00             | 00            | 100         | 00            | 10.00       | 00           | 33.33        | 66.66        | 00           |
| Dryness of throat                             | 40.00         | 12             | 10            | 78          | 00            | 43.33       | 15.4         | 23.1         | 61.5         | 00           |
| Sore throat                                   | 20.22         | 20             | 00            | 80          | 00            | 26.66       | 12.5         | 50.00        | 37.5         | 00           |
| Excoriation of skin of nasal vestibule        | 35.22         | 10             | 00            | 90          | 00            | 36.66       | 36.4         | 45.41        | 9.1          | 9.1          |
| Low grade fever                               | 30.66         | 20             | 00            | 80          | 00            | 10.00       | 33.3          | 66.7          | 00           | 00           |
| Feeling of being unwell                       | 20.44         | 15             | 20            | 65          | 00            | 23.33       | 28.6         | 71.4         | 00           | 00           |
| Gastro intestinal discomfort                  | 7.90          | 15             | 00            | 85          | 00            | 10.00       | 00           | 100.00       | 00           | 00           |
| Chronic bronchitis                            | 9.45          | 00             | 00            | 90          | 10            | 10.00       | 75.00        | 25.00        | 00           | 00           |
| Tenderness of the sinus                       | 20.99         | 00             | 00            | 100         | 00            | 13.33       | 25.00        | 75.00        | 00           | 00           |

Partial relief – Symptoms of the patient is reduced to some extent but not complete; Complete relief - It means symptoms completely disappeared after treatment; Aggravated - Symptoms were aggravated after treatment; Unchanged – Symptoms did not change after treatment
Materials and Methods

Clinical studies
Sixty patients suffering from Kaphaja Shirsha Shoola (chronic sinusitis) were selected from the Ayurveda Teaching Hospital, Borella, Sri Lanka and Bandaranayake Memorial Ayurveda Research Institute, Nawinna, Sri Lanka. The clinical study was carried out on the basis of placebo controlled single blind study. These patients were examined and relevant investigations were carried out. Patients suffering from bronchial asthma, diabetes mellitus and hypertension were excluded from this study. Selected patients were randomly divided in to two groups. The first group, consisting of thirty patients, was treated with 120 ml of decoction of Pitawakka Navaya twice a day for fourteen days. Second group of thirty patients was treated with 120 ml of placebo twice a day for fourteen days. The response to the treatment was recorded by using a graded scale according to the severity of symptoms.

Preperation of medicine
Preparation of decoction of Pitawakka Navaya and Placebo are described below.

Preperation of decoction of Pitawakka Navaya
6.7 g each of root of Phyllanthus amarus (Family: Euphorbiaceae; Sanskrit name: Bhoomyamalaka), dried seeded fruit of Terminalia chebula (Family: Combretaceae; Sanskrit name: Harithaki), roots of Pygmaeopremna herbacea (Family: Verbenaceae; Sanskrit name: Bharangi), dried fruits of Piper chavya (Family: Piperaceae; Sanskrit name: Chavya), dried entire creeper of Solanum trilobatum (Family: Solanaceae; Sanskrit name: Salarka), dried stem of Tinospora cordifolia (Family: Menispermaceae; Sanskrit name: Guduchi), dried rhizome of Zingiber officinalae (Family: Zingiberaceae; Sanskrit name: Shunti), dried fruit of Piper nigrum (Family: Piperaceae; Sanskrit name: Amla) and Piper longum (Family: Piperaceae; Sanskrit name: Pippali) and are cut into small pieces.[44] A measured quantity of 1920 ml of water is added and boiled down to 240 ml.

Preperation of placebo for decoction of Pitawakka Navaya
Permitted brown food coloring was added to 240 ml of boiled and cooled water. This was used as placebo for decoction of Pitawakka Navaya.

Observations and Results
Patients with Kaphaja Shirsha Shoola (chronic sinusitis) mostly complained of Guru (heaviness of head), Shirouabhitapa (headache), Prathishtabdha (fullness of head), Tandra (drowsiness), Alasya (lassitude), nasal obstruction, nasal discharge and dryness of throat. Most of them are between 10

Table 2: Change in white blood cell count during treatment with decoction of Pitawakka Navaya in Kaphaja Shirsha Shoola (chronic sinusitis)

| Investigation               | Control group (mean ± SE) | Treated group (mean ± SE) |
|-----------------------------|----------------------------|----------------------------|
|                             | Before treatment | After treatment | Before treatment | After treatment |
| Total WBC count/cu.mm       | 9467 ± 376  | 9307 ± 580    | 7800 ± 1977  | 6533 ± 1622    |
| Neutrophil%                 | 55.33 ± 2.96 | 54 ± 3.06     | 51.33 ± 4.33 | 53 ± 3.79      |
| Lymphocyte%                 | 39 ± 2.89   | 40.67 ± 2.85  | 41.67 ± 4.06 | 42 ± 5.29      |
| Eosinophil%                 | 4.66 ± 1    | 4.66 ± 1      | 6.33 ± 2.85  | 4.33 ± 1.86    |

Table 3: Ayurvedic properties of ingredients of Pitawakka Navaya

| Ingredients             | Sanskrit name | Rasa   | Guna  | Veerya | Vipaka |
|-------------------------|---------------|--------|-------|--------|--------|
| Phyllanthus amarus      | Bhoomyamalaka| Kashaya| Laghu | Sheetha| Katu   |
| Terminalia chebula      | Haritaki      | Kashaya, Madhura Amla, Katu, Tikta, | Laghu, Ruksha | Ushna | Madhura |
| Pygmaeopremna herbacea | Bharangi      | Tikta, Katu Kashaya | Laghu, Ruksha | Ushna | Katu   |
| Piper chavya            | Chavya        | Katu   | Laghu, Ruksha | Ushna | Katu   |
| Solanum trilobatum     | Salarka       | Tikta, Katu | Laghu, Ruksha, Teykenha | Ushna | Katu   |
| Piper longum            | Pippali       | Katu   | Laghu, Snigdha Teykenha | Anushna | Madhura |
| Tinospora cordifolia    | Guduchi       | Tikta, Kashaya | Guru, Snigdha | Ushna | Madhura |
| Zingiber officinalae    | Shunthi       | Katu   | Laghu, Snigdha | Ushna | Madhura |
| Piper nigrum            | Maricha       | Katu, Tikta | Laghu, Ruksha, Teykenha | Ushna | Katu   |
and 30 years of age. Many of these patients lose sleep during the night due to studies or being in occupations such as security service and nursing. Most of them had the habit of bathing at night. Some of them were allergic to dust and/or mist. Some patients were allergic to foods such as pineapple, tomato, and cold foods.

In some patients, the symptoms were aggravated after treating with decoction of Pitawakka Navaya. In 6.3% patients Guru (heaviness of head), in 11.8% Shiroabhitapa (headache), in 7.7% Manda Rija (mild headache), in 14.3% Karna Kandu (itching inside the ears), in 6.7% nasal obstruction, in 5.9% nasal discharge, and in 66.7% abnormalities of smell were aggravated.

Table 1 shows the percentage (%) of symptomatic relief during the treatment with decoction of Pitawakka Navaya. When Kaphaja Shishra Shoola patients were treated with decoction of Pitawakka Navaya, they showed a statistically significant reduction in eosinophil count. These results are given in Table 2. In some patients, X-ray reports indicated that thickening of mucous membrane in para nasal sinuses, especially in maxillary sinus, was reduced.

**Discussion**

Decoction of Pitawakka Navaya is used as Samshamana decoction by traditional physicians in Sri Lanka. Kaphaja Shishra Shoola (Chronic Sinusitis) is a disease that occurs due to vitiation of Kapha and Vata Dosha. Ingredients of Pitawakka Navaya have the properties of pacifying vitiated Vata Dosha and Kapha Dosha. They also have the Rasa properties such as Kashaya Rasa, Katu Rasa, Tikta Rasa and Amla Rasa; Gunas properties such as Laghu Guna, Raksha Guna, Teekshna Guna and Snigdha Guna and the properties of Katu Vipaka and Ushna Veerya.

The properties of Pitawakka Navaya such as Kashaya Rasa, Katu Rasa, Tikta Rasa, Laghu Guna, Raksha Guna, Teekshna Guna, Ushna Veerya and Katu Vipaka are opposite to characteristics of Kapha Dosha and because of these, decoction of Pitawakka Navaya pacifies vitiated Kapha Dosha. Hence, this traditional decoction is beneficial for diseases originating due to vitiation of Kapha Dosha. The properties of Pitawakka Navaya such as Madhura Rasa, Snigdha Guna, Guru Guna, Madhura Vipaka are opposite to characteristics of Vata Dosha and because of these, decoction of Pitawakka Navaya pacifies vitiated Vata Dosha. Hence, this decoction is beneficial in pacifying diseases originated by vitiation of Vata Dosha and Kapha Dosha including Kaphaja Shishra Shoola (Chronic Sinusitis). Rasa, Guna, Veerya and Vipaka of Pitawakka Navaya is given in Table 3.

It was observed that among 6.3% of patients Guru (heaviness of head), 11.8% patients Shiroabhitapa (headache), 74.3% Karna Kandu (itching inside the ears), 6.7% nasal obstruction, 5.9% nasal discharge and 66.7% abnormalities of smell were aggravated after the treatment.

**Conclusion**

It is concluded that decoction of Pitawakka Navaya is beneficial for Kaphaja Shishra Shoola (chronic sinusitis). This decoction also reduces the eosinophil count in blood.

X-rays of sinuses show that decoction of Pitawakka Navaya reduces thickening of mucous membrane in para nasal sinuses, specially in maxillary sinuses.

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