Clinical Research

A clinical trial of Sri Lankan traditional decoction of Pitawakka Navaya in the treatment of Kaphaja Shirsha Shoola

M. G. S. K. Maragalawaththa, E. R. H. S. S. Ediriweera, P. B. Chandimarathne

Institute of Indigenous Medicine, University of Colombo, Rajagiriya

Address for correspondence: Dr. E. R. H. S. S. Ediriweera
Senior Lecturer, Institute of Indigenous Medicine, University of Colombo, Rajagiriya, Sri Lanka.
E-mail: ayurvedadocsujatha@yahoo.com

Abstract

Authentic Ayurvedic texts mention 11 types of Shiro Roga (diseases in the 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 the sinuses. It can be correlated with Kaphaja Shirsha Shoola. Decoction of Pitawakka Navaya consists of nine ingredients; these are: Bhoomyamalaka, Haritaki, Bharangi, Chavya, Pippali, Salaraka, 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 the treatment of Kaphaja Shirsha Shoola. Hence, this clinical study was conducted to evaluate the efficacy of the decoction of Pitawakka Navaya in the treatment of Kaphaja Shirsha Shoola. Sixty patients suffering from Kaphaja Shirsha Shoola were selected and examined. These patients were randomly divided into two groups of 30 patients each. The first group was treated with 120 ml of decoction of Pitawakka Navaya twice a day for 14 days. The second group was treated with 120 ml of placebo twice a day for 14 days. After treatment, most of the patients' symptoms were completely or partially relieved. In <10% of the patients, some symptoms were unchanged or aggravated. It is observed that the traditional decoction Pitawakka Navaya is beneficial for Kaphaja Shirsha Shoola (chronic sinusitis).

Key words: Chronic Sinusitis, Kaphaja Shirsha Shoola, Decoction of Pitawakka Navaya

Introduction

In authentic Ayurvedic texts, it is mentioned that there are 11 types of Shiro Roga (diseases in the head). Kaphaja Shirsha Shoola is a disease that occurs in the Urdhawajathrungatha Pradesha (area above the clavicle). The clinical features of Kaphaja Shirsha Shoola are Guru (heaviness of the head), Prathishtadbha (fullness of the head), Himam (coldness of the head), Shiroabhitaqa (headache), Shuna Akshikuta (swelling around the eyes), Shuna Vadanam (swelling in the face), Shuna Nasa (swelling of the nose), Saptha (numbness), Tanda (drowsiness), Alasya (lassitude), Arochaka (anorexia), Sthimitha (rigidity in the head), Shiranispandatha (veins not pulsating), Karnau Kandu (itching inside the ears), Rukmanda Ahanya Adikacanishi (mild pain during day time and severe at night) and Anthak Kaphalipatham (feeling of having a coating of phlegm inside the head).

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, for more than 12 weeks, this condition is known as chronic sinusitis.

Chronic 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, gastrointestinal discomfort, chronic bronchitis, excoriation of skin of the nasal mucosa and tenderness of the sinuses.

Pitawakka Navaya is a decoction used by traditional Sri Lankan physicians in the treatment of Kaphaja Shirsha Shoola (chronic sinusitis). This name was given because this decoction contains nine ingredients, namely: Bhoomyamalaka, Haritaki, Bharangi, Chavya, Salaraka, 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 the efficacy of Pitawakka Navaya in the treatment of Kaphaja Shirsha Shoola (chronic sinusitis).
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 Bandaranayke Memorial Ayurveda Research Institute, Nawinna, Sri Lanka. The clinical study was carried out on the basis of a 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 into two groups. The first group, consisting of 30 patients, was treated with 120 ml of decoction of Pitawakka Navaya twice a day for 14 days.

Table 1: Percentage of symptomatic relief during treatment with the decoction of Pitawakka Navaya in Kaphaja Shirsha Shoola (chronic sinusitis)

| Symptoms                        | % of patients | Control group | Treated group |
|---------------------------------|---------------|---------------|--------------|
| Guru (heaviness of head)        | 44.00         | 38            | 0            | 62          | 0            | 53.33        | 43.70        | 37.5         | 12.5        | 6.3         |
| Prathishtabdha (fullness of the head) | 30.66         | 40            | 0            | 60          | 0            | 36.66        | 27.3         | 45.4         | 27.3        | 0           |
| Shiroabhitapa (headache)        | 43.33         | 25            | 0            | 65          | 10           | 56.66        | 23.52        | 41.2         | 23.52       | 11.8        |
| Shuna Akshikuta (swelling around the eyes) | 33            | 0             | 15           | 85          | 0            | 26.66        | 37.5         | 37.5         | 25          | 0           |
| Shuna Vadanum (swelling in the face) | 13            | 0             | 15           | 85          | 0            | 16.66        | 40.00        | 60.00        | 0           | 0           |
| Shuna Nasa (swelling of the nose) | 33            | 0             | 15           | 85          | 0            | 26.66        | 37.5         | 37.5         | 25          | 0           |
| Tandra (drowsiness)             | 44.00         | 22            | 0            | 78          | 0            | 53.33        | 31.25        | 31.25        | 37.5        | 0           |
| Alasya (lassitude)              | 37.77         | 20            | 10           | 70          | 00           | 43.33        | 46.1         | 30.8         | 23.1        | 0           |
| Arochaka (anorexia)             | 23            | 15            | 15           | 70          | 00           | 16.66        | 60.00        | 40.00        | 0           | 0           |
| Sthimitha (rigidity of the head) | 30            | 0             | 10           | 90          | 00           | 23.33        | 42.85        | 42.85        | 14.3        | 0           |
| Kama Kandu (itching inside the ears) | 35.88         | 15            | 15           | 70          | 00           | 33.33        | 40.00        | 50.00        | 10.00       | 0           |
| Rukmanda Ahanaya Adikanishi (pain is mild during day and severe at night) | 30            | 5             | 0            | 90          | 05           | 23.33        | 0           | 28.6         | 57.1        | 14.3        |
| Anthak Kaphaliptham (feeling of having a coating of phlegm inside the head) | 20.44         | 10            | 0            | 90          | 00           | 23.33        | 28.6         | 71.4         | 0           | 0           |
| Nasal obstruction               | 36.77         | 10            | 0            | 90          | 00           | 50.00        | 40.00        | 53.33        | 6.66        | 0           |
| Nasal discharge                 | 50.25         | 00            | 0            | 100         | 00           | 56.66        | 35.3         | 47.00        | 11.8        | 5.9         |
| Tendency to clear one’s throat frequently | 16.22         | 20            | 0            | 80          | 00           | 56.66        | 18.2         | 54.5         | 27.3        | 0           |
| Abnormalities of smell          | 15.12         | 00            | 0            | 100         | 00           | 16.66        | 40.00        | 60.00        | 0           | 0           |
| Epistaxis                       | 8.55          | 00            | 0            | 100         | 00           | 10.00        | 0           | 33.33        | 66.66       | 0           |
| Dryness of throat               | 40.00         | 12            | 10           | 78          | 00           | 43.33        | 15.4         | 23.1         | 61.5        | 0           |
| Sore throat                     | 20.22         | 20            | 0            | 80          | 00           | 26.66        | 12.5         | 50.00        | 37.5        | 0           |
| Excoriation of skin of nasal vestibule | 35.22        | 10            | 0            | 90          | 00           | 36.66        | 36.4         | 45.41        | 9.1         | 9.1         |
| Low-grade fever                 | 30.66         | 20            | 0            | 80          | 00           | 10.00        | 33.3         | 66.7         | 0           | 0           |

Partial relief: Symptoms of the patient are reduced to some extent, Complete relief: Symptoms completely disappeared after treatment, Partial relief: Not completely relieved, Aggravated: Symptoms were aggravated after treatment, Unchanged: Symptoms did not change after treatment.
days. The second group of 30 patients was treated with 120 ml of placebo twice a day for 14 days. Response to the treatment was recorded using a graded scale according to the severity of the symptoms.

**Preparation of Medicine**
Preparation of the decoction of Pitawakka Navaya and placebo are described below.

**Preparation 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: Haritaki), roots of Pygmaepremna herbeacea (Family: Verbenaceae; Sanskrit name: Bharangi), dried fruits of Pipper chayya (Family: Piperaceae; Sanskrit name: Chavya), dried entire creeper of Solanum trilobatum (Family: Solanaceae, Sanskrit name: Salarka), dried stem of Tinospora cordifolia (Family: Menispermacae; Sanskrit name: Guduchi), dried rhizome of Zingiber officinale (Family: Zingiberaceae; Sanskrit name: Shunthi), dried fruit of Piper nigrum (Family: Piperaceae; Sanskrit name: Maricha) and Piper longum (Family: Piperaceae; Sanskrit name: Pippali) are cut into small pieces and 1,920 ml of water is added and boiled down to 240 ml.

**Preparation 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 preparing the decoction of Pitawakka Navaya.

**Observations and Results**
Patients with Kaphaja Shirsha Shoola (chronic sinusitis) mostly complained of Guru (heaviness of head), Shiroabhitapa (headache), Prathishtabdiha (fullness of head), Tandra (drowsiness), Alasya (lassitude), nasal obstruction, nasal discharge and dryness of throat. Most of them were between 10 and 30 years of age. Many of these patients lose sleep during the night due to studies or were 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/mist. Some patients were allergic to foods such as pineapple, tomato and cold foods.

In some patients, the symptoms were aggravated after treatment with decoction of Pitawakka Navaya. In 6.3% of the patients Guru (heaviness of head), in 11.8% Shiroabhitapa (headache), in 7.7% Manda Ruja (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 Shirsha Shoola patients were treated with the decoction of Pitawakka Navaya, they showed a statistically significant reduction in the eosinophil count. These results are given in Table 2. In some patients, the X-ray reports indicated that thickening of the mucous membrane in paranasal sinuses, especially in maxillary sinuses, was reduced.

**Discussion**
The decoction of Pitawakka Navaya is used as Samshumana decoction by traditional physicians in Sri Lanka. Kaphaja Shirsha 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 Rasa properties, such as Kashaya Rasa, Katu Rasa, Tikta Rasa and Amla Rasa; Guna properties, such as Laghu Guna, Ruksha Guna, Theekshna Guna and Snigdha Guna; and properties of Katu Vipaka and Ushna Vipaka.

The properties of Pitawakka Navaya, such as Kashaya Rasa, Katu Rasa, Tikta Rasa, Laghu Guna, Ruksha Guna, Theekshna Guna, Ushna Vipaka and Katu Vipaka are opposite to the characters of Kapha Dosha and, because of these, the 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 and Madhura Vipaka are opposite to the characters of Vata Dosha and, because of these, the 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 Shirsha Shoola (chronic sinusitis). Rasa, Guna, Vipaka and Vipaka of Pitawakka Navaya are presented in Table 3.

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

X-rays of the sinuses show that the decoction of Pitawakka Navaya reduces the thickening of the mucous membrane in the paranasal sinuses, especially in the maxillary sinuses.

**Table 2: Change in the white cells blood count during the 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                |

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Table 3: Ayurvedic properties of the ingredients of Pitawakka Navaya

| Botanical name and family | Sanskrit name | Rasa          | Guna      | Veerya | Vipaka  |
|---------------------------|---------------|---------------|-----------|--------|---------|
| Phyllanthus amarus        | Bhoomyamlaka  | Kashaya       | Laghu     | Sheetha| Katu    |
| Terminalia chebula        | Haritaki      | Kashaya, Madhura | Laghu,  | Ushna  | Madhura |
| Pygmaeoprenna herbacea    | Barangi       | Tikta, Katu, Kashaya | Laghu,  | Ushna  | Katu    |
| Piper chavya (Piperaceae) | Chavya        | Katu          | Laghu,    | Ushna  | Katu    |
| Solanum trilobatum        | Salaraka      | Tikta, Katu   | Laghu,    | Ushna  | Katu    |
| Piper longum (Piperaceae) | Pippali       | Katu          | Laghu, Snigdha, Teekshna | Anushna | Madhura |
| Tinospora cordifolia      | Guduchi       | Tikta, Kashaya | Guru, Snigdha | Ushna  | Madhura |
| Zingiber officinale       | Shunthi       | Katu          | Laghu, Snigdha | Ushna  | Madhura |
| Piper nigrum (Piperaceae) | Maricha       | Katu, Tikta   | Laghu,    | Ushna  | Katu    |

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हिन्दी सारांश
कफज शिरःशूल की चिकित्सा में पितवक्का नवाय का प्रभाव

एम.जी. एस. के. मार्गलवथा इ. आर. एच. एस. एस. इंडिरावीरा पी. बी. चण्डीमार्गने
कफज शिरःशूल आयुर्वेद में वर्गीत शिरोरोगों में से एक है। जीर्ण सायनुसायटीस को कफज शिरःशूल से संबंधित किया जा सकता है। प्रस्तुत अध्ययन में श्रीलंकन पारंपरिक आयुर्विज्ञान ‘पितवक्का नवाय क्राथ’ के कफज शिरःशूल में चिकित्सकीय प्रभाव का परीक्षण किया गया है। पितवक्का नवाय क्राथ में नौ औषधियों जैसे बीयामलकी, हरितकी, भारंगी, चव्य, पिप्पली, सर्क, गुड्डी, शृंगी, और मरीच सम्बंधित हैं। कफज शिरःशूल के रूप में दो विषमताओं में समान रूप से वृद्धि प्राप्त की गयी। समूह ‘आ’ में पितवक्का नवाय क्राथ १२० मिलियन में दो बार १५ दिनों के लिए दिया गया। समूह ‘ब’ में प्लासिमों क्राथ १२० मिलियन में दो बार १५ दिनों के लिए दिया गया।
परिणाम पर: पितवक्का नवाय क्राथ कफज शिरःशूल में लाभदायी प्रभाव गया।