

## Clinical Research

A Clinical trial of Sri Lankan traditional decoction of *Pitawakka Navaya* in treatment of *Kaphaja Shirsha Shoola* (chronic sinusitis)M. G. S. K. Maragalawaththa, E. R. H. S. S. Ediriweera<sup>1</sup>, Chandimarathne P. B.<sup>1</sup>Ayurveda Teaching Hospital, Borella, <sup>1</sup>Institute of Indigenous Medicine, University of Colombo, Rajagiriya, Sri Lanka

## 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*, *Shunti* 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 *Urdhawajathrugatha Pradesha* (area above the clavicle). The clinical features of *Kaphaja Shirsha Shoola* are *Guru* (heaviness of the head), *Prathishtabdh* (fullness of head), *Himam* (coldness of the head), *Shiroabhitapa* (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), *Sthimitha* (rigidity in head), *Shiranispandatha* (veins not pulsating), *Karna Kandu* (itching inside the ears), *Ruknanda Ahanya Adikacanishi* (mild pain during day time and severe at night) and *Anthak Kaphaliptham* (feeling of having a coating of phlegm inside the head).<sup>[1-3]</sup>

*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 more than twelve weeks, then 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, gastro intestinal discomfort, chronic bronchitis, excoriation of skin of nasal mucosa and tenderness of the sinuses.<sup>[7]</sup>

*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*, *Harithaki*, *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.

**Address for correspondence:** Dr. Ediriweera E.R.H.S.S., Senior Lecturer-Institute of Indigenous Medicine, University of Colombo, Rajagiriya, Sri Lanka.  
Email: ayurvedadocsujatha@yahoo.com  
DOI: 10.4103/0974-8520.72390

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

Symptoms	(% of patients)	Control group				Treated group				
		Partial relief (%)	Complete relief (%)	Unchanged (%)	Aggravated (%)	(%) of patients	Partial relief (%)	Complete relief (%)	Unchanged (%)	Aggravated (%)
<i>Guru</i> (heaviness of head)	44.00	38	00	62	00	53.33	43.70	37.5	12.5	6.3
<i>Prathishtabdha</i> (fullness of the head)	30.66	40	00	60	00	36.66	27.3	45.4	27.3	00
<i>Shiroabhitapa</i> (headache)	43.33	25	00	65	10	56.66	23.52	41.2	23.52	11.8
<i>Shuna Akshikuta</i> (swelling around the eyes)	33	00	15	85	00	26.66	37.5	37.5	25	00
<i>Shuna Vadanum</i> (swelling in the face)	13	00	15	85	00	16.66	40.00	60.00	00	00
<i>Shuna Nasa</i> (swelling of the nose)	33	00	15	85	00	26.66	37.5	37.5	25	00
<i>Tandra</i> (drowsiness)	44.00	22	00	78	00	53.33	31.25	31.25	37.5	00
<i>Alasya</i> (lassitude)	37.77	20	10	70	00	43.33	46.1	30.8	23.1	00
<i>Arochaka</i> (anorexia)	23	15	15	70	00	16.66	60.00	40.00	00	00
<i>Sthimitha</i> (rigidity of head)	30	00	10	90	00	23.33	42.85	42.85	14.3	00
<i>Karna Kandu</i> (itching inside the ears)	35.88	15	15	70	00	33.33	40.00	50.00	10.00	00
<i>Ruknanda Ahanaya Adikanishi</i> (Mild pain during day and severe pain at night)	30	5	00	90	05	23.33	00	28.6	57.1	14.3
<i>Anthak Kaphaliptham</i> (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.

### Preparation of medicine

Preparation of 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: *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: *Maricha*) and *Piper longum* (Family: Piperaceae; Sanskrit name: *Pippali*) and are cut into small pieces.<sup>[4-6]</sup> A measured quantity of 1920 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 decoction of *Pitawakka Navaya*.

## Observations and Results

Patients with *Kaphaja Shirsha Shoola* (chronic sinusitis) mostly complained of *Guru* (heaviness of head), *Shiroabhitapa* (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					
Botanical name and family	Sanskrit name	Rasa	Guna	Veerya	Vipaka
<i>Phyllanthus amarus</i> (Euphorbiaceae)	Bhoomyamalaka	Kashaya	Laghu	Sheetha	Katu
<i>Terminalia chebula</i> (Combretaceae)	Haritaki	Kashaya, Madhura	Laghu, Ruksha	Ushna	Madhura
<i>Pygmaeopremna herbacea</i> (Verbenaceae)	Bharangi	Amla, Katu, Tikta, Kashaya	Laghu, Ruksha	Ushna	Katu
<i>Piper chavya</i> (Piperaceae)	Chavya	Katu	Laghu, Ruksha	Ushna	Katu
<i>Solanum trilobatum</i> (Solanaceae)	Salarka	Tikta, Katu	Laghu, Ruksha	Ushna	Katu
<i>Piper longum</i> (Piperaceae)	Pippali	Katu	Laghu, Snigdha	Anushna	Madhura
<i>Tinospora cordifolia</i> (Menispermaceae)	Guduchi	Tikta, Kashaya	Guru, Snigdha	Ushna	Madhura
<i>Zingiber officinalae</i> (Zingiberaceae)	Shunthi	Katu	Laghu, Snigdha	Ushna	Madhura
<i>Piper nigrum</i> (Piperaceae)	Maricha	Katu, Tikta	Lagu, Ruksha, Teekshna	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 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 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 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 the Rasa properties such as Kashaya Rasa, Katu Rasa, Tikta Rasa and Amla Rasa; Guna properties such as Laghu Guna, Ruksha 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, Ruksha 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 Shirsha 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 Shirsha 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.

## References

1. Sharma AP. Chaukambha Orientalia. Varanasi, India: Charaka Samhitha; 1983. p. 116.
2. Murthy KR. Chaukambha Orientalia. Varanasi, India: Madhava Nidana; 1986. p. 217.
3. Murthy KR. Chaukambha, Orientalia. Varanasi, India: Sustruta Samhita; 1998. p. 134.
4. Jayaweera DM. The National Science Council of Sri Lanka. Vol. 2. Colombo, Sri Lanka: Medicinal Plants; 1980. p. 37-227.
5. Jayaweera DM. The National Science Council of Sri Lanka. Vol. 4. Colombo, Sri Lanka: Medicinal Plants; 1985. p. 81-203, 207, 209.
6. Jayaweera DM. The National Science Council of Sri Lanka. Vol. 5. Colombo, Sri Lanka: Medicinal Plants; 1982. p. 99-170, 217.
7. Bull PD. Lecture Notes of the Disease of the Ear, Nose, and Throat. UK: Black Well Science; 1996. P. 101

## हिंदी सारांश

कफज शिरः शूल में श्रीलंकन पारम्परिक औषधि पितवाक्कनवाय का चिकित्सकीय प्रभाव  
मारगलवत्था एम.जी.एस.के., इडिरिवीरा इ.आर.एच.एस., चंडिमारत्ने पी.बी.

आयुर्वेद संहिताओं में वर्णित ११ शिरोगों में कफज शिरःशूल कफ और वात दोष दुष्टी के कारण होता है। पितवाक्कनवाय क्वाथ इसकी चिकित्सा में प्रयुक्त होता है। इस क्वाथ में भूम्यामलकी, हरितकी, भारंगी, चव्य, पिप्पली, सलर्क, गुडुची, शुण्ठी और मरिच इन नौ वनस्पतियों का समावेश होता है जो वात और कफ दोषों का शमन करती है। प्रस्तुत चिकित्सकीय अध्ययन में कफज शिरःशूल के कुल ६० रूग्णों को दो समूहों में बाँटा गया। प्रथम समूह में ३० रूग्णों को पितवाक्कनवाय क्वाथ १२० मिली मात्रा में दिन में दो बार १४ दिनों तक दिया गया। द्वितीय समूह में प्लासेबो क्वाथ समान मात्रा में कालावधि तक दिया गया। परिणामस्वरूप, पितवाक्कनवाय क्वाथ कफज शिरः शूल के रूग्णों में उपयुक्त पाया गया।