



Clinical Research

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

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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*, *Barangi*, *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 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 *Urdhawajathrugatha Pradesha* (area above the clavicle). The clinical features of *Kaphaja Shirsha Shoola* are *Guru* (heaviness of the head), *Prathishtabdha* (fullness of the 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 the head), *Shiranispandatha* (veins not pulsating), *Karna Kandu* (itching inside the ears), *Rukmanda Ahanya Adikacanisshi* (mild pain during day time and severe at night) and *Anthak Kaphaliptham* (feeling of having a coating of phlegm inside the head).

Kaphaja Shirsha Shoola can be correlated with chronic sinusitis.

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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*, *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 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

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				
		Partially relief (%)	Complete relief (%)	Un-changed (%)	Aggravated (%)	% of patients	Partial relief (%)	Complete relief (%)	Un-changed (%)	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 the 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>Rukmanda Ahanaya Adikanishi</i> (pain is mild during day and severe 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

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 *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: *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), *Prathishtabdha* (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/or 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 Rujā* (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 sinus, was reduced.

Discussion

The 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 *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 Veerya*.

The properties of *Pitawakka Navaya*, such as *Kashaya Rasa*, *Katu Rasa*, *Tikta Rasa*, *Laghu Guna*, *Ruksha Guna*, *Theekshna Guna*, *Ushna Veerya* 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 the 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*, *Veerya* 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

Table 3: Ayurvedic properties of the ingredients of Pitawakka Navaya

Ingredients		Rasa	Guna	Veerya	Vipaka
Botanical name and family	Sanskrit name				
<i>Phyllanthus amarus</i> (Euphorbiaceae)	<i>Bhoomyamlaka</i>	<i>Kashaya</i>	<i>Laghu</i>	<i>Sheetha</i>	<i>Katu</i>
<i>Terminalia chebula</i> (Combretaceae)	<i>Haritaki</i>	<i>Kashaya, Madhura</i> <i>Amla, Katu, Tikta</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Madhura</i>
<i>Pygmaeopremna herbacea</i> (Verbenaceae)	<i>Barangi</i>	<i>Tikta, Katu, Kashaya</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Katu</i>
<i>Piper chavya</i> (Piperaceae)	<i>Chavya</i>	<i>Katu</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Katu</i>
<i>Solanum trilobatum</i> (Solanaceae)	<i>Salarka</i>	<i>Tikta, Katu</i>	<i>Laghu, Ruksha,</i> <i>Teekshna</i>	<i>Ushna</i>	<i>Katu</i>
<i>Piper longum</i> (Piperaceae)	<i>Pippali</i>	<i>Katu</i>	<i>Laghu, Snigdha,</i> <i>Teekshna</i>	<i>Anushna</i>	<i>Madhura</i>
<i>Tinospora cordifolia</i> (Menispermaceae)	<i>Guduchi</i>	<i>Tikta, Kashaya</i>	<i>Guru, Snigdha</i>	<i>Ushna</i>	<i>Madhura</i>
<i>Zingiber officinale</i> (Zingiberaceae)	<i>Shunthi</i>	<i>Katu</i>	<i>Laghu, Snigdha</i>	<i>Ushna</i>	<i>Madhura</i>
<i>Piper nigrum</i> (Piperaceae)	<i>Maricha</i>	<i>Katu, Tikta</i>	<i>Lagu, Ruksha,</i> <i>Theekshna</i>	<i>Ushna</i>	<i>Katu</i>

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हिन्दी सारांश

कफज शिरःशूल की चिकित्सा में पितवक्का नवाय का प्रभाव

एम.जी. एस. के. मारगलवथथा इ. आर. एच. एस. एस. इडिरिवीरा पी. बी. चण्डीमारथने

कफज शिरःशूल आयुर्वेद में वर्णित शिरोरोगों में से एक है। जीर्ण सायनुसायटीस को कफज शिरःशूल से संदर्भित किया जा सकता है। प्रस्तुत अध्ययन में श्रीलंकन पारम्परिक औषधि 'पितवक्का नवाय क्वाथ' के कफज शिरःशूल में चिकित्सकीय प्रभाव का परीक्षण किया गया है। पितवक्का नवाय क्वाथ में नौ औषधियाँ जैसे भूम्यामलकी, हरितकी, भारंगी, चव्य, पिप्पली, सलर्क, गुडूची, शुण्ठी, और मरीच सम्मिलित हैं। कफज शिरःशूल के रूग्णों को दो वर्गसमूहों में समान रूप से बाँटा गया। समूह 'अ' में पितवक्का नवाय क्वाथ १२० मि.ली. दिन में दो बार १४ दिनों तक दिया गया। समूह 'ब' में प्लासिबो क्वाथ १२० मि.ली. दिन में दो बार १४ दिनों तक दिया गया। परिणामतः पितवक्का नवाय क्वाथ कफज शिरःशूल में लाभदायी पाया गया।