

ORIGINAL RESEARCH ARTICLE

A Clinical Study on the Efficacy of *Shreshtanimbadi* Decoction in the Management of *Kaphaja Shirsha Shoola*

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ABSTRACT

Shirsha Shoola (Headache) is a very common condition of current society. Ayurveda *Acharyas* have been explained *Shirsha Shoola* as a type of *Shiro Roga* (diseases in the head). *Kaphaja Shirsha Shoola* is a common type of 07 *Shirsha Shoola* types. *Kaphaja Shirsha Shoola* occurs mainly due to vitiation of *Kapha Dosha* and *Vata Dosha*. With signs and symptoms, this condition can be correlated with chronic sinusitis. *Shreshtanimbadi* decoction consist of ten ingredients; *Thriphala* (*Embolica officinalis*, *Terminalia bellirica*, *Terminalia chebula*), *Nimba Tvak* (*Azadirachta indica*), *Patola* (*Trichosanthes cucumerina* L.), *Megha* (*Cyperus rotundus*), *Rajini* (*Curcuma Longa*), *Thrayanthi* (*Baccopa Monneiri*), *Hema* (*Cassia angustifolia*), and *Amrita* (*Tinospora ordifolia*). These herbs, which pacify vitiated *Vata Dosha* and *Kapha Dosha* to treat *Kaphaja Shirsha Shoola*. Forty selected patients were randomly divided into two groups of 20 for each treatment arm and controlled arm. The treatment group was treated with 120 ml of decoction of *Shreshtanimbadi* twice a day for 14 days. The second group was treated with 120 mL of placebo twice a day for 14 days. All patients were advised to follow *Pathya* (Wholesome food and behaviors). Assessment has been done before and after treatments. After treatment, treatments arm most of the patients' symptoms were completely or partially relieved compared to controlled group ($P < 0.001$). Such as headache with 76.91%, heaviness of the head from 87.9%, loss of appetite from 78.67%, peri-orbital edema from 73.20%, and ear itching from 70.00%. After the treatment, nine patients have been completely cured and all patients have been showed reduction of symptoms. It is observed that the *Shreshta nimbadi* decoction is beneficial for *Kaphaja Shirsha Shoola* (chronic sinusitis) Management.

1. INTRODUCTION

Shirah shoola (Headache) is a common condition in present scenario. Sometimes it appears as a symptom of a disease, complication of a disease or main complain of patients. *Shirah shoola* word explains all discomforts and pains related or located in *Shiras* (head), and it is considered as a synonym of *Shiro Roga*. *Charaka* among all classifications of *Shiro Roga* and *Kaphaja Shirah Shoola* is common condition which has explained in all Ayurveda authentic texts.

Considering the features of *Kaphaja Shirah Shoola*, it can be correlated with acute sinusitis condition which is common in current society. Similar to this, headaches in modern science explained and classified based on their sinus origin, which is linked to comorbid symptoms such as post-nasal drip, nasal discharge, and blockage. One of the most

common conditions that significantly lower an individual's quality of life is sinusitis. According to latest findings of researchers, sinusitis prevalence is vary within 1–12% worldwide.^[1]

1.1. Aim and Objectives of the Research

1.1.1. General objective

- To evaluate the comparative effect of *Shreshtanimbadi* decoction in the management of *Kaphaja Shirah Shoola*

1.1.2. Specific objectives

- Review on *Shreshtanimbadi Kashaya* in Ayurveda classical texts
- Review on *Shiro Roga* in Ayurveda classical texts
- Evaluate post-treatment complications of the study.

2. LITERATURE REVIEW

According to Ayurveda texts, *Shirsha shoola* has explained as *svathanthra roga* (individual disease), *purva rupa* of another disease (pre monitory

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symptom of another disease), *Rupa* of a *Vyadhi* (main symptom of another disease), and *Asadhya lakshana* of a *Vyadhi* (incurable feature of a disease). Classification of shira roga are give in Table 1.

2.1. Common Causes of *Shiro Roga*^[4]

Exposure to smoke, sunlight and snow, over indulgence in water sports, excessive sleep and keeping awake, severe sweating, exposure to heavy direct breeze and eastern breeze, suppressing tears or weeping too much, drinking too much of water and alcoholic beverages, presence of intestinal worms (*Krimi roga*), and suppression of natural physical urges. Avoiding pillows and bed or cushions/mattresses, lack of cleanliness and anointing the body, long duration and continuously looking down, exposure to unaccustomed, obnoxious and raw smell, and too much of speaking and loud speaking.

2.2. Causes of *Kaphaja Shirah Shoola*^[5]

Sedentary habits and lifestyle, excessive sleeping, and over intake of diet which are heavy to digest and too much unctuous [Table 2].

2.3. Features of *Kaphaja Shirah Shoola*^[6-8]

Dull pain of the head, numbness, cold sensation and heaviness of the head, drowsiness, lassitude and, anorexia, feeling of head (palate) and the throat covered with a coat of sticky mucus, and feel cold, rigid and heavy, and cannot be turned about, and the face and the eyes look swollen or flabby, veins not pulsating, pain is mild during day and severe at nights, itching inside vomiting are features of *Kaphaja Shirah Shoola*.

2.4. *Chikithsa* of *Kaphaja Shirah Shoola* (Treatments)^[10,11]

According to *Susrutha Samhitha*, *Kapha dosha shamaka karma* (subduing measures), such as strong emetics (*theekshna virechana*), head-purgatives (*Sirovireka*), and gargling (*Kavala*), should be added. *Vagbhata* has explained and advised following treatment plan. First patient should be given oleation therapy (*Sneha Karma*) by drinking of old ghee (*Accha Peya*) and then administered emesis (*Virechana Karma*) therapy using drugs which are pungent taste (*Katu Rasa*), fomentation (*Sweda Karma*), external application of paste (*Alepa, Lepa*), nasal medication (*Nasya Karma*), etc., and he has advised to use drugs having properties such as dry (*Ruksha*), penetrating (*Theekshna*), and hot (*Ushna*) and he has highlighted that avoidance of food is ideal in this treatment protocol.

2.5. Drug Review

Shreshtanimbadi Kashaya is a common medicine which is using in the management of *Kaphaja Roga*, especially *Urdhvajathrugata Kaphaja Roga* by Sri Lankan vise physicians. However, there was no any reference in main Ayurveda classic text such as *Vrihatraya* (*Caraka Samhita*, *Susruta Samhita*, *Ashtanga Hridaya Samhita*), *laghutraya* (*Madhava nidana*, *Bhavaprakasha*, *Sharangadhara samhita*) or *Yoga ratnakara*, *Yogamrita Sindhu*, *Vaidhya Jeevana*, *Sarartha samgraha*, and *Sara samkshepa* about this Kashaya. Special fact is there was no any reference in *Ayurveda Aushadha Samgraha* (Sri Lanka Ayurveda Formulary) which contains all the medicinal recipes used in Sri Lanka. Only reference is *Yoga Chintamani* which was written in 17th century by Shri Harsakirti Suri.

There are 10 ingredients in this decoction and there is few different explanation about few ingredients among Sri Lankan traditional practitioners [Table 3].

3. METHODOLOGY

The study was a randomized placebo-controlled double-blind comparative clinical study.

3.1. Inclusion Criteria

- Male and female patients
- Patients with prominent *Kaphaja Shirah Shoola*
- Age between 18 and 40 years old
- Chronicity <2 months.

3.2. Exclusion Criteria

- Age below 18 years old, over 41 years old
- Pregnant mothers
- Patients suffering from cancers and non-communicable diseases
- Patients with complications
- Chronicity more than 2 months.

3.3. Selection and grouping of the patients

Forty *Kaphaja Shirah Shoola* patients were selected from OPD of National Ayurveda hospital Sri Lanka. Randomly divided into two groups, namely, Group A and Group B with 20 patients in each group. Group A was treated with *Shreshtanimbadi kashaya* and Group B was treated with placebo medicine. All individuals were asked to take the $\frac{1}{2}$ pata (120 mL) of decoction morning and night before meal for 14 days. Follow-up period was 30 days after the treatment period. All patients were advised to follow *Pathya* (Dos) and avoid *Apathya* (Don'ts) within study and follow-up period.

3.4. Evaluation Criteria

Common signs and symptoms were assessed before the treatment and after follow-up period [Table 4].

4. RESULTS AND OBSERVATION

Out of 40 population all patients had headache (*Shirah Shoola*) as a common symptom. About 77.5% had heaviness of head (*Shiro gauravata*), 27.5% were affected with peri-orbital edema (*Akshi kuta shophya*), 27.5% were affected with ear itching (*Karna kandu*), 15% were affected with heaviness of body (*Gauravata*), 37.5% were affected with anorexia (*Aruchi*), and 05% were affected with vomiting (*Vamaka*).

The mean value of headache (*Shirah Shoola*) has been changed from 2.80 to 0.65 compared to after treatment and its reducing percentage is 76.69%. The mean value of heaviness of head (*Shiro gauravata*) has been changed from 2.73 to 0.33 compared to after treatment and its reducing percentage is 87.31%. The mean value of anorexia (*Aruchi*) has been changed from 2.11 to 0.45 compared to after treatment and its reducing percentage is 78.67%. The mean value of peri-orbital edema (*Akshi kuta shophya*) has been changed from 2.50 to 0.67 compared to after treatment and its reducing percentage is 73.26%. The mean value of ear itching (*Karna kandu*) has been changed from 2.00 to 0.60 compared to after treatment and its reducing percentage is 70.00%.

The mean value of headache (*Shirah Shoola*) has been changed from 2.70 to 2.20 compared to after treatment and its reducing percentage is 18.51%. The mean value of heaviness of head (*Shiro gauravata*) has been changed from 2.49 to 1.87 compared to after treatment and its

reducing percentage is 25.20%. The mean value of anorexia (*Aruchi*) has been changed from 1.83 to 1.67 compared to after treatment and its reducing percentage is 08.74%. The mean value of peri-orbital edema (*Akshi kuta shophya*) has been changed from 2.20 to 1.80 compared to after treatment and its reducing percentage is 18.18%. The mean value of ear itching (*Karna kandu*) has been changed from 1.83 to 1.50 compared to after treatment and its reducing percentage is 18.03% results are shown in Tables 5-7 and Chart 1.

5. DISCUSSION

Majority of the patients were presented in 21–25 age group (40%) and 33.33% patients were in 26–30 age group. These results indicate that *Kaphaja Shirah Shoola* is more common in young adults. According to Haritha samhitha without *Thapa/Rakta*, *Shirah Shoola* will not occur. These age groups are more *Kapha* and *Pitta dosha* prominent group. Hence, incidence of *Kaphaja Shirah Shoola* will be increase in these ages.

The highest percentage of patients of are female (66.66%), it is nearly twice count of male patients (33.3%). Considering behaviors of females, *Diva swapna* (day time sleep), *Sandhya snana* (evening bath), *Atapa sewana* (excessive heat exposure), *Jagarana* (sleeplessness), and increased working time with water, this kind of *Kapha uthklesha nidana Karana sewana* is more common than males. That indicates females are vulnerable to have *Kaphaja Shirah Shoola* than males. Based on this sample study, there was not any relationship between this condition and the religion of patients since majority are Buddhist. About 40% percentage of patients are unemployed. About 16.67% are tailors. Students and clerks count are equal and percentage is 13.33%. Considering above jobs, dust inhalation, early morning and evening bathing, work in AC rooms, sleeplessness at night, early morning wakeup, lack of exercises, and day sleep could be identified as *Kapha dosha kopakara* causative factors among majority.

Considering the properties of *Shreshtanimbadi Kashaya*, majority of ingredients have *Thikta rasa* (36.46%) and *Katu* and *Kashaya rasa* (23.08%) each. There was no any *Lavana rasa* prominent ingredient. *Madhura* and *Amla rasa* were very lowest prominent tastes; it is 7.69% each as a percentage. *Ruksha guna* (36.84%), *Laghu guna* (42.12%), *Snigdha guna* (10.52), *Guru guna*, and *Thikshna guna* (5.26%) each as prominent qualities (*Guna*). Majority ingredients have *Ushna virya* (70.00%) and 30% have *Shitha virya*. About 60% percentages of ingredients have *Katuka vipaka* and only 40% of them have *Madhura Vipaka*. Considering above *Rasadi panchaka*, *Shreshtanimbadi Kashaya* is prominent with *Thikta*, *Katu* and *Kashaya rasa*, *Ruksha* and *Laghu guna*, and *Ushna virya* and *Katu vipaka* which are having *Kapha dosha shamaka* actions and potency to *Khandana* of *Samprapti* of *Kaphaja Shirah Shoola*.

In the trial group, symptoms and signs related to *Kaphaja Shirah Shoola* have taken improvement such as headache (76.79%), heaviness of head (87.91%), anorexia (78.67%), peri-orbital edema (73.20%), and ear itching (70.00%). In control group, also symptoms have reduced but comparatively minute changes to trial group such as headache (18.51%), heaviness of head (25.20%), anorexia (8.74%), peri-orbital edema (18.13%), and ear itching (18.18%).

6. CONCLUSION

When considering the changes of symptoms and signs of *Kaphaja Shirah Shoola* of Group A and B, Groups A findings are statistically

significant ($P < 0.05$). Considering the comparative evaluation of study findings, it can be conclude that *Shreshtanimbadi Kashaya* has more effect on the management *Kaphaja Shirah Shoola*.

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Nil.

8. AUTHORS' CONTRIBUTIONS

All the authors contributed equally to the design and execution of the article.

9. FUNDING

Nil.

10. ETHICAL APPROVALS

This study is approved by the Institutional Ethical Committee.

11. CONFLICTS OF INTEREST

Nil.

12. DATA AVAILABILITY

This is an original manuscript and all data are available for only review purposes from principal investigators.

13. PUBLISHERS NOTE

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Table 1: Classification of *Shiro Roga*^[2,3]

Type of <i>Shiroa Roga</i>	Ch.sa	Su.sa	A.H	Mad	B.P	Y.R	Harita	Sarang	S.S
<i>Vataja Shirah Shoola</i>	+	+	+	+	+	+	+	+	+
<i>Pittaja Shirah Shoola</i>	+	+	+	+	+	+	+	+	+
<i>Kaphaja Shirah Shoola</i>	+	+	+	+	+	+	+	+	+
<i>Sannipataja Shirah Shoola</i>	+	+	+	+	+	+	+	+	+
<i>Raktaja Shirah Shoola</i>	-	+	+	+	+	+	+	+	+
<i>Kshayaja Shirah Shoola</i>	-	+	-	+	+	+	-	-	+
<i>Krimija Shirah Shoola</i>	+	+	+	+	+	+	-	+	+
<i>Suryavarta</i>	+	+	+	+	+	+	+	+	+
<i>Anataavata</i>	+	+	-	+	+	+	-	-	+
<i>Ardhavabedhaka</i>	+	+	+	+	+	+	+	+	+
<i>Shamkhaka</i>	+	+	+	+	+	+	-	+	+
<i>Shirah kampa</i>	+	-	+	-	-	-	-	+	-

Cha.sa: Charaka samhita, Su.sa: Susruta samhita, A.H: Ashtanga hridaya samhita, Mad: Madhava nidana, B.P: Bhava prakasha, Y.R: Yoga rathnakar, Harita: Harita samhita, Sarang: Sharangadhara samhita, S.S: Sarartha samgraha

Table 2: *Samprapti ghataka* of *Kaphaja Shirah Shoola*^[9]

Criteria	Specific <i>Samprapti ghataka</i> of <i>Kaphaja Shirah Shola</i>
<i>Dosha</i>	<i>Kapha Pradhana</i> and <i>Pitta, Vata anubandha</i>
<i>Dushya</i>	<i>Sira ashrita Rakta</i>
<i>Adhisthana</i>	<i>Shirasa/Mastiska, Vayu Kotharaka</i>
<i>Udbhavasthana</i>	<i>Amashaya</i>
<i>Vyakta Sthana</i>	<i>Akshikoota</i> (Periorbital area), <i>Vadanam</i> (Face), <i>Nasa</i> (Nose), <i>Galam</i> (Pharynx)
<i>Agni</i>	<i>Jatharagnimandya</i>
<i>Rogamarga</i>	<i>Madhyama Rogamarga</i>
<i>Srotas</i>	<i>Rasavaha, Raktavaha, Mamsavaha, Asthivaha, Pranavaha, Annavaha</i>

Table 3: Ingredients of *Shreshtanimbadi Kashaya* with pharmacological description^[12]

Ingredient	Scientific name	Rasa	Guna	Virya	Vipaka	Prabhava
<i>Haritaki</i>	<i>Terminalia chebula</i>	<i>Madhura, Amla, Katu, Tikta, Kashaya</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Madhura</i>	<i>Tridosha hara</i>
<i>Vibhitaki</i>	<i>Terminalia bellerica</i>	<i>Kashaya</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Madhura</i>	-
<i>Amalaki</i>	<i>Embelica officinale</i>	<i>Madhura, Amla, Katu, Tikta, Kashaya</i>	<i>Laghu, Ruksha, Theekshna</i>	<i>Shita</i>	<i>Madhura</i>	-
<i>Nimba</i>	<i>Azadirachta indica</i>	<i>Tikta, Kashaya</i>	<i>Laghu</i>	<i>Shita</i>	<i>Katu</i>	-
<i>Patola</i>	<i>Trichosanthes cucumerina</i>	<i>Tikta, Katu</i>	<i>Laghu, Ruksha, Theekshna</i>	<i>Ushna</i>	<i>Katu</i>	-
<i>Musta</i>	<i>Cyperus rotundus</i>	<i>Tikta, Katu, Kashaya</i>	<i>Laghu, Ruksha</i>	<i>Shita</i>	<i>Katu</i>	-
<i>Rajini</i>	<i>Curcuma longa</i>	<i>Katu, Tikta</i>	<i>Ruksha, Laghu</i>	<i>Ushna</i>	<i>Katu</i>	-
<i>Trayanti</i>	<i>Bacopa monneri</i>	<i>Tikta</i>	<i>Laghu, Snigdha</i>	<i>Ushna</i>	<i>Katu</i>	-
<i>Hema</i>	<i>Cassia angustifolia</i>	<i>Katu, Tikta, Kashaya</i>	<i>Laghu, Ruksha, Theekshna</i>	<i>Ushna</i>	<i>Katu</i>	<i>Rechana</i>
<i>Amrita</i>	<i>Tinospora cordifolia</i>	<i>Tikta, Kashaya</i>	<i>Snigdha, Guru</i>	<i>Ushna</i>	<i>Madhura</i>	<i>Tridosaghna</i>

Table 4: Assessment criteria

Criteria	Explanation	Grade
Headache	Unbearable continues pain interrupt day today activities	3
	Continues pain, not interrupt day today activities	2
	On and off pain	1
	No headache	0
Heaviness of the head	Unbearable continues, interrupt day today activities	3
	Continues but not interrupt day today activities	2
	On and off heaviness of head	1
	No heaviness of head	0
Peri-orbital edema	Difficult to open eye, excessive tearing with edema	3
	Excessive tearing with edema	2
	Mild edema	1
	No edema	0
Ear itching	Excessive continues itching	3
	Mild continues itching	2
	On and off itching	1
	No itching	0
Anorexia	Complete anorexia with aversion of food, coated tongue	3
	Sit in-front of food, aversion of food, coated tongue	2
	Ingestion of food without any interest	1
	No anorexia	0

Table 5: Analysis of symptoms of patients

Symptom	Group A		Group B		Total percentage
	Total	Percentage	Total	Percentage	
Headache (<i>Shirah shoola</i>)	20	100	20	100	100
Heaviness of head (<i>Shiro gauravata</i>)	15	75	16	76.66	77.5
Peri-orbital edema (<i>Akshi kuta shopha</i>)	06	30	05	25	27.5
Ear itching (<i>Karna kandu</i>)	05	25	06	30	27.5
Heaviness of body (<i>Gauravata</i>)	02	10	04	20	15
Anorexia (<i>Aruchi</i>)	09	45	06	40	37.5
Vomiting (<i>Vamaka</i>)	01	05	01	05	05

Table 6: Effect of *Shreshtanimbadi Kashaya* on assessment parameters (Treatment group)

Parameter	Mean		%	x	SD	SE	T	P
	BT	AT						
Headache (<i>Shirah Shoola</i>)	2.80	0.65	76.69	2.15	0.88	0.20	10.98	<0.001
Heaviness of head (<i>Shiro gauravata</i>)	2.73	0.33	87.91	2.40	0.82	0.21	11.22	<0.001
Anorexia (<i>Aruchi</i>)	2.11	0.45	78.67	1.66	0.86	0.28	5.77	<0.001
Peri-orbital edema (<i>Akshi kuta shopha</i>)	2.50	0.67	73.26	1.83	0.75	0.30	5.67	<0.001
Ear itching (<i>Karna kandu</i>)	2.00	0.60	70.00	1.40	0.55	0.24	5.71	<0.001

SD: Standard deviation, SE: Standard error, BT: Before treatment, AT: After treatment

Table 7: Effect of placebo on assessment parameters (Control group)

Parameter	Mean		%	x	SD	SE	T	P
	BT	AT						
Headache (<i>Shirah Shoola</i>)	2.70	2.20	18.51	0.50	0.50	0.16	3.00	>0.05
Heaviness of head (<i>Shiro gauravata</i>)	2.49	1.87	25.20	0.62	0.74	0.26	2.36	>0.05
Anorexia (<i>Aruchi</i>)	1.83	1.67	08.74	0.16	0.14	0.17	1.00	>0.05
Peri-orbital edema (<i>Akshi kuta shopha</i>)	2.20	1.80	18.18	0.40	0.54	0.24	1.63	>0.05
Ear itching (<i>Karna kandu</i>)	1.83	1.50	18.03	0.33	0.51	0.21	1.58	>0.05

SD: Standard deviation, SE: Standard error, BT: Before treatment, AT: After treatment

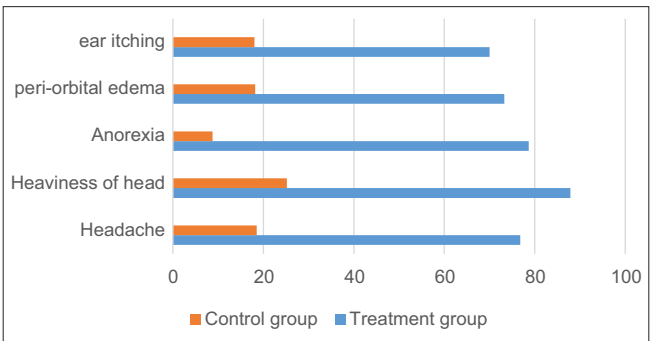


Chart 1: Comparative analysis of symptoms of *Kaphaja Shirah Shoola* in treatment group and control group after the treatment