



**A CLINICAL EVALUATION OF EFFICACY OF NAVASADARA – SHUKTI YOGA
INHALATION IN THE SYMPTOMATIC RELIEF OF SHIRAHSHOOLA**

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ABSTRACT

Navasadara - Shukti yoga is a unique formulation of Ayurveda mentioned in Bhavaprakasha, Yogaratnakara and Bhashajyaratnavali where the evolved fumes from the formulation are inhaled to treat shirorogas. In this study Navasadara - Shukti yoga was prepared as per standard operative procedure by using of Shukti in four forms. Among that the one which emitted maximum fumes was subjected to clinical study to evaluate the therapeutic efficacy in shirahshoola and also to assess the type of shirahshoola in which it is more effective. 30 patients suffering from shirahshoola were subjected for the inhalation of fumes emitted from Navasadara- marita Jalashukti yoga and evaluated thoroughly based on subjective parameters such as severity, duration, frequency and associated symptoms. Collected data was analyzed statistically with paired T test. Navasadara – marita Jalashukti yoga inhalation showed statistically significant improvement in severity and duration of shirahshoola. Excellent improvement was observed in patients suffering from vata kaphaja shirahshoola and vataja shirahshoola.

KEY WORDS: Navasadara, Shukti, Navasadara-Shukti yoga, Shirahshoola, Dhuma nasya, Clinical study.

INTRODUCTION

Inhalants are the drugs or chemicals which in the vapour form are inhaled or administered through the respiratory system in the body. When fumes are inhaled they bring about various pharmacological actions. These are dependent on nature of fumes, its concentrations and the condition in which it used.^[1] It means action and effect of fumes will be different under different conditions. Navasadara - Shukti yoga is one such unique formulation mentioned in various texts like Bhavaprakasha^[2], Yogaratnakara^[3] and Bhaishajyaratnavali^[4] under the chapter of Shiroroga. Where fumes evolved from this is used for inhalation to treat shirashoola. Yogaratnakara instead of Shukti, Kalikachurna i.e., Sudha is used and specified the action of it as kaphavatahara. The procedure where the fumes are inhaled through the nose is placed under dhooma nasya in Ayurveda which is indicated in the diseases confined to the parts above the clavicle.^[5]

In the present study an attempt was made to prepare Navasadara- Shukti yoga using shodhita Jalashukti, shodhita Mukdashukti, marita Jalashukti and marita Mukdashukti powders along with equal quantity of shuddha Navasadara and 5 drops of water in order to obtain optimum quantity of fumes. Maximum evolution of fumes was observed in the combination of shuddha Navasadara and marita Jalashukti. Hence this

combination was selected for the clinical study. According to Modern Chemistry, combination of Ammonium chloride along with Calcium carbonate or Calcium oxide in the presence of moisture leads to slow evolution of Ammonia gas when exposed to air at ordinary temperature. This fumes acts as counter - irritant, vasoconstrictor and respiratory stimulant.

Headache is one of the most common, and yet the most difficult clinical problem encountered by the physician. Headache means “pain in various parts of the head, not confined to the area of distribution of any nerve”. Most often headache is a symptomatic expression of some minor ailment, mental tension or fatigue, and in the vast majority of cases the cause is non-neurological. 90% of the individuals have at least once headache per year and 10 to 20% of the population goes to physician with headache as their primary complaint. It is also a major cause of absenteeism from work and of avoidance of social and personal activities.^[6]

Ayurveda lays emphasis on “Shiras” by saying it as the Uttamanga - the important part of the body because all the sensory organs are located in the head along with the vital of the individual. Various scholars have elaborated Shiroroga which describes the prevalence of the disease from ever since and need of requiring their management. “Naasa hi Shirasodwaram” nose is the route for the

administration of medicine for the diseases confined to the parts above the clavicle.^[7] To evaluate the efficacy and to assess the type of shirahshoola, this study was carried out with the title “A clinical evaluation of efficacy of Navasagara - Shukti yoga inhalation in the symptomatic relief of Shirahshoola”.

MATERIALS AND METHODS

Selection criteria

30 Patients suffering from shirashoola, who fulfilled the criteria of inclusion were randomly selected for the study from OPD and IPD of SDM Ayurveda hospital, Udipi, irrespective of their gender, caste, economic status and educational status.

Inclusion criteria

- Patients aged between 8 - 80years.
- Patients suffering from headache.

Exclusion criteria

- Patients below 8 years and above 80 years
- Patients suffering from Ischaemic heart disease.
- Headache due to meningeal irritation.
- Headache due to traction on intracranial structures.

Intervention

Patient was made to sit on a comfortable chair and was instructed to inhale the fumes emitted from Navasagara –

marita Jalashukti yoga deeply through the nose for 3times in one sitting at the time of headache.

Assessment criteria

The efficacy of the trial drug fumes inhalation was analysed in terms of relief produced in the subjective parameters before and after treatment. Follow up was done for 2months. Patients were evaluated thoroughly on the basis of visual analogue scale, and were analyzed statistically with paired T test.

Subjective parameters

- Severity of headache
- Duration of headache
- Reduction in associated symptoms.
- Frequency of headache.

Criteria for assessment of overall effects

Overall effect of the therapy was assessed in terms of complete remission, excellent improvement, moderate improvement, and mild improvement and unimproved.

- Complete remission: 100% relief in symptoms
- Excellent improvement: < 100% to > 75% relief in symptoms
- Moderate improvement : <75% to <50% relief in symptoms
- Mild improvement: <50% to >25% relief in symptoms
- Unimproved: 25% to 0% relief in symptoms

OBSERVATION AND RESULTS

Table 1: Incidence of types of shirashoola.

Types of Shirahshoola	No Of Patients	Percentage
Vataja	11	36%
Vatakaphaja	17	57%
Vatapittaja	2	7%

Table 2: Effect on intensity, duration and frequency of headache.

Parameters of Headache	Mean score		%	Mean in difference	S.D	S.E	't'	P
	B.T	A.T						
Intensity	2.60	0.60	77%	2.000	1.11	0.20	9.832	<0.001
Duration	2.77	1.60	42%	1.167	1.05	0.192	6.07	<0.001
Frequency	2.27	2.10	7%	0.167	0.592	0.108	1.542	0.134

Table 3: Effect on associated symptoms.

Associated symptoms	Mean score		%	Mean in difference	S.D	S.E	't'	P
	B.T	A.T						
Nausea	0.43	0.24	24%	0.103	0.310	0.058	1.797	0.083
Vomiting	0.10	0.067	3%	0.033	0.183	0.033	1.000	0.326
Photophobia	1.33	0.27	80%	1.067	1.230	0.225	4.750	<0.001
Heaviness	2.90	0.13	95%	2.767	0.504	0.092	30.066	<0.001
Tenderness	1.13	0.33	70%	0.800	1.095	0.200	4.000	<0.001
Giddiness	0.53	0.33	37%	0.200	0.551	0.101	1.989	0.056

Table 4: Overall effect of Navasadara - Shukti yoga in 30 patients of shirashoola.

Overall effect of Navasadara - Shukti yoga	No of patients	Percentage
Complete remission	0	0%
Excellent improvement	15	50%
Moderate improvement	8	27%
Mild improvement	4	13%
Unimproved	3	10%

Table 5: Overall effect of Navasadara - Shukti yoga in vataja shirashoola.

Overall effect in vataja shirashoola	No of patients	Percentage
Complete remission	0	0%
Excellent improvement	8	73%
Moderate improvement	2	18%
Mild improvement	0	0%
Unimproved	1	9%

Table 6: Overall effect of Navasadara - Shukti yoga in vatakaphaja shirashoola.

Overall effect in vatakaphaja shirashoola	No of patients	Percentage
Complete remission	0	0%
Excellent improvement	15	88%
Moderate improvement	2	12%
Mild improvement	0	0%
Unimproved	0	0%

Table no 7: Overall effect of Navasadara - Shukti yoga in vatapittaja type of shirashoola.

Overall effect in vatapittaja shirashoola	No of patients	Percentage
Complete remission	0	0%
Excellent improvement	0	0%
Moderate improvement	0	0%
Mild improvement	0	0%
Unimproved	2	100%

DISCUSSION

Initially pilot study was carried out in 5 patients where the patients were made to sit comfortably on the chair and was instructed to inhale the formulation 3 times directly from the glass bottle. The patients were exposed to sudden rush of fumes which were suffocating. So the funnel like instrument was used to reduce the quantity of fumes. It was found better than direct method from the bottle for the patients to inhale hence this methodology was adopted in all 30 patients who were taken for the clinical study. Maximum patients had pain in whole head (50%) followed by in temporal region (33%). Nature of headache was throbbing pain (53%) in maximum number of patients followed by pulsating type (43%). The study revealed that before treatment maximum patients i.e. 40% were had moderate type of pain followed by severe pain i.e. 30%, then 20% were having excruciating pain and 10% patients had mild pain. After treatment maximum patient had no pain (53%), mild pain (33%) and moderate pain (14%). The duration of the headache before treatment, it was observed that maximum patients i.e. 33% were suffering from headache for 3-6 hours (moderate) followed by 30% was more than 12 hours

(severe) then 27% were having pain for 6-12 hours (excruciating) and 10% patients had pain for 0- 3 hours (mild). After treatment maximum patients had pain for 0- 3 hrs (53%), followed by 3-6 hrs (27%), no pain (10%), for more than 12 hours (7%) and for 6-12 hrs (3%). It was observed before treatment, that maximum patients (37%) were suffering from headache weekly once, 27% were suffering 15 days once, 20% were suffering from daily/ irregular headache and 17% were suffering monthly once. After treatment, maximum patients had weekly headache (43%), followed by 20% each for 15 days once and monthly, then 17% in daily / irregular. The study revealed that before treatment, all 30 patients were having heaviness, 15 patients were having photophobia, 12 patients were having tenderness, each 4patients were having nausea and giddiness and 2 patients were having vomiting. After treatment, 8 patients were having tenderness, 7 patients were having photophobia, each 4 patients were having heaviness and nausea, 3 patients were having giddiness and 2 patients were having vomiting.

The effect of Navasagara-Shukti yoga inhalation on Headache showed that there was statistically significant (<0.001) improvement in intensity (77%) and duration (42%) of headache. Frequency of headache (7%) showed no significant improvement. Statistically highly significant ($p<0.001$) improvement in heaviness (92%), photophobia (80%) and tenderness (70%) and no improvement was found in nausea, vertigo and vomiting. Out of 30 patients, 15 patients (50%) gained excellent improvement, 8 patients (26%) gained moderate improvement, 4 patients (13%) gained mild improvement and 3 patients (10%) were unimproved in shirashoola. Out of 30 patients suffering from Shirashoola, 17 patients (57%) had vatakaphaja shirashoola, 11 patients (36%) had vataja shirashoola, and 2 patients (7%) had vatapittaja shirashoola. Out of 17 patients suffering from vatakaphaja shirashoola, 15 patients (88%) gained excellent improvement and 2 patients (12%) had moderate improvement. Out of 11 patients suffering from vataja shirashoola, 8 patients (73%) gained excellent improvement 2 patients (18%) gained moderate improvement, and 1 patient (9%) was unimproved. Out of 2 patients suffering from vatapittaja shirashoola, both the patients (100%) were unimproved.

According to Modern Chemistry, combination of Navasagara - Shukti i.e., Ammonium chloride and Calcium carbonate or Calcium oxide in the presence of moisture leads to slow evolution of ammonia gas when exposed to air at ordinary temperature. This fume acts as counter - irritant, vasoconstrictor, rubefacient, respiratory stimulant and also increases the heart rate. Ammonia gas is very alkaline, and an irritant to mucous surfaces. Inhaled, it causes an overpowering sense of suffocation and spasm of the glottis, and when prolonged, violet inflammation of the air- passages¹. When cautiously employed gives relief from acute catarrh, sick headache and Migraine.

On the basis of nidana and lakshanas of vataja shirashoola, it can be compared with vascular headache which is a chronic neurological disorder. According to Acharya Vagbhata when vataja shirashoola is confined to one half of the head is named as Ardhavabhedaka^[8] that can be compared with Migraine which is relieved by pressure and fomentation. Main pathophysiology of migraine is vasodilatations of blood vessels where the line of treatment is towards vasoconstriction. The Navasagara - Shukti formulation liberates Ammonia gas which acts as vasoconstrictor and helps to relieve Headache when used cautiously. According to Acharya Charaka, Gaurava & Mandaruja are the main symptoms of kaphaja shirashoola.^[9] The similar symptoms are mentioned under Sinus headache in modern science. Allergies and upper respiratory infections increase nasal secretions and cause tissue lining the nasal passages to swell. This results in nasal congestion and stuffiness. The nasal passages become blocked and normal drainage cannot occur. Secretions that are trapped in the sinuses may be become infected with bacteria or rarely fungus.

The swollen tissue/ infection may create pain and pressure. The line of treatment for sinus headache should consist of opening the nasal passage and to allow the sinus cavities to drain. Nasya karma also known as shirovirechana is having utmost importance in the treatment of shirorogas as nose is the only gateway to eliminate the doshas outside from the shiras. Ammonia liberated from the Navasagara - Shukti yoga acts as counter irritant and removes the nasal congestion leading to opening of nasal passage. When nasal passages are opened, the drainage of sinus cavities occurs properly and indirectly it helps to relieve Headache.

CONCLUSION

Inhalation of Navasagara- Shukti yoga fumes has better result in vataja and vata kaphaja shirashoola. Among them, this formulation is best effective in vata kaphaja shirashoola. Statistically significant results were also observed in associated symptoms like heaviness and tenderness. Cautious inhalation of fumes evolved from Navasagara- Shukti yoga is safe in the treatment of shirashoola. This study was limited to only one sitting in each patient during time of one attack of headache. By increasing the number sittings of treatment better result can be expected.

REFERENCES

1. G.R.Chatwal. Pharmaceutical Chemistry-Inorganic (volume1). Edited by M Arora. 2nd edition. Mumbai :Himalaya Publishing House; Reprint 2003.Pp.488.p.266,269.
2. Bhavamishra. Bhavaprakasha. Bulusu Seetaram Commentary. 2nd volume.1st edition. Varanasi:Chaukambha Orientalia;2006. Pp.770.p.603.
3. Yogaratnakara.Vidyotini Hindi Commentary. Brahmashankar Shastri editor. Varanasi: Chaukambha Prakashana; Pp.1077.p.913.
4. Govinda Das. Bhaishajyaratnavali. Kaviraja Ambikadatta Shastri, Rajeshwara Dutta Shangri editors. 20th edition. Varanasi: Chaukambha Prakashana;2010.Pp.1312.p.1021.
5. Bhela. Bhela Samhita. Girijadayalu Shukla editor. Varanasi:Chaukambha Bharati Academy; Reprint 1999. Pp.285.p.257-259.
6. www.Wikipedia.com- Calcium carbonate
7. Agnivesha. Charaka Samhita. Yadavji Trikamji Acharya editor. Varanasi:Chaukambha Orientalia; Reprint 2007.Pp.738.p.722.
8. Vagbhata. Astanga Sangraha. Shashilekha Sanskrit Commentary. Shivaprasad Sharma editor. 2nd edition. Varanasi: Chaukambha Sanskrit series office: 2008.Pp.965.p.766.
9. Agnivesha. Charaka Samhita. Ayurveda Dipika Commentary by Chakrapanidatta. V. D. Harishchandra Singh Kudhwaha. Varanasi: Chaukambha Orientalia; Reprint 2009.Pp.964.p.257-260.