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ISSN 2321 - 6328

Research Article

EFFECT OF NASYA IN APEENASA (PARANASAL SINUSITIS): AN RCT

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Article Received on: 01/07/19 Accepted on: 02/08/19

DOI: 10.7897/2321-6328.074109

ABSTRACT

Background: As per Ayurvedic classics apeenasa is one of the nasagata rogas (nasal disorders) that be considered as the paranasal sinusitis according to the conventional medicine. The terms peenasa and apeenasa can be used based on the stages and the types of paranasal sinusitis. Objectives: To evaluate the efficacy of nasya karma (nasal instillation therapy) and vyoshadi vati in patients of apeenasa having nasasrava (nasal discharge), shirogurutwa (heaviness of head) and kshavatu (sneezing) of patients suffering from apeenasa. Design: This was a randomized controlled study with thirty patients divided into three groups, 10 in each. In Group A, Nasya karma was given once a day for 7 days, in Group B, Vyoshadi vati was given twice a day for 7 days and in Group C, Nasya karma and Vyoshadi vati was given in combination for 7 days. Results: Statistically significant results were seen in reduction of nasasrava, shirogurutwa and kshavatu of patients suffering from apeenasa with $p < 0.001$. Conclusions: Group C (Nasya karma with vyoshadi vati) showed statistically significant results compared to Group A (nasya karma) and Group C (Vyoshadi vati) in reduction of nasasrava, shirogurutwa and kshavatu of patients suffering from apeenasa.

Keywords: Apeenasa, Paranasal sinusitis, Nasya karma, Peenasa.

INTRODUCTION

The paranasal sinuses are air-filled spaces located within the bones of the skull and facial bones. They are centered on the nasal cavity and have various functions, including lightening the weight of the head, humidifying and heating inhaled air, increasing the resonance of speech, and serving as a crumple zone to protect vital structures in the event of facial trauma.^{1,2} Humans possess four paired paranasal sinuses, divided into subgroups that are named according to the bones within which the sinuses lie: The maxillary sinuses, the largest of the paranasal sinuses, are under the eyes, in the maxillary bones (open in the back of the semilunar hiatus of the nose). They are innervated by the trigeminal nerve. The frontal sinuses, superior to the eyes, in the frontal bone, which forms the hard part of the forehead. They are also innervated by the trigeminal nerve. The ethmoidal sinuses are formed from several discrete air cells within the ethmoid bone between the nose and the eyes and are innervated by the ethmoidal nerves, which branch from the nasociliary nerve of the trigeminal nerve. The sphenoidal sinuses are located in the sphenoid bone and are innervated by the trigeminal nerve.³

Sinusitis is the inflammation of the mucosa of any one or all of the paranasal sinuses. When all sinuses are involved it is called as pansinusitis.⁴ One in eight Indian suffers from sinusitis caused by the inflammation of the Para nasal sinuses. The worldwide incidence of sinusitis is recorded as 31 million cases in US that is 146 per 1000 population, and in Indian incidence, it is estimated that 134 million Indians are suffering from chronic sinusitis.⁵

Diseases of Paranasal sinuses (PNSs) commonly affect the varied range of population, ranging from inflammatory conditions to neoplasms, both benign and malignant.^{6,7} These are a common site of infection in children and adolescents.⁸ Infections of these sinuses cause frequent morbidity and rarely may result in life-threatening complications. It may be difficult to distinguish children with uncomplicated viral upper respiratory infections or adenoiditis from those with an episode of acute bacterial sinusitis.⁹ Most viral infections of the upper respiratory tract involve the nose and the paranasal sinuses (viral rhinosinusitis).¹⁰ Patients with bacterial infection of the paranasal sinuses have purulent (thick, colored, and opaque) nasal drainage. Chronic inflammation of the paranasal sinuses results in noninfectious conditions such as allergy, environmental pollutants, cystic fibrosis, or gastro-esophageal reflux.¹¹

Paranasal sinusitis can be correlated to the disease Apeenasa in Ayurveda based on the symptoms and has been opined the same by all Acharyas. one of the Complementary and Alternative Medicine has described in detail the intervention called as nasya karma that has shown to be effective in peenasa, the allergic rhinitis. But there are no studies concerning the disease apeenasa, the para nasal sinusitis, therefore the present study was carried out to evaluate the role of nasya karma therapy in the management of apeenasa, the paranasal sinusitis.

MATERIALS AND METHODS

The data were collected from the OPD and IPD of Shalaky Tantra, S. J. I. M. Hospital, Bangalore. Patients with the features of apeenasa (paranasal sinusitis) with chronicity of less than 1 year and both males and females aged between 10 to 60yrs were included for the study. Patients with the features of disorders other than apeenasa and DNS were excluded from the study.

Ethical clearance and consent

The study was approved by the institutional ethical committee and signed informed consent was obtained from all patients.

Design: In this randomized control study, 30 subjects who satisfied the study criteria were divided into three groups, Group A, Group B and Group C with 10 patients in each group. Group A received Nasya karma with tulasi swarasadi taila for 7 days, Group B were administered with vyoshadi vati for 7 days and Group C received both nasya karma with tulasi swarasadi taila and vyoshadi vati for 7 days. All the patients were subjected to detailed clinical and laboratory investigations prior to and after the completion.

Outcome measures:

Nasavrava (nasal discharge), shirogurutwa (heaviness of head) and kshavatu (sneezing) were assessed before and after the treatment. Patients were evaluated at an interval of 3 to 7 days.

INTERVENTION

Group A

Group A received the nasya karma with tulasi swarasadi taila for 7 days. The whole procedure was explained to the patient and was advised to complete their early morning chores by cleaning their teeth and washing face with warm water. Also, they were advised to take a non-spicy light diet. Then they were taken to a comfortable room that was devoid of dust, extreme breeze and sun light. Actual procedure of the therapy was administered with bahya snehana (external application) over the shiras (oil massage over the head), gentle oil massage over gala (chin), kapola

(cheeks), lalata (forehead) and karna (ears). After snehana (oil massage), mild swedana (fomentation) was carried out to the area above the shoulders with eyes being closed. After this, patients were made to lie down on a table in supine position, eyes covered with a cloth folded in four layers. Then tulasi swarasadi Taila was taken in a small crucible and is kept tepid by placing it in hot water. The head of the patient was slightly raised, nostrils widened with the index little finger of the left hand and tulasi swarasadi taila was poured through the right hand by using a pad of cotton wool. The other nostril was closed while administering nasya karma through one nostril. The instillation of tulasi swarasadi taila was slow and in an uninterrupted stream known as "avicchinna dhara". The patient was advised to inhale the medicine administered slowly and forcefully. The same procedure was repeated in other nostril too. As post therapy instructions, patient was advised not to make any movements with his head and slowly gentle massage of skanda (shoulders), karna (ears), hasta (palms), padatara (plantar aspect of foot) was done and patients were advised to spit out the content of taila (oil) through mouth, strictly instructed not to swallow taila and to carry on the act of spitting till the smell and the taste of tulasi swarasadi taila disappears from the throat.

After this, patients were advised to relax in the same position for few minutes followed by paschat karma (post procedure) of kavalagraha (gargling) with hot water. Also instructed them to avoid excessive intake of fluid, not to succumb to the emotional disturbances, smoke, dust, exposure to sun light and intake of snigdha and abhishyandhi ahara (unctuous food). They were also advised not to take head bath and travelling for one day. This procedure was carried out for 7 consecutive days.

Group B

In this group, Patients were administered vyoshadi vati twice a day, after food for 7 days.

Group C

In this group, both the interventions of Group A and Group B were administered.

Table 1 Demographic data

Sl.No	Demographic parameters	Group A	Group B	Group C	Total
1.	Age				
	10-20 yrs	1	5	1	7
	21-40 yrs	9	4	5	18
	41-60 yrs	0	1	4	5
2.	Sex				
	Males	0	4	4	8
	Females	10	6	6	22
3.	Religion				
	Hindu	12	5	8	25
	Muslim	1	0	2	3
	Christian	0	0	2	2
4.	Occupation				
	House Wives	4	0	4	8
	Teachers	2	0	0	2
	Students	1	5	2	8
	Factory Employees	3	0	3	6
	Office Working Staff	0	3	0	3
	D.Y.S.P	0	2	1	3
5.	Dietic Significance				
	Veg	5	7	2	14
	Non-Veg	5	3	8	16
6.	Chronicity of the illness				
	< one month	1	3	6	10
	<Three months	7	7	1	15
	< Six months	2	0	3	5

RESULTS

Thirty patients with features of apeedasa or the paranasal sinusitis were registered for the study. In the present study, the incidence of apeedasa was more in 21-40 years age group, 22 were females, 25 were Hindus, the factory employees and the workers of Sericulture Department were more prone for Apeedasa. The house wives also had high incidence of Apeedasa due to cleaning of the house and cooking in smoke.

Table 2 Results between Groups

	<3 Days		<5 Days		<7 Days		>7 Days	
	Excellent		Good		Moderate		Poor	
Group	No. of Patients	%	No. of Patients	%	No. of Patients	%	No. of Patients	%
A	0	0	0	0	4	40%	6	60%
B	0	0	0	0	1	10%	9	90%
C	0	0	2	20%	7	70%	1	10%
Total			2		12		16	

After 5 days of treatment, Patients in Group A and Group B found no relief, whereas in Group C, 2 patients had good relief, After 7 days of treatments, 4 patients in Group A, 1 in Group B and 7 patients in Group C moderate relief.

Table 3 Overall results

Group	Relieved	Not Relieved	Total	% +ve
A	4	6	10	40
B	1	9	10	10
C	8	2	10	80
Total	13	17	30	42.90

In Group A, 4 patients were completely relieved from their symptoms with 40% and 6 patients had no relief, In Group B, 1 patient was completely relieved with 10% and 9 patients were not relieved. Whereas in Group C, 8 patients had complete relief from all their symptoms with 80% and 2 patients had no relief.

Nasavrava

Group C showed significant results with nasya karma and vyoshadi vati in the reduction of nasavrava compared to Group A and Group with only nasya karma and vyoshadi vati with $p < 0.001$.

Shirogurutwa

Group C showed significant results with nasya karma and vyoshadi vati in the reduction of shirogurutwa compared to Group A and Group with only nasya karma and vyoshadi vati with $p < 0.001$.

Kshavatu

Group C showed significant results with nasya karma and vyoshadi vati in the reduction of kshavatu compared to Group A and Group with only nasya karma and vyoshadi vati with $p < 0.001$.

DISCUSSION

Shalaky Tantra is an important branch of Ayurveda which deals with the study and treatment of diseases of eye, ear, nose, teeth, throat, head and mouth.¹² In Ayurveda, the paranasal sinusitis can be correlated to apeedasa and peenasa to allergic rhinitis where, Peenasa is described as Vatakaphaj and a Krichasadhya Vyadhi (disease that can be cured with difficulty).¹³ Allergic rhinitis is described as peenasa and the concept of allergy is explained under "Asatmyaja vyadhi" (allergic disorders), while its effects are explained in Viruddhahara (incompatible foods) and Dushivisha (polluted substances or allergic agents) and Ritu sandhi (seasonal changes). Effective therapeutic methods for allergic rhinitis including internal as well as external treatments are also found in Sri Lankan traditional system of medicine and in Ayurveda medicine.¹⁴

Ancient Ayurvedic science also describes many therapies like nasya karma, akshitarpara (local therapy for eyes), putapaka (local therapy for eyes) etc which is said to be very effective in the shirogata rogas (diseases of head) among which apeedasa is one such condition that can be correlated to paranasal sinusitis based on the symptoms. As there were no studies on the same, present study was planned to evaluate the efficacy of nasya karma in apeedasa. In this randomized control study, 30 subjects who satisfied the study criteria were divided into three groups, Group A and Group B and Group C with 10 patients in each group. Group A received Nasya karma with tulasi swarasadi taila for 7 days, Group B were administered with vyoshadi vati for 7 days and Group C received both nasya karma with tulasi swarasadi taila and vyoshadi vati for 7 days. All the patients were subjected to detailed clinical and laboratory investigations prior to and after the completion. In the present study, higher incidence of apeedasa was seen in females (22) compared to males (8), 18 patients in the age group of 21 to 40yrs, and in Hindus(25) and in the patients with the occupation of factory employees, workers of sericulture department and house wives. Out of 30 patients (15) patients were with the history of chronicity of illness, from three months and below three months.

Nasya karma, one among the Panchakarma (five kinds of therapies) therapies is beneficial for the maintenance of health and eradication of diseases. Nasal route of drug administration is the natural choice for the treatment of local nasal disorders as well as other supraclavicular diseases. In this therapy, the medicine is administered through nose either in the form of ghee, oil, powder, liquid or smoke. It is particularly useful in the treatment of diseases occurring in the organs situated above the clavicle but indirectly it works on the whole body by improving the functioning of the endocrine glands and nervous system. Nasa is said to be the main doorway to Shiras. Nasya aushadhi (medicines of nasal therapy) reaches to brain via nasal route and acts on higher centers of brain controlling different neurological, endocrinal and circulatory functions and thus showing local as well as systemic effects. This administration of drugs through nasal route opens a new hope for the both local and systemic drug administration. Nasal route drug administration is a promising

alternative route of drug administration for local, systemic and central nervous system action.¹⁵

In the present study, In group A, only one patient showed relief by Nasa Srava and rest of the complaints were retained. All the complaints were relieved in 4 patients by 7th day of treatment showing 40% response to the Nasya Karma alone.

In group B, all the 10 patients were given Vyoshadi Vati depending upon their body weight for 7 days. Only in one patient Shirogurutwa (heaviness of head) was reduced. The remaining 9 patients did not respond for the treatment. The response in group B was only 10%. In the classics, though Amapaachana (proper digestive fire) is said to be necessary for the therapy, in this clinical trial. Only Abhyantara Chikitsa (oral medication) with Vyoshadi Vati did not show a good response.

In group C, on 3rd day, 1 patient, 4th day, 5 patients and 7th day, 4 patients on were relieved of nasa srava. Analysis of the results obtained in respect of Shirogurutwa (heaviness of head) and Kshavatu, 10% of the patients showed a good response on 5th day. On 4th day, in 50% of the patients these complaints were relieved. 40% of the patients were relieved by Shirogurutwa and Kshavatu (sneezing) on 7th day. However, by the 7th day of treatment in Group C all the patients showed a moderate response. Around 80% of the patients showed moderate response for the therapy with Tulasi Swarasadi Taila-Nasya and Abhyantara Chikitsa (oral medication) with Vyoshadi Vati.

Several Randomized controlled clinical trials have shown the effectiveness of nasya karma. In one such study on cervical spondylosis, nasya karma has shown significant reduction in the signs and symptoms by nasya.¹⁶ Clinical trials of nasya have been carried out¹⁷ for myopia.¹⁸ Pradhamana nasya (type of nasal therapy) is used by Ayurvedic physicians and have been found useful to treat chronic sinusitis.^{19,20}

In the study of Dave et al, total 30 patients having classical sign and symptoms of Dushta Pratishyaya (Chronic Sinusitis) were registered and were randomly divided into two groups (Group A- Vyaghri Haritaki Avaleha and Anutaila Nasya, Group B- Vyaghri Haritaki Avaleha). The patients were given Vyaghri Haritaki Avaleha for the duration of two months and Anutaila Nasya in 3 sittings of seven days in each with the interval of seven days. Total 26 patients completed the treatment, 13 in each. 46.15 % and 53.85 % patients got marked relief, 38.46 % and 23.08 % patients got moderate relief, 15. 38% and 23.08 % patients got mild relief in signs and symptoms of the disease in Group A and B respectively.²¹

In the present study, Nasya karma and vyoshadi vati in combination showed the significant results in the reduction of nasasrava, shiroguruta and the kshavatu compared to only nasya karma or the vyoshadi vati individually with p<0.001.

CONCLUSION

Nasya karma and vyoshadi vati in combination showed the significant results in the reduction of nasasrava, shirogurutwa and kshavatu compared to only nasya karma or the vyoshadi vati individually.

Strengths of the study

Nasya karma was easily applicable with no side effects or complications.

Limitations of the study

Although, this disease apeenasa is described by Acharya Sushruta and Vagbhata, there were no studies conducted and this was the first study to be carried out on apeenasa. Further, more number of studies with more sample size needs to be carried out on the same.

Suggestions and Recommendations

More number of clinical studies on apeenasa needs to be carried out. Other drugs mentioned in Ayurveda for apeenasa (paranasal sinusitis) also can be evaluated.

ACKNOWLEDGEMENTS

We sincerely acknowledge our thanks to all the staff of the Department of Shalakya Tantra, GAMC, Bangalore and Ms. Lavanya of AAYUSH Ayurveda Center, Bangalore.

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Cite this article as:

Vanishree et al. Effect of nasya in apeenasa (paranasal sinusitis): An RCT. *J Biol Sci Opin* 2019;7(4):40-44.
<http://dx.doi.org/10.7897/2321-6328.074109>

Source of support: Nil; Conflict of interest: None Declared

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