

The effect of *pratidina* (daily) practice and *ekahantara* (alternate) practice of *nasya* with *anutaila* in chronic sinusitis – A comparative clinical trial

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Abstract

Nasya is the panchakarma to eliminate morbid doshas in head and neck. Vagbhatacharya opines that except for Vatika clinical conditions *Nasya* should be done for 7a days but as *ekahanthara* (alternate) that is with a gap of one day in between. As no previous studies were available on the efficacy and safety of *ekahanthara nasya*, a comparative clinical study was conducted with *anutaila* in chronic sinusitis. 20 participants were divided by convenience sampling into group A (*pratidina nasya*) and group B (*ekahanthara nasya*). The assessment was done by Scoring of symptoms, Haematological evaluation, Rhino sinusitis disability index, Event evaluation scale and *Nasya samyak lakshana*.

Significant reduction in symptoms score was seen in both group A ($p < 0.01$) and group B ($p < 0.001$). The *samyak yoga* score was 82% in group A while in group B it was 95%. *Asmyak yoga* score in group A was 18% and 5% in group B and the difference was statistically significant ($p < 0.05$). Hence the present clinical trial concludes that the *ekahanthara* practice of *nasya* with *Anutaila* was more safe and effective compared to *pratidina* practice of *nasya* in chronic sinusitis.

Keywords: *Ekahanthara nasya*, *Pratidina nasya*, Chronic sinusitis, *Anutaila*.

Introduction

Among the *Panchakarma* (five biopurificatory procedures), *Nasya* (Errhine therapy) is said to be effective in curing diseases of *Urdhvajatra* (supraclavicular region). It is practically more feasible and economic compared to other *panchakarma* procedures, even at outpatient department and widely practiced with high degree of clinical success. A lot of disparity exists in routine practice regarding the dose and procedure of *Nasya*. Vagbhata opines that *nasya* can be done in morning and evening for 7 days in *vaata* predominant conditions like *sirasoola*, *hidhma*, *apatanaka*, *manyasthambha* and *swarabhramsa*. But in all other conditions *nasya* may be done on alternate days for 7 days (*ekahanthara*).¹ Thus it will take 13 days to finish one course of *nasya*. *Nasya* is routinely practiced with *sneha* because of its feasibility, availability and inherent *kaphahara* property. *Anutaila* was selected for the present study considering its *trodoshahara* properties with special action in *naasaroga* and *sirasoola*.

Due to the increased environmental pollution and hectic life, rhinitis is a common condition nowadays, and improper management leads to Sinusitis and later it results into chronic sinusitis. The features of the disease *Dushta pratisyaya* is similar to chronic sinusitis in ayurvedic literature.² This disease is characterized by nasal blockage, nasal discharge, headache, sneezing, heaviness in head, halitosis etc. *Dushtapratishyaya* is *vata kapha pradhana tridoshaja vyadhi*. Caraka has mentioned *Nasya* as the first line of treatment in *dushta pratisyaya*. So a comparative study was planned on chronic sinusitis with *anutaila* between *pratidina* and *ekahanthara* practice of *nasya* to find out the safety and efficacy.

Objectives

1. To assess the safety and efficacy of *pratidina* practice of *nasya* with *Anutaila* in the management of chronic sinusitis
2. To assess the safety and effect of *ekahanthara* practice of *nasya* with *Anutaila* in the management of chronic sinusitis
3. To compare the effects of *pratidina* practice and *ekahanthara* practice of *nasya* in the management of chronic sinusitis

Materials and Methods

Study Design: Comparative clinical trial

Setting: OPD VPSV Ayurveda College Kottakkal, Kerala

Duration of Study: 18 months

Sample Size: Two groups each with 10 participants

Sampling Technique: 20 samples were divided in two equal groups by using convenience sampling.

Ethical Clearance was obtained from the Ethics Committee VPSV Ayurveda College Kottakkal (IEC/ Doc/18/12 dated 28/05/2012)

Diagnostic Criteria^{3,4}

A) Chronicity – 12 weeks or more duration

B) Signs and symptoms:

Two or more of the following:

1. Muco purulent drainage (anterior, posterior or both)
2. Nasal obstruction (congestion)
3. Facial pain-pressure-fullness, or
4. Decreased sense of smell

C) Inflammation finding documented by one or more of the following findings⁵

1. Purulent (not clear) mucus or edema in the middle meatus or ethmoid region
2. Polyps in nasal cavity or the middle meatus, and/or

- Radiographic imaging showing inflammation of the paranasal sinuses

Inclusion Criteria

- Participants indicated for nasya
- Participants between 20- 60 years of age
- Sex- no discrimination
- Participants who have given informed consent

Exclusion Criteria

- Participants with chronic debilitating infectious diseases
- Participants with nasal polyp requiring surgical treatment
- Participants with the poorly controlled HTN, DM
- Pregnant/ lactating woman

Table: 1 Details of materials and intervention

Particulars	Group A	Group B
Sample size	10	10
Drug	<i>Anutaila</i>	<i>Anutaila</i>
Dose and procedure	4ml (8bindu) in 2 instillations in each nostril in morning	4ml (8bindu) in 2 instillations in each nostril in morning
Duration of treatment	Max.7 days continuously	Max.7 days alternately (total 13 days)
Follow up period	30 days	30 days

The trial drug was purchased from arya vaidya sala Kottakkal (GMP certified company), Batch No: 161968, Mfg date: August 2012

Assessment

- Assessment was done before the treatment and on 8th day after treatment and after follow up period for chronic sinusitis.
- Assessment of *samyak yoga* and *asamyak yoga* of *nasya* was done on each day of *nasya*.

Assessment criteria

- Scoring of the symptoms

- Haematological examination- Blood routine
- Rhino sinusitis Disability index ^{7,9}
- Event Evaluation scale

Data analysis

A detailed Case Record Form (CRF) was used to collect the data. The clinical symptoms, subjective parameters and laboratory parameters were tabulated and subjected to statistical analysis manually with the help of excel sheet.

Observation and Analysis

Table 2: Effect of therapy on haematological values

Group A

Haematological values	Mean BT	Mean AT	MD	%	SD	t	P
Total blood count	9750	9530	580	5.94	633.89	0.818	>0.05
Polymorph	50.5	49.9	0.6	1.1	633.85	0.823	>0.05
Eosinophil	3.1	4	-0.9	29	1.56	0.152	>0.05
Lymphocyte	45	44.9	0.1	0.22	5.1	0.039	>0.05
ESR	14.6	12	2.6	17.8	3.94	2.081	>0.05
Hb	12.7	12.9	-0.2	3.53	0.38	1.712	>0.05

Group B

Haematological values	Mean BT	Mean AT	MD	%	SD	t	p
Total blood count	9440	9050	650	6.88	811.3	1.25	>0.05
Polymorph	50.5	49	0.5	0.91	811.3	1.25	>0.05
Eosinophil	4.9	3.9	1	20.4	0.84	2.37	<0.05
Lymphocyte	40.3	39.1	1.2	2.97	6.21	0.46	>0.05
ESR	14.3	11.3	3	20.9	5.81	1.40	>0.05
Hb	12.6	13.17	-0.55	4.32	0.24	4.07	<0.05

On analysing the effect of treatment on mean total count using paired t-test, the result was insignificant statistically ($p>0.05$) in both the groups. Similarly, the effect on Polymorph ($p>0.05$) and on ESR ($p>0.05$) was insignificant. However the effect on Eosinophil was significant ($p<0.05$) in group B, with a reduction of 28.57% and effect on Hb was found to be significant ($p<0.05$) with the improvement of 4.6% in the *ekahantara* group (Gp B)

Effect of Therapy on Rhino Sinusitis Disability Index:

The effect of therapy in both the groups were analysed using paired t-test and was found statistically highly significant at $p<0.001$. *Nasya* with *Anutaila* was effective in reducing the Rhino sinusitis disability questionnaire scores of both the groups.

Table 2 Comparison of the effect of treatment on Rhino sinuitis disability index in both groups

Group	Mean AT	t	P
A	7.2	1.735	>0.05
B	9.3		

Effect of Therapy on Clinical Symptoms of the Diseases:

The effect of therapy on clinical symptoms was assessed comparing the mean scores, before, after the treatment and after a follow up period of 30 days in both the groups. The symptoms analysed were *naasavrava*, *kshavthu*, *naasavarodha*, *sirasoola*, and *sirogourava*, *kaasa*, *ghranaviplava*, *swarabedha aruchi*, post nasal drip and *mukhadourgandhya*.

Table 3: Effect of treatment on Group A

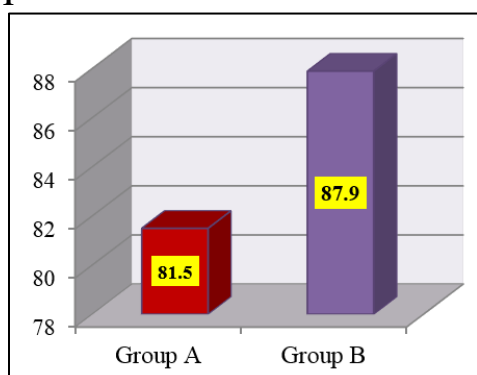
Clinical symptoms	Mean BT	Mean AT	MD	%	SD	t	p
<i>Nasavrava</i>	0.8	0.1	0.7	87.5	1.15	1.90	>0.05
<i>Kshavthu</i>	1.9	0.6	1.3	68.4	1.70	3.15	<0.01
<i>Nasavrodha</i>	3	0.9	2.1	70	0.87	7.58	<0.001
<i>Ghranaviplava</i>	2.2	0.8	1.4	63.3	1.34	3.74	<0.01
<i>Post nasal drip</i>	2.8	0.6	2.2	78.5	0.91	7.50	<0.01
<i>Kasa</i>	1.4	0.3	1.1	78.5	1.59	2.18	>0.05
<i>Aruchi</i>	0.7	0.3	0.4	57.1	0.69	1.80	>0.05
R.D.I	34.7	7.2	27.5	78.6	7.94	11.3	<0.001

Table 4: Effect of treatment on Group B

Clinical symptoms	Mean BT	Mean AT	MD	%	SD	t	p
<i>Nasavrava</i>	1.6	0.4	1.2	75	1.13	3.34	<0.01
<i>Kshavthu</i>	2.7	0.5	2.2	81.4	1.05	5.65	<0.001
<i>Nasavrodha</i>	3	0.8	2.2	73.3	0.42	16.4	<0.001
<i>Ghranaviplava</i>	1.5	0.4	1.1	73.3	1.10	3.16	<0.01
<i>Post nasal drip</i>	1.8	0.3	1.5	83.3	1.17	4.02	<0.001
<i>Kasa</i>	1.7	0.3	1.4	82.3	1.34	3.27	<0.01
<i>Aruchi</i>	0.5	0	0.5	100	0.84	1.86	>0.05
R.D.I	33.4	6.2	27.2	81.43	5.19	14.6	<0.001

Table 5: Comparison of effect of treatment

Clinical symptoms	Group A Mean AT	Group B Mean AT	t	p
<i>Kshavthu</i>	0.51	0.52	0.42	>0.05
<i>Nasavrodha</i>	0.7	0.4	0.37	>0.05
<i>Ghranaviplava</i>	0.6	0.4	0.53	>0.05
Post nasal drip	0.6	0.3	1.11	>0.05
R.D.I	7.2	9.3	1.73	>0.05

Overall effect of clinical symptoms**Graph 1**

In both groups effect of therapy was analysed using paired t test and a statistical significance of $p < 0.01$ was obtained in group B and statistically insignificant $p > 0.05$ for group A, for *nasavrava*, *kasa* and *aruchi*. It shows that *nasya* with *Anutaila* gave a significant relief for these symptoms in group B and for group A there was no significant relief.

When the scores before and after the treatment were compared, statistical significance of $p < 0.001$ was obtained for all clinical symptoms except *kshavthu*, *nasaavarodha*, *ghranaviplava*, *aruchi*, Post nasal drip and Rhinosinusitis Disability Index.

Repeated measures of ANOVA test was used to compare the effect of treatment in group A, before treatment, after treatment and after the follow up. Significance $p < 0.001$ was obtained for *shirasoola*, *shirogaurava*, *kasa* and *mukhadourgandhya*. Before

treatment and after the follow up, significance was $p < 0.01$ and after the treatment and after the follow up, the result was insignificant with $p > 0.05$. Therefore it was concluded

that the effect of treatment was sustained up to the follow up period.

Table 4: Comparison of mean *Samyak yoga* between group A and group B

S. No	Symptoms	Group A mean	Group B mean	M.D (B-A)
1	<i>Sroto sudhi</i>	3.64	5.35	1.71
2	<i>Vikaropasama</i>	6.5	7.35	0.85
3	<i>Indria chitta prasada</i>	3.42	5.14	1.72
4	<i>Swara prasada</i>	3.21	3.35	0.14
5	<i>Varna prasada</i>	0	0	0
6	<i>Sukhaswapna prabodha</i>	2.85	3.42	0.57
7	<i>Sukhocchvaasanisvasa</i>	3.353	5.78	2.43
8	<i>Akshapatavam</i>	3.14	2.71	-0.43
9	<i>Akshi laghuta</i>	5	5.42	0.42
10	<i>Vakra sudhi</i>	4.14	4.71	0.57
11	<i>Urah laghuta</i>	4.14	3.35	-0.79
12	<i>Kshavathu</i>	2.7	3.71	1
	Total	3.83(31.9%)	4.57(38.14%)	0.74(6.21%)

Observation on *Nasya Samyak Yoga*

The *samyak yoga lakshana* of *nasya* were analysed with respect to 12 *lakshanas* compiled from classics. In both groups, the *samyak lakshana* had no significant difference statistically. The score was higher in group A indicating a better and sustained effect. *Samyak yoga* was assessed daily and 24 hours after each day's *nasya*. Mean *samyak yoga* score in group A was 3.83 out of 12. On first day mean score was 0.41 and became 5.37 on the last day of *nasya*. Highest score 7.5 was observed on 5th day. Mean score of *swaraprasada* and *akshapatavam* gradually increased from 1st to 7th day in group A. For rest of the symptoms the mean score showed sudden decrease on 6th and 7th day in group A. Among all symptoms *vakrasudhi* was observed with more score. Mean *samyak yoga* in group B was 4.57 out of 12. On

first day mean score was 0.751 and became 6.2 on the last day of *nasya*. Highest score was observed on 9th day.

Graph 2

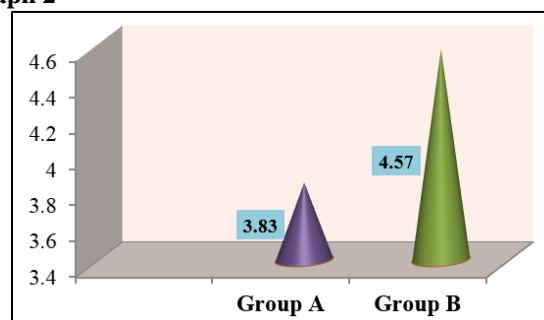
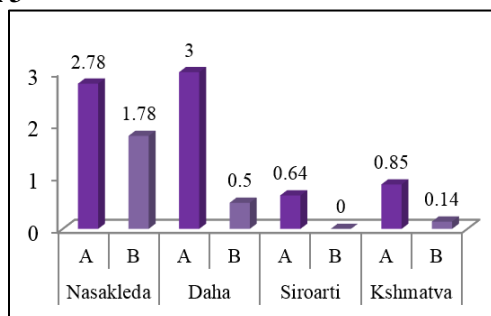


Table 5: Mean score – *asamyak lakshana*

No.	Symptoms	Group A Mean	Group B Mean	M.D (B-A)
1	<i>Nasakleda</i>	2.57	1.78	0.79
2	<i>Daha</i>	2	0.57	1.43
3	<i>Shiroarti</i>	1.28	0	1.28
4	<i>Kshmatva</i>	1.71	0.14	1.42
	Total score	1.82 (7.9%)	0.37 (2.61%)	1.45 (5.3%)

Graph 3



Total 23 symptoms were assessed for *Nasya asamyak yoga*. It included symptoms of *Heena yoga*, *atiyoga* and *Vyaapat*. The mean *Asamyak yoga* score in group A was 0.85 (3.6%) out of 23.

On the first day of *Nasya* the mean *Asamyak yoga* score was 1.3 (5.6%) which became 1.4 (6.2%) on the last day. The total mean score was maintained same throughout the course of *Nasya*. In *pratidina nasya* mean score was 2 times more than that of *ekahantara nasya*. There was difference of 1.3 (5.7%) between two groups as *kandu*, *shirogaurava*, *guruta* was not observed in *pratidina nasya* group during

the course of *nasya*. As all the symptoms were absent in *pratidina nasya*, *heena yoga* of *S'odhana* was absent. Only *galoplepa* was present during first two days of *nasya*. As this is a subjective feeling, no *heena yoga lakshanas* can be justified. Among the *Asamyak yoga* symptoms *nasakleda*, *daha* and *kshmatva* were observed in the *pratidina* group. As *Nasya* is a *S'odhana* procedure and all *nasya* causes *s'irovirecana* irrespective of *br'mhana* or *s'amana* action. *Atiyoga* of *S'odhana* may manifest as *nasakleda*, *daha* and *kshmatva* symptoms. Thus it can be stated that *pratidina* practice of *nasya* caused *Ati yoga* of *S'odhana*.

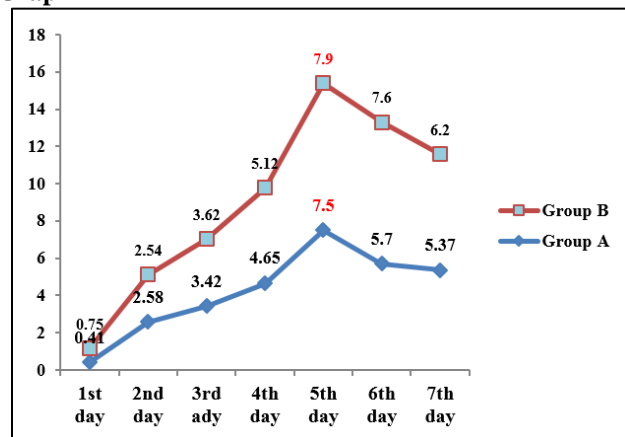
On comparison it was found that *nasakleda*, *daha* score were present more in group A compared to group B. In group A total *Asamyak yoga* score was 0.857 (3.69%) and in group B total *Asamyak yoga* score was 0.23 (1%). There was difference of 0.625 (2.71%) between two groups. On comparison it is shown that mean difference in *Asamyak yoga* score between group A and group B is 0.625 which are statistically significant at <0.05 level.

Discussion

Sukhswapnabodha, *swaraprasada*, *akshilaghuta*, *urahlaghuta* & *kshvathu* have achieved maximum score in *ekahantara* practice of *nasya* which indicates that *kapha s'odhana* was more in *ekahantara* practice of *nasya*.

Comparative illustration of *Samyak Yoga* from 1st day to 7th day

Graph 4



On comparison it was found that *srotoshudhi* in group A on 1st day was 4.1% and which became 41% on last day. In group B, 29.1% first day score changed to 66.6%. In chronic sinusitis, patients will have nasal obstruction which has been assessed in terms of *srotoshudhi* as *samyak lakshana*. The more score in *ekahantara nasya* proved that reduction in nasal obstruction by *ekahantara nasya* was more. Because of more *kaphas' odhana* obtained in *ekahantara nasya* compared to *pratidina nasya* which ultimately resulted in *srotoshudhi* symptom. Similarly on comparison it was found that *sukhocchnisvasa* in group A on 1st day was 8.3% and which became 41.6% on last day. In group B, 37% first day score changed to 70.8%. The more score in *ekahantara nasya* proved that reduction in

swasavrodha by *ekahantara nasya* was more. This symptom is dependent on the *srotoshudhi*. Nature of *kapha s'odhana* was more in *ekahantara nasya* which resulted in achievement of *srotoshudhi* & *sukhocchavaasa* symptoms.

Swaraprasada in group A on 4th day was 8.3% and which became 66.6% on last day. In group B, 12.5% third day score changed to 70.8%. For *Akshapatvam* in group A on 3th day was 4.1% and which became 66.6% on the last day. In group B, 12.5% fifth day score changed to 79.1%. In chronic sinusitis, patients will have change in voice as symptom which has been assessed in terms of *swaraprasada* as *samyak lakshana*.¹⁰ Because of enhanced *kapha s'odhana* in *ekahantara nasya*, more reduction of *avarana* of *vata* by *kapha* & hence, *swarabheda* score was obtained in more percentage in *ekahantara nasya* compared to *pratidina nasya*.

Vikaropsama in group A on 1st day was 16.6% and which became 60% on last day. In group B, 16.6% first day score changed to 83.3%. For *Indriya cittaprasada* in group A on 3rd day was 8.3% and which became 37.5% on the last day. In group B 20.8% third day score changed to 58.7%. The more score in *ekahantara nasya* proved that reduction in clinical symptoms of disease by *ekahantara nasya* was more as *kapha nirharna* was obtained significantly more in *ekahantara nasya*.

Sukhswapnabodhana in group A on 2nd day was 8.3%, which became 37.5% on fourth day and later became 25%. In group B, 20.8% third day score changed to 58.3% on eleventh day and on last day it was changed to 54.1%. 'Disturbances in night sleep' due to nasal obstruction, cough & headache was present with the entire participants. Due to reduction in nasal obstruction, cough & headache *Sukhswapnabodhana* was observed in *ekahantara nasya* attained by *srotoshudhi*, *sukhocchanisvasa* & *vikaropashma* symptoms.

Akshilaghuta in group A on 2nd day was 29.9%, which became 75% on fifth day & which became 62.5% on the last day of *nasya*. In group B 16.6% first day score changed to 79.1%. *Urolaghuta* in group A on 3rd day was 4.1%, which became 75.1% on the last day. In group B 16.6% first day score changed to 75%. In chronic sinusitis, patients will have heaviness in chest and head as symptom which has been assessed in terms of *akshilaghuta* & *urolaghuta* as *samyak lakshana*. *Kapha* is mainly responsible for producing *guruta*. Upto fifth day there was proper expulsion of *kapha* which resulted in *samyak lakshana* as *akshilaghuta* & *urolaghuta* but beyond fifth day *kapha s'odhana* was less. In group B *akshilaghuta* & *urolaghuta* score gradually increased upto last day of *nasya* which indicated there was negligible *atiyoga lakshana* on last days of *nasya*. As it was op level study, patients had to travel daily for seven days and more exposed to environmental aggravating factors. These factors resulted in patient's psychological as well as general health condition. Hence, many *asamyak lakshanas* were also obtained in *pratidina nasya*.

There was continuous expulsion of *kapha* in *pratidina nasya* and on alternate days in *ekahantara nasya*. So the accumulated *kapha* during the rest day was expelled out the

next day in *ekahantara nasya*. At the same time patient was not exposed to frequent aggravating factors like environmental, physical exertion by travelling etc. Hence there was attainment of more *samyak lakshanas* and negligible *asamyak lakshanas* in *ekahantara nasya*.

There was very higher percentage of *Naasaakleda* in group A compared to group B from the first day onwards. The score on last day was 0 in group B. 50% participants were having the history of deviated nasal septum, hypertrophied turbinate in 100% and congested nasal mucosa in 80% of participants. It was observed that due to deviation, nasal volume reduced on deviated side and not enough capacity to accommodate more amount of medicine leading to nasal congestion or *naasaakleda*. In *pratidina* group participants *vatakopa* was observed because of daily excessive *kapha sodhana* and also these participants were more exposed to environmental factors which have role in development of transient nasal obstruction. But mean score showed that the severity of these symptoms were within the manageable limits and it did not affect the safety of the *nasyakarma*.

There was very higher percentage of *daha* in group A compared to group B from the first day onwards. The score on last day was 0 in both the groups. *Anutaila* possess *sheeta veerya* and *ushna veerya* drugs. Dose was also high which could also be contributory. *Nasya* acts by irritating nasal mucosa irrespective of the drug. In *pratidina* group nasal mucosa was continuously exposed to drug. This continuous irritation of mucosa led to more *daha* symptom score in *pratidina* group compared to *ekahantara* group. Irritating nature of *nasya* assessed by the objective parameter, eosinophil count. In *pratidina* group after treatment the count increased where as in *ekahantara nasya* it decreased. The irritation of nasal mucosa healed on resting day and did not lead to inflammation in *ekahantara nasya*.

There was very higher percentage of *shiroarti* & *kshmatva* in group A compared to group B on last three days of *nasya*. The mean score was more on last days of *nasya* in group A whereas it was 0 on last days in group B for *kshmatva*. *shiroarti* was not observed in group B. *Shiroarti* and *kshmatva* mainly developed by *vaatakopa*. In *pratidina nasya* daily *kapha s'odhana* led to *vaatakopa* mainly during last days of *nasya*. Physical exertion and travelling also contributed for the vitiation of *vaata*. In *ekahantara nasya* there was proper expulsion of accumulated *kapha* which caused minimal *vaatakopa* and minimum mean score of *kshmatva* was observed on last three days of *nasya*.

Conclusion

The main objective of the study was to compare the effect, safety and attainment of *samyak lakshana* of *marsa nasya* with the routinely practiced (*pratidina*) continuous days and (*ekahantara*) alternate days of *nasya* in chronic sinusitis. Chronic sinusitis is an *urdhvajatrugata vikara* and has *vaatakapha* predominance and the disease can be seen in paralance with ayurveda literature as *Dushta pratisyaya*.

Anutaila being *ushna* in *veerya* and *tridosahara* property helps in breaking the *samprapti* of chronic sinusitis. The conclusion drawn on the basis of this clinical study conducted in 20 participants of chronic sinusitis are as follows:

1. The significant difference obtained for *asamyak lakshana* as *daaha* in *pratidina nasya* compared to *ekahantara nasya* $p < 0.05$, but within manageable limit.
2. *Pratidina* practice of *nasya* with *Anutaila* in chronic sinusitis is safe and effective.
3. *Ekahantara* practice of *nasya* with *Anutaila* in chronic sinusitis is safe and effective.
4. On comparing the effect of treatment in *pratidina* and *ekahantara* group, more result was obtained in *ekahantara* group.
5. The present study recommends *ekahantara* practice of *nasya* with *Anutaila* in chronic sinusitis in OPD basis.

Limitations and Recommendations

1. The dose, number of instillation and number of days of *Nasya* was predetermined.
2. Rhinosinusitis disability index questionnaire could have been assessed daily.
3. No objective parameter is used in the study.
4. Highly sensitive tools are not available to assess *Samyak* and *Asamyak yoga* of *nasya*.
5. Effects of climate variation couldn't be avoided, as in rainy and cloudy days *nasya* is contraindicated.
6. Sample size was small.

Recommendations

1. Objective parameters can be used to make study more scientific and reliable such as CT scan etc.
2. Validation and revalidation of *samyak* and *asamyak yoga* proforma can be done.
3. *Asamyak yoga* should be critically analyzed according to drug, dose & procedure.
4. Study can be done in larger sample.
5. Study can be done in IPD level to avoid effect of external environmental factors.
6. *Shamana* medicine after *nasya* can be given for better result after treatment.
7. *Nasya* can be done upto achievement of *samyak lakshanas* irrespective of days.

Conflict of Interest: Nil.

References

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