

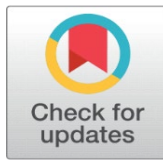
ANALYSIS OF EFFICACY OF KALINGADI TAILA NASYA IN THE APEENASA MANAGEMENT

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ABSTRACT

Apeenasa is a first and foremost among the different types of Nasagata Roga described by Sushrut. There is vitiation of pitta and Kapha Dosha characterized by nasal obstruction, running nose, dryness of nose, anosmia and loss of taste and foul smell emanating from nasal cavity. This condition can be co-related with atrophic rhinitis because most of the signs and symptoms are similar. Apeenasa or atrophic rhinitis when reviewed in the texts has been an issue to be dealt with on a regular basis. The disease comprising of the association of Vata and Kapha doshas leading to a local Nasagata Samprapti causing lakshanas like Kshavathu (Sneezing), Nasavarodha (Congestion), Kalingadistrava (Running nose). Contemporary literary review indicates that same symptoms are found in allergic rhinitis which is induced by an IgE mediated inflammation of the nasal membrane. The chosen drug for conducting the study Kalingadi Taila and Shad Bindu Taila were considered as they are found to be effective in the treatment of the Kshavathu which is the predominant symptom of Apeenasa.

Keywords: Apeenasa, Nasagata Roga, Shad Bindu Taila

1. INTRODUCTION

Apeenasa or atrophic rhinitis when reviewed in the texts has been an issue to be dealt with on a regular basis. The disease comprising of the association of Vata and Kapha doshas leading to a local Nasagata Samprapti causing lakshanas¹. Contemporary literary review indicates that same symptoms are found in allergic rhinitis which is induced by an IgE mediated inflammation of the nasal membrane. The chosen drug for conducting the study Kalingadi Taila and Shad Bindu Taila were considered as they are found to be effective in the treatment of the Kshavathu which is the predominant symptom of Apeenasa². The subjects enrolled for the study were randomly divided into two groups where they were administered the designated medicine in the form of Nasya for a period of seven days in equal doses. The subjects were then followed up for a period of 60 days and assessment was done after the completion and during the

follow ups. The completion of the study revealed the factors like pollen house dust and industrial pollution were found to affect the disease condition leading to aggravation of the symptoms in the enrolled subjects. Also, a seasonal variation of colder climate was reported as one of the precipitating factors.

On treatment the symptoms like Congestion and Ear symptoms showed improvement in the group treated with Kalingadi Taila Nasya³. The other symptoms did not show much variation in both the group comparatively. It was observed that parameter like ESR, AEC and Nasal Smear were reduced but comparatively followed same pattern in both the groups.

2. MATERIALS AND METHODS

1) Source of data:

• Literary Source:

The Classical, Modern literature and Contemporary text books including the websites, and Journals to gather information about disease and the drugs.

Sample Source:

The 40 patients will be selected from the OPD & IPD of Shalakya Tantra, Govt. Ayurvedic College & Hospital, Patna randomly eligible for study.

Drug Source:

The identified raw drugs required for study will be collected and trial drug will be prepared in the pharmacy, Govt. Ayurvedic College, Patna.

2) Grouping of patients

There will be 2 groups as follow.

- Group A- Trial Drug- 20 patients will be treated with Shad Bindu Taila Nasya.
- Group B- Control Drug- 20 patients will be treated with Kalingadi Taila Nasya.

Dose of drug: 6-8 drops in each nostril per sitting.

Duration of therapy: Nasya for 7 days followed by a gap of 7 days total 3 sittings.

Follow up: 15 days after completion of treatment for 2 months.

3) Criteria for selection of patients-

Inclusion Criteria:

- Age: 10 to 50yrs.
- Sex: Male and Female.
- Patients having specific Lakshanas of APEENASA.

Exclusion Criteria:

- Patients below 10 years and above 50 yrs of age.
- Patients suffering from any systemic disease.
- Patient suffering with Nasal polyps, DNS or any other nasal mass.

Diagnostic Criteria:

- Clinical features: Rhinorrhoea, Sneezing and Nasal obstruction.
- Anterior and posterior Rhinoscopy for signs of allergy e.g. Pale Oedematus turbinate with thin strings of mucus.
- Absolute Eosinophil Count – levels above 440
- Nasal smear – positive confirmation (>10% eosinophils).

Laboratory investigations

- 1) Absolute Eosinophil Count
- 2) Erythrocyte Sedimentation rate

- 3) Nasal smear
- 4) Laboratory Investigation: CBC, ESR, BT, CT
- 5) Radiological Investigation: X-ray of Nose & PNS

Criteria for assessment:

Record and follow up of all the patients included in the trial will be documented and maintained. The efficacy of the therapy will be assessed on subjective and objective criteria and multi-dimensional scoring system will be adopted for the result score.

Statistical analysis:

After treatment completion, the patients will be observed for the progress and it will be noted in the specially prepared case sheet. The observations will be analyzed on the basis of criteria for assessment (both subjective and objective) critically and scientifically. The results will be statistically analyzed for its significance with the consultation of biostatistician.

Method of Collection of Data:

40 patients who fulfilled the inclusive criteria were being selected irrespective of sex, religion, economic status and marital status.

Grouping: 2 groups:

- Group A:- Treatment with Kalingadi Taila Nasya (Includes Pre & Post Procedure).
- Group B:- Treatment with Shad Bindu Taila Nasya (Includes Pre & Post Procedure).

Posology:

- Group A – Nasya with Kalingadi Taila – QS (6 drops1 in each nostril)
- Group B – Nasya with Shad Bindu Taila –QS (6 drops1 in each nostril)

Treatment duration:

- Group A – Nasya with Kalingadi Taila – 60 days (in 3Sittings having 7 day interval)
- Group B – Nasya with Shad Bindu Taila – 60 days (in 3Sittings having 7 day interval)

Mental state Regular counseling will be done to avoid stress, tension, anxiety and aggressiveness.

Center of study:

OPD & IPD of Institute.

Duration of study:

Patient study will be of 60 days

Withdrawal Criteria:

During the course of treatment, if any serious condition or any serious adverse events occurred or if subject himself / herself wanted to withdraw from the study, such subjects were withdrawn from the study.

Criteria of Diagnosis:

The methods of diagnosis were done on Ayurvedic lines which includes chief complaints of patient and its duration, sign, symptoms, detail personal and family history was taken Sarvadehik parikshan was done on the basis of Prakriti pariksha⁴ as well as Ashtavidh pariksha. Nasa parikshan⁵ was done in detail subsequently with the help of modern viewing technique like Rhinoscopy.

Subjective Criteria:

Assessment has been done on the basis of improvement in the signs and symptoms of the disease on the basis of the score decided. 0, 1, 2, 3 and 4 symptom score were adopted for the assessment.

Total effect of therapy will be marked as:

Effect	Percentage of relief	Comparative Relieving factor
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Complete relief	100% = 0	4.00
Marked relief	> 75% = 1	3.00
Moderate relief	51-75% = 2	2.00
Mild relief	26-50% = 3	1.00
No relief	<25% = 4	0.00

OBSERVATION**MASTER CHART FOR SUBJECTIVE CRITERIA OF APEENASA OF GROUP A**

S NO	CR NO	COMPARATIVE NASAL SYMPTOMS)				COMPARATIVE THROAT, EYES SYMPTOMS & HEADACHE				COMPARATIVE ESR SCORES				OVER ALL			
		BT	15D	30D	AT	BT	15D	30D	AT	BT	15D	30D	AT	BT	15D	30D	AT
1	A29398	4	3	3	3	2	2	2	2	3	3	3	1	2	2	2	0
2	A30176	4	1	1	1	1	1	1	1	2	1	1	1	3	2	2	1
3	0487	3	2	2	2	1	1	1	1	3	3	3	3	4	4	4	3
4	A30358	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
5	A30077	4	2	2	1	3	2	2	2	2	2	2	1	3	2	1	1
6	A30076	2	0	0	0	2	2	2	2	1	1	1	1	2	2	1	0
7	A30468	2	1	1	1	1	1	1	1	2	2	2	2	1	1	1	1
8	A30526	3	1	1	1	2	2	2	2	2	2	1	1	1	1	0	0
9	A30525	3	0	0	0	1	1	1	1	2	2	1	1	1	1	0	0
10	A30469	2	2	1	0	1	1	1	0	1	1	1	0	1	1	0	0
11	A30770	4	1	0	0	3	3	3	2	1	1	1	0	3	2	2	2
12	A30733	4	0	0	0	1	1	1	1	1	1	0	1	2	1	1	0
13	A30856	3	2	2	2	2	2	2	2	3	3	3	3	2	2	2	2
14	A30189	3	2	2	1	2	2	2	1	3	3	2	1	4	3	2	0
15	A30160	4	2	2	2	1	1	1	1	1	1	1	1	0	0	0	0
16	A30308	4	1	1	0	1	1	1	1	2	1	1	1	2	2	1	0
17	A30158	3	1	1	1	2	2	2	1	3	3	2	2	3	2	1	0
18	A30622	2	1	1	1	2	2	2	2	1	1	1	1	2	2	2	2
19	A30621	4	1	1	1	2	2	2	3	2	2	2	2	2	1	1	1
20	A30573	3	2	1	1	2	2	2	2	3	3	3	2	2	2	1	1

BT- Before treatment, AT-After treatment

$$Z = -/n/pq/e^2$$

n = sample size

z = confidence level =

1.96 p = prevalence rate q = (1 - p)

e = error of margin n = z²pq/e²

Prevalence rate = 100% = $p \cdot n = z^2 pq / e^2$

= $(1.96)^2 \times 0.3 \times 0.7 / (0.05)^2$

= $3.8416 \times 0.3 \times 0.7 / 0.0025$

= $0.806736 / 0.0025$

= 322.6944

= relieving factor against Kalingadi Taila Nasya = 3.2

MASTER CHART FOR SUBJECTIVE CRITERIA OF APEENASA OF GROUP B

S NO	CR NO	COMPARATIVE NASAL SYMPTOMS				COMPARATIVE THROAT, EYES SYMPTOMS & HEADACHE				COMPARATIVE ESR SCORES				OVER ALL			
		BT	15D	30D	AT	BT	15D	30D	AT	BT	15D	30D	AT	BT	15D	30D	AT
1	A30958	3	1	1	1	2	2	2	1	3	3	2	2	3	2	1	0
2	A30322	2	1	1	1	2	2	2	2	1	1	1	1	2	2	2	2
3	A30421	4	1	1	1	2	2	2	3	2	2	2	2	2	1	1	1
4	A30973	3	2	1	1	2	2	2	2	3	3	3	2	2	2	1	1
5	A30355	4	2	2	2	3	3	3	3	2	2	2	3	1	1	1	1
6	A20352	3	1	1	1	2	2	2	2	2	2	2	2	3	3	3	3
7	A30442	2	2	2	1	1	1	1	1	1	1	1	1	2	2	1	0
8	A33058	3	1	1	1	2	2	2	2	1	1	1	1	2	2	1	0
9	A30433	4	1	1	0	1	1	1	1	2	2	1	0	2	2	1	1
10	A30276	4	3	3	2	2	2	2	2	2	2	2	1	2	2	1	1
11	A32192	4	2	2	2	3	3	3	3	2	2	2	2	3	3	3	3
12	A33261	4	4	4	4	3	3	3	3	2	2	2	2	1	1	1	1
13	A33485	4	2	1	0	1	1	1	1	2	2	1	1	1	1	0	0
14	A32099	3	1	1	0	2	2	2	2	1	1	1	1	1	1	0	0
15	A30967	3	1	0	0	3	3	3	3	2	2	2	2	2	2	1	1
16	A30561	2	1	0	0	2	2	2	2	2	2	1	1	1	1	1	1
17	A32951	4	3	3	3	2	2	2	2	1	1	1	1	2	2	2	2
18	A30923	3	0	0	0	2	2	2	2	1	1	1	1	3	3	2	1
19	A32122	4	4	3	3	3	3	3	3	3	3	3	3	3	3	2	1
20	A32559	3	1	1	1	3	3	3	2	3	3	2	2	2	2	2	1

BT- Before treatment, AT-After treatment

$Z = -/n/pq/e^2$

n = sample size

z = confidence level =

1.96 p = prevalence rate q = (1 - p)

e = error of margin n = $z^2 pq / e^2$

Prevalence rate = 100% = $p \cdot n = z^2 pq / e^2$

= $(1.64)^2 \times 0.3 \times 0.7 / (0.05)^2$

= $3.1416 \times 0.3 \times 0.7 / 0.0025$

= 0.731884/0.0025

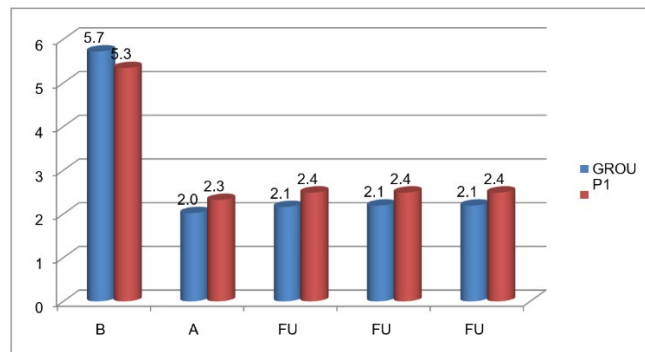
= 292.7539

=relieving factor against Kalingadi Taila Nasya = 2.9

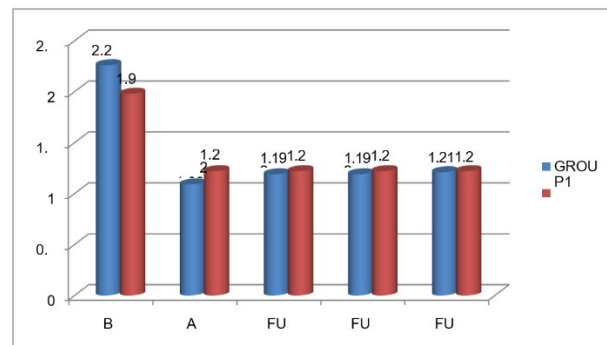
Group A; Relieved by an assessment factor of 3.2

Group B; Relieved by an assessment factor of 2.9

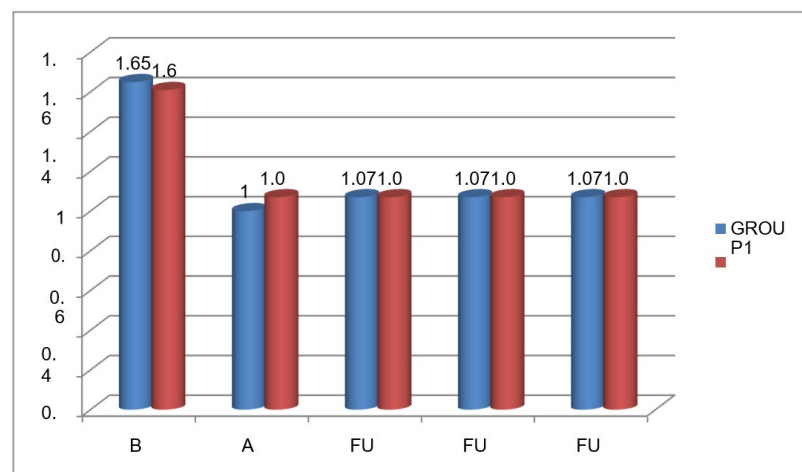
Graph No: 01 Representing Comparative Total Nasal Symptoms (VAS) Scores of the two groups



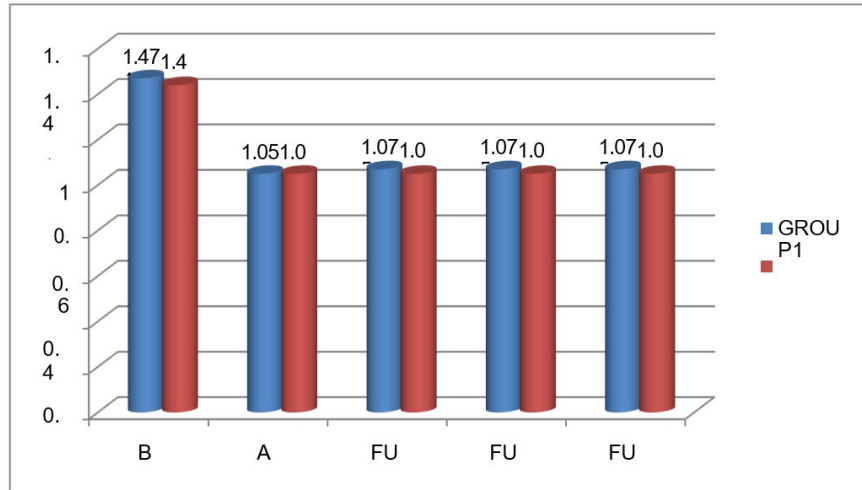
Graph No: 02 Representing Comparative Eye Symptom (VAS) Scores of the two group



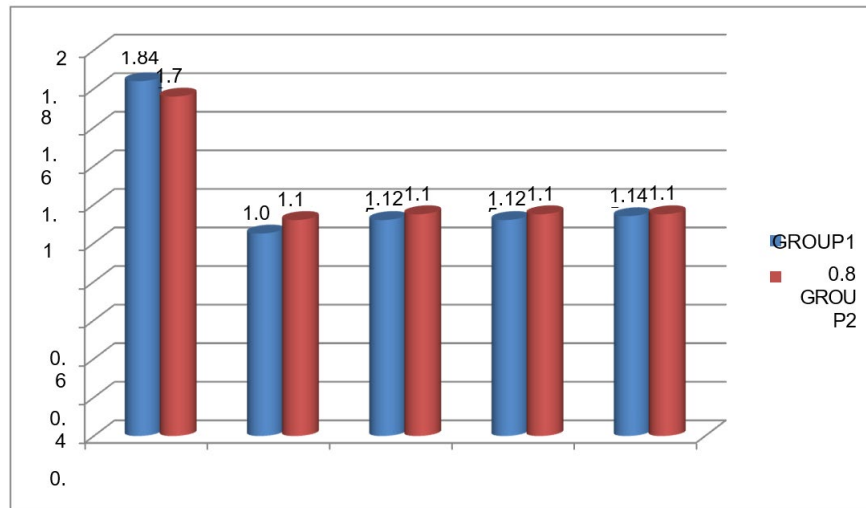
Graph No: 03 Representing Comparative Ear Symptoms (VAS) Scores of the two groups



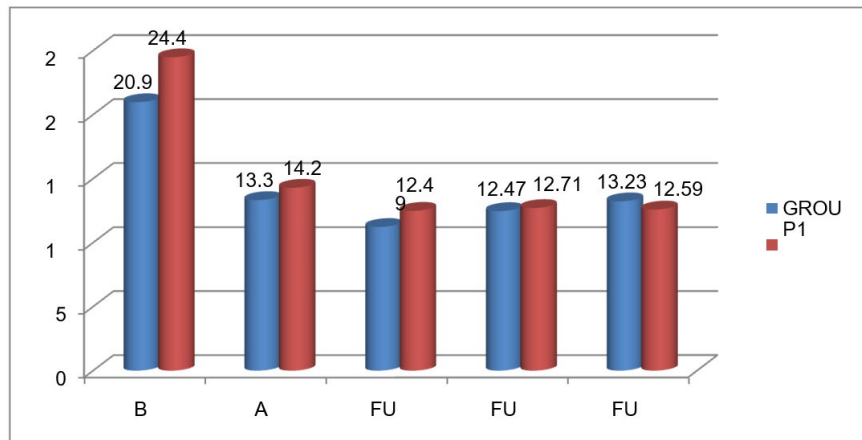
Graph No: 04 Representing Comparative Throat Symptoms (VAS) Scores of the two groups



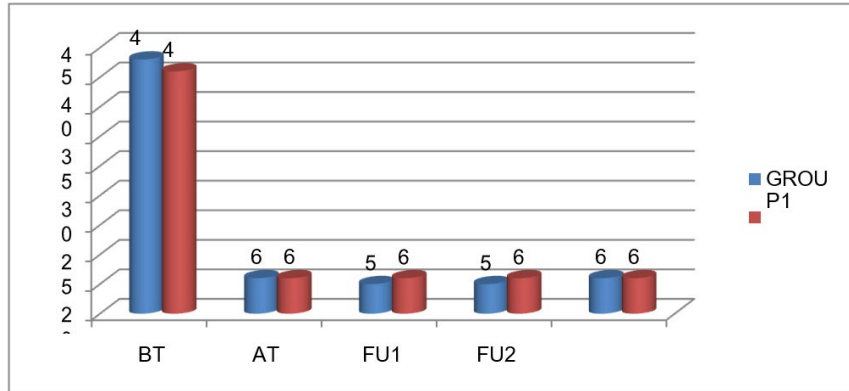
Graph No: 05 Representing Comparative Headache (VAS) Scores of the two groups



Graph No: 06 Representing Comparative ESR Scores of the two groups



Graph No: 07 Representing Comparison of No. of Patients with Positive smear test between the two groups



3. RESULTS

Out of the Total enrolled subjects the sample consisted the age group 15-25 years showed a predominance of the condition (36.90%). In a past study conducted by Bhakti Chaya et al. at Jamnagar found 50% of subjects in the same age group. S.P. S Yadav et al. in their study in North Indian region found Maximum number of these subjects found in the age of second and third decade. This may be due to the immune-suppression in the later age where antibody levels and number of T cells in blood decline considerably, while these are much higher in younger age. The age incidence in our studies is almost same as previous studies.

We know that sources say much about the incidence of the allergic rhinitis in Male than female. The higher incidence in males than females was possibly due to more exposure of males to work place related allergens and stress. In our study we found almost equal distribution of 52.38% male and 47.61% female patients. Almost all the patients belonged to the religion Hinduism (88.09%) may be due to the dominance of Hindu people in this region and visiting our OPD.

Our study showed a predominance of middleclass patients (59.52%). Previous studies also show similar incidence among middle class people as they are more exposed to atmospheric pollution, stress and strain.

The maximum number of patients was students (17.07%) followed by housewives (16.66%) and factory workers (15.47%). In an epidemiological study of allergic rhinitis in North India conducted by S.P.S Yadav et al. found similar incidence. Fleming and Crombie reported the maximum incidence among college students and housewives. Probably this might be due to the indoor pollution among housewives, exposure to dust and smoke in students and factory workers. Though most of the patients (90.47%) didn't show any family history of the condition. Usually, there is a strong genetic component to the allergic response, which is driven through mucosal infiltration and action on plasma cells, mast cells, and eosinophils.

Most of the patients enrolled in our study belonged to urban living areas (55.84%). The incidence is usually more in city dwellers which is due to industrialization and vehicular pollution in towns. In rural areas, people are more exposed to pollens, hay and weather changes while in cities the industrial dust, smoke, cosmetics, and food additives form the pollen allergens.

The commonest aggravating factor found to be responsible was dust (34.52). The number of allergens is increasing daily with modernization. Many workers have named seasonal changes, house dust and industrial pollution as the main predisposing factors of allergy. In previous studies conducted, a variation of 40-73% of allergic to house dust was observed. 24% had aggravation of symptoms during the change of weather. Most of the patients showed moderate eating pattern (53.57%). The allergy to food was reported to 3.9% by Yadav et al. and 2.3% by Rosenthal et al.

Almost all the patients had a normal (45.23%) sleeping pattern followed by disturbed patterns of sleep (36.90%). The maximum number of patients who suffered from the condition had Vata Kapha prakruti (51.19%). Vata and Kapha dosha individuals are more prone for Pratishyaya.

4. SUMMERY

Kalingadi Taila Nasya administered in the dose of eight drops per nostril for seven days provided statistically significant reduction in nasal congestion ($p=0.0045$), ear itching ($p=0.0001$) as compare to the group treated with Kalingadi Taila and statistically insignificant effect on sneezing, watery nasal discharge, AEC count as well as Eosinophil count in nasal smear ($p>0.05$) when both the groups were judged against each other.

It may be concluded that over-all both the drugs i.e. Kalingadi Taila and Shad Bindu Taila provided similar and comparable effect on signs and symptoms of Apeenasa or atrophic rhynitis and sustained effect were noticed for three months of follow up period.

Nasya Karma is considered best for cleaning mild vitiated Kapha Doshas, urdhwajatrugat rog, after Vaman Karma and also as a faster route of drug administration. It should be practiced in daily life style as mentioned under Dincharya. But for getting proper benefit one needs to be aware of proper procedure, drug selection, administration etc. In this scenario the present article is very helpful for getting good health.

In order to study the significance of this method of treatment, a study on another group of patients of Apeenasa with Shad Bindu Taila Nasya, which has already been established by previous study, is also taken up

5. CONCLUSION

Kalingadi Taila Nasya is mentioned in Chakradat Samhita for general Nasagata Rogas. Kalingadi Taila drugs are having Ushna, Tikshna guna, Vata-Kaphahara properties and anti-inflammatory action. So, it has Shothhara, Vednasthapana, Shirashoolahara analgesic action on Apeenasa (atrophic rhinitis). Also, the drugs used in Kalingadi Taila are easily available and cost effective. Considering the above factors this study is taken up where the efficacy of Kalingadi Taila Nasya in the management of Apeenasa will be successfully studied arising the relieving by a factor of 3.2, while the Shad Bindu taila nasya comprised by a factor of 2.9. It represents particular greater efficiency of Kalingadi taila with respect to Shad Bindu taila for the management Apeenasa w.s.r. to Atrophic Rhinitis.

CONFLICT OF INTERESTS

None.

ACKNOWLEDGMENTS

None.

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