International Journal for Multidisciplinary Research (IJFMR)
E-ISSN: 2582-2160 ● Website: www.ijfmr.com ● Email: editor@ijfmr.com

Open Label Controlled Clinical Study to Evaluate the Efficacy of Kalingadi Taila Nasya and Vyoshadi Vati in the Management of Kaphaja Prathishyaya W.S.R to Chronic Rhinosinusitis

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ABSTRACT:
Chronic rhinosinusitis (CRS) is a prevalent condition characterized by persistent inflammation of the nasal and sinus mucosa lasting for at least 12 weeks. It is associated with significant morbidity, affecting quality of life and causing symptoms such as nasal obstruction, facial pain, and postnasal drip. National Institute of Allergy and Infectious Diseases (NIAID) estimates 1 in 8 Indians hit by chronic sinusitis. CRS has metaphorical features with *Kaphaja Pratishyaya* explained in Ayurvedic classics. Nasya karma which is proven to be useful in *Urdhwajatrugata Vikaras* it is chosen as a chief treatment along with oral medications in reversing the pathophysiology.

Objectives: To evaluate the therapeutic efficacy of *Kalingadi taila Nasya* and *Vyoshadi vati* in the management of Kaphaja Pratishyaya w.s.r to Chronic Rhinosinusitis. To compare the therapeutic efficacy of *Vidanga taila Nasya* and *Kalingadi taila Nasya* in the management of *Kaphaja Pratishyaya* w.s.r to Chronic Rhinosinusitis.

Methods: Total 100 subjects with clinical features of Kaphaja Pratishyaya W.S.R to Chronic Rhinosinusitis coming under inclusion criteria approaching OPD and IPD of *Shalakya Tantra*, SDMIAH, Bengaluru were screened and randomly assigned into two groups i.e., Group A (Control Group) and Group B (Trial Group), each comprising minimum of 50 patients who completed the study.

Results: In both clinical and objective evaluations, results were encouraging in both the groups. Clinical assessment of Rhino sinusitis was found statistically significant with Kalingadi Taila Nasya than Vidanga Taila Nasya in Clinical features of Chronic Rhinosinusitis like Nasal discharge Nasal Obstruction, Heaviness of Head, Dull facial pain and Headache.

Keywords: Kaphaja Pratishyaya, Chronic Rhinosinusitis, Kalingadi Taila, Vidanga Taila, Vyoshadi Vati

INTRODUCTION:

Rhinosinusitis is an inflammation of the nasal and paranasal sinus mucosa. According to the duration of the symptoms, Rhinosinusitis is classified into two forms, as acute or chronic. Acute sinusitis is defined as inflammation for less than eight weeks in children and 12 weeks in adults [1]. Chronic Rhinosinusitis in

adults is in most guidelines defined as an inflammation of the nose and the paranasal sinuses characterized by at least 8-12 weeks of at least 2 symptoms, like nasal blockage/obstruction/congestion, nasal discharge (anterior/posterior nasal drip), facial pain/pressure and/or reduction or loss of smell and either endoscopic signs of disease or relevant CT scan changes. Recurrent rhinosinusitis is 4 or more episodes of acute sinus infection in one year with each episode lasting for about a week [2].

Clinical presentation of Chronic rhinosinusitis includes purulent nasal discharge, nasal obstruction, facial pain, purulent discharge or edema of the middle meatus, and decreased smell perception [3]. Triggering factors of rhinosinusitis include air pollutants, allergens, cold exposure, chemical sensitizers, infections etc.

Clinical features of *Kaphaja Pratishyaya* are explained by *Acharya Vagbhata* and *Acharya Sushruta* [4][5]. *Acharya Kashyapa* says the condition is *Chira Kaleena* i.e., chronic in nature [6]. Repeatedly whitish discharge of *Kapha* through Nose, feeling of whiteness all over the body, Swollen eyes, Heaviness of head and face, Excessive itching in the scalp, throat, lips and Palate are the characteristic features as explained by *Acharya Sushrutha*. *Acharya Vagbhata* adds cough, loss of taste, dyspnea and vomiting (repeated spitting and clearing the throat repeatedly). Though in initial stages it can be correlated to Chronic Simple rhinitis when it involves paranasal sinuses it can be correlated to Chronic Rhinosinusitis.

Vidanga taila is explained by Acharya Sharangadhara composed of *Vidanga* and *Tila taila Vyoshadi vati* is explained by *Acharya Sharangadhara* is prepared of *Vyosha, Amlavetsa, Chavya, Taleesa, Chitraka, Jeeraka, Tintidika, Twak, Patra, Ela Guda* is indicated in *Peenasa, Pratishyaya & Swasa* [7]. Kalingadi taila is explained in *Chakradutta* in the *Nasaroga chikitsa*. The *taila* for *Nasya karma* is composed of *Kalinga, Hingu, Maricha, Laksha, Tulasi, Katphala, Kushta, Vacha, Shigru* and *Vidanga* [8]. As both the drugs are *Kaphahara, deepaka, pachaka* it aids contradicting *samprapthi* of the *Vyadhi.* Hence, the present study was an attempt to scientifically validate the effect of *Kalingadi Taila Nasya* and *Vyoshadi Vati* administration in the management of *Kaphaja Prathishyaya* w.s.r. to Chronic rhinosinusitis.

MATERIALS AND METHODS:

Total 100 subjects with clinical features of Kaphaja Pratishyaya W.S.R to Chronic Rhinosinusitis coming under inclusion criteria through screening approaching OPD and IPD of *Shalakya Tantra*, SDMIAH, Bengaluru was randomly assigned into two groups i.e., Group A (Control Group) and Group B (Trial Group), each comprising minimum of 50 patients who completed the study.

Design: Controlled double arm open label Prospective, Interventional study with pre hoc and post hoc test design. The sample collection was initiated with post approval from the Institutional Ethics Committee. Study was also registered under Clinical Trial Registry of India.

The raw drugs required for *Nasya* (*Vidangadi Taila* and *Kalingadi Taila*) were collected from the identified vendors and the drugs were authenticated by the faculty of *Dravya Guna* and were prepared in Teaching pharmacy of *Rasa Shastra* and *Bhaisajya Kalpana*, SDMIAH, Bangalore.

DIAGNOSTIC CRITERIA [9]:

- Nasal discharge
- Nasal obstruction
- Dull facial pain
- Heaviness
- Hyposmia/anosmia

- Oedema of the middle meatus
- Headache

INCLUSION CRITERIA:

- Patients with signs and symptoms of *Kaphaja Pratishyaya* (Chronic rhinosinusitis)
- Patients irrespective of chronicity will be included
- Patients of either sex
- Patients of age group between 18-60 years

EXCLUSION CRITERIA:

- Patients of any other systemic disorders that may interfere the course of treatment
- Any associated conditions like Migraine headache, referred pain from dental pathology will be excluded
- Patients with nasal polyps along with rhinosinusitis will not be considered for the study

INTERVENTION – Duration of intervention is 21 days including 7 days Nasya karma followed by 14 days *Vyoshadi Vati* administration.

Group A- *Sthanika Snehana* with *Asana Vilwadi Taila* followed by 8 drops of *Vidanga taila Nasya* to each nostril, *ushna Jala Gandusa* as *Paschath Karma* for 7 days. After *Nasya karma* all the subjects will be administered *Vyoshadi Vati* of 6 numbers in divided dosage after food with *ushna Jala* as *Anupana* for a period of 21 days.

Group B- *Sthanika Snehana* with *Asana Vilwadi Taila* followed by 8 drops of *Kalingadi taila Nasya* to each nostril, *ushna Jala Gandusa* as *Paschath Karma* for 7 days. After *Nasya karma* all the subjects will be administered *Vyoshadi Vati* of 6 numbers in divided dosage after food with *ushna Jala* as *Anupana* for a period of 21 days.

Assessment schedule:

Assessment	Stage	Day
1st	BT (Before treatment)	Day 0
2nd	AT1(After treatment 1)	Day 8
3rd	AT2(After treatment 2)	Day 30
4th	AF 1(After follow-up1)	Day 45
5th	AF 2(After follow-up 2)	Day 60

Assessment criteria:

Nasal obstruction, Purulent discharge, Facial pain/pressure, Head ache, Anosmia/Hyposmia Hypertrophy of turbinates

Gradation index: Scored from 0-3

0-No symptom

1. Mild
2. Moderate
3. Severe

Observations:

Gender: In the present study, 46(46.5%) were females and 53(53.5%) were males.

Religion: Out of 100 subjects in both the groups, 95(96.0%) subjects were Hindus, 2 (2.0%) subjects were Muslims and 2(2.0%) were Christians.

Education: In present study, 64(64.6%) were graduates, 21(21.2%) were high school, 10(10.1%) were Post graduates, 3(3.0%) were middle school, and 1(1%) was illiterate

Marital status: In this study, 56(56.6%) were married and 43(43.4%) were single.

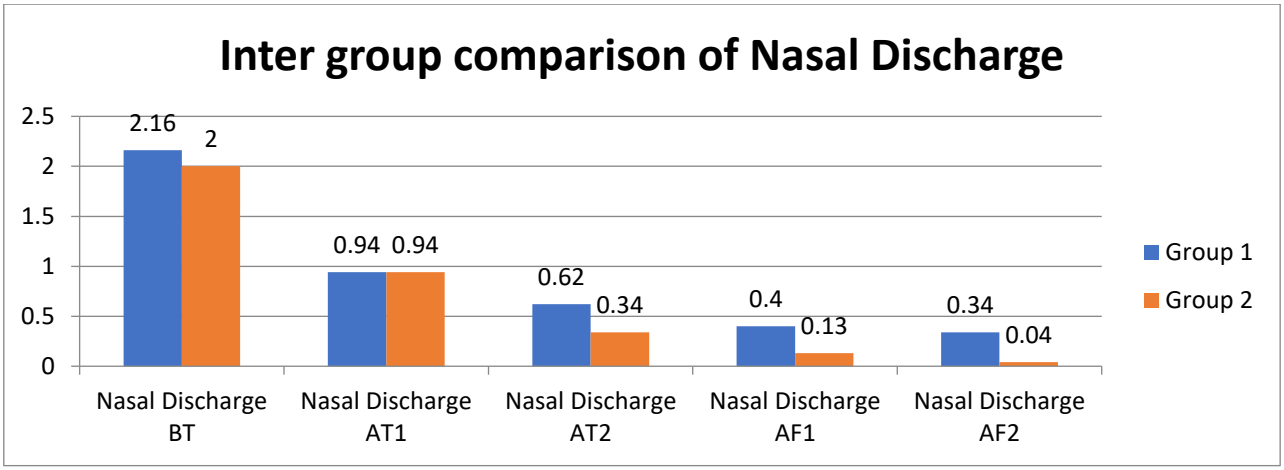
Socio-economic status: In this present study, 63(63.6%) were upper middle class, 35(35.4%) were lower middle class,1(1.0%) was upper class.

Occupation: In the present study, 31(31.3%) were desk workers, 23 (23.2%) of the subjects were students,11(11.1%) subjects were Homemakers, 3(3.0%) were from Business field and 8 (8.1%) were field workers, 1(1.0%) Office workers, 1 (1.0%) was priest, 1(1.0%) was teacher, 6 (6.1%) were other fields.

Results: The parameters considered for the clinical study were subjected to Wilcoxon Sign rank test to compare the Mean values within the groups and Mann Whitney U test to compare the Mean difference values between the groups at different time points like before treatment (BT), after treatment (AT) and at follow-up (AF). The differences in the mean values were considered highly significant at p 0.05.

Table:1 Effect of treatment on Nasal Discharge between group A and group B

	Group	N	Mean	Std. Deviation	Std. Error Mean	Median	Mann-Whitney U value	Z value	p value of Mann-Whitney U test
Nasal Discharge BT	1	50	2.16	.710	.100	2	1152.000	-.183	.855#
	2	47	2.00	1.103	.161	2			
Nasal Discharge AT1	1	50	.94	.682	.097	1	1173.500	-.012	.991#
	2	47	.94	.791	.115	1			
Nasal Discharge AT2	1	50	.62	.667	.094	0	886.000	-2.413	.016*
	2	47	.34	.635	.093	0			
Nasal Discharge AF1	1	50	.40	.535	.076	0	875.500	-2.849	.004**
	2	47	.13	.337	.049	0			
Nasal Discharge AF2	1	50	.34	.479	.068	1	825.500	-3.670	.000**
	2	47	.04	.204	.030	0			



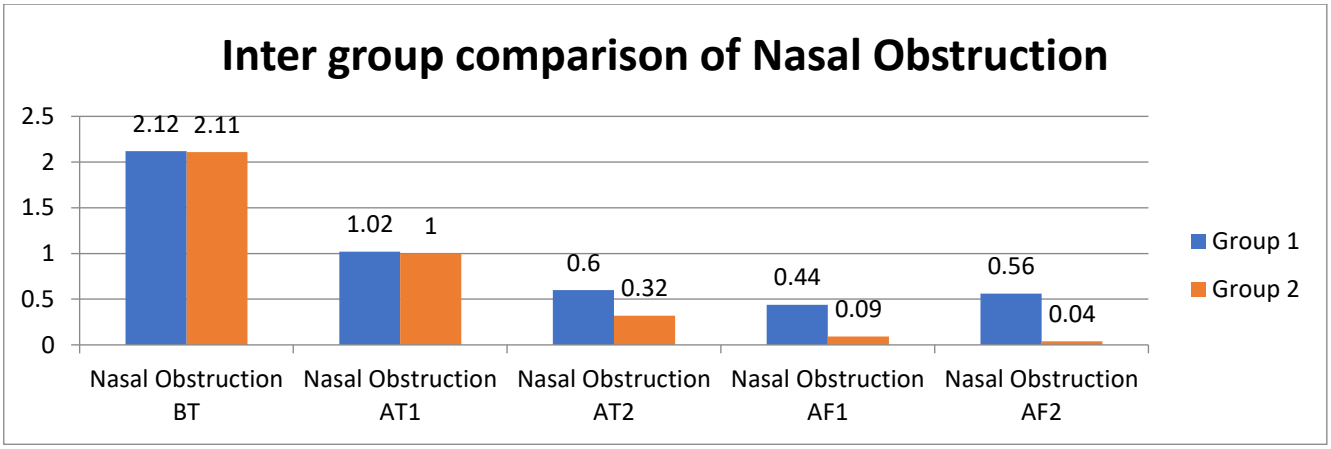
That was a statistically highly significant difference seen for the values between the groups($p<0.01$) for Nasal Discharge AFI, AF2 with higher values in Group A

There was a statistically significant difference seen for the values between the groups($p<0.05$) for Nasal Discharge AT2 with higher values in Group A

There was a statistically non-significant difference seen for the values between the groups ($P>0.05$) for Nasal Discharge BT, AT1

Table 2: Effect of treatment on Nasal obstruction on group A and group B

	Group	N	Mean	Std. Deviation	Std. Error Mean	Median	Mann-Whitney U value	Z value	p value of Mann-Whitney U test
Nasal Obstruction BT	1	50	2.12	.773	.109	2	1145.500	-.239	.811#
	2	47	2.11	.890	.130	2			
Nasal Obstruction AT1	1	50	1.02	.654	.093	1	1157.000	-.145	.885#
	2	47	1.00	.692	.101	1			
Nasal Obstruction AT2	1	50	.60	.728	.103	0	947.000	-1.918	.055#
	2	47	.32	.515	.075	0			
Nasal Obstruction AF1	1	50	.44	.541	.076	0	779.500	-3.762	.000**
	2	47	.09	.282	.041	0			
Nasal Obstruction AF2	1	50	.56	.541	.076	1	589.500	-5.318	.000**
	2	47	.04	.204	.030	0			



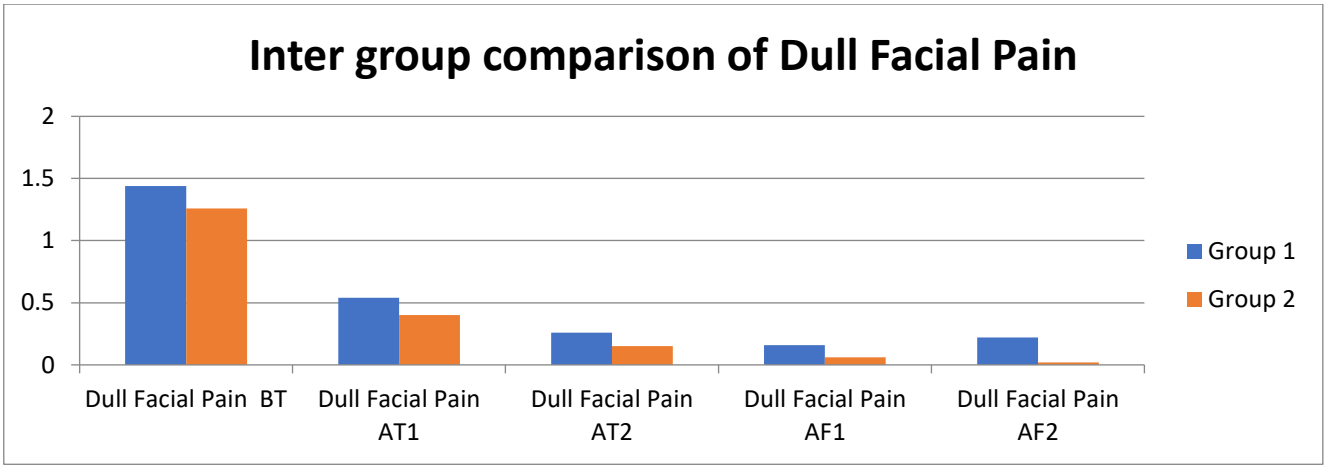
There was a statistically highly significant difference seen for the values between the groups ($p<0.01$) for Nasal Obstruction AF1 with higher values in Group A

There was a statistically highly significant difference seen for the values between the groups ($P<0.01$) for Nasal Obstruction AF2 with higher values in Group A

There was a statistically non-significant difference seen for the values between the groups ($P>0.05$) for Nasal Obstruction BT, AT1, AT2

Table 3 Effect of treatment on Dull facial pain between group A and group B

	Group	N	Mean	Std. Deviation	Std. Error Mean	Median	Mann-Whitney U value	Z value	p value of Mann-Whitney U test
Dull Facial Pain BT	1	50	1.44	.972	.137	0	1086.500	-.693	.488#
	2	47	1.26	1.188	.173	2			
Dull Facial Pain AT1	1	50	.54	.579	.082	0	986.000	-1.575	.115#
	2	47	.40	.681	.099	0			
Dull Facial Pain AT2	1	50	.26	.527	.075	0	1084.500	-.968	.333#
	2	47	.15	.360	.052	0			
Dull Facial Pain AF1	1	50	.16	.422	.060	0	1084.000	-1.246	.213#
	2	47	.06	.247	.036	0			
Dull Facial Pain AF2	1	50	.22	.418	.059	0	941.500	-2.955	.003**
	2	47	.02	.146	.021	0			

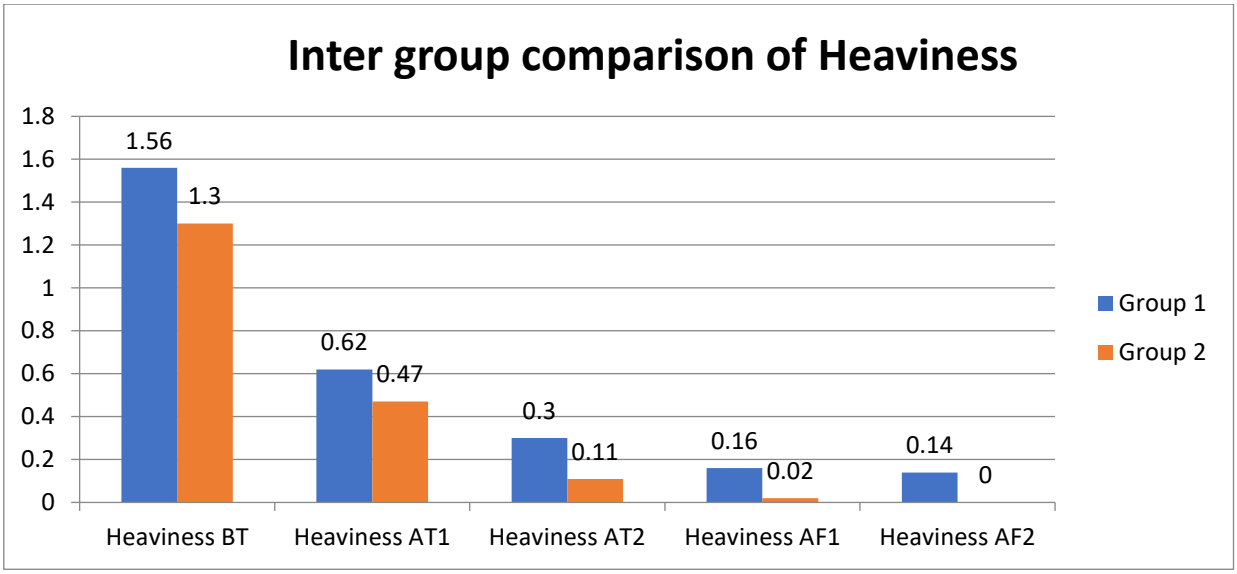


There was a statistically highly significant difference seen for the values between the groups ($p<0.01$) for Dull Facial Pain AF2 with higher values in Group A

There was a statistically non-significant difference seen for the values between the groups ($p>0.05$) for Dull Facial Pain BT, ATI, AT2, AF1

Table 4 Effect of treatment on Heaviness of head between group A and group B

	Group	N	Mean	Std. Deviation	Std. Error Mean	Median	Mann-Whitney U value	Z value	p value of Mann-Whitney U test
Heaviness BT	1	50	1.56	.861	.122	2	1063.000	-.906	.365#
	2	47	1.30	1.178	.172	2			
Heaviness AT1	1	50	.62	.602	.085	1	996.000	-1.454	.146#
	2	47	.47	.654	.095	0			
Heaviness AT2	1	50	.30	.505	.071	0	968.500	-2.166	.030*
	2	47	.11	.312	.045	0			
Heaviness AF1	1	50	.16	.370	.052	0	1012.000	-2.341	.019*
	2	47	.02	.146	.021	0			
Heaviness AF2	1	50	.14	.351	.050	0	1010.500	-2.649	.008*
	2	47	.00	.000	.000	0			

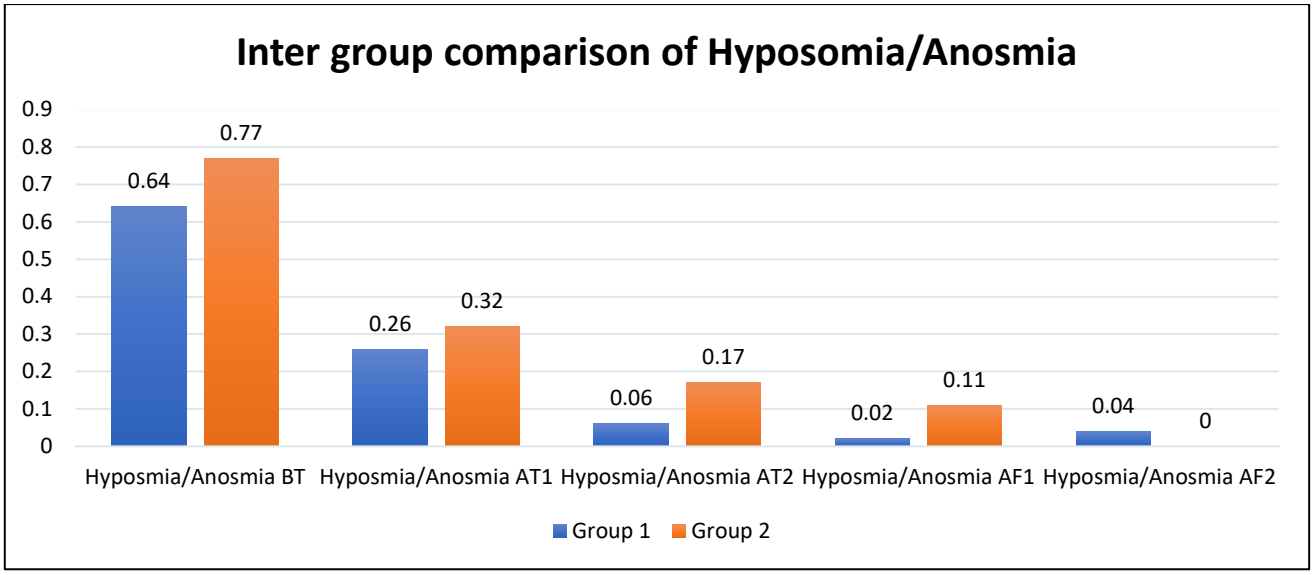


There was a statistically highly significant difference seen for the values between the groups (P<0.01) for Heaviness AF2 with higher values in Group B

There was a statistically significant difference seen for the values between the groups (p<0.05) Heaviness AT2, AF1 with higher values in Group B

Table 5 Effect of treatment on Hyposmia/Anosmia between group A and group B

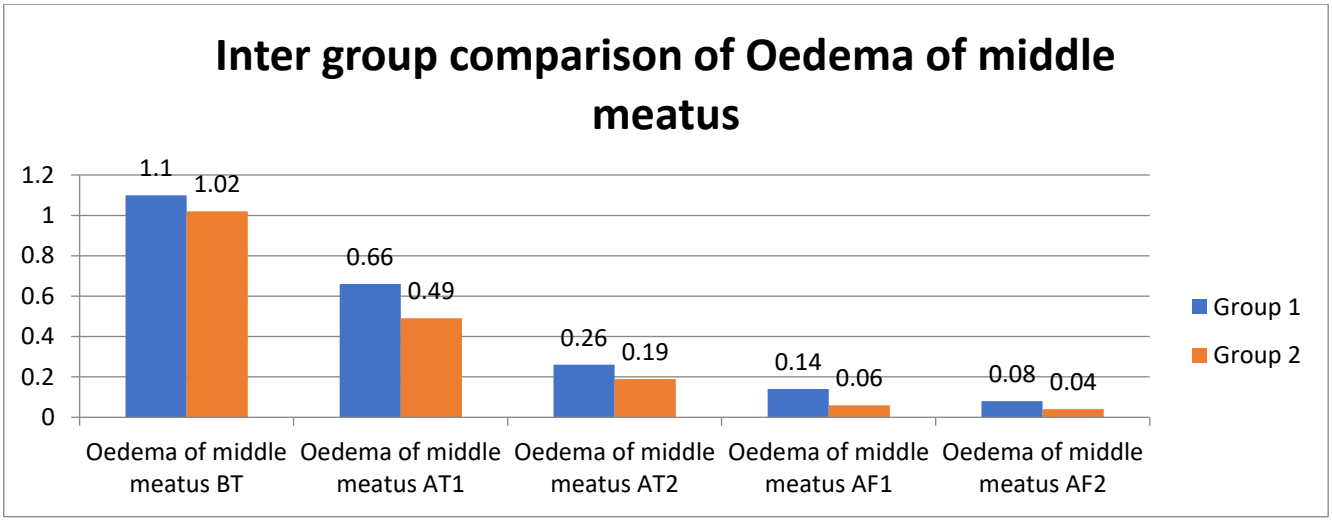
	Group	N	Mean	Std. Deviation	Std. Error Mean	Median	Mann-Whitney U value	Z value	p value of Mann-Whitney U test
Hyposmia/ Anosmia BT	1	50	.64	.827	.117	0	1166.000	-.074	.941#
	2	47	.77	1.127	.164	0			
Hyposmia/ Anosmia AT1	1	50	.26	.443	.063	0	1170.500	-.043	.966#
	2	47	.32	.629	.092	0			
Hyposmia/ Anosmia AT2	1	50	.06	.240	.034	0	1092.500	-1.184	.236#
	2	47	.17	.481	.070	0			
Hyposmia/ Anosmia AF1	1	50	.02	.141	.020	0	1073.500	-1.756	.079#
	2	47	.11	.312	.045	0			
Hyposmia/ Anosmia AF2	1	50	.04	.198	.028	0	1128.000	-1.378	.168#
	2	47	.00	.000	.000	0			



There was statistically non-significant difference seen for the values between the groups ($p>0.05$) for Hyposmia /anosmia BT, AT1, AT2, AF1, AF2.

Table 6 Effect of treatment on Oedema of middle meatus between Group A & Group B

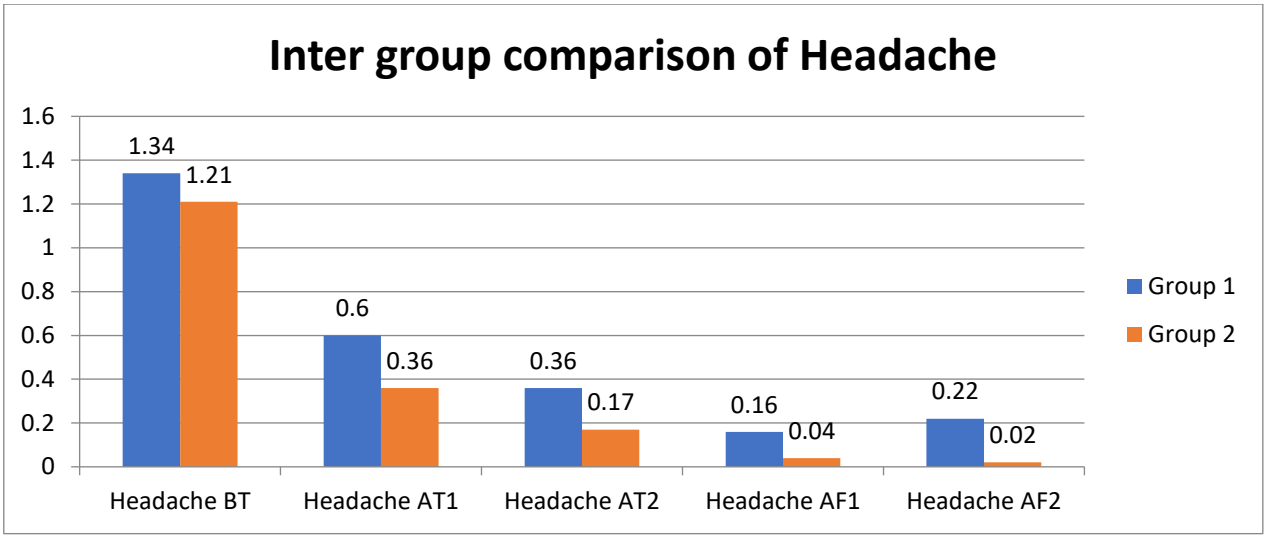
	Group	N	Mean	Std. Deviation	Std. Error Mean	Median	Mann-Whitney U value	Z value	p value of Mann-Whitney U test
Oedema of middle meatus BT	1	50	1.10	1.015	.144	1	1123.000	-.411	.681#
	2	47	1.02	1.151	.168	0			
Oedema of middle meatus AT1	1	50	.66	.688	.097	1	993.500	-1.466	.143#
	2	47	.49	.718	.105	0			
Oedema of middle meatus AT2	1	50	.26	.527	.075	0	1114.000	-.639	.523#
	2	47	.19	.449	.066	0			
Oedema of middle meatus AF1	1	50	.14	.405	.057	0	1086.000	-1.347	.178#
	2	47	.06	.323	.047	0			
Oedema of middle meatus AF2	1	50	.08	.274	.039	0	1108.000	-1.262	.207#
	2	47	.04	.292	.043	0			



There was statistically non-significant difference seen for the values between the groups ($p>0.05$) for oedema of middle meatus BT, AT1, AT2, AF1, AF2

Table 7 Effect of treatment on Headache between group A & group B

	Group	N	Mean	Std. Deviation	Std. Error Mean	Median	Mann-Whitney U value	Z value	p value of Mann-Whitney U test
Headache BT	1	50	1.34	.917	.130	1	1105.500	-.533	.594#
	2	47	1.21	.977	.142	2			
Headache AT1	1	50	.60	.670	.095	0.5	930.000	-2.045	.041*
	2	47	.36	.640	.093	0			
Headache AT2	1	50	.36	.598	.085	0	1010.500	-1.605	.108#
	2	47	.17	.380	.055	0			
Headache AF1	1	50	.16	.370	.052	0	1037.000	-1.891	.059#
	2	47	.04	.204	.030	0			
Headache AF2	1	50	.22	.418	.059	0	941.500	-2.955	.003*
	2	47	.02	.146	.021	0			



There was a statistically highly significant difference seen for the values between the groups ($p<0.01$) for Headache AF2 with higher values in Group A

There was a statistically significant difference seen for the values between the groups ($P<0.05$) Headache AT1 with higher values in group 1

There was a statistically non-significant difference seen for the values between the groups ($P>0.05$) for Headache BT, AT2, AF1.

Discussion:

Selection of the drug mainly aimed at different aspects of pathophysiology involved like etiological factors, Oedema and inflammation of mucous membranes of Nose, Excessive mucous secretion, Nasal Obstruction

Kalingadi taila Dravya administration in the form of *Vairechanika Nasya* [10] as trial drug and *Vidanga taila Nasya* as control group to achieve smooth elimination of doshas without causing much damage to the mucosal surfaces.

Though the medicament was in taila form the *Teekshnata* and *Kapha Vilayana* properties helps to combat pathology. It also helps in balancing the *dhatus* concerned with *Urdhwajatrugata Vikaras*. The potency of the drugs emphasizes to *Vairechanika* drugs and hence *Nasya* was administered in empty stomach in morning hours [11]. It does *Kapha vilayana*, *Sroto Shodhana, Shothahara* and pacifies the *Vata dosha* as it is in *Taila* form [12].

The Sneha Paka of the Nasya is of *Mrudu paka* which maintains the water solubility for diffusing through olfaction epithelium and lipid solubility for interacting with the lipid nature of morbid factors [13]. The *Sneha guna* of both the *taila* helps to stimulate the olfactory mucosa. Since the drug is directly administered to the targeted tissue it has the immediate effect on the affected part.

Kalingadi Taila is a polyherbal formulation whereas *Vidanga Taila* has only *Vidanga* and *Tila taila*. The potency of the drugs is stronger, penetrate to the mucosal blanket and reduces mucosal oedema and secretions, thereby easing the drainage from sinuses by clearing the clogging of ostia and further relieving from heaviness of head, Nasal obstruction [14].

The acidic factors of the drug causes irritation in mucosa, increases watery secretions, makes the viscid and adhered secretion to loosen up from the mucosa and enhance the functions of cilia.

Conclusion:

Kalingadi Taila may be used for Nasya as a drug of choice in the management of Chronic Rhinosinusitis with different combinations of internal medications based on the Prakruti and involvement of Sinuses for quick and success rates.

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