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EFFICACY OF KATPHALA SIDDHA TAILA PRATIMARSHA NASYA IN RHINITIS – A PILOT STUDY

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Abstract
Ayurveda is an eternal and continuous flow of ancient medicine. Nowadays, there are some diseases which need to be given special attention. Changing lifestyles, increased pollution, urbanisation and increased resistance to antibiotics are responsible for the prevalence of many diseases. Nose being exposed to the external environment, is more prone to all these causes and recurrent infections. The most common and frequent problem is Pratishyaya or Rhinitis. Repeated attacks, improper management or negligence of the acute stage leads the disease to the chronic phase (Dushta Pratishyaya).

Keywords - Ayurveda, Pratishyaya, Katphala, Tila taila, Pratimarsha Nasya

Introduction

Due to the development of science, Industrialisation and urbanisation changed the ecosystem. The environment gets polluted. Due to environmental pollution, global warming, unnatural seasonal variation, excessive use of A.C. and refrigerator, use of fast chinese food and excessive nariprasanga etc. a very common and frequent disease Pratishyaya occurs in human beings. Pratishyaya is also a vata-kaphaj roga mainly. It is closely resembles as Rhinitis as described in modern medical science.

In *Ayurved Samhitas,* different types of treatment & procedures are suggested to cure the nasal diseases. *Nasya* is one of the best treatments for *Nasagata Vikaras. Nasya* means the application of medication into the nostrils to eliminate *doshas* from the *Urdhvajatrugata* region. All the ancient Acharyas have given tremendous importance to *Nasya karma* in the treatment of various *Nasagata and Shirogata Rogas*. This *Nasya karma* is not only used for the *Swasthavrutta* but also for the curative purpose. According to Ayurveda '*Nasa'* is the gateway of *'Shira'. Sushrutacharya* the ancient surgeon had explained various diseases of *Urdhvangas* where the *Pratishyaya* is classified under *Nasagata Rogas*. *Katphala* have property of '*Vata-Kaphghna, Shirovirechan & Shothahar' and Tila Tail* also has the property of *Vata-Kaphagna. In Pratishyaya* mainly *Vata-Kapha Dosha* is vitiated, hence I have selected this subject for my

study.

Aim And Objectives

To Study the efficacy of '*Katphala siddha tila taila Pratimarsha Nasya'* in Rhinitis.

Materials & Methods

Type of Study

The study is single-blind randomized clinical trial and the entire study is based on clinical findings & narration of patients.

Materials –

Drug :

Trial Group: Katphala Siddha Taila Pratimarsha Nasya

Control Group: Oxymetazoline Nasal Drop (0.05%)

Methodology –

Patients

The grouping of patients was done as follows:

1) The study includes 20 patients

2) They were divided into two groups of 10 patients in each group.

3) A separate case paper was designed for evaluation of included patients.

Inclusion Criteria:

1. Patients having any type of Rhinitis were randomly selected.
2. Selection was irrespective of sex, religion & socio economical class.
3. Patients above 18 years & below 60 year of age were selected.

Exclusion Criteria:

1) Patients up to 18 years & above 60 years of age were excluded.

2) Recently operated patients of nasal surgery.

3) Pregnant women.

4) Patients of *Dushta pratiksyay.*

Drug

Trial Group:- *Katphala siddha taila*.

Method of Preparation of *Katphala siddha taila* according to **'***Snehapak Kalpana'.*

a. Katphala churna is collected in raw form, and then converted into kalka form.

b. Tila taila is heated on low flame till it gets hot and then it is cooled.

c. Tila taila, kalka and jala is mixed in the ratio of 1:4:16 and heated on low flame again, until testing criteria is achieved. Standard guidelines of Snehasiddhi lakshanas from Sharangdhar Samhita are followed.

d. Siddha taila is filtered and packed in air tight 10 ml plastic dropper bottles which is sterilized through Ethylene Oxide (ETO) Sterilization and labelled.

e. It is then stored in cool and dry place.

Dose & time of administration of drugs:
Trial group - 10 Patients – Katphala Siddha Taila Pratimarsha Nasya
2 drops in each nostril in the morning and evening for 7 days

Control group - 10 Patients **–** Oxymetazoline Nasal Drop (0.05%)
2 drops in each nostril in the morning and evening for 7 days

(Snehan, swedan etc. was not given to patient)

Follow up –
Follow-up was done on 0, 2nd, 4th, 6th, 8th days & observation was recorded in tabular form.

Observations:-
a) All groups were advised standard proper hygienic care of nose.
b) Observations were noted in tabular form according to the severity of signs & symptoms.

Sr no	Lakshanas (Sign and Symptoms)	0 (BT)	2nd	4th	6th	8th (AT)
1.	Sakashta Shwasan (Difficulty in breathing)					
2.	Shirahshoola (Headache)					
3.	Kshavathu (Sneezing)					
4.	Aaraktata (Redness)					
5.	Nasa Srava (Nasal discharge)					

6.	Nasagata shleshmal kalashoth (Inflammation of nasal mucosa)					

Gradation of symptoms:-
0 – Normal
+ - Mild
++ - Moderate
+++ - Severe

Criteria for the assessment:
Assessment was done on the basis of improvement in the clinical condition of the patient i.e. relief in signs and symptoms. Scoring was done according to the following scale:

Sakashta Shwasan (Difficulty in breathing)*:*
No obstruction: 0
Partially,occasionally and unilateral : +
Partially, occasionally and bilateral: ++
Complete,frequently and unilateral : +++

Shirahshoola **(**Headache**):**
No headache: 0
Occasionally with low intensity: +
Frequently with moderate intensity but do not disturb daily routine work : ++
Always with moderate intensity, sometimes disturb routine work: +++

Kshavathu *(*Sneezing*):*
No sneezing: 0
Occasionally <5/day: +
5-10 times / day: ++
11-15 times / day : +++

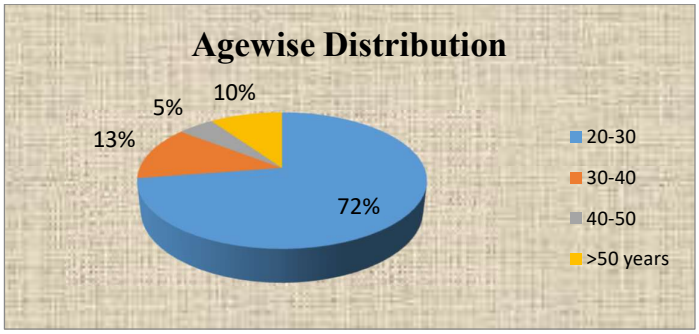
Aaraktata (Redness)
No redness 0
Mild redness+
Mild to moderate++
Moderate to severe+++

Nasa Srava **(Nasal discharge***)*
No discharge : 0
Occasional: +
Frequent : ++
Continuous heavy +++

Nasagata Shleshmal Kalashoth (Inflammation of Nasal Mucosa)
No Inflammation 0
Mild Inflammation +
Mild to moderate Inflammation ++
Moderate to severe Inflammation +++

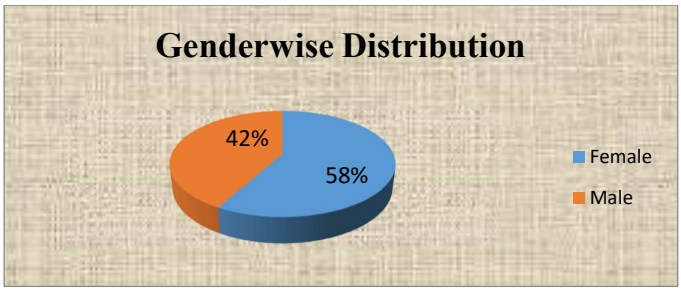
Statistical Analysis –

- **Age Wise Distribution :**



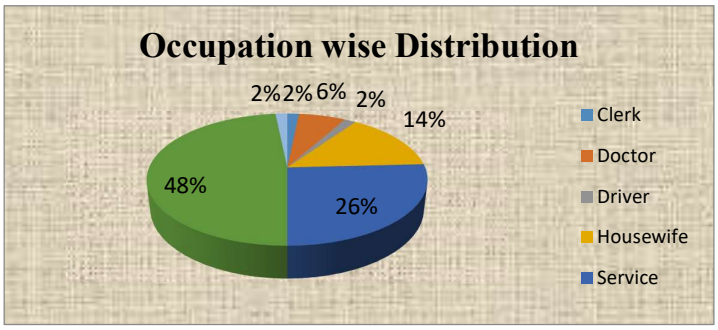
In this study maximum no of patients found in the interval of 20-30 age group.

- **Gender Wise Distribution :**



From above table we found that maximum no of patients were females.

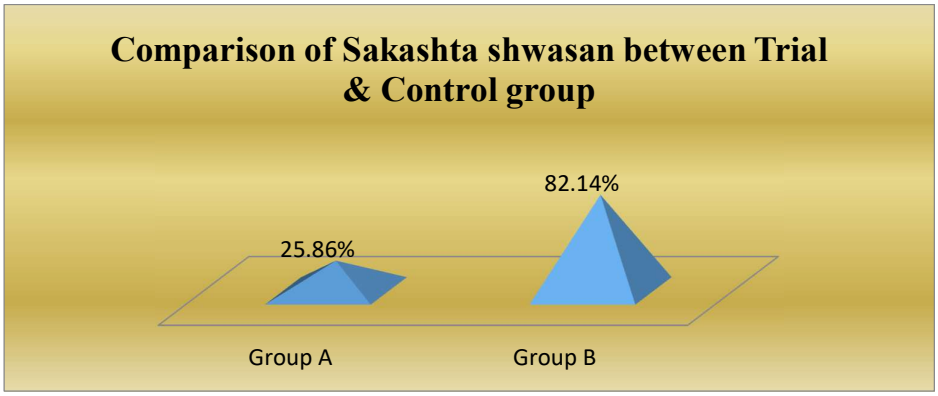
- **Occupation Wise Distribution**



From above table we found that maximum no patients were students.

I. Comparison Of Trial Group And Control Group in Sakashta Shwasan (Difficulty in breathing)

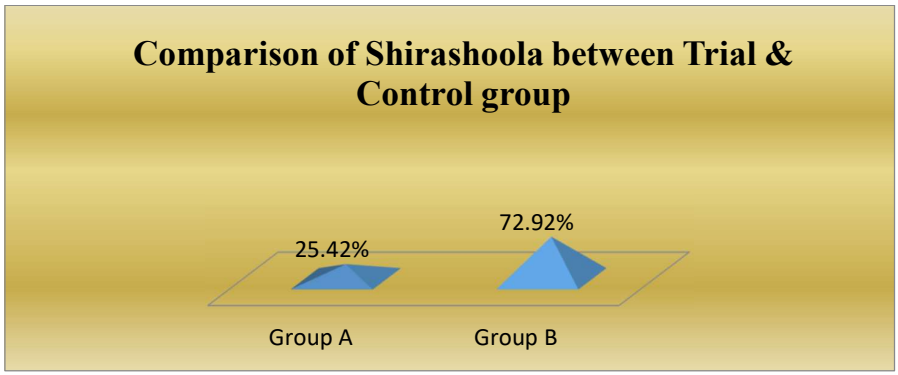
Parameter	Group	% of improvement	Mann Whitney u	Z	P VALUE
Sakashta shwasan	Trial Group	25.86%	0	-7.6	0
	Control Group	82.14%			



As p value<0.05 we found that there was a statistically significant difference between Group A and Group B on DIFFICULTY IN BREATHING in Rhinitis. Also as the percentage of improvement seen from the above table, we get the percentage of improvement in Group B was more than Group A; hence we can say that **Control group is more effective as compared to Trial group on Sakashta shwasan in Rhinitis.**

II. Comparison Of Trial Group And Control Group in Shirashoola (Headache)

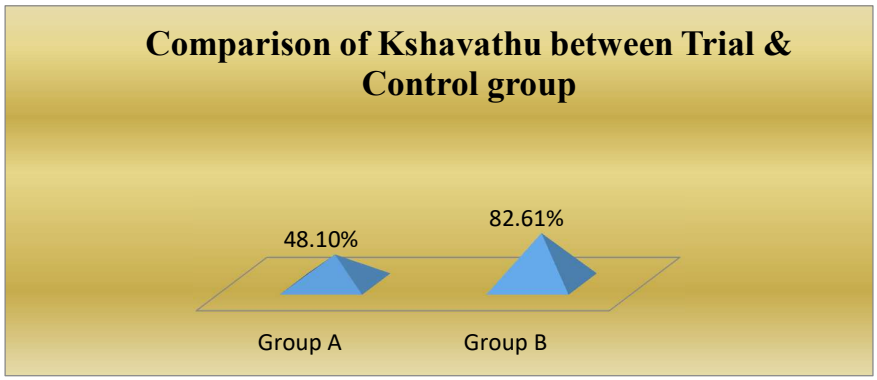
Parameter	Group	% of improvement	Mann whitney u	z	P VALUE
Shirashoola	Trial Group	25.42%	481	0	1
	Control Group	72.92%			



As p value>0.05 we found that there was no statistical significant difference between Group A and Group B on HEADACHE in Rhinitis. Also as percentage of improvement seen from above table we get percentage of improvement in Group B was more than Group A hence we can say that **Control group is more effective as compared to Trial group on Shirashoola in Rhinitis.**

III. Comparison Of Trial Group And Control Group in Kshavathu (Sneezing)

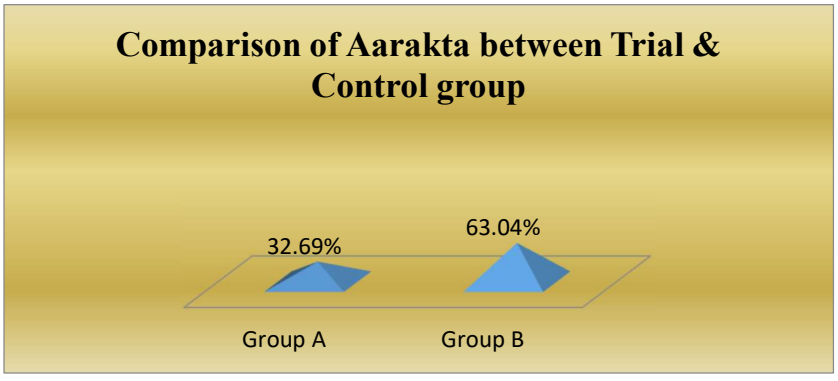
Parameter	Group	% of improvement	Mann whitney u	z	P VALUE
Kshavathu	Trial Group	48.10%	0	-7.7	0
	Control Group	82.61%			



As p value<0.05 we found that there was statistical significant difference between Group A and Group B on SNEEZING in Rhinitis. Also as percentage of improvement seen from above table we get percentage of improvement in Group B was more than Group A hence we can say that **Control group is more effective as compared to Trial group on Kshavathu in Rhinitis.**

IV. Comparison Of Trial Group And Control Group in Aarakta (Redness)

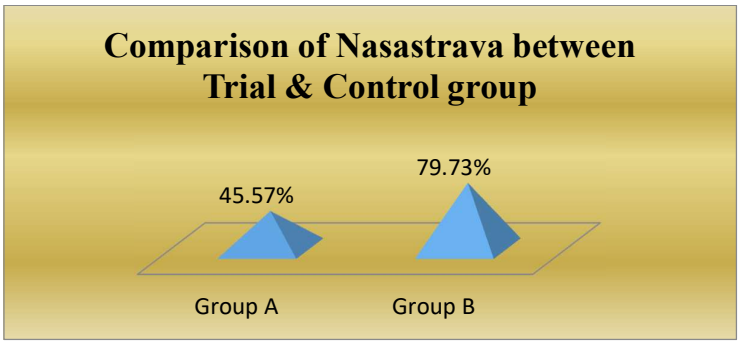
Parameter	Group	% of improvement	Mann whitney u	z	P VALUE
Aarakta	Trial Group	32.69%	450	-1.4	0.15
	Control Group	63.04%			



As p value>0.05 we found that there was no statistical significant difference between Group A and Group B on REDNESS in Rhinitis. But as percentage of improvement seen from above table we get percentage of improvement in Group B was more than Group A hence we can say that **Control group is more effective as compared to Trial group on Aarakta in Rhinitis.**

V. Comparison Of Trial Group And Control Group in Nasastrava (Nasal Discharge)

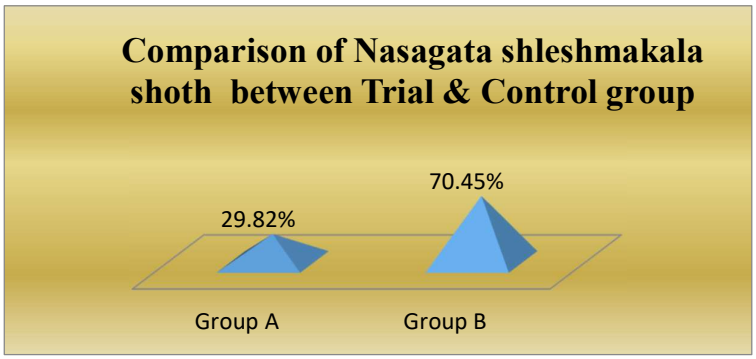
Parameter	Group	% of improvement	Mann whitney u	z	P VALUE
Nasastrava	Trial Group	45.57%	0	-7.6	0
	Control Group	79.73%			



As p value<0.05 we found that there was statistical significant difference between Group A and Group B on NASAL DISCHARGE in Rhinitis. Also as percentage of improvement seen from above table we get percentage of improvement in Group B was more than Group A hence we can say that **Control group is more effective as compared to Trial group on Nasastrava in Rhinitis.**

VI. Comparison Of Trial Group And Control Group in Nasagata shleshmakala shoth (Inflammation Of Nasal Mucosa)

Parameter	Group	% of improvement	Mann whitney u	Z	P VALUE
Nasagata shleshmakala shoth	Trial Group	29.82%	465	-1	0.32
	Control Group	70.45%			



As p value<0.05 we found that there was statistical significant difference between Group A and Group on **Nasagata shleshmakala shoth** in Rhinitis. Also as percentage of improvement seen from above table we get percentage of improvement in Group B was more than Group A hence we can say that **Control group is more effective as compared to Trial group on Nasagata shleshmakala shothin Rhinitis.**

Discussion

- One of the nasaroga, "Pratishyaya," is thoroughly elucidated by our Acharyas in every classical literature. It is regarded as the most serious illness since improper treatment or negligence can result in complications such diseases of the head, neck, or ears. Thus, it needs to be treated promptly with the right prescription.
- Pratishyaya is a vatakapha-predominant illness. Vegadharana, Rajo, Dhooma, Dhuli, Sevana, Sheetambupana, diwaswapna, and mitya ahara-vihara are some of the nidanas.
- According to the classics, the nidana leads Vatadosha to become vitiated, which is the samprapti. In moordha pradesha, it gets vimargagamana and sanchaya. There, it further perturbs the doshas of Kaphadi and results in the pratigamana of Kaphadi sickness, which causes the doshas to continuously flow out of the nose.
- Sakashta shwasan (Difficulty in breathing), Shirahshoola (Headache), Kshavathu (Sneezing), Aaraktata (Redness), Nasa Srava (Nasal discharge) and Nasagata shleshmakala shoth (Inflammation of nasal mucosa) are symptoms of Pratikshyay. In contemporary medicine, these symptoms were shown to be somewhat associated with those of Rhinitis.
- A co-relationship between Pratikshyay and Rhinitis was attempted because some of its lakshanas seem similar to that of Rhinitis, despite the fact that our Acharyas explained the disease in multiple classes, making it impossible to attribute to one particular modern disease.

Clinical trial schedule adopted for the study :

The present study was designed in the form of comparative clinical study. 62 patients fulfilling all the diagnostic criteria of the disease were selected and grouped into –

Group-A (Trial group) –

The patients were instructed to instill two drops of Katphala siddha taila pratimarsha nasya in

each nostril 2 times in a day for seven days.

Group B (Control group)-
Patients were instructed to instill two drops of Oxymetazoline nasal drop (0.05%) in each nostril 2 times in a day for seven days.

The observation and results which was obtained out of 62 patients are discussed below :
Age:
The age range of 20 to 30 years was found to have a higher frequency of Rhinitis. Most likely as a result of increased exposure to dust, smoke and pollution for longer time.

Gender:
Females were found to have a higher incidence of Rhinitis than males. It is most likely due to the fact that the majority of patients in this study were female.

Occupation :
Occupation plays an important role in causing Rhinitis. The persons who are exposed to dust, air pollution, pollens and outer environment, irritants, and smoke have a higher incidence of getting Rhinitis. It is clear from the study that a high incidence was seen in students.

Probable Mode Of Action Of Katphala Siddha Taila

- Pratishyaya is a vataj predominate condition where vitiated vata along with kapha and pitta doshas along with rakta or independently is localized in shira due to etiological reasons. Through nasapradesha, further vitiated vata expels rakta, pitta, and kapha.
- The qualities of Katu Rasa (pungent rasa), Ushna Virya (hot potency), Katu Vipak, and Kapha reduction are all possessed by Katphala. Due to Katu Rasa, it could also aggravate Vayu. The main cause of Marga Avarodh (Obstruction) is the body's evacuation of Kapha, which may be aided by an increase in Vayu.
- Consequently, Sankochana (Contraction-spasm) in Pranavaha Srotas may also be caused by an increase in Vayu. As Kapha leaves the body, Vayu could feel relieved.
- Like Madhur, Kashaya, Tikta, Katu Rasa, Ushna Virya, Madhur Vipaka, Guru, Snigdha, and Sookshma Guna, Tila Taila is easily penetrated. It is also among the best oils for those with Vata vyadhis.
- Katphala has kapha-vatashamak properties.
- Katphala contains Alkaloids, which are stimulants of the central nervous system, along with Saponin, Flavonoids, Tannin, Terpenoid, Phenols, and Minerals. Its antioxidant qualities come from flavonoids, phenols, and saponins, which also have anti-cancer, immune-boosting, and antioxidant characteristics. Oil's tannin content confers antiviral, antibacterial, and astringent properties. The presence of terpenoid confers antimicrobial.

Katphala siddha taila

Vata-kaphahara, Bruhana, Vatanulomana, Shothahara, Snehana, Stravahara properties

Removing the Kapha avarana vata

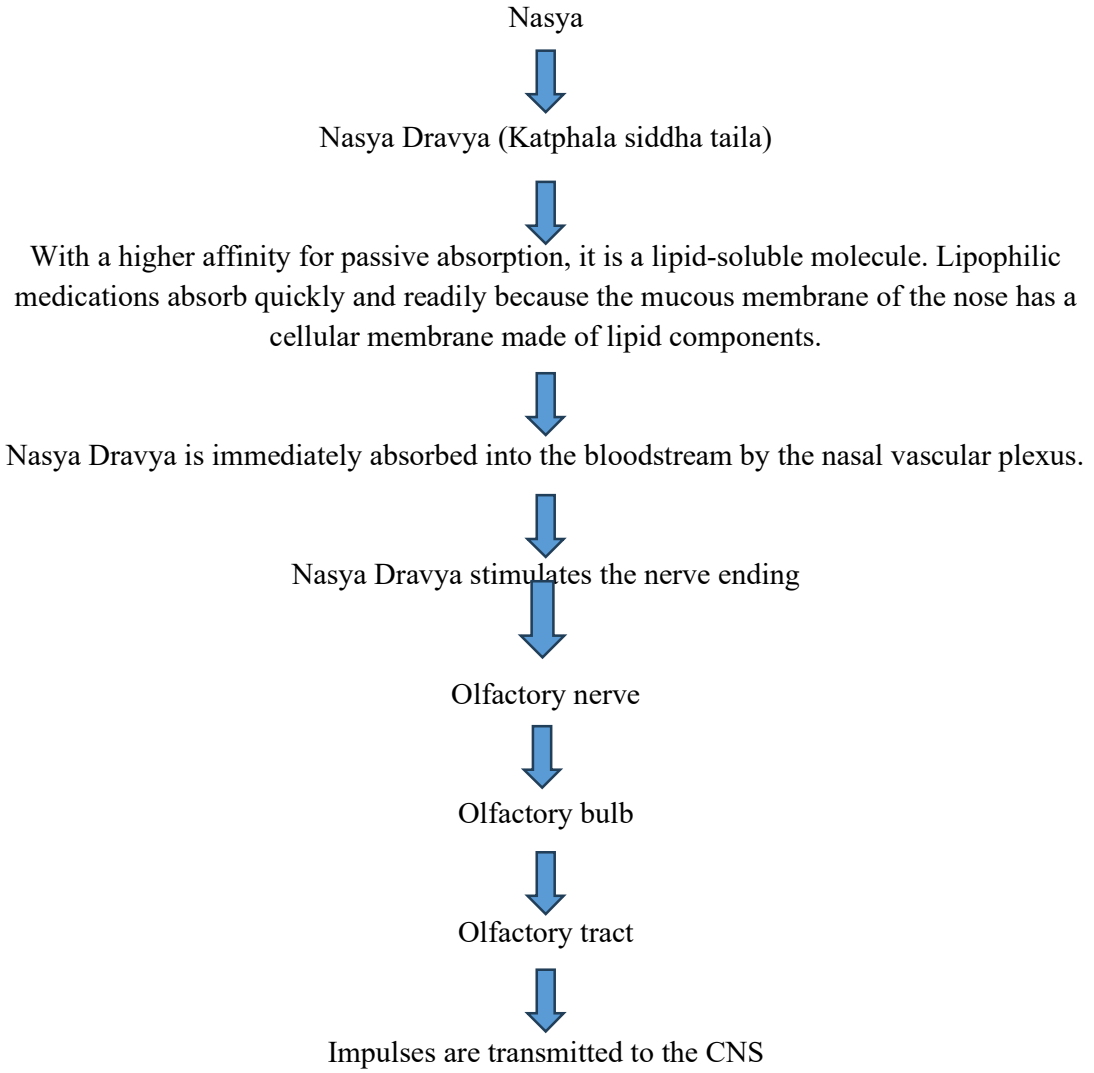
Promoting Vata swamarga pravrutti

Capable of controlling signs and symptoms of Pratishyaya

- According to modern science, using antihistamine medications and steam inhalation are the main ways to treat Rhinitis. These techniques assist in minimizing the patient's episodes of watery nasal discharge and sneeze attacks by relieving nasal congestion and sneezing attacks.
- As a result, the medications and techniques listed above have the qualities and effectiveness to examine Pratishyay's pathology in relation to Rhinitis.

Probable Mode Of Action Of Nasya Karma

- Nasya karma is one of the panchakarma procedure which acts as shodhana of jatrudwa bhaga. It is a unique procedure mentioned in classics especially in the management of nasarogas and shirorogas.
- It not only clears the local pathology but also acts on the sense perception of smell.
- Locally nasya may act as stravahara, shothahara, strotho shodhana regenerates nasal mucus membrane.
- The Samhitas do not provide information on nasya's precise mechanism of action. From the information that is available, we can infer a speculative theory about how it works. According to this theory, the medicine is administered via the nasal route, which may reach up to shringataka marma. It is then spread throughout the entire urdhvajatru and removes morbid dosha from shira by siras of netra, kantha, and shrotra.
- The middle cephalic fossa of the skull, known as Shringataka Marma, is home to meningeal nerves and veins as well as paranasal sinuses. As per Acharya Sushruta, shringataka marma is considered "siramarma" since it is the combination of nasa, karna, akshi, and jihva siras.



- **Venous blood route** :

Since lipids make up the mucous membrane of the nose, lipophilic medications can pass through it quickly and readily. Additionally, the mucous membrane is a highly vascularized area. Thus, the medication is delivered by nasal delivery, where it is immediately absorbed by capillaries and enters the systemic circulation.

- **Nervous pathway :**

Trigeminal and olfactory nerves are intimately linked to the nasal mucosa. Therefore, any medication administered by nasal route comes into direct contact with the olfactory nerve, passes through the olfactory bulb and olfactory tract, and stimulates the nerve endings, which then send impulses to the central nervous system.

- **Lymphatic route :**

The nasal cavity's lymphatic pathways align with the subarachnoid space and the olfactory nerves. Through the epithelial membranes, lipid-soluble material was transferred. and pass through the expanded arachnoids sheath that connects the brain to the nasal submucosal region,

gaining access to lymphoid tissue and the brain.

Conclusion

- A detailed description about *Pratikshyay* is found in Brihatrayees, as well as Laghutrayees.
- Etiological factors, symptoms and etiopathogenesis are almost similar in Ayurveda and Modern science.
- Group A showed nearly good response in Kshavathu (Sneezing) and Nasa Srava (Nasal discharge) while showed some significant response in Sakashta shwasan (Difficulty in breathing), Shirahshoola (Headache), Aaraktata (Redness) and Nasagata shleshmakala shoth (Inflammation of nasal mucosa).
- According to a statistical study, NULL HYPOTHESIS is accepted; therefore it can be concluded that the effect of Oxymetazoline (0.05%) nasal drop is more effective than Katphala siddha taila pratimarsha nasya.

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