

A Comparative Clinical Study on the effect of *Vachadi Avaleha* versus *Mustakadi Avaleha* in the management of *Pratishyaya* (~Recurrent Rhinitis) in school going children: A Single-blind Randomized Control Trial

Research Article

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Abstract

Background: In Ayurveda, *Pratishyaya* (~Recurrent Rhinitis) is described in *Shiro-roga* (Head disease). *Pratishyaya* (~Recurrent Rhinitis) is a common disease of childhood and it is well known for its recurrence. Immature *Dhatu* (tissues) state in children makes them more susceptible to recurrent infections. Clinical features of *Pratishyaya* (~Recurrent Rhinitis) can be correlated with rhinitis. **Aim & Objective:** To study the effect of *vachadi avaleha* and *mustakadi avaleha* in management of *pratishyaya* (~recurrent rhinitis). To study comparative efficacy of *vachadi avaleha* and *mustakadi avaleha* in management of *pratishyaya* (~recurrent rhinitis). **Material & Method:** Study comprises total 60 patients of *Pratishyaya* (~recurrent rhinitis) randomly divided into two equal groups. Group A (Experimental group) was treated with *Vachadi avaleha* two times a day after meal with honey and Group B (Control group) was treated with *Mustakadi Avaleha* administered two times a day after meal for 90 days. Patients were assessed for subjective parameters like rhinorrhoea, sneezing, nasal congestion, recurrence of rhinitis, duration of rhinitis per episode. Patients were assessed on every 30th day till completion of study period. **Result-** The effect of *Mustakadi Avaleha* (Group B) is significant at $p < 0.05$ for subjective criteria such as *nasastrava* (rhinorrhoea), *kshavathu* (sneezing), and *nasavarodha* (nasal congestion) of *pratishyaya* (~Recurrent Rhinitis). **Conclusion:** *Vachadi Avaleha* is not as significant as *Mustakadi avaleha* in *Pratishyaya* (~Recurrent Rhinitis).

Keywords: Immunity, *Kaumarabhritya*, *Mustakadi Avaleha*, *Nasaroga*, *Shiro roga*, Rhinitis.

Introduction

In ayurveda, *Pratishyaya* (~Recurrent Rhinitis) is described in *shiro-roga* (head diseases). Which is described as a condition where the nasal secretions are produced owing to the vitiation of accumulated humor (*vata* and *kapha*)(1). The origins, pathophysiology, symptoms and treatments of *Pratishyaya* (~Recurrent Rhinitis) as described in the canonical ayurveda texts. *Vataja*, *pittaja*, *kaphaja* and *sannipataja* are the four different categories of *Pratishyaya* (~Recurrent Rhinitis) (1). As *Pratishyaya* (~Recurrent Rhinitis) is the most prevalent ailment in children, *acharya kashyap* dedicated a particular chapter to it in *kashyap samhita*. According to *kashyap vata* that is aggravated vitiates towards the upper region of *kapha*, congests the channels in the mouth and causes abnormalities there. When this happens, ear ailments

also arise. It is referred to as *Pratishyaya* (~Recurrent Rhinitis) when *kapha*, *pitta*, or *rakta* (blood) is present towards the nasal root(2). Recurrence of *Pratishyaya* (~Recurrent Rhinitis) occurs because *doshas* (body humor) reside in their latent stage and give rise to the same disease when factors are favorable(3). Although it is treatable in its early stages, the condition is well recognized for its chronicity and recurrence, which cause several problems like *badhirya* (deafness), *andhatava* (blindness)(4). The characteristic of *Pratishyaya* (~Recurrent Rhinitis) is comparable to the present scientific description of rhinitis, which is marked by nasal obstruction, nasal discharge, sneezing, headache, etc. Many cases of rhinitis have been observed in general pediatric practice due to India's reputation for industrial pollution and dust. Recurrent rhinitis is also influenced by seasonal change, aging and other environmental variables like crowding and passive smoking (4). Modern medicine includes nasal decongestants, antihistamines and leukotriene inhibitors for treatment of rhinitis. Most *samhitas* in ayurveda literature describe *Pratishyaya* (~Recurrent Rhinitis) and numerous therapeutic procedures are also described. The medicine *vachadi kashaya*(5), which was manufactured in the form of *avaleha* for palatability reasons, was designated in *harita samhita*

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and was the trial drug of the current study. *Vachadi avaleha* contains *vacha*, *triphala*, *yavani*, and *shunthi*, all these drugs are *vata kaphahar* (pacifying vata and kapha) hence able to treat *Pratishtyaya* (~Recurrent Rhinitis). Contents like triphala & vacha is having immunomodulatory action and has efficacy against bacterial and viral infections (6-7-8). Hence this drug was selected for study and administered to patients for evaluation of the efficacy of *vachadi avaleha*. *Mustakadi avaleha* is mentioned in the *yogaratanakara* under *balarogadhikara*. It contains *mustaka*, *ativisha*, *pippali*, *karkatshringi*, *vasa*. It contains all the ingredients of a very popular remedy for children named as *balchaturbhadrachurna* and *vasa*. This drug is having immune modulator, anti inflammatory, anti bacterial activity, antioxidant activity & analgesic activity (9). It treats respiratory conditions as a preventative measure as well as a treatment because of its taste, light property and hot potency. Effects of the *vachadi avaleha* and *mustakadi avaleha* were observed on patients.

Aim

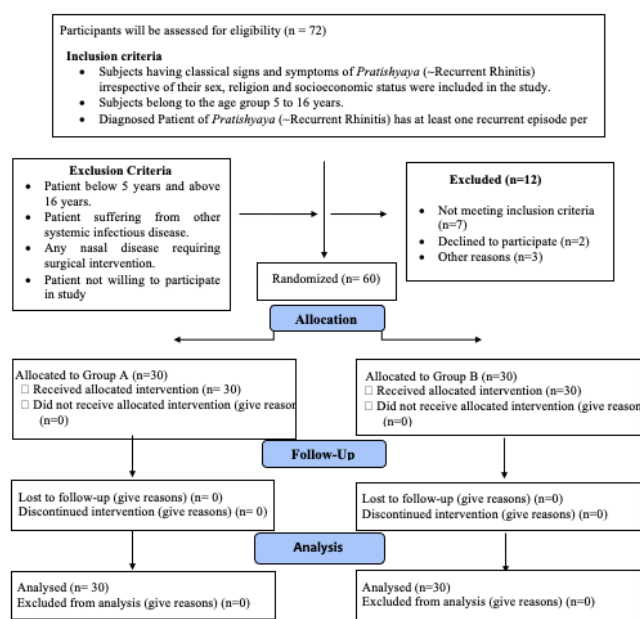
To study the effect of *vachadi avaleha* in the management of *Pratishtyaya*(~Recurrent Rhinitis) with special reference to rhinitis.

Objectives

- To study the effect of *vachadi avaleha* on *Pratishtyaya* (recurrent rhinitis).
- To study the effect of *mustakadi avaleha* on *Pratishtyaya* (recurrent rhinitis).
- Comparative study of the effect of *vachadi avaleha* & *mustakadi avaleha* on *Pratishtyaya* (recurrent rhinitis).

Materials and Methods

Figure 1: CONSORT flow chart



- Study design-Randomized single-blind control trial.
- Study setting (location) OPD of *Kaumarbhritya* department.
- Study population: The study was carried out on the patients suffering from signs and symptoms of *Pratishtyaya* (~Recurrent Rhinitis) w.s.r. to recurrent rhinitis in those attending OPD
- Trial drug: *Vachadi Avaleha*
- Control drug: *Mustakadi Avaleha*
- Duration of study: 90 Days
- Sampling technique: Simple randomized sampling technique by lottery method
- Sample Size: 60 (trial group 30 patients and control group 30 patients)

Inclusion criteria

- Subjects having classical signs and symptoms of *Pratishtyaya* irrespective of their sex, religion and socioeconomic status were included in the study.
- Subjects belong to the age group 5 to 16 years.
- Diagnosed patient of *pratishtyaya* (~recurrent rhinitis) has at least one recurrent episode per month for 1year.

Exclusion Criteria

- Subjects below 5 years and above 16 years.
- Subjects suffering from other systemic infectious disease.
- Any nasal disease requiring surgical intervention.
- Subjects not willing to participate in study

Diagnostic criteria

A special research proforma was prepared that included *Ayurvedic* and modern parameters for assessment as, *Nasastrava* (rhinorrhoea), *Kshavathu* (sneezing), Recurrence of rhinitis per month, duration of *Pratishtyaya* (rhinitis)(10). Presence of minimum 2 classical features of *Pratishtyaya* as mentioned above.

Method of preparation of drug

Raw drugs were purchased from the market. According to the standard procedure outlined in the *Sharangadhar Samhita* (11), each drug was taken in an equal amount and *avaleha* was prepared for palatability purposes.

Research proforma

A special research proforma was prepared that included *Ayurvedic* and modern parameters for assessment of the condition of *Pratishtyaya* with special reference to recurrent rhinitis. Subjects were assessed before and after treatment on given classical sign and symptoms.

- *Nasastrava* (Rhinorrhoea)
- *Kshavathu* (Sneezing)
- *Nasavarodh* (Nasal Congestion)
- Recurrence of rhinitis (*Pratishtyaya*) per month
- Duration of *Pratishtyaya*

Table 1: Vachadi avaleha drug formulation details (12)

| Drug | Latin Name | Rasa | Virya | Vipak | Guna | Karma | Chemical constituent & their Effect |
|----------|--------------------------------|-------------------------------------|--------|---------|------------------|--|--|
| Vacha | <i>Acorus Calamus</i> | Katu, Tikta | Ushna | Katu | Laghu, Tikshna | Vata Kaphahsamak Dipaniya, | α & β -asarone- antibacterial effect and ethanol extracts shows antihistaminic effect |
| Yavani | Trachyspermum ammi | Tikta, Katu | Ushna | Katu | Ruksha | Shothhara, Vednasthapa-ka | Alkaloids, flavonoids, steroids and polyphenols which are responsible for the antinociceptive action |
| Amalaki | Emblica officinalis | Amla Ras Pradhan Lavan-varjit | Sheeta | Madhura | Guru, Ruksa | Tridosahara, Rasayana | Tannins, alkaloids, phenolic compounds, amino acids & carbohydrates antipyretic |
| Bibhitak | Terminn- <i>alia Bellerica</i> | Kashaya | Ushna | Madhur | Ruksha Laghu | Tridosahar Kaphagn & shothhar | Glucoside, gallo -tannic acid, resins, ellagic acid, gallic acid, lignans, ethyl gallate, mannitol etc shows antimicrobial & |
| Haritaki | Terminalia Chebula | Lavan Rahit Pancharas | Ushna | Madhur | Ruksha Laghu | Kapha and vata shamak Tridosahar jwarghan | Gallic acid and ethyl ester shows antibacterial, antiamoebic and immunomodulatory |
| Shunthi | Zingiber Officinalis | Katu | Ushna | Madhur | Laghu Snigdha | Kapha vata shamak Dipaniya Kaphagn | Gingerol shows anti-inflammatory and analgesic effect hexane, ethyl acetate & |

Table 2: Mustakadi avaleha drug formulation details (20)

| Drug | Latin Name | Rasa | Virya | Vipak | Guna | Karma | Chemical constituent & |
|---------------|--------------------------------|-------------------------|--------------|---------|-------------------------------|---|--|
| Mustaka | <i>Cyperus rotundus.</i> | Tikta, katu, kashaya | Shit | Katu | Laghu, ruksha | Kapha- pitta shamaka, Dipan, Pachana | Flavonoids, glycosides, saponins, anthraquinone glycosides, has antibacterial |
| Ativisha | <i>Aconitum heterophyllum.</i> | Tikta katu | Ushna | Katu. | Laghu, ruksha | Kasa, jwarhar | Atisine, atidine ,tannic acid, starch, fat, glycerides etc antimalarial analgesic |
| Pippali | <i>Piper longum</i> | Katu. | Anushnashit. | Madhur. | Laghu, tikshna, snigdha | Kaphavata shamak vedanashamak Medhya, yogavahi, shoolaghna | Piperine and piper – longumine shows antifungal, antiamoebic, antimicrobial, anti-asthmatic, antidiabetic, |
| Karkatshringi | <i>Pistacia integerrima</i> | Kashaya, tikta | Ushna | Katu. | Laghu, ruksha | Kaphanissarankasa, shwasa | Pistagremic acid analgesic and anti- |
| Vasa | <i>Adhatoda vasica</i> | Tikta, kashaya | Shit | Katu. | Ruksha, laghu | Kaphapitta shamaka, Kasa, Shwasa | Vasicine/peganine adhatodine, anisotine vasicoline and vasicolinone anti-microbial, anti- |

Scoring was done on the following predefined scale (20-26)

Subjective parameter

Nasastrava (rhinorrhoea)

- Grade 0 No discharge
- Grade 1 Rhinorrhoea with occasional running nose with or without visible fluid
- Grade 2 Continuous rhinorrhoea with copius fluid needs moping but controllable
- Grade 3 Severe rhinorrhoea with copius fluid needs continuously moping but is uncontrollable

Kshavathu (sneezing)

- Grade 0 No sneezing
- Grade 1 Sneezing after expose to allergen
- Grade 2 Sneezing in the morning
- Grade 3 Always sneezing

Nasavarodh (nasal congestion)

- Grade 0 No congestion
- Grade 1 Occasionally congestion throughout the day.
- Grade 2 Frequent congestion throughout the day
- Grade 3 Congestion associated with mouth breathing during sleep

Objective parameter

Recurrence of *pratishyaya* (~recurrent rhinitis) per month

- Grade 0 No recurrence
- Grade 1 Recurrence 1/month
- Grade 2 Recurrence 2/month
- Grade 3 Recurrence >2/month

Duration of *pratishyaya* (~recurrent rhinitis) per episode

- Grade 0 Nil
- Grade 1 1 to 3 days
- Grade 2 4 to 7 days
- Grade 3 >7 days

The Wilcoxon Signed Rank Test and the Paired t test were used for the statistical analysis of the obtained data. P value of < 0.05 was considered as statistically significant. The level of significance was noted and interpreted accordingly. Overall assessment of the study was done by calculating the mean of parameters. An assessment scale was framed to assess the rate of improvement. At the end of treatment, the percentage of relief in both subjective and objective was calculated and classified in given table.

Assessment of result

- Excellent 76-100% clinical relief
- Good 51-75% clinical relief
- Fair 26-50% clinical relief
- Poor Below 25% clinical relief

Observations and Results

A total of 60 subjects were registered for the study of which 30 subjects in Group A and 30 in Group B. The maximum number of children in Group A and Group B were 29 (96.67%) and 27(90%) aged between 5-10 years rest among them were from 11 to 16 age group. Among 60 subjects, 47 Hindu and 13 Buddhist were enrolled of which 39 were from the middle class and 21 from lower class families. 45 children each had average, poor, and good personal hygiene respectively. Maximum numbers of children were given a history of a gradual mode of onset and intermittent time of occurrence. Kapha vata dosha was found dominant.

Overall assessment of the results

The intensity of the symptoms determined the numerical grading. The results of the comparison of subjective and objective criteria before and after therapy are shown in tables 3 through 5.

Effect of vachadi avaleha

In group A, 30 patients of *Pratishyaya* (~Recurrent Rhinitis) completed the full course of treatment and so the effect of group A therapy is quoted from here onwards.

Statistical Analysis

All the values in the following tables are calculated by using the Wilcoxon sign rank test and Paired t-test for subjective and objective criteria respectively. Statistical analysis of every symptom is described separately in the following tables.

Table 3

| Associated complains | Mean BT | Mean AT | S.D (±), B.T. | S.D (±), A.T. | S.E. (±), B.T. | S.E. (±), A.T. | Wilcoxon sign rank test and Paired t-test | Result |
|---------------------------------------|---------|---------|---------------|---------------|----------------|----------------|---|-------------|
| <i>Nasastrava</i> (Rhinorrhoea) | 2.1 | 0.5 | 0.712 | 0.629 | 0.13 | 0.115 | W-406, Z- 4.622, P- P<0.05 | Significant |
| <i>Kshavathu</i> (Sneezing) | 1.7 | 0.6 | 0.651 | 0.498 | 0.118 | 0.09 | W-351, Z- 4.45, P- P<0.05 | Significant |
| <i>Nasavarodha</i> (Nasal Congestion) | 2.033 | 0.5 | 0.614 | 0.508 | 0.112 | 0.092 | W-435, Z- 4.7, P- P<0.05 | Significant |
| Objective criteria | | | | | | | | |
| | Mean BT | Mean AT | S.D | | S.E. | | Wilcoxon sign rank test and Paired t-test | Result |
| Recurrence of rhinitis | 1.633 | 0.467 | 0.379 | | 0.069 | | T-16.85 P- P<0.05 | Significant |
| Duration of <i>Pratishyaya</i> | 3.933 | 1.3 | 1.098 | | 0.2 | | T-13.13 P- P<0.05 | Significant |

Effect of *Mustakadi Avaleha*

In group B, 30 patients of *Pratishyaya* (~Recurrent Rhinitis) completed the full course of treatment and so the effect of group B therapy is quoted from here onwards.

Table no 4

| Associated complains | Mean BT | Mean AT | S.D (±), B.T. | S.D (±), A.T. | S.E. (±), B.T. | S.E. (±), A.T. | Wilcoxon sign rank test and | Result |
|---------------------------------------|---------|---------|---------------|---------------|----------------|----------------|---------------------------------|-------------|
| <i>Nasastrava</i> (Rhinorrhoea) | 1.867 | 0.633 | 0.628 | 0.614 | 0.114 | 0.112 | W-378, Z- 4.54, P- P<0.05 | Significant |
| <i>Kshavathu</i> (Sneezing) | 1.467 | 0.333 | 0.628 | 0.479 | 0.114 | 0.087 | W-378 Z- 4.54 P- P<0.05 | Significant |
| <i>Nasavarodha</i> (Nasal Congestion) | 2.1 | 0.767 | 0.803 | 0.504 | 0.146 | 0.092 | W-351 Z- 4.45 P- P<0.05 | Significant |
| Objective criteria | | | | | | | | |
| | Mean BT | Mean AT | S.D | | S.E. | | Wilcoxon sign rank test and | Result |
| Recurrence of rhinitis | 1.767 | 0.733 | 0.668 | | 0.122 | | T-8.46 P- P<0.05 | Significant |
| Duration of <i>Pratishyaya</i> | 3.7 | 0.5 | 0.99 | | 0.181 | | T-17.58 P- P<0.05 | Significant |

Table 5: Overall efficacy of *Vachadi Avaleha* over *Mustakadi Avaleha*

| Parameter | Control Group | Trial Group | Comparative efficacy |
|---------------------------------------|---------------|-------------|--|
| <i>Nasastrava</i> (Rhinorrhoea) | Significant | Significant | The effect of <i>Vachadi Avaleha</i> was not significant as <i>Mustakadi Avaleha</i> |
| <i>Kshavathu</i> (Sneezing) | Significant | Significant | |
| <i>Nasavarodha</i> (Nasal Congestion) | Significant | Significant | |
| Recurrence of Rhinitis | Significant | Significant | |
| Duration of <i>Pratishyaya</i> | Significant | Significant | |

Discussion

The drug chosen for this study was *vachadi avaleha*, which is prepared from *vachadi kashaya*. It is mentioned in the *harita samhita*. The drug was transformed into *avaleha* preparation for palatability reasons. *Vachadi avaleha* consists of *vacha*, *triphala*, *shunthi* and *yavani*. *Vacha* heals *pratishyaya* (~recurrent rhinitis) by *katu tikta rasa*, *ushna virya*, and *tikshna guna*, which are *vataghna* and *kaphaghna* characteristics (27). As mentioned earlier *vacha* is having antipyretic (28) as well as immunomodulatory effect(29) which helps to reduce the recurrence of rhinitis. *Yavani's* *katu tikta rasa*, *ushna virya*, and *laghu ruksha tikshan guna* affect the *kapha* and *vata doshas* also it has antimicrobial, analgesic, anti-inflammatory, antipyretic activities which was proved in different clinical and experimental studies(30). According to the ayurvedic formulary of india, combination of three fruits made up of equal amounts (1:1:1) of dried *emblica officinalis gaertn* (euphorbiaceae), *terminalia bellerica linn* (combretaceae) and *terminalia chebula* (combretaceae) fruits is known as *triphala*.(31) It is having antiviral and antibacterial effects. (32) It is having proven immunomodulatory effect.(33) *Amalaki's* *rasa virya vipaka* makes it *tridoshghna*(34).It has proven action on recurrent respiratory tract infection(35). *Bibhitaka* has anticough and mucolytic action (36).The main *doshas* that cause *pratishyaya* (~recurrent rhinitis) are *kapha* and *vata*, which are both affected by *bibhitaka majja*. *Haritaki* also act as *tridoshghna* (37) due to its *rasa virya vipaka*. *Haritaki* is indicated in *kashyap samhita* for *pratishyaya* (~recurrent rhinitis) (38). Due to its *madhura snigdha* and *ushna* qualities, *shunthi* has *kapha* and *vata shaman* powers; it possesses *amapachana* properties as well. It behaves like a

jwaraghna (fever suppressing) because of its *amapachana* activity(39). *Shunthi* is recommended for *pratishyaya* (~recurrent rhinitis) in the *kashyapa samhita*. According to recent researches it has antipyretic, analgesic, antibacterial and immunomodulatory effect (40).

The major constituent in *Mustakadi avaleha* is *vata kapha shamak* which are potent *dosha* in *pratishyaya* (~recurrent rhinitis). *Ativisha* is specially indicated for the treatment of childhood disorders (41). As well as *pippali* and *vasa* are proven *rejuvenating* drugs for the respiratory system (42-43). *Musta* is useful in acute conditions as it reduces nasal secretions (44). Constituents in *mustakadi avaleha* and *balchaturbhadra churna* which is a popular ayurvedic formulation for children are same. *Balchaturbhadra churna* is specially indicated for respiratory disorders in children (45) and *vasa* which has antitussive, antibacterial, antiviral, immunomodulatory action (46-47) are present in *mustakadi avaleha*. The present study was conducted among 30 patients for each trial and control group. All patients were assessed based on scores given to them before and after treatment. *Vachadi avaleha* was given to 30 patients for 90 days. *Mustakadi avaleha* was given to 30 patients for 90 days in the control group. Significant relief was observed in the symptoms of *pratishyaya* (~recurrent rhinitis) like *nasastrava* (rhinorrhoea), *kshavathu* (sneezing), *nasavarodh* (nasal congestion), recurrence of rhinitis per month, duration of *pratishyaya* (~recurrent rhinitis). The difference between the scores before treatment and after treatment was calculated for both groups separately. The differences thus obtained were compared using the wilcoxon signed ranked test and the paired t-test. From statistical analysis, both *vachadi avaleha* and *mustakadi avaleha* were found

effective in *pratishtyaya* (~recurrent rhinitis). In comparative analysis of both drugs, it is observed that *mustakadi avaleha* is found more efficacious than *vachadi avaleha*. Because the *Balchaturbhadra churna's* ingredient has immunostimulant, anti-inflammatory, antibacterial, antioxidant and analgesic properties which are also present in *mustakadi avaleha*. *Pippali* and *vasa* in *mustakadi avaleha* have a rejuvenating (*rasayana*) effect on the respiratory system, which prevents recurrence of rhinitis and exhibits superior efficacy than *vachadi avaleha*.

Conclusion

The effect of the *Vachadi Avaleha* (Group A) and *Mustakadi avaleha* (Group B) on symptoms observed in *Pratishtyaya* (~Recurrent Rhinitis) was statistically proven to be significant on subjective and objective criteria individually. *Mustakadi avaleha* has produced outcomes that are incredibly substantial across both subjective and objective measures. With regard to subjective criteria like *Nasastrava*(Rhinoorrhoea), *Kshavathu* (Sneezing), *Nasavarodha* (Nasal Congestion), the overall effect was statistically significant. The effect of *Vachadi Avaleha* (Group A) was not significant as that of *Mustakadi Avaleha* (Group B) for subjective criteria. The effect of *Vachadi Avaleha*(Group A) was not significant as that of *Mustakadi Avaleha* (Group B) for objective criteria such as Recurrence of Rhinitis, Duration of *Pratishtyaya* (~Recurrent Rhinitis). Due to lack of hygiene and health awareness, *Pratishtyaya* (~Recurrent Rhinitis) was more prevalent in lower-class and poorer families (26). Maximum figures of kids exhibited *Kapha vata* dominance. Regardless of *dosha* dominance, the medication *mustakadi avleha* is beneficial in treating all forms of *Pratishtyaya* (~Recurrent Rhinitis). When compared to Group A, the outcome was just slightly better in Group B. The current investigation demonstrated the *Mustakadi avaleha's* efficacy as a secure and reliable preparation to treat *Pratishtyaya* (~Recurrent Rhinitis) without any documented adverse effects.

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