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Efficacy of *Vyaghriharitaki Avaleha* in the management of *Vataja Kasa* w.s.r. to Pulmonary Eosinophilia - An Open Label Randomized Controlled Clinical Trial

Manjushri P[1], Gopalakrishna G.[2]

[1]*Post Graduate Scholar, Department of PG Studies in Kayachikitsa, Sri Sri College of Ayurvedic Science and Research, Bengaluru, Karnataka, India.*

[2]*Professor and HOD, Department of PG Studies in Kayachikitsa, Sri Sri College of Ayurvedic Science and Research, Bengaluru, Karnataka, India.*

ABSTRACT

Background: *Vataja Kasa* (cough caused by *Vata Dosha*) occurs due to *Pranavaha Srotodushti* (causes of deformity in channels of respiratory system) characterized by dry paroxysmal cough that resembles Pulmonary eosinophilia (PE) with an elevated Absolute eosinophilic count (AEC) and eosinophilic lung infiltration. *Vyaghriharitaki Avaleha* is mentioned in *Ayurveda* classics under the context of *Kasa* (cough). The current study was carried out to assess its efficacy based on literary indications and the need for more potent medications to treat *Vataja Kasa.* **Aim:** Evaluation of the efficacy of *Vyaghriharitaki Avaleha* in the management of *Vataja Kasa.* **Materials and Methods:** A randomized, open label, parallel group, active controlled pre and post test clinical study was conducted comprising of 30 subjects. They were randomly allocated into 2 groups, subjects of Group A received *Vyaghriharitaki Avaleha* 5g BD and subjects of Group B received *Vidangadi Churna* 5g BD for 30 days. AEC and Signs & symptoms of *Vataja Kasa* were assessed before (0th day) and after treatment (30th day), after follow up (45th day). The data obtained were recorded, tabulated and statistically analyzed using Unpaired t test, Paired t Test, Mann Whitney U Test, Wilcoxon Signed rank test. **Results:** Analysis of the data within groups showed statistically highly significant ($p<0.01$) results and between the groups analysis showed statistically non-significant ($p>0.05$) results in reducing AEC and signs & symptoms of *Vataja Kasa* suggesting almost similar action of both drugs. **Conclusion:** It can be inferred that *Vyaghriharitaki Avaleha* is as efficient as *Vidangadi Churna* in the management of *Vataja Kasa*.

Key words: *Vataja Kasa; Vyaghriharitaki Avaleha; Pulmonary Eosinophilia; AEC*

INTRODUCTION

Pulmonary Eosinophilia is characterized by Pulmonary infiltration with a predominant eosinophilic exudate, an allergic and inflammatory hyper-response, accompanied by a significant rise in the peripheral eosinophilic count. Dry Paroxysmal cough, chest pain, malaise commonly seen in PE cases.[1] Elevated levels of AEC is a pre-requisite for determining Pulmonary eosinophilia. *Kasa* (cough) is a *Pranavaha Sroto* (channels of respiratory system) disease affecting *Prana* & *Udana Vayu* (types of *Vata Dosha*). *Vataja Kasa* (cough caused by *Vata Dosha*) a type of *Kasa* mainly characterized by *Shushka Kasa* (Dry cough), *Prasakta Kasa Vega* (Paroxysmal Cough) and *Hrit Shula* (chest pain), *Shira Shula* (Headache), *Swarabheda* (Hoarseness of voice).[2] *Acharyas* mentioned the causes of *Kasa* as *Dhumopaghata* (inhalation of smoke) and *Raja Sevana*[3] (inhalation of dust) which holds good even today. Due to industrialization and urbanization there is an increased environmental pollution which is a major cause for respiratory disorders. As per recent data, in 2019, chronic respiratory diseases were the third leading cause of death responsible for 4.0 million deaths with a prevalence of 454.6 million cases globally.[4]

Address for correspondence:
Dr. Manjushri P
Post Graduate Scholar Department of PG Studies in Kayachikitsa, Sri Sri College of Ayurvedic Science and Research, Bengaluru, Karnataka, India.
E-mail: manjushri.ayu@gmail.com

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Many medications like NSAID, systemic antibiotics, most specifically nitrofurantoin and various, diverse environmental exposures such as particulate metals, scorpion stings, and inhalational drugs of abuse cause pulmonary eosinophilia.[5] ICD -10-CM J82 is the specific code indicates the diagnosis of PE.[6]

In the contemporary science the acute treatment for PE includes Corticosteroids, Diethylcarbamazine (DEC) and Bronchodilators.[5] Side effects of these medications include headache, joint pain, anorexia, nausea, and vomiting. Despite of this, relapse occurs in many individuals. So, there is a limitation to the administration of these medications. In absence of successful treatment, this can lead to progressive pulmonary damage. Though *Kasa* appears to be simple disease, it may end up in poor prognostic condition if not managed properly. Thus, there is a demand for better management of PE through *Ayurveda*. Study was taken up to evaluate and compare efficacy of *Vyaghriharitaki Avaleha* with proven drug *Vidangadi Churna.*

Aim and Objectives

Aim: Evaluation of the efficacy of *Vyaghriharitaki Avaleha* in the management of *Vataja Kasa*

Objective: To evaluate and compare the efficacy of *Vyaghriharitaki Avaleha* and *Vidangadi Churna* in the management of *Vataja Kasa* on the basis of improvement in signs and symptoms of *Vataja Kasa* and AEC grade.

Materials and Methods

Study design

A randomized, open labelled, parallel group, active controlled pre and post-test clinical study.

Study Setting & Ethics

The Study has been carried out at Sri Sri College of Ayurvedic Science and Research hospital, Bengaluru. The participants were recruited from May 2022 to November 2022. Ethical clearance was obtained from the SSIEC, Bengaluru with SSIEC protocol number: SSIEC/183/2021. The trial was registered prospectively in CTRI on 22/06/2022 with CTRI number CTRI/2022/06/043421.

Drug source, collection, preparation

Trial drug *Vyaghriharitaki Avaleha* was manufactured by GMP certified Kumar Ayurveda Ashrama, Bengaluru with Batch No. 136 was obtained for the study. Control drug *Vidangadi Churna* ingredients were procured from Amrith Kesari Depot, Bengaluru, authenticated by the Dept of *Dravyaguna* and fine powder manufactured in Dept. of RSBK of the institution. Treatment protocol used in study is shown in Table 1.

Table 1: Showing Intervention of Trial and Control group

Features	Trial Group A	Control Group B
Sample size	15	15
Intervention	*Vyaghriharitaki Avaleha*[7]	*Vidangadi Churna*[8]
Anupana	Hot water	Hot water
Dosage	5g BID	5g BID
Time of Administration	One Hour Before Food	After Food
Trial period	30days	30days
Follow up	15 days	15 days
Total duration	45 days	45 days

Study Participants

The total of thirty subjects, fulfilling the selection criteria who gave written informed consent were enrolled for the present study, from Outpatient & In-patient department of the institution. Participants were allocated to Group A and B using lottery method in ratio of 1:1. All the subjects involved in the study were ensured that they have taken medicine in prescribed dosage and follow-up was ensured through telephonic contacts.

Inclusion criteria

Subjects aged between 21 to 60 years having dry cough with three or more classical signs & symptoms of *Vataja Kasa.*

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AEC from 500 cells/cu mm to 2500 cells/cu mm and willing to participate with written informed consent were included for the clinical trial.

Exclusion criteria

Subjects who were diagnosed with other Respiratory diseases like Pulmonary Tuberculosis, Bronchial Asthma, Pneumonia, Pleurisy, CA Bronchus, Emphysema and Covid-19 cases. Subjects with uncontrolled Diabetes Mellitus Type I & II and Hypertension. Pregnant and Lactating women were excluded.

Outcomes

Primary outcome measure was reduction in AEC count assessed on baseline, after treatment (30^{th} day) and after follow-up on 45^{th} day. Secondary outcome was reduction in signs and symptoms of *Vataja Kasa* which were assessed on 0^{th} day, 15^{th} day, 30^{th} day, and 45^{th} day based on gradings from 0-4.

Sample Size

The sample size was calculated based on standard deviation of previous study with 95% confidence interval, and 80% power using formula 2 $(SD)^2$ X $(Zb^2+Z1a^2)/d^2$-. It was estimated to be 38 samples in each group, total of 76. Since, the study duration was of short period, the Study sample was limited to 30 subjects.

Statistical methods

Statistical analysis of recorded data was done using IBM SPSS windows version 26 and Sigma stat version 3.1. For the assessment of primary outcome AEC Paired t-test, Repeated measures ANOVA test for within the group and Unpaired t-test for between the groups were applied. For the assessment of secondary outcomes signs & symptoms of *Vataja Kasa* Wilcoxon signed rank test (W), Friedman's test (Fr) for within the group and Mann Whitney U test (U) for between the groups were applied. The confidence level was set at 95%, the corresponding P value was noted, and obtained results were interpreted as nonsignificant ($P > 0.05$), significant ($P < 0.05$), and highly significant ($P < 0.01$).

To ascertain whether the statistical analysis correlates with clinical improvement, Effect size determination was carried out for all the subjective, objective parameters and interpreted as

Nil-0, Very Small<0.1, Small- 0.1 to <0.3, Medium- 0.3 to 0.5, Large >0.5 to 0.8,

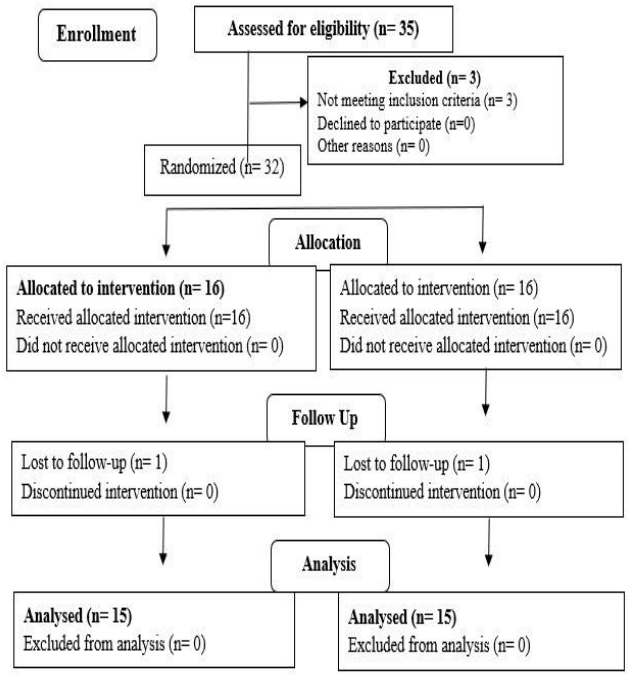
Very Large >0.8 for between the groups.

Nil-0, Small- 0.1, Medium- 0.3, Large- 0.5 for within the groups.

Observations and Results

Out of 32 subjects, there were 2 dropouts (1 from each group), both lost to follow-up. Hence the study was completed over 30 subjects (Figure 1).

Figure 1: STUDY FLOW CHART



Demographic profile of study participants:

It was observed that majority of subjects were from the age group of 51-60 years (40%), Female gender (60%), having occupation of housewife (33.3%). 56.6% participants were from *Sadharana Desha* following vegetarian diet, 70% of the subjects were addicted to Tea, 50% to Coffee, 76.6% subjects were accustomed to moderately active lifestyle. 90% of subjects did not have family history, 86.6% had intake of dry food articles, 83.3% had inhalation of dust, 73.3% inhalation

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of smoke as etiological factors. (Table 2, Table 3, Figure 2)

Table 2: Demographic data of patients

Parameters	Group A	Group B
Age group (in years)		
21-30	2 (13.3%)	1 (6.6%)
31-40	6 (40%)	4 (26.6%)
41-50	1 (6.6%)	4 (26.6%)
51-60	6 (40%)	6 (40%)
Gender		
Male	6 (40%)	6 (40%)
Female	9 (60%)	9 (60%)
Marital status		
Married	12 (80%)	14 (93.3%)
Unmarried	3 (20%)	1 (6.6%)
Occupation		
Housewife	3 (20%)	7 (46.6%)
Self-employed	4 (26.6%)	2 (13.3%)
Employed for salary	3 (20%)	3 (20%)
Student	2 (13.3%)	1 (6.6%)
Retired	3 (20%)	2 (13.3%)
Educational qualification		
Primary education	1 (6.6%)	2 (13.3%)
Secondary education	3 (20%)	0 (0%)
Higher secondary education	2 (13.3%)	1 (6.6%)
Graduate	7 (46.6%)	10 (66.6%)
Postgraduate	2 (13.3%)	1 (6.6%)
Illiterate	0 (0%)	1 (6.6%)
Socio-economic status		
Upper middle class	5 (33.3%)	6 (40%)
Middle class	9 (60%)	6 (40%)
Lower middle class	0 (0%)	0 (0%)
Upper class	1 (6.6%)	3 (20%)
Lifestyle		
Sedentary	0 (0%)	5 (33.3%)
Moderately active	13 (86.6%)	10 (66.6%)
Highly active	3 (20%)	0 (0%)
Diet		
Vegetarian	9 (60%)	8 (53.3%)
Mixed	6 (40%)	7 (46.6%)
Habits and addiction		
Tea	10 (66.6%)	11 (73.3%)
Coffee	8 (53.3%)	7 (46.6%)
Cold drinks	1 (6.6%)	1 (6.6%)
Smoking	0 (0%)	0 (0%)
Alcohol	0 (0%)	1 (6.6%)
Tobacco	1 (6.6%)	0 (0%)
Prakruti		
Vata-Pittala	5 (33.3%)	9 (60%)
Pitta-Shleshmala	5 (33.3%)	4 (26.6%)
Shleshma-Pittala	0 (0%)	2 (13.3%)
Vata-Shleshmala	5 (33.3%)	0 (0%)

Table 3: Incidence of Etiological factors

Etiological factors	Group A	Group B
Ruksha	15 (100%)	12 (80%)
Alpa	7 (46.6%)	12 (80%)
Sheeta	12 (80%)	9 (60%)
Pramita	3 (20%)	7 (46.6%)
Kashaya	1 (6.6%)	0 (0%)
Anashana	2 (13.3%)	5 (33.3%)
Dhumopaghata	11 (73.3%)	11 (73.3%)
Bhojana Vimargagatva	2 (13.3%)	2 (13.3%)
Rajah Sevana	13 (86.6%)	13 (86.6%)
Kshavathu Vegadharana	2 (13.3%)	1 (6.6%)

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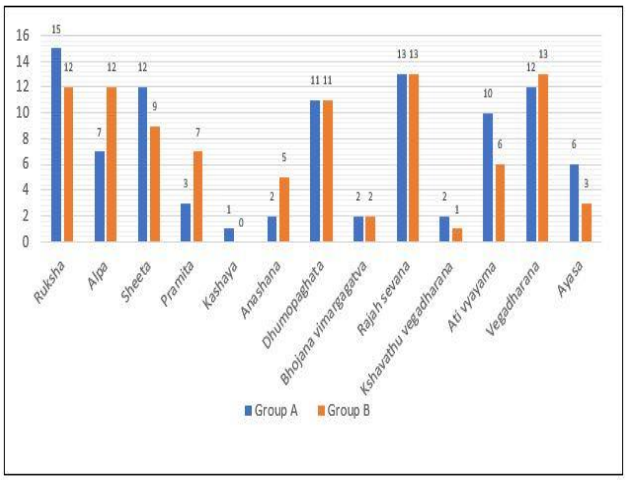
Ati Vyayama	10 (66.6%)	6 (40%)

Figure 2: Incidence of causative factors



Effect of therapy on outcomes within the Group

Primary outcome

Trial drug and Control drug showed statistically highly significant ($p<0.01$) results in reducing AEC after intervention. In Trial Group, AEC mean reduced from baseline 631.4±114.9 to 512.2±77.4 on 30th day of treatment whereas in Control Group AEC mean reduced from baseline 611.6±101.55 to 483.06±96.85 (30th day) [Table 4].

Trial drug showed statistically significant($p<0.01$) results and control drug showed non-significant ($p>0.05$) results after drug free follow-up (45th day).

Effect size calculation shows that there was medium effect band and Large effect band after intervention within trial group & control group respectively, whereas small effect band after drug free follow up in both groups. [Table 4]

Table 4: Effect of therapy on outcomes (within group)

Parameters	Group	Baseline (mean ± SD)	30th day (mean ± SD)	p Value	Effect size
AEC	A	631.4±114.9	512.2±77.4	0.001	0.4
	B	611.6±101.55	483.06±96.85	0.000	0.5
Dry cough	A	3.0±0.0	1.26±0.45	0.000	0.3
	B	2.93±0.25	1.00±0.53	0.000	0.3
Paroxysmal cough	A	2.66±0.49	0.58±0.513	0.002	1.4
	B	2.58±0.51	0.58±0.514	0.002	0.4
Chest pain	A	2.33±1.22	1.00±0.50	0.023	1.5
	B	2.28±0.48	0.57±0.53	0.014	2.2
Headache	A	2.42±0.53	1.00±0.00	0.015	0.4
	B	2.00±0.63	0.54±0.52	0.004	0.3
Flanks pain	A	2.41±0.51	0.75±0.45	0.002	0.3
	B	2.72±0.46	0.63±0.67	0.003	0.4
Hoarseness of voice	A	2.08±0.51	0.16±0.38	0.001	0.2
	B	1.85±0.53	0.35±0.49	0.001	0.3
Dryness of mouth	A	2.00±3.00	1.00±1.00	0.023	0.6
	B	1.20±0.44	0.40±0.54	0.046	1.0

Values expressed as mean ± Standard deviation

*analyzed with Paired t test & Wilcoxon signed rank test

Secondary Outcome

Statistically highly significant ($p<0.01$) results were observed in reduction of signs & symptoms of *Vataja Kasa* after intervention except symptom Dryness of mouth which showed statistically significant ($p<0.01$) result on 30th day. Trial drug showed statistically significant ($p<0.01$) results for all symptoms except Chest pain, Hoarseness of voice and control drug showed non- significant ($p>0.05$) results on 45th day.

In main symptom Dry cough out of 15 participants having Grade 3, 11 got relief (73.3%) and severity reduced to Grade 1 after intervention in both the groups. Paroxysmal cough reduced from Grade 3 to Grade 0 in 8 participants (53.3%). [Table 5]

Effect of therapy on outcomes between the Group

AEC, signs & symptoms of *Vataja Kasa* showed statistically non-significant ($p>0.05$) results on 30th and 45th day of intervention. However, few signs & symptoms like Headache, Dryness of mouth showed significant ($p<0.05$) result on 30th day, Hoarseness of

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voice showed significant ($p<0.05$) result on 45th day. [Table 5]

Table 5: Effect of Treatment on Parameters

Parameters	Group A				Group B			
	Baseline		30th day		Baseline		30th day	
	N	%	N	%	N	%	N	%
AEC								
Grade 0	0	0	5	33.3	0	5	8	53.3
Grade 1	15	100	10	66.6	100	10	7	46.6
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Dry Cough								
Grade 0	0	0	0	0	0	0	2	13.3
Grade 1	0	0	11	73.3	0	0	11	73.3
Grade 2	0	0	4	26.6	0	0	2	13.3
Grade 3	15	100	0	0	15	100	0	0
Paroxysmal cough								
Grade 0	0	0	8	53.3	3	20	8	53.3
Grade 1	0	0	7	46.6	0	0	7	46.6
Grade 2	4	26.6	0	0	5	33.3	0	0
Grade 3	8	53.3	0	0	7	46.6	0	0
Chest pain								
Grade 0	9	60	9	60	8	53.3	11	73.3
Grade 1	0	0	6	40	0	0	4	26.6
Grade 2	4	26.6	0	0	5	33.3	0	0
Grade 3	2	13.3	0	0	2	13.3	0	0
Headache								
Grade 0	8	53.3	8	53.3	4	26.6	9	60
Grade 1	0	0	7	46.6	2	13.3	6	40
Grade 2	4	26.6	0	0	7	46.6	0	0
Grade 3	3	20	0	0	2	13.3	0	0
Flanks pain								
Grade 0	3	20	6	40	4	26.6	9	60
Grade 1	0	0	9	60	0	0	5	33.3
Grade 2	7	46.6	0	0	3	20	1	6.66
Grade 3	5	33.3	0	0	8	53.3	0	0
Hoarseness of voice								
Grade 0	3	20	13	86.6	1	6.66	10	66.6
Grade 1	1	6.66	2	13.3	3	20	5	33.3
Grade 2	9	60	0	0	10	66.6	0	0
Grade 3	2	13.3	0	0	1	6.66	0	0
Dryness of mouth								
Grade 0	7	46.6	15	100	10	66.6	13	86.6
Grade 1	1	6.66	0	0	4	26.6	2	13.3
Grade 2	7	46.6	0	0	1	6.66	0	0
Grade 3	0	0	0	0	0	0	0	0

The effect size calculation shows that there was medium effect band after intervention and small effect band after drug free follow up in both the groups. [Table 6]

Table 6: Effect of therapy on outcomes (between groups)

Parameters	p Value (30th day)	p Value (45th day)	Effect size (30th day, 45th day)
AEC	0.371	0.754	1.07, 0.11
Dry cough	0.163	0.732	0.25, 0.06
Paroxysmal cough	1.000	0.140	0, 0.26
Chest pain	0.079	0.805	0.32, 0.04
Headache	0.041	0.638	0.37, 0.08
Flanks pain	0.518	0.314	0.1, 0.18
Hoarseness of voice	0.284	0.011	0.2,0.46

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Dryness of mouth	0.034	0.077	0.38,0.32

*Analyzed using unpaired t test & Mann-Whitney U test

DISCUSSION

Pulmonary Eosinophilia is diagnosed by raised AEC characterized by dry paroxysmal cough which is understood as *Vataja Kasa*. In this disease, *Vata Pradhana Tridosha* vitiation is mainly involved. Thus, drugs possessing *Tridoshahara* (pacifying three regulatory functional factors of body) property would promote *Samprapti Vighatana* (breaking pathogenesis). *Vyaghriharitaki Avaleha* consists of *Kantakari* (*Solanum xanthocarpum* Sch. & Wendl.), *Haritaki* (*Terminalia chebula* Retz.), *Shunti* (*Zingiber Officinale* Roscoe), *Maricha* (*Piper nigrum* Linn.), *Pippali* (*Piper longum* Linn.), *Tvak* (*Cinnamomum zeylanica* Blume), *Patra* (*Cinnamomum tamala (Buch.-Ham.) Nees & Eberm.*), *Ela* (*Elettaria cardamomum* (Linn.) Maton), *Nagakeshara* (*Mesua ferrea* Linn.) as ingredients.

Kantakari is *Kaphavatahara* (pacifying *Kapha* & *Vata Dosha)* does the *Srotoshodana* (clears minute channels), *Vatanulomana* (regularizing physiologic movement of *Vata Dosha*) might have helped in removing Sroto *Sanga Vimargagamana* (obstruction in channels, deviation from normal movement of *Doshas)* and is having Anti-inflammatory, Anti-allergic, Anthelmintic, Immunomodulatory activity[9] might have helped in reducing AEC. *Haritaki* is *Tridoshahara, Vatanulomana* and is having anti-microbial, anthelminthic property.[10] *Shunti, Maricha, Pippali* are having *Vatakaphahara, Deepana* (carminative), *Vatanulomana, Amadoshahara* (pacifying the state of incomplete transformation of food or *Doshas*) action and is having anti-inflammatory, anti-tussive property.[11,14] *Tvak, Patra* are having *Kaphavatahara*, *Kandughna* (anti-pruritic), *Kantashuddhikara* (reduces throat irritation) and is having anti-microbial property.[15,16] *Ela Tridoshahara, Kantashuddhikara* and anti-inflammatory, anti-tussive property.[17,14] *Nagakeshara* is *Kaphapittahara,* carminative and anti-inflammatory properties.[18] These all above properties of drugs might have helped in reducing Absolute Eosinophilic Count.

Majority of drugs having *Kasahara* (anti-tussive), *Vatanulomana, Krimigna* (anti-microbial) property, *Tikshna Guna* (quick acting), *and Katu Rasa* (pungent taste), *Ushna Virya* (hot in potency), *Madhura*(sweet) *Vipaka* (end stage of digestion) which might have helped to pacify vitiated *Vata, Kapha* and removes *Sanga(obstruction), Vimargagamana* (diversion to the flow of contents to improper channels) promotes *Vatanulomana.* Thus, helps in *Samprapti Vighatana. Vidangadi Churna* contains *Vidanga (Embelia ribes), Pippali, Nagara (Zingiber Officinale Roscoe), Rasna (Pluchea lanceolata), Hingu (Freula narthax), Saindhava (Rock salt), Bharangi (Clerodendrum serratum), Yava Kshara (Elettaria cardamomum (Linn.) Maton)* as ingredients. It is having *Katu, Tikta Rasa* (bitter taste), *Ushna Virya, Laghu* (light), *Snigdha Guna* (unctuousness), *Katu Vipaka* and *Kaphavatahara* property. It is also proven to possess all the aspects of Pharmaco-therapeutic effect like anti-inflammatory, anthelminthic, anti-allergic, anti-tussive, anti-histaminic properties.[19] *Vyaghriharitaki Avaleha* and *Vidangadi Churna* exhibited statistically significant improvement in reducing primary and secondary outcomes after intervention. Clinically *Vidangadi Churna* was productive after intervention and *Vyaghriharitaki Avaleha* was more efficacious after drug free follow up. *Kantashuddhikara* property of *Tvak, Patra, Ela* of *Vyaghriharitaki Avaleha* might have helped in reducing Hoarseness of voice and its *Rasayana* (rejuvenative) effect[20] might be contributing to its effectiveness after drug free followup. Diet regimen and lifestyle modification were also advised to follow during the trial period which might have helped in reducing Signs and symptoms.

According to studies, elderly age group is more susceptible to get respiratory illness due to declined immune responses with advancing age.[21] Similar observations were made in the study (51-60 years age group with 40%). Maximum participants had causative factors in relation to food habits as intake of food in less quantity, intake of dry & cold food articles, which

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causes aggravation of *Vata Dosha*[22] and in external causative factors inhalation of dust and smoke which results in *Pranavaha Srotodushti*[23] and leads to onset of *Vataja Kasa.* In majority of subjects the onset of symptoms was seasonal in nature and was aggravated during winter, rainy season and cold weather. The study's limitation is that a large sample size needs to be used in order to extrapolate the treatment adopted. Future research on this topic could potentially be conducted using the IgE parameter in addition to AEC.

CONCLUSION

According to the outcomes of the present research, *Vyaghriharitaki Avaleha* and *Vidangadi Churna* were statistically efficient in reducing AEC and the signs and symptoms of *Vataja Kasa.* Clinically, *Vyaghriharitaki Avaleha* was more efficient after drug-free follow-up, though *Vidangadi Churna* was more productive following intervention. However, to determine which medication is superior, research with a larger sample size can be carried out. The anti-inflammatory, immunomodulatory, anti-allergic, anti-tussive, and anthelminthic properties of the drugs in these formulations enabled therapy to be effective.

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