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Research Article

A COMPARATIVE CLINICAL STUDY ON THE EFFICACY OF *VISHWADI LEHA* AND *BHARANGYDI LEHA* IN THE MANAGEMENT OF *VATAJA KASA* W.S.R TROPICAL PULMONARY EOSINOPHILIA

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ABSTRACT

Vataja Kasa (presented by *Shushka Kasa, Prasakta Vega, Shirah Shoola, Hrit Shoola, Parshwa Shoola, Swara Bheda* and *Kshamanana*) has an increasing prevalence overtime due to the external influences such as industrialization, urbanization, environmental pollution and population explosion. Since it's a demanding health concern, *Vataja Kasa* was taken up for the present clinical study and was approximately co-related to Tropical Pulmonary Eosinophilia (TPE) which is an immune hyper-responsiveness to microfilariae trapped in the lungs, characterised by paroxysmal nocturnal cough, breathlessness, wheezing, chest pain, scanty sputum production and eosinophilia. The study was conducted with the prime aim of assessing the efficacy of the trial drugs *Vishwadi Leha* and *Bharangyadi Leha* in the management of *Vataja kasa* – TPE. The Clinical trial included 40 patients of *Vataja Kasa* categorized into two groups (20 in each). In Group A-*Vishwadi Leha* (3 gms) and in Group B- *Bharangyadi Leha* (3 gms) were administered thrice daily along with quantity sufficient warm water after food for 30 days. The findings were recorded, assessed and graded accordingly on the 14th and 30th day. The results were analysed statistically for 'p' value using student's paired t-test before and after treatment. Significant results ($p<0.001$) were observed in both groups. Comparative study between percentages of improvement in Group A showed 5% (based on subjective parameters) and 7% (based on objective parameters) more improvement than that of Group B. Based on the results, it was concluded that *Vishwadi Leha* has a slightly better result than *Bharangyadi Leha* in the management of *Vataja Kasa*-TPE.

KEYWORDS: *Vataja Kasa, Vishwadi leha, Bharangyadi leha,* Tropical Pulmonary Eosinophilia (T.P.E).

INTRODUCTION

Breathing involving to and fro movement of air through the *Pranavaha Srotas,* is a normal phenomenon and a vital sign indicative of life, the normalcy of which is suggestive of good health. Its abnormality leads to disease and its cessation leads to the death of an individual. This unique sign of life is affected by a condition called as *Kasa*, because of the continuous exposure of the respiratory system to the external environment affected by industrialization and population explosion, with an influence of modern life style leading to the agitation of the individual in the routine activities. As a result of *Raja* and *Dhuma* (dust and smoke), the main cause of *Pranavaha srotas dusti*, have become unavoidable, making *Kasa* the most common disease, where *Shuska Kasa* is a prominent symptom.[1] The scientific and systematic description of *Kasa* termed as cough by allied science, is versified in Ayurveda as an independent disease entity as well as symptom of other diseases. *Kasa* though seems simple, when neglected or mismanaged leads to a disease with poor diagnosis.[2] Amongst the 5 major types of *Kasa*[3], *Vataja Kasa* presenting with *Shushka Kasa, Shirah Shoola, Parshwa Shoola, Hrit Shoola, Swara Bheda, Prasakta Vega, Kshamanana* seems to be very common condition in the locality. It may be taken as a special reference to Tropical Pulmonary Eosinophilia (TPE) because of the similarities in the signs and symptoms. In 1943, Weingarten first described the condition of spasmodic bronchitis, eosinophilic leukocytosis and disseminated mottling of both lungs as TPE.[4] The syndrome is largely confined to the tropics and is particularly endemic in regions of Indian subcontinent, South East Asia, South America

and Africa. In India, it is mostly found around coastal regions from Maharashtra to Kerala and West Bengal to Tamil Nadu.[5] Affects male and females in ratio 4:1 and is rarely seen in children.[6] TPE could result in a fair degree of respiratory morbidity if left untreated. Treatment consists of Diethylcarbamezine for at least 3 weeks despite which about 12-25% of patients may relapse[7] and also exhibits few common side effects such as dizziness, nausea, fever, headache or pain in the muscles or joints.[8] Though evaluation works and progress have been made in the management of *Vataja Kasa,* there has been very little work done on the efficient drugs. In *Shamana Chikitsa* of *Vataja Kasa, Lehya* are explained to treat effectively. From these prospects the present study has been taken to evaluate and compare the efficacy of *Vishwadi Leha*[9] and *Bharangyadi Leha*[10] both containing mostly *Ushna Virya, Vatahara* and *Vata Kapha Shamaka* drugs,[11] in the management of *Vataja Kasa*.

OBJECTIVES

To compare the efficacy of *Vishwadi Leha* and *Bharangyadi Leha* in the management of *Vataja Kasa* w.s.r. Tropical Pulmonary Eosinophilia.

MATERIALS AND METHODS

40 patients of either sex fulfilling the inclusion criteria of *Vataja Kasa* attending the OPD and IPD of A.L.N.Rao Memorial Ayurvedic Medical College & Hospital (ALNRMAMC, Koppa), from medical camps and other referrals were incidentally selected and randomly categorised into 2 groups- Group A and Group B with 20 patients each for the study. Written consents from the patients were obtained before clinical trial. The trial drugs *Vishwadi Leha* and *Bharangyadi Leha* were prepared in the pharmacy of ALNRMAMC, Koppa as per the standard method of preparation of *Churna Kalpana* according to AFI guidelines.[12]

Study Design

Single blind Randomized Comparative clinical study.

Inclusion Criteria

1. Patients diagnosed with *Vataja Kasa* based on classical signs and symptoms of either sex aged 18 to 60 yrs.
2. Patients with increased Absolute Eosinophil Count (more than 400cells/cumm[13]) will be selected.

Exclusion Criteria

1. T.P.E with complications/ secondary infections/ asthma/ syndrome's are excluded. *Vataja kasa* as an associated symptom in other system illnesses like Bronchial asthma, Pneumonia, other Eosinophilic lung diseases are excluded.
2. Patients with uncontrolled systemic diseases like Diabetes Mellitus and Hypertension.
3. Patients with complication of *Kasa* i.e. *Rajayakshma,* carcinoma of bronchus, pulmonary tuberculosis, pleurisy, pneumonia are excluded.
4. All the other varieties of *Kasa*.
5. Pregnant and lactating women are excluded.

Assessment Criteria: Criteria for assessment is given in the following table.

Table 1: Grading system of *Vataja Kasa* based on subjective and objective parameters

Subjective Parameters

S.No.	Symptoms	Grade 0	Grade 1	Grade 2	Grade 3
1.	*Shushka Kasa* (dry cough)	No cough (during the day or night)	Mild (cough for one short period during the day not interfering with daily activities; wake once at night due to cough)	Moderate (frequent cough not interfering with usual day time activities; frequent waking during night due to cough)	Severe (Distressing cough most of the day and night)
2.	*Prasakta Vega* (paroxysms of dry cough)	No paroxysms.	Mild paroxysms of cough /24 hrs.	Moderate paroxysms of cough/ 24 hrs.	Severe (continuous) paroxysms of cough/ 24hrs.
3.	*Shirah Shoola* (Headache)	No pain	Mild (Present only during cough)	Moderate (intermittently present irrespective of cough, not affecting routine activities)	Severe (continuously present irrespective of cough affecting the daily activities)
4.	*Parshwa Shoola* (Pain in the flanks)				
5.	*Hrit Shoola* (pain in the chest)				
6.	*Swara Bheda* (hoarseness in the	No hoarseness	Mild hoarseness in the voice	Moderate hoarseness in the voice.	Severe hoarseness in the voice.

	voice)	in the voice.			
7.	*Kshamanana* (Pallor on face)	No pallor	Mild pallor on face	Moderate pallor on face	Severe pallor on the face.

Objective Parameter

S.No	Parameters	Grade 0	Grade 1	Grade 2	Grade 3
8.	Absolute Eosinophil Count (A.E.C)	400-999 cu/mm	1000-1599 cu/mm	1600-2100 cu/mm	>2100 cu/mm

Intervention

Criteria	Group A	Group B
Sample Size	20	20
Medicine	*Vishwadi Leha*	*Bharangyadi Leha*
Dose	3 gms, thrice daily, after food	3 gms, thrice daily, after food
Anupana	*Ushna Jala* (quantity sufficient)	*Ushna Jala* (quantity sufficient)
Duration	4 weeks	4 weeks
Follow Up	After 2 weeks	After 2 weeks

Pathya Ahara and *Vihara* were advised to all the subjects.

Statistical Analysis

Statistical analysis was carried out using the SPSS (32 bit) software. All the observed data were statistically analysed using students paired "t-test".

Observation

Table 2: Incidence based on the presenting symptoms

Symptoms	Trial group A	Percentage	Trial group B	Percentage
Shushka kasa	20	100	20	100
Prasakta vega	20	100	20	100
Shirah shoola	16	80	17	85
Parshwa shoola	18	90	20	100
Hrit shoola	4	20	6	30
Swara bheda	16	80	20	100
Kshamanana	10	50	11	55

Amongst 40 patients selected for the clinical trial, 40 (100%) patients were reported to have had *Shushka Kasa*, 40 (100%) had *Prasakta Vega*, 38 (95%) patients had *Parshwa Shoola*, 36 (90%) patients had *Swara Bheda*, 33(82.5%) patients had *Shirah Shoola* and 22 (55%) patients had *Kshamanana.*

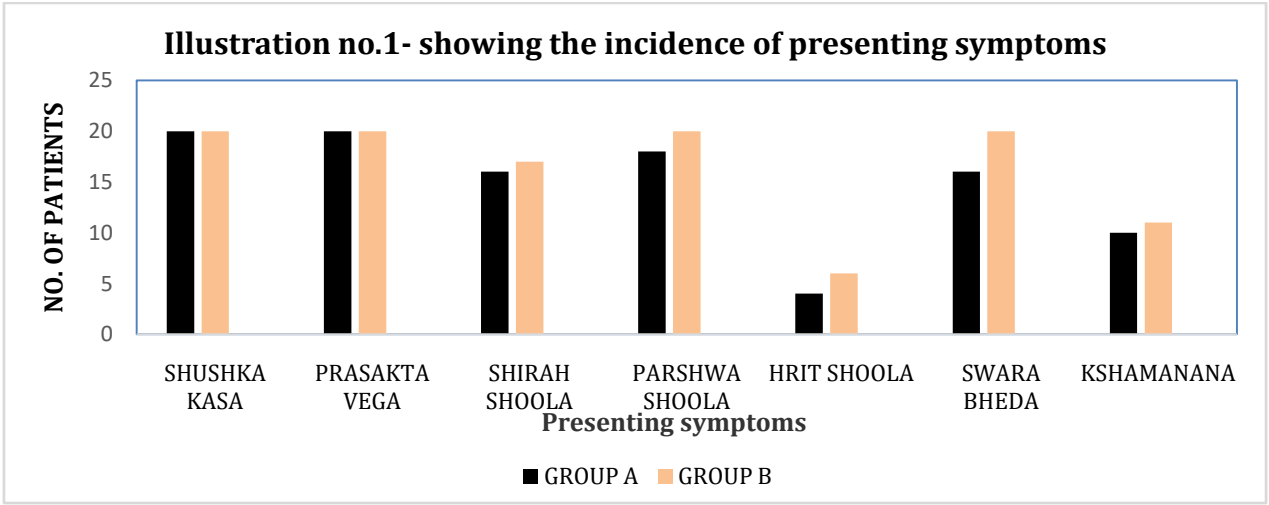
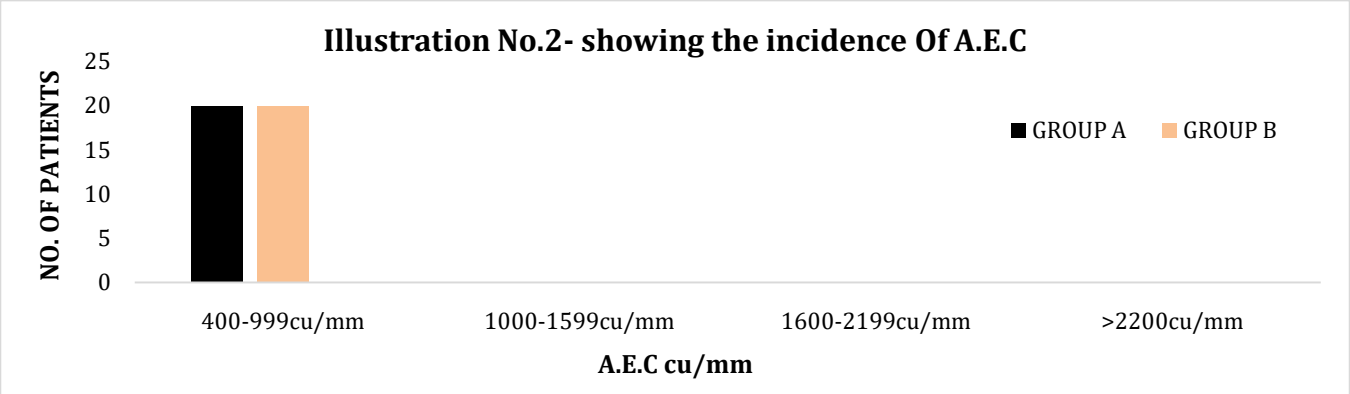


Table 3: Incidence based on A.E.C (cu/mm)

A.E.C cu/mm	Trial group A	Percentage	Trial group B	Percentage
400-999	20	100	20	100
1000-1599	0	0	0	0
1600-2199	0	0	0	0
Above 2200	0	0	0	0

All 40 (100%) patients chosen for the clinical trial were reported to have A.E.C (peripheral blood smear) levels ranging from 400-999 cu/mm.



RESULTS AND DISCUSSION

Table 4: Study of total percentage of improvement in subjective parameter of both groups

Group	Total Effect on *Shushka kasa*	Total Effect on *Prasakta vega*	Total Effect on *Shirah shoola*	Total Effect on *Parshwa shoola*	Total Effect on *Hrit shoola*	Total Effect on *Swara bheda*	Total Effect on *Kshamanana*	Grand Total Percentage of parameters
Group A	97%	100%	100%	100%	100%	100%	100%	99%
Group B	96%	100%	100%	100%	100%	100%	100%	94%

Comparative study between percentages of improvement in subjective Parameters of Both Groups reveal almost similar results but Group A (*Vishwaadi Leha*) showed 5% more improvement than that of Group B (*Bharangyadi Leha*).

Table 5: Comparative study – overall effect on the subjective parameters of treatments in both groups

Group	Percentage of Improvement (Number of Patients=40)					
	Complete Improvement (100%)	Marked Improvement (76-99%)	Moderate Improvement (51-75%)	Average Improvement (26-50%)	Below Average Improvement (1-25%)	No Change (0%)
Group A	18	2	0	0	0	0
Group B	18	2	0	0	0	0

After the completion of 4 week course of treatment in the two groups the overall assessment of the patients was made as shown in the table above. The analysis revealed 18 patients from Group A and 18 patients from Group B had 100% relief from the symptoms of *Vataja Kasa*. 2 patients from Group A and 2 patients from Group B showed marked improvement while moderate improvement was seen in 0 patients in Group A and 0 patients in Group B. Average improvement was seen in 0 patients in Group A and in 0 patients in Group B. Meanwhile 0 patients had shown below average improvement or no change from both Groups.

From the above study it is also clear that the total improvement in the both groups is almost similar.

Table 6: Study of total percentage of improvement in objective parameter of both groups

Group	Total effect On A.E.C (cu/mm)	Grand Total percentage parameter
Group A	47%	47%
Group B	40%	40%

Comparative study between percentages of improvement in Objective Parameters of Both Groups reveals almost similar results but Group A (*Vishwaadi Leha*) had shown 7% more in total improvement than that of Group B (*Bharangyadi Leha*).

Table 7: Comparative study –overall improvement of both groups in treatment of A.E.C (cu/mm)

Group	Percentage of Improvement (Number of Patients=40)					
	Complete Improvement (100%)	Marked Improvement (76-99%)	Moderate Improvement (51-75%)	Average Improvement (26-50%)	Below Average Improvement (1-25%)	No Change (0%)
Group A	0	0	8	10	2	0
Group B	0	0	7	9	4	0

After the completion of 4 week course of treatment in the two groups the overall assessment of the patients was made as shown in the table above. The analysis revealed 8 patients from Group A and 7 patients from Group B had Moderate improvement in normalizing Absolute Eosinophil Count. 0 patients in both Group A and Group B showed 100% improvement while marked improvement was seen in 0 patients in Group A and 0 patients in Group B.

Average improvement was noticed in 10 patients in Group A and 9 patients in Group B.2 patients in Group A and 4 patients from Group B had shown below average improvement meanwhile 0 patients from both groups had shown No change.

Group A Shown a total of 47% improvement in the effect on Absolute Eosinophil Count while Group B shown a total of 40% improvement in the same.

Table 8: Statistical Analysis on the total effect of both groups

Statistical Analysis	Group A					Group B				
Parameters	Mean (difference)	SD (difference)	SEM	T value	P value	Mean (difference)	SD (difference)	SEM	T value	P value
Shushka Kasa	2.750	0.444	0.099	27.683	P<0.001	2.800	0.523	0.117	23.936	P<0.001
Prasakta Vega	2.550	0.510	0.114	22.342	P<0.001	2.450	0.605	0.135	18.116	P<0.001
Hrit Shoola	0.200	0.410	0.0918	2.179	P=0.042	0.300	0.470	0.105	2.854	P=0.010
Parshwa Shoola	1.500	0.688	0.154	9.747	P<0.001	2.000	0.649	0.145	13.784	P<0.001
Shirah Shoola	1.550	0.945	0.211	7.339	P<0.001	1.250	0.786	0.176	7.109	P<0.001
Swarabheda	1.250	0.786	0.176	7.109	P<0.001	1.250	0.444	0.0993	12.583	P<0.001
Kshamanana	0.500	0.513	0.115	4.359	P<0.001	0.550	0.510	0.114	4.819	P<0.001
A.E.C cu/mm	270.300	108.069	24.165	11.186	P<0.001	242.500	122.900	27.481	8.824	P<0.001

Statistically, the results obtained regarding the subjective parameters is highly significant (p<0.001) in both groups with 100% relief in symptoms such as *Prasakta Vega, Hrit Shoola, Parshwa Shoola, Shirah Shoola, Swarabheda* and *Kshamanana* whereas the parameter *Shuskha Kasa* had a relief of 97% in Group A and 96% relief in Group B. Overall, 18 subjects from each Group (A & B) showed complete relief (100%) and 2 subjects from each Group A & B showed marked improvement (76-99%).

Likewise, the results obtained regarding the parameter A.E.C (cu/mm) is significant (p <0.001) in both groups i.e. in Group A, 8 subjects had moderate improvement (51-75%) and 10 patients showed average improvement (26-50%) whereas in Group B, 7subjects had moderate improvement (51-75%) and 9 patients showed average improvement (26-50%).

Table 9: Comparative Statistical Analysis between two trial groups

Effect on Parameters	Mean (difference)	SD (difference)	SEM	T value	P value
Shushka Kasa	0.050	0.079	0.0177	0.326	P=0.746
Prasakta Vega	0.100	0.095	0.021	0.565	P=0.575
Hrit Shoola	0.100	0.060	0.0132	0.0717	P=0.478
Parshwa Shoola	0.500	0.039	0.009	2.364	P=0.023
Shirah Shoola	0.300	0.159	0.035	1.092	P=0.282
Swarabheda	0.000	0.324	0.0767	0.000	P=1.000
Kshamanana	0.050	0.003	0.001	0.309	P=0.759
A.E.C cu/mm	27.800	14.831	3.316	0.760	P=0.452

Comparative statistical study between trial Group A and trial Group B, in the effect on *Shushka Kasa, Prasakta Vega, Hrit Shoola, Parshwa Shoola, Shirah Shoola, Swarabheda, Kshamanana* and A.E.C cu/mm shows an insignificant statistical difference. From this, it can be understood that both groups have almost similar actions on the selected parameters for conducting the trial.

DISCUSSION ON RESULTS

***Shushka Kasa*:** The *Rooksha Guna* of *Vata* creates *Shushkata* in the concerned area and *Chala Guna* of *Vata* causes repeated bouts of cough resulting in dryness in mouth, throat, chest and head regions which in turn causes *Shushkata.*

This *Shushkata* can be rectified by *Ushna Veerya* and *Madhura Vipaka* of the drug. The specific *Doshahara Karma* i.e., *Kasahara* property helps to pacify *Shushka Kasa*.

***Prasakta vega*:** *Prasakta Vega* is *Satata Vega* or persistent cough, which occurs due to the increased stimulation of *Vata Nadis* by the *Chala Guna* of *Vayu*. This *Chala Guna* of *Vayu* in turn causes *Shushkata* in the *Urah* and *Kanta Pradesha.*

This *Shushkata* can be rectified by *Ushna Veerya* and *Madhura Vipaka* of the drugs. The specific *Doshahara Karma* i.e., *Kasahara* property helps to pacify *Shushkata* and reduce the bouts of cough.

Shirah shoola: The *Prana Vayu* situated in the *Shirah Pradesha* gets vitiated and obstructs the *Srotas* in the concerned area. This *Marghavarodha* affects the *Chala Guna* of *Vayu* leading to an increased pressure inside the *Srotas.* This in turn causes the contraction of muscles in the *Shirah Pradesha* during the act of coughing. The neuro-muscular irritability resulting due to repeated and excessive contraction-relaxation of the muscles in the head region and the increased intra cranial pressure produced during the act of cough leads to manifestation of pain in the head region.

Laghu- Snigdha Gunas, Ushna Veerya and *Madhura Vipaka* of the trial drugs help in *Kasaharana.* Whereas, *Ushna Veerya*, *Katu-Tikta-Kashaya Rasa* and *Tikshna Guna* of the trial drugs relieves the *Avarodha.*

***Parshwa shoola*:** When *Prana Vata* and *Udana Vata* gets vitiated, it dries out the *Shleshma* present in the lungs, causing it to dry up and clog the lungs. This leads to *Margavarodha* to *Vayu Sanchara*. Obstructed *Vayu* then blocks the *Strotas* in the chest region. Thus increased pressure in the lungs leads to forceful contraction of the muscles in the chest region for the forceful expulsion of *Vayu* resulting in cough. This repeated contraction and relaxation of muscles in the chest leads to stabbing like pain in the flank region. *Parshwa Shoola* may also result as a complication of cough i.e. due to fracture of a rib.

Ushna Veerya, Tikshna Guna and *Katu-Tikta Rasa* present in the trial drug help in clearing out the *Margavarodha* and clears out the *Kapha*. Meanwhile *Ushna Veerya* and *Madhura Vipaka* also present in the trial drugs help in pacifying the *Prakupita Vata*.

***Hrit shoola*:** The obstruction to the movement of *Vayu* resulting in increased pressure leads to stabbing like pain in the chest region. The sudden excessive contraction and relaxation of muscles in the chest during the act of cough which is dry and paroxysmal leads to *Hrit Shoola.*

Ushna Veerya, Madhura Vipaka and the *Rasayana* property present in the trial drugs help in pacifying the vitiated *Vata.* The drugs in the trial group has *Kasahara, Doshaharakarma* and *Vatahara* property which includes analgesic, anti-histaminic, anti-oxidant and anti-spasmodic effects helping in relieving *Hrit Shoola.*

***Swara Bheda*:** *Swarabheda* is a condition resulted due to the vitiation of *Udana Vayu.* This leads to an increase in the stimulation of recurrent laryngeal nerve as a result on increase in vibration of vocal cords present in the larynx and also due to excessive and frequent stimulation of concerned nerve causes

impairment in producing sound resembling a broken bronze vessel.

The trial drugs possess *Ushna Veerya, Madhura Vipaka, Kasahara- DipanaKarma* along with the *Rasayana* property which helps in pacifying the vitiated *Vayu* simultaneously soothning the mucus membrane of the throat region.

***Kshamanana*:** *Kshamana* refers to lusterless face (*Shushka Mukha Vatena Shoshannath*). Due to *Ojakshaya DhatuKshaya* and *Bala Kshaya* which are already present in this disease are held responsible in lusterless face. Increase in Eosinophilic count in peripheral blood in order to activate defense mechanism, MBP (Major Basic Protein) present in the Eosinophils are utilized to act against the invading organism. This increased utility of proteins leads to a lustreless face.

Madhura Vipaka, Snigdha Guna and the *Rasayana Karma* of the trial drugs help in relieving the symptom. The anti-oxidant and anti-histaminic properties of the drug included under *Vata Shamaka Gunas* are also responsible for bringing back luster to the face.

A.E.C cu/mm: In group A, 8 patients had moderate improvement ranging between 51-75%, 10 patients had average improvement ranging between 26-50% and 2 patients had below average improvement ranging between 1-25%. This was probably due to *Vata Shamaka* and *Kasahara* properties of *Vishwadi Leha.*

In group B, 7 patients had moderate improvement ranging between 51-75%, 9 patients had average improvement ranging between 26-50% and 4 patients had below average improvement ranging between 1-25%. This was probably due to *Vata Shamaka* and *Kasahara* properties of *Bharangyadi Leha.*

From the above results, it can be observed that *Vishwadi Leha* possesses slightly better (7%) results than *Bharangyadi Leha.*

CONCLUSION

In the present study it is observed that both *Vishwadi Leha* and *Bharangyadi Leha* effectively reduced the signs and symptoms of *Vataja Kasa,* with *Vishwadi Leha* showing slightly better (5%) results than *Bharangyadi Leha.* Similarly, with regards to Absolute Eosinophilic Count, *Vishwadi Leha* showed slightly better (7%) results compared to *Bharangyadi Leha.* It was observed that in both the groups, patients were relived of symptoms of *Vataja Kasa* within 30 days after the commencement of treatment.

Statistically, the results obtained regarding the subjective parameters is highly significant ($p<0.001$) in both groups with 100% relief in symptoms such as *Prasakta Vega, Hrit Shoola, Parshwa Shoola, Shirah Shoola, Swarabheda* and *Kshamanana* whereas the parameter *Shuskha Kasa* had a relief of 97% in Group A and 96% relief in Group B. Overall, 18 subjects from each Group (A & B) showed complete relief (100%) and 2 subjects from each Group A & B showed marked improvement (76-99%).

Likewise, the results obtained regarding the parameter A.E.C (cu/mm) is significant ($p <0.001$) in both groups i.e. in Group A, 8 subjects had moderate improvement (51-75%) and 10 patients showed average improvement (26-50%) whereas in Group B, 7subjects had moderate improvement (51-75%) and 9 patients showed average improvement (26-50%). It is clear that the total improvement in the both groups are almost similar, even though a slightly better percentage of improvement can be noticed in the Group A where *Vishwaadi Leha* was used than Group B where the *Bharangyadi Leha* was put into trial. Both *Vishwadi Leha* as well as *Bharangyadi Leha* are effective in the management of *Vataja kasa.*

The sample size was not enough to draw generalized conclusion. Study should be done by increasing the sample size for getting a generalized conclusion. The study of this work is restricted to a particular geographical area. Multi-centric study has to be conducted to re-establish the efficacy, including the people of different geographical distribution.

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