



## A Report of the Randomized Controlled Trial in the modulation of 'Serum Immunoglobulin E' Levels of 'Allergic Rhinitis' Patients treated with *Galphimia glauca.6C*, *Luffa Operculata.6C* & *Penthorum Sedoides.6C*

P. K. Sudhir<sup>1</sup> and H. Venkatesan<sup>2\*</sup>

<sup>1</sup>Vice Chancellor, Vinayaka Mission's Research Foundation Deemed to be University, Salem

<sup>2\*</sup>Research Coordinator & Associate Professor, Vinayaka Mission's Homoeopathic Medical College & Hospital, Salem, Tamilnadu, India

\*venkathompath@gmail.com

### ABSTRACT

Allergic rhinitis is an inflammatory disorder of the nasal mucosa induced by allergen exposure triggering IgE-mediated inflammation. Around 20-30 % of the Indian population suffers from allergic rhinitis. Clinically, it is characterized by four major symptoms - rhinorrhea, sneezing, nasal itching, and nasal congestion. Allergic Rhinitis symptoms result in sleep disturbance, fatigue, depressed mood and cognitive function compromise that impairs quality of life and productivity. The efficiency of its treatment can be assessed by the Serum Immunoglobulin E lowering effect. Various Clinical Trials conducted have demonstrated the efficacy of Homoeopathic Medicines like *Allium cepa*, *Sabadilla*, *Aurum triphyllum*, *Euphrasia*, *Hepar sulphuris*, *Arsenicum iodatum*, *Kalium iodatum*, etc., in treating Allergic Rhinitis. Lesser known drugs like *Galphimia glauca.6C*, *Luffa operculata.6C* & *Penthorum Sedoides.6C* are also found to be clinically effective in treating Allergic Rhinitis by literature survey. But their effect on modulation of Elevated Serum Immunoglobulin-E levels in Allergic Rhinitis patients is not yet explored by any of the previous Researches. These details intended us to do a randomized controlled trial on the effectiveness of the three said medicines in the modulation of Serum Immunoglobulin-E levels in Allergic Rhinitis patients. 30 Allergic Rhinitis patients were treated with the specific medicines for about 90 days. On average *Galphimia glauca.6C* reduced the Serum IgE level by 134.71 Ku/L (n=10) with p Value 0.00021, *Luffa Operculata.6C* reduced the Serum IgE level by 201.49 Ku/L (n=10) with p Value 0.000018 and *Penthorum Sedoides.6C* reduced the Serum IgE level by 104.9 Ku/L (n=10) with p Value 0.003442.

**Key Words:** Allergic rhinitis, *Galphimia glauca.6C*, Homoeopathic Medicines, *Luffa operculata.6C*, *Penthorum Sedoides.6C* & Serum Immunoglobulin E.

Received 14.04.2021

Revised 20.04.2021

Accepted 22.06.2021

### INTRODUCTION

Allergic rhinitis is an inflammatory disorder of the nasal mucosa induced by allergen exposure triggering IgE-mediated inflammation. Clinically, it is characterized by four major symptoms – rhinorrhea, sneezing, nasal itching, and nasal congestion.

It can also be associated with co-morbid conditions as Asthma, Atopic Dermatitis & Nasal polyps. Around 20–30 % of the Indian population suffers from allergic rhinitis and that 15 % develop asthma. Allergic Rhinitis symptoms result in sleep disturbance, fatigue, depressed mood and cognitive function compromise that impairs quality of life and productivity [1, 2].

A number of pharmacologic interventions are prescribed to treat Allergic Rhinitis. Intranasal corticosteroids (INC) are recommended in current guidelines as first-line therapy for patients with moderate to severe Allergic Rhinitis, particularly when nasal congestion is the prominent symptom [3].

Preservatives in the INC formulation may produce nasal irritation and may impart unacceptable taste or odour to the formulation. Further, the relative osmotic pressure or tonicity of the formulation can modulate nasal retention and absorption, thereby potentially influencing clinical efficacy.<sup>1</sup> The use of INC may tend to cause adverse effects like a stinging or burning sensation in the nose, dryness and crustiness in the nose, a dry, irritated throat, an unpleasant taste in the mouth, itchiness, redness and swelling in the nose, nosebleeds, etc. [4]. Furthermore INC could relieve the Nasal Congestion only that too for a limited

time period. They don't play a role in modulating the immunity of the patient, Prevention or Cure of the Allergic Rhinitis.

The Diagnosis of Allergic Rhinitis is based on Typical history of allergic symptoms "sneezers and runners". All patients with persistent allergic rhinitis need a nasal examination (Anterior rhinoscopy, Nasal endoscopy). The diagnostic tests are directed towards the detection of free or cell bound IgE. Immediate hypersensitivity skin tests are widely used to demonstrate an IgE-mediated allergic reaction. These represent a major diagnostic tool in the field of allergy. The measurement of allergen-specific IgE in serum is of importance and is of similar value to skin tests. They are more useful in patients having dermatitis, dermatographism, and in cases where antihistamines have to be continued during testing [5].

Various Clinical Trials conducted by 'CCRH, New Delhi' and other reputed institutions across globe have demonstrated the efficacy of Homoeopathic management of Allergic Rhinitis. Homoeopathic Medicines like *Allium cepa*, *Sabadilla*, *Aurum triphyllum*, *Euphrasia*, *Hepar sulphuris*, *Arsenicum iodatum*, *Kalium iodatum*, etc., are found to be effective in treating Allergic Rhinitis by Previous Studies [6].

Lesser known drugs like *Galphimia glauca*.6C [7], *Luffa operculata*.6C [8] & *Penthorum Sedoides*.6C [9] are also found to be clinically effective in treating Allergic Rhinitis by literature survey. But their effect on modulation of Elevated Serum Immunoglobulin-E levels in Allergic Rhinitis patients is not yet explored by any of the Researches across the World.

These details intended me to do a comparative experimental study on the effectiveness of the three said medicines in the modulation of Serum Immunoglobulin-E levels in Allergic Rhinitis patients. The Results of the same is submitted by this Short Research Report.

To show the Positive Modulation (Reduction) of the Elevated Serum Ig-E levels of Allergic Rhinitis patients after Treated with Specific Homoeopathic Medicines - *Galphimia glauca*.6C, *Luffa Operculata*.6C & *Penthorum Sedoides*.6C.

## MATERIAL AND METHODS

Methodology: Single Blind Comparative Experimental Study design of three parallel groups.

Study Subjects: Clinically diagnosed Allergic Rhinitis Patients with elevated Serum Immunoglobulin - E Levels.

Sample design: According to the inclusion, exclusion criteria 30 patients were selected by Random Sampling Method. 10 patients each for 3 Treatment Groups.

Inclusion criteria: Both Males and Female Patients; Patients in the age group of 19 - 65 yrs; Serum Immunoglobulin - E Level  $\geq 158$  IU/mL (Ku/mL) or as per the reference range in other Units / for other laboratory methods.

Exclusion criteria: Allergic Rhinitis with Systemic infection or Complications; Patients with Occupational Health Hazards or Repeated Exposure.

Sample Allocation to the 3 Treatment Groups: Pre-coded Concealed Identical Envelops.

Medicines given to the patients in the 3 Treatment groups: Group A - *Galphimia glauca*, Group B - *Luffa operculata* & Group C - *Penthorum Sedoides*.

Potency Selection: 6th Centesimal Potency (6C) was selected as this can be prescribed on the basis of 'Pathological Prescription' and in Acute Phase of the Disease.

Prognostic Tool: Pre & Post Treatment Serum Immunoglobulin - E levels; Pre & Post Treatment Scores of 'Allergic Rhinitis Questionnaire for assessing the Severity of Symptoms'<sup>10</sup>

Questionnaire used for Symptom Assessment: 'Allergic Rhinitis Questionnaire for assessing the Severity of Symptoms' developed by the 'Joint Task Force on Practice Parameters' developed by the American Academy of Allergy, Asthma & Immunology, the American College of Allergy, Asthma & Immunology, and the Joint Council of Allergy, Asthma & Immunology [10].

Data collection: Patients were selected from Medical unit IV Outpatient Department of Vinayaka Mission's Homoeopathic Medical College Hospital; Required data were gathered by 'Case taking' in the College 'Standard Case Format'; Patient's Clinical Lab Investigatory findings, past history & reports were also considered; The Serum Immunoglobulin E levels of patients were investigated prior to the initiation of the treatment and after the completion of the Treatment.

Analysis of Data: The collected Data from the patient were analyzed based on the following criteria; Age / Gender / Occupation wise Distribution of Allergic Rhinitis Patients; Familial history of Disease in the patients; Common Causative factors.

Analysis of outcome: The Serum Immunoglobulin - E levels of the patients before and after treatment were taken for statistical consideration. The statistical method used to assess the effect of the medicines with respect to each other was made by "Analysis of Variance-ANOVA". 'Allergic Rhinitis Questionnaire for assessing the Severity of Symptoms' scoring before and after treatment were used for Statistical Analysis

using The Wilcoxon signed-rank test. The result has been given by combining both qualitative and statistical results.

Managing Adverse Effects: There were no known side effects or adverse effects noticed during treatment.

## RESULTS AND DISCUSSION

**Table no.1 - Age wise distribution of Patients in Each Group**

S. No	Age Groups	No. of Patients				Percentage
		Group A	Group B	Group C	Total	
1.	19 – 25	03	02	01	06	20%
2.	26 – 35	00	01	02	03	10%
3.	36 – 45	03	03	02	08	26.67%
4.	46 - 55	02	03	04	09	30%
5.	56 - 65	02	01	01	04	13.33%

Maximum Prevalence (56.67%) of Allergic Rhinitis in the Age Group 36 to 55 Years.

**Table no.2 - Gender wise distribution of Patients in Each Group**

S. No	Gender	No. of Patients				Percentage
		Group A	Group B	Group C	Total	
1.	Male	06	06	04	16	53.33%
2.	Female	04	04	06	14	46.67%

Study showed almost an equal prevalence of Allergic Rhinitis in Males and females.

**Table no.3 - Family History of Allergic Rhinitis Patients**

S. No	Disease	No. of Patients			
		Group A	Group B	Group C	Total
1.	Allergic Rhinitis	02	03	02	07
2.	Atopic Asthma	02	02	01	05
3.	Atopic Dermatitis	01	02	01	04
4.	Urticaria	01	00	01	02
5.	Pollen Allergy	00	01	00	01
6.	Food Allergy	01	00	00	01
	<b>Total</b>	<b>07</b>	<b>08</b>	<b>05</b>	<b>20</b>

20 patients (66.67%) patients have shown Relevant Family History of some Allergic Conditions.

### Some other Observations:

20 patients (66.67%) belonged to High/ Upper Middle Socio Economic Class. 09 patients (30%) were working in Air-conditioned office; 09 patients (30%) were House wives; 06 (20%) patients have been working in relation to farming; 03 (10%) patients were weavers and 03 (10%) patients were students. 18 patients (60%) were already known for their Allergic Rhinitis. 09 patients (30%) had Dust Allergy; 09 patients (30%) had Seasonal Allergy; 06 patients (20%) had Pollen allergy; 03 (10%) patients had Dander allergy as Causative Factor and / or Triggering Factor.

**Table no.4a – Serum Ig E levels of Patients of Treatment Group-A (Galphimia glauca.6C)**

Sl.No	Pt. No.	OPD Reg. No.	Before Treatment		After Treatment		Actual Modulation (Ku/L)	
			Date	Value	Date	Value		
1	2	02090/20	07.07.20	397.0	09.10.20	245.7	-151.3	↓
2	8	02116/20	24.07.20	181.6	27.10.20	89.0	-92.6	↓
3	9	02121/20	27.07.20	274.9	28.10.20	192.7	-82.2	↓
4	13	02135/20	04.08.20	316.9	07.11.20	109.0	-207.9	↓
5	15	02138/20	05.08.20	371.5	07.11.20	209.2	-162.3	↓
6	17	02144/20	07.08.20	412.9	09.11.20	374.2	-38.7	↓
7	22	02157/20	13.08.20	669.2	16.11.20	436.7	-232.5	↓
8	23	02160/20	14.08.20	421.3	17.11.20	392.9	-28.4	↓
9	26	02168/20	17.08.20	390.7	19.11.20	242.1	-148.6	↓
10	28	02174/20	18.08.20	437.8	19.11.20	235.2	-202.6	↓

**Table no.4b - Serum Ig E levels of Patients of Treatment Group-B (Luffa Operculata.6C)**

Sl.No.	Pt.No.	OPD Reg No.	Before Treatment		After Treatment		Actual Modulation (Ku/L)	
			Date	Value	Date	Value		
1	1	02088/20	06.07.20	302.3	07.10.20	118.4	- 183.9	↓
2	3	02092/20	10.07.20	211.7	12.10.20	98.8	- 112.9	↓
3	5	02102/20	16.07.20	186.8	19.10.20	72.1	- 114.7	↓
4	6	02109/20	20.07.20	201.9	23.10.20	99.2	- 102.7	↓
5	11	02129/20	01.08.20	576.6	02.11.20	367.9	- 208.7	↓
6	14	02136/20	05.08.20	410.0	07.11.20	237.1	- 172.9	↓
7	19	02148/20	11.08.20	591.6	12.11.20	277.9	- 313.7	↓
8	24	02162/20	14.08.20	397.7	16.11.20	164.8	- 232.9	↓
9	29	02175/20	19.08.20	482.5	20.11.20	187.7	- 294.8	↓
10	30	02176/20	19.08.20	390.2	20.11.20	112.5	- 277.7	↓

**Table no.4c - Serum Ig E levels of Patients of Treatment Group-B (Penthorum Sedoides.6C)**

Sl.No.	Pt.No.	OPD Reg No.	Before Treatment		After Treatment		Actual Modulation (Ku/L)	
			Date	Value	Date	Value		
1	4	02097/20	13.07.20	548.4	16.10.20	274.3	- 274.1	↓
2	7	02114/20	22.07.20	247.1	24.10.20	132.6	- 114.5	↓
3	10	02126/20	28.07.20	198.7	30.10.20	126.3	- 72.4	↓
4	12	02130/20	03.08.20	242.0	04.11.20	112.4	- 129.6	↓
5	16	02139/20	06.08.20	782.2	09.11.20	739.6	- 42.6	↓
6	18	02146/20	10.08.20	368.5	12.11.20	153.5	- 215.0	↓
7	20	02150/20	11.08.20	380.9	12.11.20	298.0	- 82.9	↓
8	21	02156/20	13.08.20	297.1	16.11.20	302.9	+ 5.8	↑
9	25	02163/20	14.08.20	609.2	17.11.20	571.7	- 37.5	↓
10	27	02169/20	17.08.20	477.7	19.11.20	391.5	- 86.2	↓

**Table no.5 - Average of Serum Ig E levels Before & After Treatment**

Serum Ig-E levels (Ku/L)	Group A Galphimia glauca.6C			Group B Luffa Operculata.6C			Group C Penthorum Sedoides.6C		
	Before Treatment	After Treatment	Modulation	Before Treatment	After Treatment	Modulation	Before Treatment	After Treatment	Modulation
<b>Total n=30</b>	387.38	252.67	<b>134.71↓</b>	375.13	173.64	<b>201.49↓</b>	415.18	310.28	<b>104.9↓</b>
<b>Males</b>	405.2	283.21	<b>121.98↓</b>	382.28	168.32	<b>213.97↓</b>	348.85	279.9	<b>68.95↓</b>
<b>Females</b>	360.65	206.85	<b>153.8↓</b>	364.4	181.62	<b>82.77↓</b>	459.4	330.53	<b>128.87↓</b>

**Table no.6 - Descriptive Statistics of Serum IgE levels in IU/ml Before & After Treatment**

Treatment Group	Values	Minimum	Maximum	Median	Mean	Standard Deviation	Confidence Interval @ 95% LOS
Group.A Galphimia glauca.6C	Pre Treatment	181.60	669.20	393.85	387.38	126.53	387 ± 78.7 (308 to 466)
	Post Treatment	89.00	436.70	238.65	252.67	116.28	253 ± 71.9 (181 to 325)
Group.B Luffa Operculata.6C	Pre Treatment	186.80	591.60	393.95	375.13	148.48	375 ± 91.7 (283 to 467)
	Post Treatment	72.10	367.90	141.6	173.64	94.95	174 ± 58.9 (115 to 233)
Group.C Penthorum Sedoides.6C	Pre Treatment	198.70	782.20	374.7	415.18	187.50	415 ± 117 (298 to 532)
	Post Treatment	112.40	739.60	286.15	310.28	208.14	310 ± 129 (181 to 439)

**Table no.7 - Average of 'Allergic Rhinitis Symptom Severity Questionnaire Scores' Before & After Treatment**

Serum Ig-E levels (Ku/L)	Group A Galphimia glauca.6C			Group B Luffa Operculata.6C			Group C Penthorum Sedoides.6C		
	Before Treatment	After Treatment	Modulation	Before Treatment	After Treatment	Modulation	Before Treatment	After Treatment	Modulation
<b>Total n=30</b>	37.9	17.6	<b>20.3↓</b>	40.4	17.5	<b>22.9↓</b>	42.4	17.5	<b>24.9↓</b>

**Analysis of variance (ANOVA) for Pre & Post Treatment Serum IgE Levels:**

The Pre and Post treatment Serum Ig E Levels of the Allergic Rhinitis patients of 3 Treatment groups were independently compared by 'One Way Repeated Measure Analysis of Variance'.

Null Hypothesis (H<sub>0</sub>) : There is no statistical significant difference in the modulation of Serum Ig E levels of the patients in Treatment Groups before & after treatment.

Alternate Hypothesis (H<sub>a</sub>) : There is a statistical significant difference in the modulation of Serum Ig E levels of the patients in Treatment Groups before & after treatment.

**Inference on Group A Result:**

- Since the Calculated Critical F Value (35.6531) is greater than the Tabulated F Value at 5% (5.12) Level of Significance, the Null Hypothesis (H<sub>0</sub>) is Rejected and the Alternate Hypothesis (H<sub>a</sub>) is Accepted.
- So we can accept that the before and after treatment difference is statistically highly significant in Group A patients and this is not due to any chance since the p Value calculated is 0.00021.

**Inference on Group B Result:**

- Since the Calculated Critical F Value (67.15219) is greater than the Tabulated F Value at 5% (5.12) Level of Significances, the Null Hypothesis (H<sub>0</sub>)<sup>2</sup> is strongly Rejected and the Alternate Hypothesis (H<sub>a</sub>)<sup>2</sup> is Accepted.
- So we can accept that the before and after treatment difference is statistically significant in Group B patients and this is not due to any chance. Since the p Value calculated is 0.000018, the modulation is considered significant.

**Inference on Group C Result:**

- Since the Calculated Critical F Value (15.46922) is greater than the Tabulated F Value at 5% (5.12) Level of Significances, the Null Hypothesis (H<sub>0</sub>)<sup>3</sup> is strongly Rejected and the Alternate Hypothesis (H<sub>a</sub>)<sup>3</sup> is Accepted.
- So we can accept that the before and after treatment difference is statistically significant in Group C patients and this is not due to any chance. Since the p Value calculated is 0.003442, the modulation is considered significant.

**'Wilcoxon Signed-Rank Test' for Pre & Post Treatment Questionnaire Scores:**

The Pre and Post treatment Scores of 'Allergic Rhinitis Questionnaire for assessing the Severity of Symptoms'<sup>10</sup> were analyzed statistically by 'Wilcoxon Signed-Rank Test' to evaluate the significant modulation.

Null Hypothesis (H<sub>0</sub>) : There is no statistical significant difference in the Pre & Post Treatment Questionnaire Scores of Group A Patients

Alternate Hypothesis (H<sub>a</sub>): There is a statistical significant difference in the Pre & Post Treatment Questionnaire Scores of Group A Patients

**Inference on 'Wilcoxon Signed-Rank Test' Results:**

- Since the Calculated Critical Z Value (-2.8031) is exceeding than the Tabulated Z Value at 5% (6) Level of Significances, the Null Hypothesis (H<sub>0</sub>) are strongly Rejected and the Alternate Hypothesis (H<sub>a</sub>) are Accepted.
- So we can accept that the before and after treatment difference of 'Allergic Rhinitis Questionnaire for assessing the Severity of Symptoms' Scores are statistically significant in all the 3 Group patients and this is not due to any chance. Since the p Values calculated are p < .05, the modulation in all the 3 Groups are considered significant.
- Since the Mean and Standard Deviation in all the 3 groups are similar, it is decided that all the 3 groups have shown equal effects before and after treatment.

**CONCLUSION**

On average Galphimia glauca.6C reduced the Serum Ig E level by 134.71 Ku/L. (n=10); On average Luffa Operculata.6C reduced the Serum Ig E level by 201.49 Ku/L. (n=10); On average Penthorum Sedoides.6C reduced the Serum Ig E level by 104.9 Ku/L. (n=10). By the above data it is noted that *Luffa Operculata.6C* has shown more effect in reducing the Serum Ig E levels of Allergic Rhinitis Patients than the other two medicines. This 'Single Blind Comparative Experimental Study' proved that the medicines Galphimia glauca.6C, Luffa Operculata.6C & Penthorum Sedoides. 6C" have shown a Good Therapeutic effect on Allergic Rhinitis patients, which has been assessed by 'Allergic Rhinitis Questionnaire for assessing the Severity of Symptoms'.<sup>10</sup> On average Galphimia glauca.6C reduced the Scores by **20.3**. (n=10); On average Luffa Operculata.6C reduced the Scores by **22.9**. (n=10); On average Penthorum Sedoides.6C reduced the Scores by **24.9**. (n=10). All the above noted modulations are found to be statistically significant by 'Wilcoxon Signed-Rank Test' and their p-values are less than 0.05.

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**CITATION OF THIS ARTICLE**

P. K. Sudhir and H. Venkatesan. A Report of the Randomized Controlled Trial in the modulation of 'Serum Immunoglobulin E' Levels of 'Allergic Rhinitis' Patients treated with *Galphimia glauca.6C*, *Luffa Operculata.6C* & *Penthorum Sedoides.6C*. Bull. Env. Pharmacol. Life Sci., Vol10 [7] June 2021 : 103-108