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Analysis of 200 cases of allergic rhinitis to evaluate the significant improvement in clinical and diagnostic parameters

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Abstract

Introduction: Allergic rhinitis is the most common upper respiratory tract disorder worldwide. 1 out of every 6 Indian is affected with this allergic condition. It is one of the important common atopic conditions characterised by elevated serum immunoglobulin E level and absolute eosinophil count.

Objectives: To determine the time taken for a significant reduction in the intensity of symptoms, serum IgE level and blood AEC levels in Chronic Allergic Rhinitis with homoeopathic treatment.

To analyse association of Allergic rhinitis with Vitamin D deficiency and other allergic conditions

Methods: 200 cases satisfying the diagnostic criteria were randomly selected from OPD of GHMCT and the clinical features were assessed using total nasal symptom score and the diagnostic parameters IgE and AEC were reviewed every 3 months.

Results: The statistical analysis shows there is significant difference in the clinical presentations of allergic rhinitis within 1 month and IgE and AEC values showed a significant reduction by 6 months.

Conclusion: Allergic rhinitis can be effectively managed with Homoeopathic treatment.

Though IgE and AEC take much time to attain normal level, statistically significant reduction can be attained in values 6 months after the administration of Homoeopathic medicines.

Symptoms can be effectively managed within 2 weeks after the administration of appropriate homoeopathic medicines through individualization.

Keywords: IgE, AEC, allergic rhinitis, homoeopathy, total nasal symptom score

Introduction

Allergic rhinitis is the most common upper respiratory tract disorder worldwide. 1 out of every 6 Indian is affected with this allergic condition [1]. It is one of the important common atopic conditions characterised by elevated serum immunoglobulin E level and absolute eosinophil count. As per a study of patients from central Kerala in 2017 children and young adults forms the major sufferers of allergic rhinitis adversely affecting their performance in school and profession [3].

Allergic rhinitis is characterised by episodes of nasal congestion, coryza and sneezing. It may be seasonal or perennial due to an immediate hypersensitivity reaction in the nasal mucosa. Seasonal antigens includes pollens from grasses, flowers, weeds or trees. Perennial allergic rhinitis may be a specific reaction to antigens derived from house dust, fungal spores or animal dander.

As allergic rhinitis is a constitutional disorder, the homoeopathic medicine selected through a thorough case taking and individualization by proper investigations of the physical constitution of the patient, his mental state, occupation, mode of living etc. has been found effective in the pilot study conducted on 100 cases. Statistically significant improvement was found in the symptom score. The IgE and AEC was found to be reduced in some of the cases, but it was not statistically significant. A more extensive study with more randomly selected samples was undertaken to evaluate the time taken to bring a significant improvement in clinical and diagnostic parameters.

Methodology

Aim

To evaluate the time taken to bring a significant improvement in the clinical and diagnostic parameters of patients with allergic rhinitis by using homoeopathic medicines.

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Objectives

- To determine the time taken for a significant reduction in the intensity of symptoms in cases with Allergic Rhinitis with homoeopathic treatment.
- To analyse the time taken for significant reduction in serum Ig E level in chronic Allergic Rhinitis with homoeopathic management.
- To analyse the time taken for significant change in blood AEC levels in chronic Allergic Rhinitis with homoeopathic management.
- To analyse association of Allergic rhinitis with Vitamin D deficiency.
- To analyse the association with other allergic conditions.
- **Study design:** Quasi experimental randomised study.
- **Study setting:** OPD at Government Homoeopathic Medical College, Thiruvananthapuram.
- **Study duration:** A period of 1 year.
- **Sample size:** 200 cases satisfying the diagnostic criteria randomly selected from OPD at Govt. Homoeopathic Medical College, Thiruvananthapuram

Methods of study

Study tool: Pre- structured, pre-tested proforma of case taking

Diagnostic criteria

- Clinical signs and symptoms of allergic rhinitis evaluated using Total Nasal Symptom Score.
- Increased serum IgE level.

- Increased serum AEC level

Methods of Data Collection

- Minimum of 200 cases satisfying diagnostic criteria of allergic rhinitis are selected randomly from the special OP.
- Cases were taken in detail including diagnostic criteria after obtaining informed consent from all participants.
- Details were collected and entered in data sheet and specific case records.
- Cases were managed with homoeopathic medicines according to homoeopathic principles.
- Study was conducted for a period of one year, each case was reviewed every two weeks.
- Diagnostic parameters of IgE and AEC were reviewed every 3 months.
- Statistical analysis of clinical and diagnostic parameters was done at the end of the study.
- Changes in clinical features were assessed using total nasal symptom score

Plan of analysis

Effectiveness of clinical study was assessed by using statistical analysis of clinical parameter done every month and diagnostic parameters done after 6 months by using appropriate statistical tests. After analysis, discussion and conclusion of the study summarized at the end of one year.

Analysis

Statistical analysis

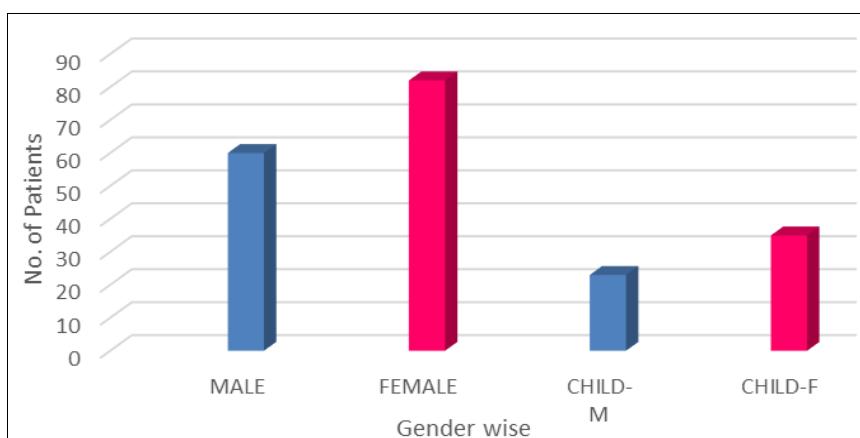


Fig 1: Gender wise distribution

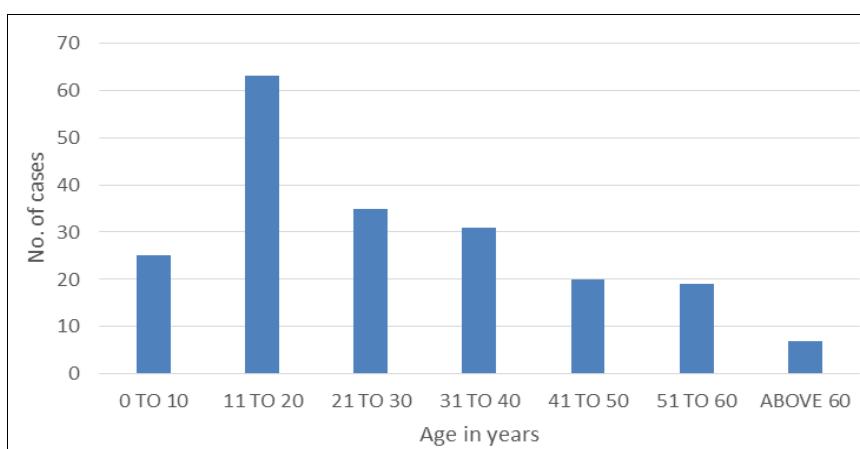
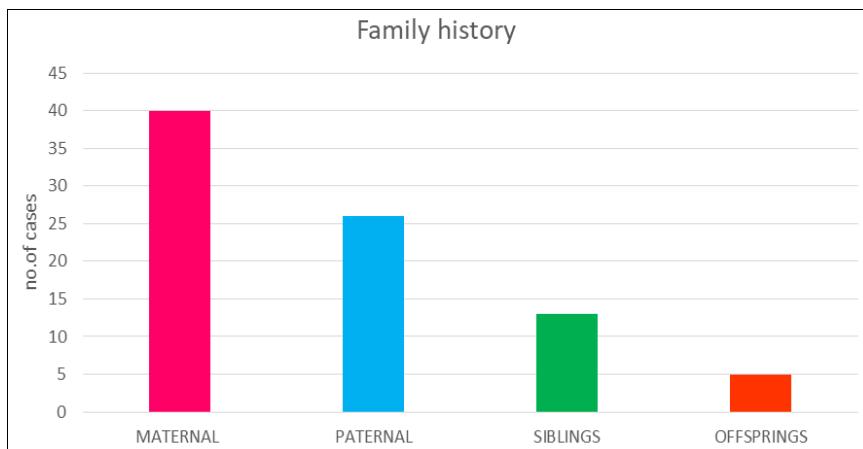
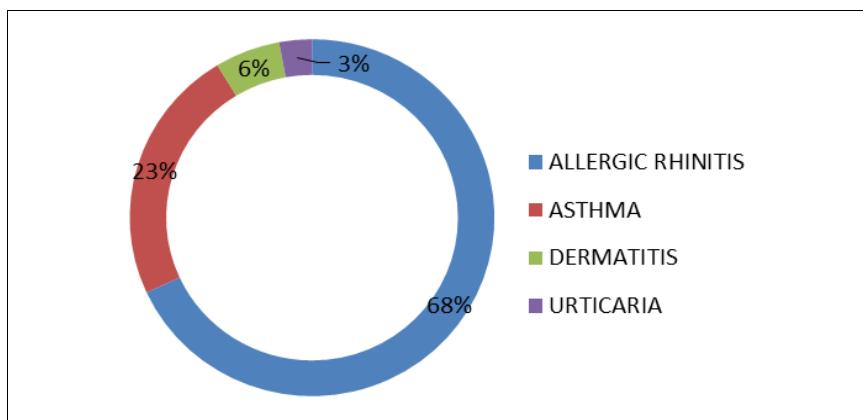
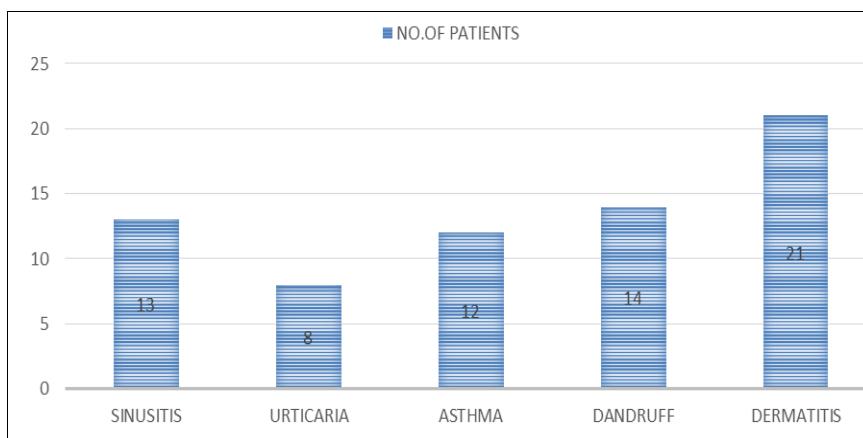
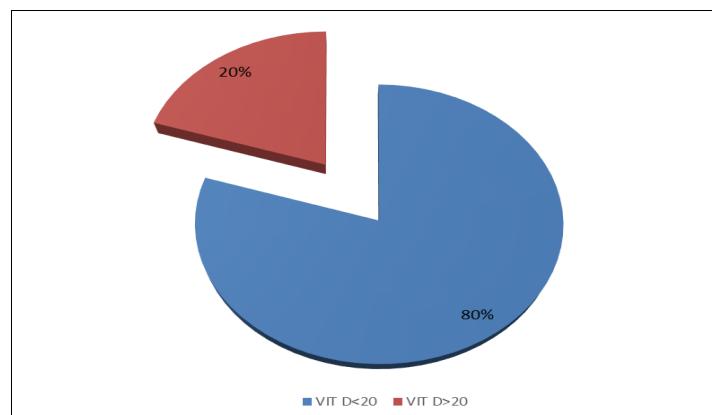


Fig 2: Age wise distribution

**Fig 3:** Family history**Fig 4:** Family history of different allergic conditions**Fig 5:** Association with other allergic conditions and sinusitis**Fig 5:** Association with Vitamin D deficiency

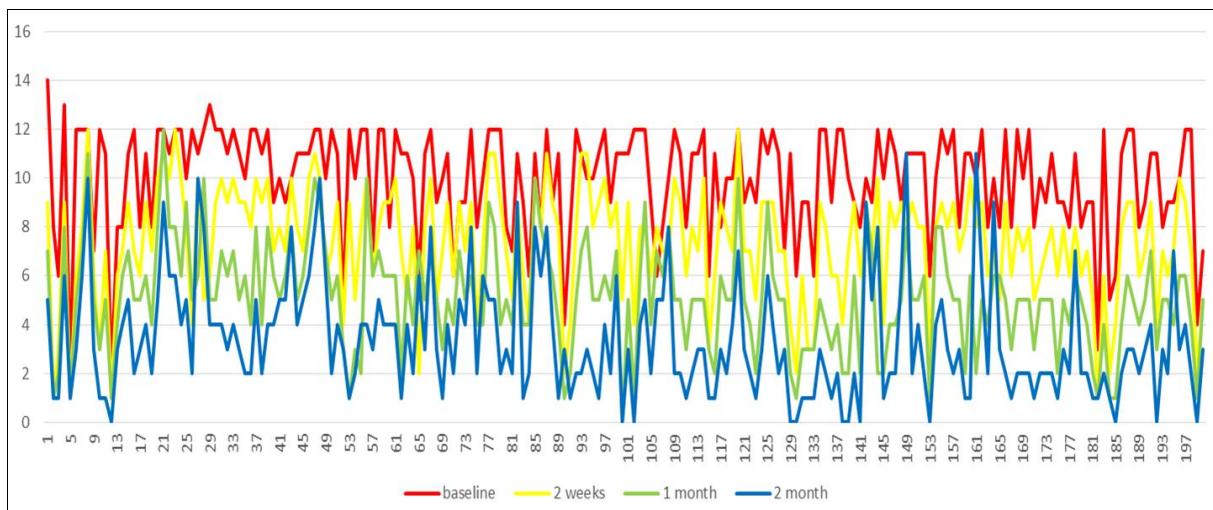


Fig 6: TNSS Score of 200 patients

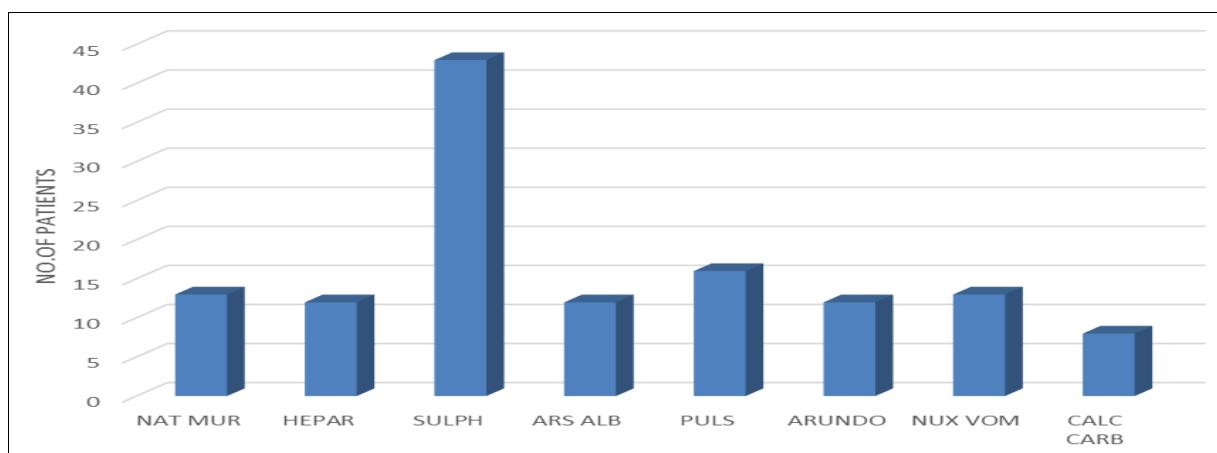


Fig 7: Frequency of medicines indicated

Results

To perform the normality test of the variables, we typically want to check if the data follows a normal distribution. This can be done using statistical tests. The Kolmogorov-Smirnov test is one of the most commonly used tests for

normality if the sample size is greater than 100. The null hypothesis for this test is that the data follows a normal distribution. If the p-value is less than a chosen significance level (e.g., 0.05), reject the null hypothesis and conclude that the data is not normal.

Table 1: Tests of normality of the variable

	Tests of Normality					
	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	DF	Sig.	Statistic	DF	Sig.
baseline	.207	200	.000	.871	200	.000
2 week	.141	200	.000	.950	200	.000
1 month	.138	200	.000	.968	200	.000
2 month	.168	200	.000	.907	200	.000

a. Lilliefors Significance Correction

From the table in this study to check the normality of the variables baseline, after 2 week, 1 month and 2 month a statistical test called Kolmogorov-Smirnov Test is applied

and they are all significant ($p < .05$). Hence, we reject the null hypothesis and conclude that these study variables are not normal.

Table 2: Descriptive statistics of the variables

	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25th	50th (Median)	75th
baseline	200	10.01	2.168	2	14	9.00	11.00	12.00
2 week	200	7.34	2.331	1	12	6.00	8.00	9.00
1 month	200	5.10	2.218	0	12	4.00	5.00	6.00
2 month	200	3.38	2.403	0	11	2.00	3.00	5.00

From the table the mean baseline score is 10.01, after two weeks the mean score becomes 7.34, after 1 month the mean score becomes 5.10 and after two months the men score becomes 3.38. The mean and median score is gradually reducing from the baseline score. Hence the observed difference is tested by a statistical test. The distribution is not normal hence a non-parametric test called Wilcoxon Signed Rank Test which is equivalent to a parametric test

called paired t-test is applied.

Testing of Hypothesis

Null Hypothesis: There is no significant difference in the TNSS score on baseline and follow up periods.

Alternative Hypothesis: There is a significant difference in the TNSS score on baseline and follow up periods.

Table 3: Wilcoxon signed rank test results of multiple comparison

Wilcoxon Signed Ranks				
		N	Mean Rank	Sum of Ranks
2 week-baseline	Negative Ranks	183 ^a	95.50	17477.00
	Positive Ranks	4 ^b	25.25	101.00
	Ties	13 ^c		
	Total	200		
1 month-baseline	Negative Ranks	196 ^d	100.46	19691.00
	Positive Ranks	2 ^e	5.00	10.00
	Ties	2 ^f		
	Total	200		
2 month-baseline	Negative Ranks	197 ^g	99.98	19697.00
	Positive Ranks	1 ^h	4.00	4.00
	Ties	2 ⁱ		
	Total	200		
1 month-2 week	Negative Ranks	169 ^j	93.33	15773.50
	Positive Ranks	11 ^k	46.95	516.50
	Ties	20 ^l		
	Total	200		
2 month-2 week	Negative Ranks	184 ^m	99.17	18246.50
	Positive Ranks	8 ⁿ	35.19	281.50
	Ties	8 ^o		
	Total	200		
2 month-1 month	Negative Ranks	172 ^p	95.46	16418.50
	Positive Ranks	17 ^q	90.38	1536.50
	Ties	11 ^r		
	Total	200		
a. 2 week < baseline				
b. 2 week > baseline				
c. 2 week =baseline				
d. 1 month < baseline				
e. 1 month > baseline				
f. 1 month = baseline				
g. 2 month < baseline				
h. 2 month > baseline				
i. 2 month = baseline				
j. 1 month < 2 week				
k. 1 month > 2 week				
l. 1 month = 2 week				
m. 2 month < 2 week				
n. 2 month > 2 week				
o. 2 month = 2 week				
p. 2 month < 1 month				
q. 2 month > 1 month				
r. 2 month = 1 month				

Table 4: Significant test result of the variables

	Test Statistics ^a					
	2 week-baseline	1 month-baseline	2 month-baseline	1 month-2 week	2 month-2 week	2 month-1 month
Z	-11.815 ^b	-12.216 ^b	-12.219 ^b	-10.967 ^b	-11.688 ^b	-10.040 ^b
Asymp. Sig. (2-tailed)	.000	.000	.000	.000	.000	.000
a. Wilcoxon Signed Ranks Test						
b. Based on positive ranks.						

In the homeopathic treatment for comparing the TNSS score at baseline and after 2nd weeks, out of 200 subjects 183 subjects have an observed TNSS Score is less after the 2nd weeks as compared to baseline score, 4 subjects have TNSS score 2nd week is greater than baseline score and 2 subjects

have ties. The observed difference in TNSS score was statistically significant on Wilcoxon Signed Rank test ($z=-11.82$, $P=0.000$). Since the P-value was less than the specified significance level of 0.05, the test results were highly statistically significant and have strong evidence

against the null hypothesis. Hence reject the null hypothesis and conclude that there is significant change in the TNSS score of patients after the 2nd week as compared to baseline after the administration of homoeopathic medicine.

Comparison between baseline and 1st month

In the homeopathic treatment for comparing the TNSS score at baseline and after 1st month, out of 200 subjects 196 subjects have an observed TNSS Score is less after the 1st month as compared to baseline score, 2 subjects have TNSS score 1st month is greater than baseline score and 2 subjects have ties. The observed difference in TNSS score was statistically significant on Wilcoxon Signed Rank test ($z=-12.216$, $P=0.000$). Since the P-value was less than the specified significance level of 0.05, the test results were highly statistically significant and have strong evidence against the null hypothesis. Hence reject the null hypothesis and conclude that there is significant change in the TNSS score of patients after the 1st month as compared to baseline after the administration of homoeopathic medicine.

Comparison between baseline and 2nd month

In the homeopathic treatment for comparing the TNSS score at baseline and after 2nd month, out of 200 subjects 197 subjects have an observed TNSS Score is less after the 2nd month as compared to baseline score, 1 subject has TNSS score 2nd month is greater than baseline score and 2 subjects have ties. The observed difference in TNSS score was statistically significant on Wilcoxon Signed Rank test ($z=-12.219$, $P=0.000$). Since the P-value was less than the specified significance level of 0.05, the test results were highly statistically significant and have strong evidence against the null hypothesis. Hence reject the null hypothesis and conclude that there is significant change in the TNSS score of patients after the 2nd month as compared to baseline after the administration of homoeopathic medicine.

Comparison between 2nd week and 1st month

In the homeopathic treatment for comparing the TNSS score at 2nd week and after 1st month, out of 200 subjects 169 subjects have an observed TNSS Score is less after the 1st month as compared to 2nd week, 11 subjects have TNSS score 1st month is greater than 2nd week and 20 subjects have ties. The observed difference in TNSS score was

statistically significant on Wilcoxon Signed Rank test ($z=-10.967$, $P=0.000$). Since the P-value was less than the specified significance level of 0.05, the test results were highly statistically significant and have strong evidence against the null hypothesis. Hence reject the null hypothesis and conclude that there is significant change in the TNSS score of patients after the 1st month as compared to 2nd week after the administration of homoeopathic medicine.

Comparison between 2nd week and 2nd month

In the homeopathic treatment for comparing the TNSS score at 2nd week and after 2nd month, out of 200 subjects 184 subjects have an observed TNSS Score is less after the 2nd month as compared to 2nd week, 8 subjects have TNSS score 2nd month is greater than 2nd week and 8 subjects have ties. The observed difference in TNSS score was statistically significant on Wilcoxon Signed Rank test ($z=-11.688$, $P=0.000$). Since the P-value was less than the specified significance level of 0.05, the test results were highly statistically significant and have strong evidence against the null hypothesis. Hence reject the null hypothesis and conclude that there is significant change in the TNSS score of patients after the 2nd month as compared to 2nd week after the administration of homoeopathic medicine

Comparison between 1st month and 2nd month

In the homeopathic treatment for comparing the TNSS score at 1st month and after 2nd month, out of 200 subjects 172 subjects have an observed TNSS Score is less after the 2nd month as compared to 1st month, 17 subjects have TNSS score 2nd month is greater than 1st month and 11 subjects have ties. The observed difference in TNSS score was statistically significant on Wilcoxon Signed Rank test ($z=-10.040$, $P=0.000$). Since the P-value was less than the specified significance level of 0.05, the test results were highly statistically significant and have strong evidence against the null hypothesis. Hence reject the null hypothesis and conclude that there is significant change in the TNSS score of patients after the 2nd month as compared 1st month after the administration of homoeopathic medicine

Fig: Comparison of median TNSS score for different follow up periods.

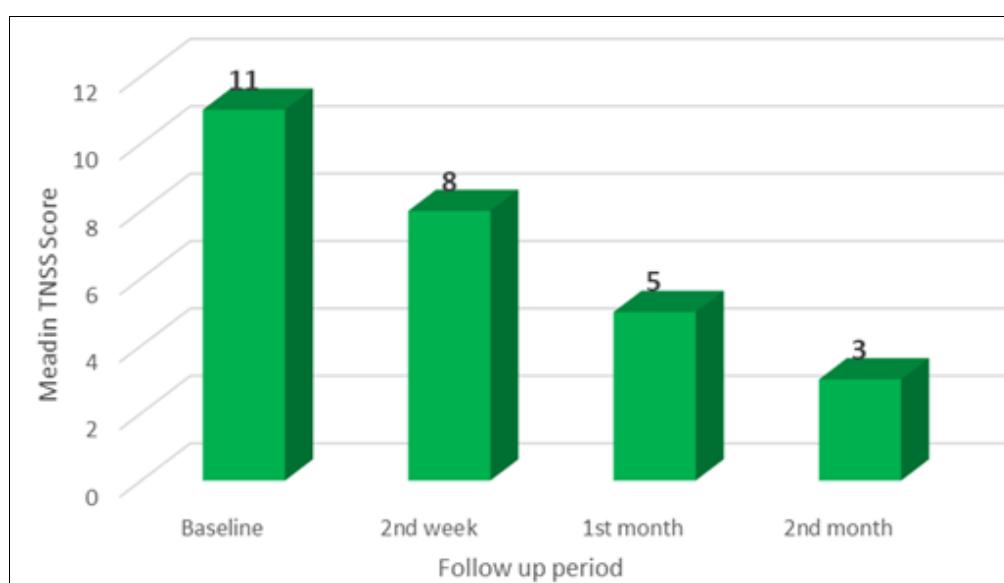


Fig 8: Comparison of Median TNSS score

Results

To perform the normality test of the variables, we typically want to check if the data follows a normal distribution. This can be done using statistical tests. The Shapiro-Wilks test is one of the most commonly used tests for normality if the

sample size is less than 50. The null hypothesis for this test is that the data follows a normal distribution. If the p-value is less than a chosen significance level (e.g., 0.05), reject the null hypothesis and conclude that the data is not normal

Table 5: Tests of normality of the variable

Tests of Normality						
	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	DF	Sig.	Statistic	DF	Sig.
TNSS First Visit	.227	25	.002	.871	25	.005
TNSS Second Visit	.250	25	.000	.727	25	.000
IGE First Visit	.230	25	.001	.752	25	.000
IGE Second Visit	.166	25	.072	.878	25	.006
AEC First Visit	.136	25	.200*	.939	25	.142
AEC Second Visit	.167	25	.070	.903	25	.021

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

From the table in this study to check the normality of the variables TNSS, IGE and AEC for first and second visit a statistical test called Shapiro Wilks Test is applied and they are all significant ($p<.05$) except AEC first visit. In general we reject the null hypothesis and conclude that these study variables are not normal.

Testing of Hypothesis-TNSS value

Null Hypothesis: There is no significant difference in the TNSS values during the first visit and second visit.

Alternative Hypothesis: There is a significant difference in the TNSS values during the first visit and second visit.

Table 6: Descriptive statistics of TNSS value

	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25 th	50 th (Median)	75 th
TNSS First Visit	25	9.84	2.135	4	12	8.00	11.00	11.50
TNSS Second Visit	25	2.24	2.026	0	8	1.00	1.00	3.00

From the table the mean TNSS value for the first visit is 9.84 and after 2nd visit the mean value becomes 2.24, the mean and median score is gradually reducing from the first visit. Hence the observed difference is tested by a statistical

test. The distribution is not normal hence a non-parametric test called Wilcoxon Signed Rank Test which is equivalent to a parametric test called paired t-test is applied.

Table 7: The ranking of the Wilcoxon signed rank test

Ranks		N	Mean Rank	Sum of Ranks
TNSS Second Visit-TNSS First Visit	Negative Ranks	25 ^a	13.00	325.00
	Positive Ranks	0 ^b	.00	.00
	Ties	0 ^c		
	Total	25		

a. TNSS Second Visit < TNSS First Visit
b. TNSS Second Visit > TNSS First Visit
c. TNSS Second Visit =TNSS First Visit

Table 8: Significant test of TNSS value

Test Statistics ^a	
	IGE Second Visit-IGE First Visit
Z	-2.099 ^b
Asymp. Sig. (2-tailed)	.036
a. Wilcoxon Signed Ranks Test	
b. Based on positive ranks.	

In the homeopathic treatment for comparing the TNSS values of 1st visit and after 2nd visit, out of 25 subjects all 25 subjects have an observed TNSS value less after the 2nd visit

as compared to 1st visit, no subject has TNSS score 2nd visit is greater than 1st visit and no subject has ties. The observed difference in TNSS value was statistically significant on Wilcoxon Signed Rank test ($z=-2.099$, $P=0.036$). Since the P-value was less than the specified significance level of 0.05, the test results were highly statistically significant and have strong evidence against the null hypothesis. Hence reject the null hypothesis and conclude that there is a significant difference in the TNSS values during the first visit and second visit after the administration of the homeopathic medicine.

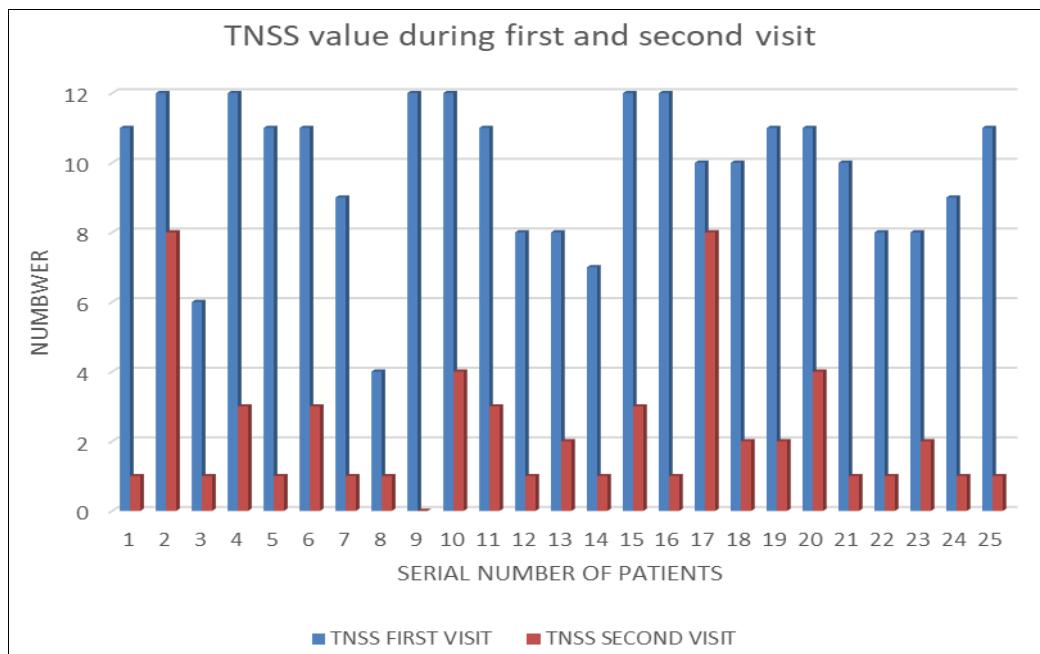


Fig 9: Bar diagram showing TNSS during first and second visit

Testing of Hypothesis-IGE value

- **Null Hypothesis:** There is no significant difference in the IGE values during the first visit and second visit.

- **Alternative Hypothesis:** There is a significant difference in the IGE values during the first visit and second visit.

Table 9: Descriptive statistics for IGE values

	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25 th	50 th (Median)	75 th
IGE First Visit	25	1181.82	1317.97	141.2	5410.0	348.30	619.20	1781.60
IGE Second Visit	25	822.01	661.86	106.0	2500.0	298.70	573.40	1203.50

From the table the mean IGE value for the first visit is 1181.82 and after the 2nd visit the mean value becomes 822.01, the mean and median score is gradually reducing from the first visit. Hence the observed difference is tested

by a statistical test. The distribution is not normal hence a non-parametric test called Wilcoxon Signed Rank Test which is equivalent to a parametric test called paired t-test is applied.

Table 10: Wilcoxon signed rank test result of IGE values

Ranks			
IGE Second Visit-IGE First Visit	Negative Ranks	N	Mean Rank
	Positive Ranks	6 ^b	11.50
	Ties	2 ^c	
	Total	25	
	a. IGE Second Visit < IGE First Visit b. IGE Second Visit > IGE First Visit c. IGE Second Visit =IGE First Visit		

Table 11: Wilcoxon signed rank test result

Test Statistics ^a	
Z	-2.099 ^b
Asymp. Sig. (2-tailed)	.036
a. Wilcoxon Signed Ranks Test	
b. Based on positive ranks.	

In the homeopathic treatment for comparing the IGE values of 1st visit and after 2nd visit, out of 25 subjects 17 subjects have an observed IGE value less after the 2nd visit as compared to 1st visit, 6 subjects have IGE score 2nd visit is greater than 1st visit and only 2 subjects have ties. The

observed difference in IGE value was statistically significant on Wilcoxon Signed Rank test ($z=-2.099$, $P=0.036$). Since the P-value was less than the specified significance level of 0.05, the test results were highly statistically significant and have strong evidence against the

null hypothesis. Hence reject the null hypothesis and conclude that there is a significant difference in the IGE

values during the first visit and second visit after the administration of the homeopathic medicine.

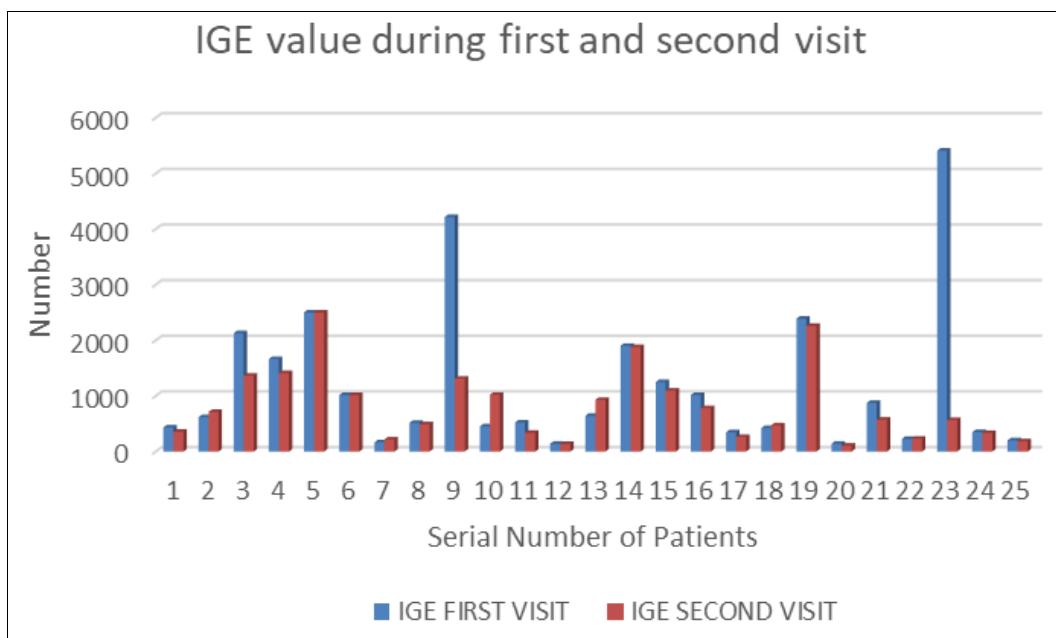


Fig 10: Bar diagram showing IGE during first and second visit

Testing of Hypothesis-IGE value

- **Null Hypothesis:** There is no significant difference in the AEC values during the first visit and second visit.

- **Alternative Hypothesis:** There is a significant difference in the AEC values during the first visit and second visit.

Table 12: Descriptive statistics for the variable AEC

	N	Descriptive Statistics		Minimum	Maximum	Percentiles		
		Mean	Std. Deviation			25 th	50 th (Median)	75 th
AEC First Visit	25	572.08	326.434	100	1500	280.50	600.00	705.00
AEC Second Visit	25	490.72	284.935	100	1000	300.00	400.00	700.00

From the table the mean AEC value for the first visit is 572.08 and after the 2nd visit the mean value becomes 490.72, the mean and median score is gradually reducing from the first visit. Hence the observed difference is tested by a

statistical test. The distribution is not normal hence a non-parametric test called wilcoxon signed rank test which is equivalent to a parametric test called paired t-test is applied.

Table 13: Wilcoxon signed rank test result

		Ranks		
		N	Mean Rank	Sum of Ranks
AEC Second Visit-AEC First Visit	Negative Ranks	16 ^a	9.97	159.50
	Positive Ranks	4 ^b	12.63	50.50
	Ties	5 ^c		
	Total	25		
a. AEC Second Visit < AEC First Visit				
b. AEC Second Visit > AEC First Visit				
c. AEC Second Visit = AEC First Visit				

Table 14: Significant test result

Test Statistics ^a		AEC Second Visit-AEC First Visit
Z		-2.038 ^b
Asymp. Sig. (2-tailed)		.042
a. Wilcoxon Signed Ranks Test		
b. Based on positive ranks.		

In the homeopathic treatment for comparing the AEC values of 1st visit and after 2nd visit, out of 25 subjects 16 subjects have an observed AEC value less after the 2nd visit as

compared to 1st visit, 4 subjects have IGE score 2nd visit is greater than 1st visit and 5 subjects have ties. The observed difference in AEC value was statistically significant on

Wilcoxon Signed Rank test ($z=-2.038$, $P=0.042$). Since the P-value was less than the specified significance level of 0.05, the test results were highly statistically significant and have strong evidence against the null hypothesis. Hence

reject the null hypothesis and conclude that there is a significant difference in the AEC values during the first visit and second visit after the administration of the homeopathic medicine.

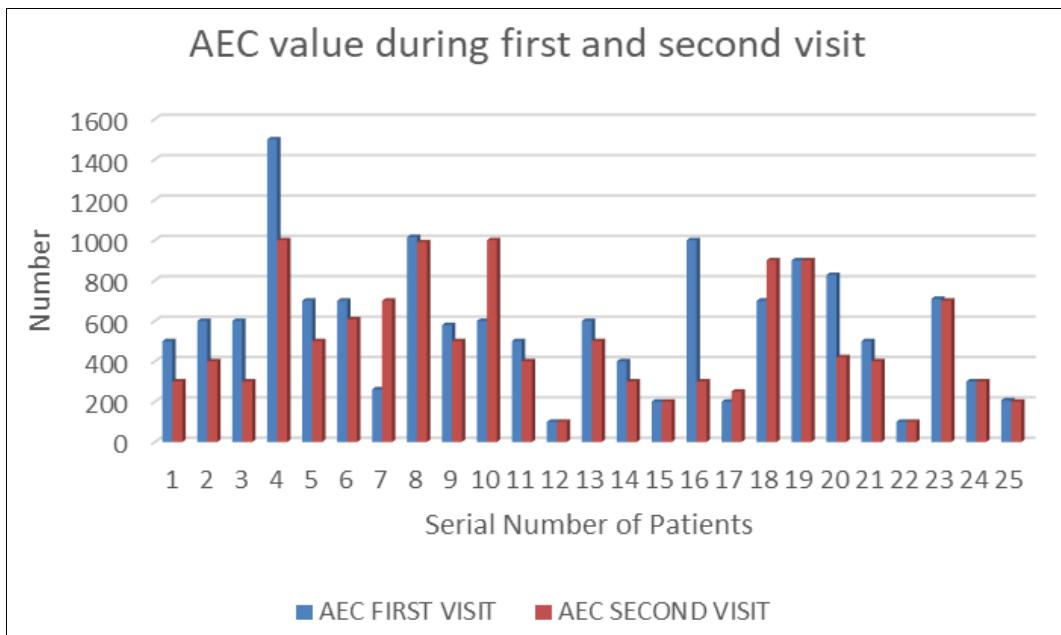


Fig 11: Bar diagram showing AEC during first and second visit

Table 15: Correlation between TNSS, IgE and AEC values

Correlations			TNSS	IgE	AEC
Spearman's rho	TNSS	Correlation Coefficient	1.000	.234	.132
		Sig. (2-tailed)	.	.260	.530
		N	25	25	25
	IgE	Correlation Coefficient	.234	1.000	.378
		Sig. (2-tailed)	.260	.	.063
		N	25	25	25
	AEC	Correlation Coefficient	.132	.378	1.000
		Sig. (2-tailed)	.530	.063	.
		N	25	25	25

From the table there is no statistically significant correlation between these variables.

Discussion

Statistical analysis of symptom score at first visit and after 2 weeks, shows there is significant change in the TNSS score of patients after the 2nd week as compared to baseline after the administration of homoeopathic medicine.

Statistical analysis of symptom score at first visit and after 1 month, shows there is significant change in the TNSS score of patients after 1 month as compared to baseline after the administration of homoeopathic medicine.

Statistical analysis of symptom score at first visit and after 2 months, shows there is significant change in the TNSS score of patients after the 2nd month as compared to baseline after the administration of homoeopathic medicine.

Statistical analysis of IgE shows there is a significant difference in the IgE values during the first visit and after 6 months after the administration of the homeopathic medicine.

Statistical analysis of AEC shows there is a significant difference in the AEC values during the first visit and after 6 months after the administration of the homeopathic

medicine.

80% of the cases had associated Vitamin D deficiency.

There is no significant correlation between TNSS, IgE and AEC

Conclusion

Allergic rhinitis can be effectively managed with Homoeopathic treatment.

Though IgE and AEC take much time to attain normal level, statistically significant reduction can be attained in values 6 months after the administration of Homoeopathic medicines. Symptoms can be effectively managed within 2 weeks after the administration of appropriate homoeopathic medicines through individualization

As the study is continuing the time taken to attain the normal level of IgE and AEC shall be studied.

Recommendation

- Effective analysis of effect on IgE and AEC and attainment of normalcy can only be done after a long time study with large sample size.
- Analysis of effect on other allergic conditions like allergic asthma, allergic dermatitis, urticaria and anaphylactic reaction also need to be studied.

Conflict of Interest

Not available

Financial Support

Not available

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