"TO ASSESS CLINICAL PRESENTATION OF ATOPIC DERMATITIS IN CHILDREN & ITS HOMOEPATHIC MANAGEMENT WITH THE AID OF SYNTHESIS REPERTORY(9.1) - AN OPEN LABEL TRIAL"

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ABSTRACT

Atopic dermatitis, also known as atopic eczema, affects a large proportion of children and is most common in infants, where it occurs in 20% of those under two years of age (1–3 year) Over the past 30 years, a twofold to threefold increase in paediatric atopic dermatitis has been reported. Most children develop atopic dermatitis before the age of two years. Significant morbidity associated with atopic dermatitis can be prevented with early diagnosis and treatment.

INTRODUCTION

Atopic dermatitis, also known as atopic eczema, affects a large proportion of children and is most common in infants, where it occurs in 20% of those under two years of age (1–3 year) Over the past 30 years, a twofold to threefold increase in paediatric atopic dermatitis has been reported. Most children develop atopic dermatitis before the age of two years. Significant morbidity associated with atopic dermatitis can be prevented with early diagnosis and treatment.[1]

AIMS AND OBJECTS

AIM

To assess the role of individualized homoeopathic medicines in cases of a topic dermatitisin children with the aid of synthesis repertory 9.1.

OBJECTIVES

1. To identify the clinical presentation in cases of atopic dermatitis
2. To assess the role of individualized homoeopathic medicines in cases of atopic dermatitis inchildren with aid of synthesis repertory 9.1 & Pre and post treatment – EASI scores.

Justification for study

Atopic Dermatitis is more common in children between the ages of 2 to 4 years. The prevalence of Atopic Dermatitis is estimated to be 15-20% in children and 1-3% in adults, and the incidence has increased by 2 to 3-fold during the past decades in industrialized countries. 16.8% of adults with Eczema experience onset after adolescence. AtopicDermatitis commonly resolves by the time a child reaches adulthood; however, approximately 10% to 30% of patients will continue to have symptoms of disease. A 2014prospective cohort study of children with mild-to- moderate eczema reported that, at any age, including up to 26 years of age, 80% of participants with ≥5 years of follow-up continued to have symptoms or had continued using medications for their atopic dermatitis.[2] Homoeopathy treats the person as a whole. It means that homoeopathic treatment focuses on the patient as a person, as well as his pathological condition. For individualization, causes of disease in that particular individual is a very important aspect. These causative factors are dependent upon the individual susceptibility of the patient andit varies from individual to individual. It can be of anything like allergens, places, situationsetc. The use of homoeopathic medicine has been limited in atopic dermatitis limited largerly due to limited proving. there are no one previous study show any significant resultin cure of atopic dermatitis with homoeopathy. This study is an attempt to assess the usefulness of homoeopathic medicines in the case of atopic dermatitis. This is a attempt tostudy and evaluate the significance of these rubrics in Synthesis Repertory 9.1 of Dr. Frederik Schroyens.[3]

MATERIALS AND METHODS

STUDY SETTING:- The present study was undertaken at OPD /IPD of M.N. Homoeopathic Medical College & R.I. Bikaner, Rajasthan.

STUDY DURATION:- The study was undertaken for a period of12 months out of which cases were registered in first 6 months and each case was follow up for a period of 3 months, and analysis of case for a period of 3 months.

SELECTION OF SAMPLES SIZE AND SAMPLING TECHNIQUE:- sample size–80

Considering 11% margin of error at 95% confidence interval, sample size for the study is 76. And considering 5% dropouts, total sample size for the study is 80 patients

INCLUSION / EXCLUSION CRITERIA

Diagnosis: - Pre diagnosed cases

Inclusion Criteria

1. Pre diagnosed cases of atopic dermatitis.

2. Children of age group 2-15year.

3. Patient willing to give voluntary informed consent and assent for the study.
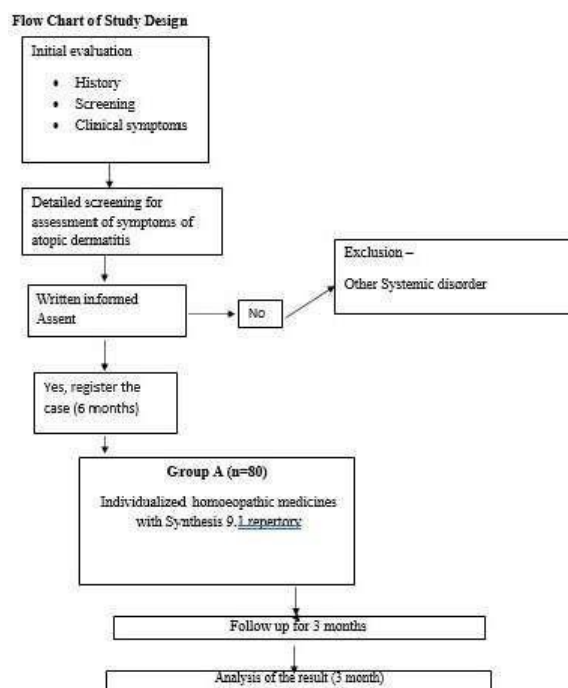
Exclusion Criteria

Patients with other Systemic disorders were excluded from the study.

Drop out

o Patients who discontinue treatment in between or without proper follow-up will Be dropped out from the study.

o The cases requiring emergency treatment.

Study Design

An open label study, single arm, non randomized trial.

Flow Chart of Study Design

EASI SCORE

Figure 5: Flow chart of study design

An EASI score is a tool used to measure the extent (area) and severity of atopic eczema (Eczema Area and Severity Index).

Body regions

There are four body regions

· Head and neck

o Face occupies 33% (17% each side), neck 33% (17% front and back) and scalp 33% of the head and neck region.

· Trunk (including genital area)

o Front occupies 55% and back 45% of the trunk.

· Upper limbs.

o Each arm occupies 50% of the upper limbs region (front or back of one arm is 25%).

· Lower limbs (including buttocks).

o Each leg occupies 45% (front or back of one leg is 22.5%) and buttocks 10% of the lower limbs region.

Area score

Area score is recorded for each of the four regions of the body. The area score is the percentage of skin affected by eczema for each body region.

Area score	Percentage of skin affected by eczema in each region
0	No active eczema in this region
1	1–9%
2	10–29%
3	30–49%
4	50–69%
5	70–89%
6	90–100%: the entire region is affected by eczema

Figure 6: Area score.

Severity score

Severity score is recorded for each of the four regions of the body. The severity score is the sum of the intensity scores for four signs. The four signs are:

1. Redness (erythema, inflammation)

2. Thickness (induration, papulation, swelling—acute eczema)

3. Scratching (excoriation)

4. Lichenification (lined skin, furrowing, prurigo nodules—chronic eczema).

The *average* intensity of each sign in each body region is assessed as: none (0), mild

(1) Moderate

(2) and severe (3).

Score	Intensity of redness, thickness/swelling, scratching, lichenification
0	None, absent
1	Mild (just perceptible)
2	Moderate (obvious)
3	Severe

Figure 7: Severity score.

Calculations

For each region, record the intensity for each of four signs and calculate the severityscore.

·   Severity score = redness intensity + thickness intensity + scratching intensity
    + lichenification intensity For each region, multiple the severity score by the area score
    and by a multiplier. The multiplier is different for each body site.

·   Head and neck: severity score x area score x 0.1 (in children 0–7 years, x0.2)

·   Trunk: severity score x area score x 0.3

·   Upper limbs: severity score x area score x 0.2

·   Lower limbs: severity score x area score x 0.4 (in children 0–7 years, x 0.3)

Add up the total scores for each region to determine the final EASI score.The minimum EASI score is 0 and the maximum EASI score is 72.[4]

Intervention

Individualised Homoeopathic medicines:

√   **Selection of medicine**: The similimum was selected on the individualization of the patient as per the causation, in consultation with the repertory of Synthesis Repertory 9.1.

√   **Potency selection**: As per case with consultation from Hahnemann Guidelines in fifth edition of organon of Medicine

√   **Repetition:** As per Hahnemann Guidelines in fifth edition of Organon of Medicine

√   **Procurement of medicine:** The medicines was procured from the pharmacy having the Good Manufacturing Practices certificate.

Selection of tools
- Case report form
- Software–RADAROpus10 - Synthesis repertory9.1
- EASI Score
- Software–SPSS

Data collection– Recording of Data

Data was recorded in approved Case taking proforma (Appendix C) Centralised data was collected in approved master chart in proper excel format.

Confidentiality – All the evaluation forms, reports and records were kept in locked file cabinet. The patient had issued a unique identification number. Any information about the patient was not be leaked out until required.

Maintenance – There were forms that were completed by each subject recruitment, including Assent forms for the patients information and his / her OR parents written Assent for the enrolment in the study. These were updated from time to time.

Data analysis–Data was analyzed as per the guidelines of reporting on homoeopathy treatments. Data analysis was done using excel.

Statistical Technique – Paired t- test was used to compare before & after score in single group.

Investigation

CBC.

Ethical Issues – Ethical clearance was obtained from the Institutional EthicsCommittee.

STATISTICAL ANALYSIS

STATISTICAL TOOL

In order to accomplish the goal sample size 80 were collected. The statistical tools used are paired t-test. The analysis has been done on IBMSPSS 20.0.

In this study sample size 80 is taken, degree of freedom (n1+n2 - 1) is 79 and level of significance is α = 0.000.

Paired t-test = tcal =

=Σni=1 d1And sd

d.f   = n-1=80-1=79

n   = Total no. of patient

d   = mean of sample

t tab at α = 0.000 with degree of freedom = n-1 = 79d.f. = n-1 = 80-1 = 79

n = Total number of Patients. d = mean of sample t tab at α = 0.000 with degree offreedom= n-1 = 79

Paired Samples Statistics		Mean	N	Std. Deviation	Std. ErrorMean
Pair 1	VAR00001	22.2375	80	9.07248	1.01433
	VAR00002	13.2625	80	7.64521	.85476
Paired Samples Correlations		N	Correlation	Sig.	
Pair 1	VAR00001 & VAR00002	80	.358	.001	

TABLE - 6

Paired Samples Test									
		Paired Differences					t	df	Sig. (2 tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	VAR00001 - VAR00002	8.97500	9.54268	1.06690	6.85138	11.09862	8.412	79	.000

According to the paired sample calculated for the means scored, After mean for EASI Score was 13.26 as compared to before mean for EASI Score as 22.33 at 0.001 significance. Thus rejecting the null hypothesis that ―No significant role of homoeopathicmedicine selected with the aid of synthesis repertory 9.1 in children case of atopic dermatitis ‖, and accepting the alternate Hypothesis- ―significant role of homoeopathic medicine selected with the aid of synthesis repertory 9.1 in children case of atopic dermatitis.

DISCUSSION

The study "TO ASSESS CLINICAL PRESENTATION OF ATOPIC DERMATITISIN CHILDREN & ITS HOMOEPATHIC MANAGEMENT WITH THE AID OF SYNTHESIS REPERTORY (9.1) - AN OPEN LABEL

TRIAL‖ was undertaken to assess the clinico- epidemiological profile of *Atopic Dermatitis.*

A Discussion on the interpretations derived from the study has been given below

As shown in given figure 8 among the 80 cases of atopic dermatitis, 41 cases(51.25%) were from age group of 7-12 yrs, 36(45%) cases were from age group of 2-6 yrs and 3 cases(3.75) were from 12-15 yrs of age group.Maximum incidence was seen in age group of 7-12 years, similar result foundin study of Virendra N Sehgal (Atopic dermatitis: A cross-sectional (descriptive) study of 100 cases) Its overall (new and old) prevalence was 0.98%, while that of new patients was 0.24%. 83 (83%) were in the age groupof 2-12 years.[5]

As shown in fig (5), among the 80 cases of *Atopic Dermatitis* male child weremore affected than female child. As shown in above figure (5), among the 80cases of *Atopic Dermatitis* 47 (65%)cases were male child; 33 (35%) cases were female child. similar result found in study of Virendra N Sehgal (Atopicdermatitis: A cross-sectional (descriptive) study of 100 cases) which show 54(83.1%) were males and 29 (82.9%) were female.[5]

As shown in above figure (6), among the 80 cases of *Atopic Dermatitis*, 34 (42.5%) cases were from urban area and 46 (57.5%) cases were from rural area.[5]

As shown in figure (7), among 80 cases of atopic dermatitis maximum cases were of 25 (17 %) were of upper socio economic status a n d middle socio economic status 29 (52%) cases, and 26 (31%) cases of lower socio economicstatus.[5]

As shown in above table (2), among the 80 cases of *Atopic Dermatitis* 6 (20%)cases showed

marked improvement, 25(23.3 %) cases showed moderate improvement, 28 (16.7%) cases showed mild improvement, 15 (35%)cases were show no significant result, 06 (5%) worse cases were showed.

As shown in above table (3) among the 80 cases of *Atopic Dermatitis* indicated medicine cases were – 18 cases of Ars. Alb, 5 cases of Graphites, 8 cases of Mezerium, 17 cases of Sulphur, 3 cases of Antim Crud, 4 cases of Hepar sulph, 3 cases of Rhus tox, 8 cases of Psorinum, 2 cases of each medicine – Calc carb, Arum triph, Anagallis, and 1 cases of each medicines – Silicea, Calendula, Kali sulph And Pix liquidia.

SUMMARY AND CONCLUSION

Homoeopathic the study "To Assess Clinical Presentation Of Atopic Dermatitis In Children & Its Homoepathic Management With The Aid Of Synthesis Repertory (9.1) - An Open Label Trial" in case of atopic dermatitis it is evident that individualized homoeopathic medicines are effective as they give symptomatic relief to patients suffering from atopic dermatitis and improving the EASI grading scale.

The most common indicated medicine prescribed on the basis of totality by using synthesis repertoty 9.1 are Ars. Alb, Graphites, Mezerium, Sulphur, Antim Crud, Hepar sulph, Rhus tox, Psorinum showed improvement and clinical presentation of atopic dermatitis was also assessed in this study.

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