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ORIGINAL ARTICLE

EFFECT OF HOMOEOPATHIC MEDICINE ON QUALITY OF LIFE IN CHILDREN WITH ATOPIC DERMATITIS: A PROSPECTIVE OBSERVATIONAL STUDY

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Abstract

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Key Word- Atopic dermatitis, CDLQI, SCORAD, Prospective observational study, Paired 't' test, Hanifin and Rajka's diagnostic criteria.

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Background: Atopic dermatitis (AD) is an acute, subacute, chronic, relapsing, endogenous non-inflammatory disease, characterized by dry skin and recurrent, pruritic, symmetric dermatitic lesions. It is the commonest form of dermatitis in children. Homoeopathic medicines have been used frequently to treat it and have shown good results. **Methodology:** A prospective observational study was conducted on 30 patients seen at OPD/IPD and nearby schools of Bakson Homoeopathic Medical College and Hospital (BHMC&H), Greater Noida, Uttar Pradesh and Homoeopathic OPD of ESIC Hospital, Sahibabad on both sexes of age group of 4-16 years, meeting Hanifin and Rajka's diagnostic criteria. Homoeopathic medicines were prescribed after proper case taking and on the basis of individualisation. Quality of life in children with AD was evaluated by Children's Dermatology Life Quality Index (CDLQI) scale and SCORing Atopic Dermatitis (SCORAD) index was used to evaluate symptom severity of the disease. Data of all patients were recorded and were statistically analysed by using Paired 't' test. **Results:** Out of 33 patients enrolled, 3 dropped out and follow-up of 30 patients was obtained with changes in CDLQI and SCORAD score. Significant differences were found comparing the first prescription and last follow up. The results were, out of 30 cases, 26 cases (86.67%) recovered, in 4 cases aggravation was seen i.e., disease condition worsened (13.34%).

Conclusion: Homoeopathic medicines have a significant role in improving Quality of life in children with Atopic dermatitis.

INTRODUCTION

“The purpose of a doctor or any human in general should not be to simply delay death of the patient, but to increase the person’s quality of life” **Patch Adams.**

Atopic dermatitis (Atopic Eczema) is an acute, subacute, chronic, relapsing, endogenous eczema, characterized by dry skin and recurrent, pruritic, symmetric dermatitic lesions. The condition is due to complex interaction between genetic susceptibility and immunological changes with heightened IgE response¹. It causes inflammation, redness, and irritation of the skin. Scratching leads to further redness, swelling, cracking, “weeping” clear fluid, ultimately crusting and scaling.

Atopic dermatitis is the commonest form of dermatitis in children. It is known to be associated with other allergic diseases known as comorbidities. These comorbid conditions include allergic rhinitis, asthma, food allergies, and allergic rhinoconjunctivitis.²

Incidence of Atopic Dermatitis has increased 2- to 3-fold in the industrialized nations. Impacting approximately 15% to 20% of children and 1% to 3% of adults worldwide. The upward trend is also true in the Indian context. Prevalence ranging between 2.4% and 6% in India. Onset of disease is most common by 5 years of age. Approximately 60% of patients develop disease in the first year of life and 90%

within the first 5 years of life. Twenty percent of children who develop AD before 2 years of age will have persisting symptoms of disease; 17% will have intermittent symptoms by 7 years of age³, therefore early diagnosis and treatment are essential to avoid complications of AD and improve the Quality of Life.

It has a wide-ranging impact on a patient’s quality of life and the burden from direct and indirect costs is shared by the families and caregivers of patients. Direct costs include prescription cost, healthcare provider visits, and hospitalizations. Indirect costs include absenteeism from work, school, and physical activities; decreased productivity (presenteeism); and decreased quality of life (due to itching, sleep disruption, irritability and general stress)³. Due to deprived sleep, there is tiredness, mood change and impaired psychosocial functioning of the child particularly at school due to embarrassments (comments, teasing, bullying) which ultimately lead to social isolation and may lead to depression or social avoidance. The child’s lifestyle is often limited in respect to clothing, holidays, staying with friends, owning pets, swimming or the ability to play or do sports. In skin a disease there is a social stigma attached in respect to its appearance and has a negative impact on the psyche of patients. AD impacts

childhood Health Related Quality of Life (HRQoL) to a greater extent than many other cutaneous skin diseases, it was even found equivalent in impact to other non-dermatological chronic diseases⁴.

Two studies were conducted, one in Italy⁵ and one in Germany⁶ which confirmed the positive therapeutic effect of homoeopathy in atopic dermatitis. However, there are only limited numbers of studies available in this area focusing on the impact of quality of life in children with atopic dermatitis. Hence, this study was intended to observe and assess the effects of indicated homoeopathic medicines on quality of life of children suffering from atopic dermatitis using standardized scales.

Atopic Dermatitis has different clinical presentation in different age groups. In infants, mainly onset after 3 months presents with extremely itchy erythematous papulovesicular rashes seen mainly on face, affecting sleep¹. While in children¹ these rashes are characterised by dry lichenified and crusted plaques, seen mainly behind the creases of elbow, knees, neck etc. These rashes or eruptions usually clear by 10 years of age but if it develops or continues to adulthood⁷ it is characterised by dry lichenified and crusted plaques, appearing in the creases of the elbow or knees or nape of neck. Apart from heightened IgE levels some

theories suggests that filaggrin, protein in corneal layer of which help in structure and formation of the corneal layer is either partially lost or completely lost due to mutation in FLG gene⁸. Lack of filaggrin may allow entry of airborne allergens causing inflammation and dryness of skin which causes itchiness. Also, harsh climatic factors, pruritogens, irritants, airborne pollutants⁹, smoke exposure, family history of atopy may be risk factors for AD.

Several standards and guidelines for the diagnosis of AD have been published, all of which are substantially the same as the disease concept of AD published by Wise et al. but mostly acceptable criteria is by Hanifin and Rajka¹⁰ who in 1980 modified and combined their respective standard and proposed a renewed diagnostic standard (validated by American academy of dermatology) proposed to diagnose AD when the patient meets at least three of these four major features and also at least three of 23 minor features.

Major features- (1) Pruritus (2) Typical morphology and distribution flexural lichenification in adults facial and extensor eruptions in infants and children. (3) Chronic or chronically relapsing dermatitis. (4) Personal or family history of atopy (asthma, allergic rhinitis, atopic dermatitis)

Minor features: (1) Xerosis (2) Ichthyosis/palmar hyper-linearity, keratosis pilaris (3) Immediate (type I) skin test reaction (4) Elevated serum Ige (5) Early age of onset (6) Tendency toward cutaneous infections (especially staph. Aureus and herpes simplex), impaired cell mediated immunity (7) Tendency toward non-specific hand or foot dermatitis (8) Nipple eczema

AD cases can be associated with super added infections¹¹, allergic rhinitis, conjunctivitis, metabolic disorder such as obesity, life style disorders, skin disorders like vitiligo, alopecia areata, psychiatric disorders like ADHD, anxiety, depression, suicidal stress and many more.

Prognosis of AD is not really bad as it is mainly childhood disease and does not cause serious ailment but worsened cases may cause serious bacterial and viral infections, embarrassments, suicidal intention, and retarded growth.

AD should be differentiated from other skin disorders like seborrheic dermatitis, contact dermatitis, psoriasis, dermatographism, impetigo, scabies which are also childhood skin disorders.

The diagnosis of AD in this study was purely done on clinical basis using Hanifin and Rajka's criteria mentioned above.

AIMS AND OBJECTIVE

- The study aimed to improve the Quality of life in children with Atopic Dermatitis using individualised homoeopathic medicines.
- The primary objective of the study was to evaluate the effectiveness of homoeopathic treatment in improving the Quality of Life in Children under the study using CDLQI scale and secondary objective was to assess the changes in the symptom severity using SCORAD index, from baseline score to last follow up score.

RESEARCH HYPOTHESIS

- **Null Hypothesis:** There is no significant improvement in the quality of life in children with Atopic Dermatitis when treated with homoeopathic medicines.
- **Alternative Hypothesis:** There is a significant improvement in the quality of life in children with Atopic Dermatitis when treated with homoeopathic medicines.

METHODOLOGY

Type of study: Prospective Observational Study.

Sample Size and Sampling Methods:

Cases were selected from screening and from OPD settings as total of 1245 children were screened from different schools of Greater Noida under health check-up camps organised by PGT's and

faculty of Bakson Homoeopathic Medical College & Hospital and Homoeopathic OPD of ESIC Hospital Sahibabad, of which in total 75 (6.02%) children were found to have atopic dermatitis. Out of total 75 children (age group 5 years to 12 years) screened out having AD, 33 were enrolled who gave consent and fulfilled the inclusion and exclusion criteria. Out of 33 patients enrolled 3 dropped out. They were briefed regarding the objectives, methods along with mode of homoeopathic treatment was explained. Before enrolment informed consent was taken from either of the parents or guardians of the patients.

Inclusion Criteria:

- Both sexes.
- Age group between 4 years to 16 years diagnosed with atopic dermatitis according to Hanifin and Rajka's criteria.

Exclusion Criteria:

- Any fungal infection.
- Patient on any other medications.
- Patient in need of medical emergency care.
- Children whose parents refused consent.
- Drop out was in cases with less than 2 Follow ups.

Duration of Study - 18 Months. This included 6 months of synopsis preparation, 5 months for enrolment of cases, 5 months

for enrolment of cases, 5 months for follow ups, 2 months for dissertation preparation.

Ethical Clearance: Ethical Clearance was obtained from Institutional Ethical Committee of Bakson Homoeopathic Medical College and Hospital, Greater Noida, U.P. for synopsis (Protocol no. BHMC/MD/2018/001/PAED) on 21/9/19.

Selection of Tools: The following tools/materials were used for the conduction of this clinical trial:

Case Recording Performa (obtained from BHMC & H) along with follow up sheet, to note down the information/data collected from the patient.

- Cartoon children dermatology quality of life index (for age group 4 years to 11 years) and Children dermatology life quality index (CDLQI- Hindi and English Version) (for age group 11years to 16years) and SCORAD index.
- Participant information sheet with consent form both in Hindi and English, Assent form.
- Homoeopathic medicines from pharmacy of BHMC&H, Greater Noida and ESI hospital Sahibabad.

Assessment Scale:

The following scales were used to assess the Quality of Life and severity of symptom index as follows-

- **Children Dermatological Life Quality Index (CDLQI)¹²**- is a 10, question index which come in different in languages and two versions that is cartoon and text. In this study CDLQI in English and Hindi were used along with cartoon version for small children (up to 11 years) and text version till the age of 16 years. This scale is a self-explanatory questionnaire and can be simply handed to the patients who are asked to fill them in the help of parent or guardian. The 10 questions are based on the experience of children with skin disease. The 10 questions CDLQI help to understand the impact of the disease under 6 headings that are Symptoms and Feelings, Leisure, School and Holidays, Personal and Relationships, Sleep and Treatment.
- **Scoring Atopic Dermatitis (SCORAD)¹³**- is a clinical tool used to assess the extend and severity of eczema. It includes- a) **Area**, to determine extend, where head and neck includes 9% of affection, upper limb 9% each, lower limb 18% each, anterior trunk 18%, back 18%, and genitals 1%. b) **Intensity**- Assessed through redness, swelling, oozing/crusting, scratch marks, skin thickening, dryness. c) **Subjective**

symptoms including sleep disturbance and intensity. These three points are taken into consideration before and after treatment to determine whether the treatment has been effective or not.

Remedy Selection: The medicines prescribed to the patients were on principles of Organon of Medicine after proper individualisation. Mental, physical and particulars of the patients were carefully taken into consideration, also patients family tendency were noted down.

Choice of Remedy and Potency: The prescription was made according to the totality of the symptoms obtained from case taking, and individualised homoeopathic medicines were prescribed. Main potencies used were 30CH, 200CH. Repetition was done in case where cases came on standstill, or in cases where no improvement was seen. Potencies were increased in cases where further improvement was required and change of medicine was done in acute phase of disease, condition worsened, and complementary to the previous. Along with the main medicine Saccharum Lactis was given as placebo.

Follow ups were taken weekly or bi-weekly depending on the convenience of the patients, but only the baseline and the last follow up were considered for statistical analysis.

Statistical Method Used:

Appropriate parametric test paired 't' test, was used to compare CDLQI score and SCORAD scores before and after the treatment and readings were obtained using Microsoft excel sheets.

OBSERVATION

The following observations were observed during the study -

➤ Gender Incidence

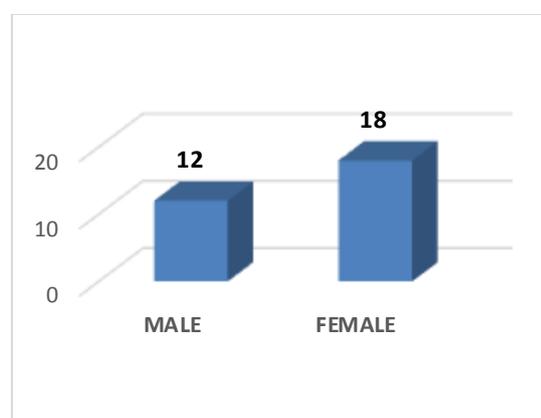


Fig 1 Bar Diagram of Gender Incidence

➤ Age and Gender Incidence

Table 1- Distribution of cases according to their age and gender.

Age Group (In years)	Gender		Total
	Male	Female	
4 - < 6	2	1	3
6 - < 8	4	0	4
8 - < 10	1	1	2
10 - < 12	0	3	3
12 - < 14	3	3	6
14 - < 16	2	8	10
16 - < 18	0	2	2
Total	12	18	30

➤ Hypersensitivity To Different Allergens.

Table 2- Distribution of cases having hypersensitivity to different allergens.

S.No	Allergens	No. Of Patients	%
1	Fatty Food	3	10
2	Egg	2	6.67
3	Milk	5	16.67
4	Cold Drink	1	3.33
5	Allopathic Medicine	3	10
6	Dust	6	20
7	Cold Air	5	16.67
8	Sun Heat	2	6.67
9	Meat	3	10
10	Gluten	2	6.67
11	Brinjal	2	6.67
12	Boiled Rice	1	3.33
13	Change Of Weather	5	16.67
14	Cabbage	1	3.33
15	Sweets	1	3.33
16	Wheat	1	3.33

➤ Past Complaints-

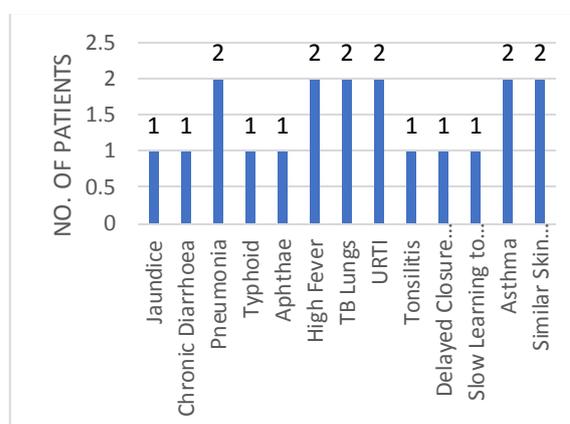


Fig 2 Past Complaints History

➤ Family History

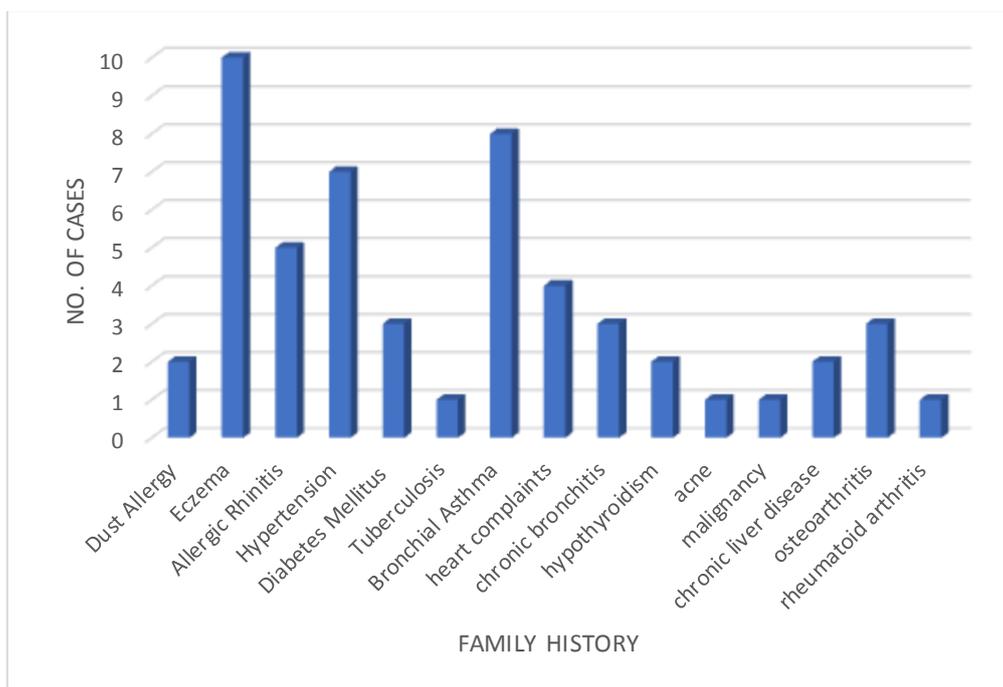


Fig 3 .Distribution showing cases with different family history

➤ Medicines Prescribed as First Prescription

Table 3- Distribution table of Medicine used in first prescription.

S.NO.	Medicine Used In First Prescription	Potencies used	Number	Improved	No change	Worsened
1	Ignatia	200	1	0	1	0
2	Rhus Toxicodendron	30,200	3	2	0	1
3	Petroleum	200	1	1	0	0
4	Graphites	30,200	2	1	1	0
5	Nitricum Acidum	200	2	2	0	0
6	Belladonna	200	1	1	0	0
7	Sulphur	200	2	1	0	1
8	Tuberculinum	30	1	1	0	0
9	Natrium Muriaticum	30, 200	3	3	0	0
10	Calcarea Carbonica	200	1	1	0	0
11	Pulsatilla Nigricans	30, 200	3	2	0	1
12	Calcarea	30	1	1	0	0

	Phosphorica					
13	Apis Mellifica	200	1	0	0	1
14	Medorrhinum	200	1	1	0	0
15	Baryta Carbonica	200	1	1	0	0
16	Arsenicum Album	30, 200	3	2	0	1
17	Mercurius Solubilis	200	1	1	0	0
18	Carbo Vegetabilis	30	1	1	0	0
19	Causticum	200	1	0	1	0

➤ **Change In Medicine And Reason Of Change**

Table 4– Table showing number of medicines changed and reason of change.

Initial Medicine	Changed To	Reasons
Ignatia	Rhus Toxicodendron	Itching was not relieved.
Rhus Toxicod	Calcarea Carbonica	Rhus Toxicodendron was given as acute medicine for the case.
Sulphur	Graphites	Condition worsened.
Calcarea Carboni	Rhus Toxicodendron	Rhus Toxicodendron was given as acute medicine for backache.
Pulsatilla Nig.	Graphites	Condition worsened.
Graphites	Psorinum	Slightly itching increased
Apis Mellifica	Sulphur	Condition worsened.
Rhus Toxicod	Graphites	Condition worsened.
Causticum	Natrium Muriaticum	Causticum improved the mental generals but itching was increased therefore Natrum Muriaticum was prescribed which improved further.

➤ **Improvement Status in General Symptoms of AD Cases.**

Table 5- Distribution table of Improvement status in general symptoms of AD cases.

S.NO.	General Symptoms	No. Of Patients	Improved	No Change	Worsened
1	Physical Generals	30	28	2	0
2	Mental Generals	25	22	1	2
3	Quality Of Life	30	26	0	4
4	Cold And Coryza	14	12	2	0
5	Breathlessness	4	3	1	0
6	Cough	4	3	1	
7	Lachrymation From Eyes.	2	2	0	0

➤ **Improvement Status in Particular Symptoms of AD Cases.**

Table 6 - Distribution table showing improvement in particular symptoms.

S.NO.	Particular Symptom	Total No. Of Cases	Improved	No Effect	Worsened
1	Itching	30	26	0	4
2	Lesions	28	24	1	3
3	Dryness	24	20	1	3
4	Lichenification	18	14	2	2
5	Sticky Watery Discharge From Lesions	16	14	1	1
6	Pus Discharge From Lesions	4	4	0	0

➤ **CDLQI Scores Before And After**

Table 7– CDLQI Score Before and After Treatment

S no.	CDLQI scores Range	Severity score	Patients scores Before treatment	Percentage	Patients score After treatment	Percentage
1	0-1	No effect of AD	0	0	6	20
2	2-6	Small effect of AD	1	3.33333	20	66.6667
3	7-12	Moderate effect of AD	7	23.3333	0	0
4	13-18	Very large effect of AD	16	53.3333	2	6.66667
5	19-30	Extremely large effect of AD.	6	20	2	6.66667

➤ **SCORAD Index Before and After:**

Table 8- SCORAD INDEX changes before and after.

S no.	SCORAD score range	SCORAD score before	Percentage	SCORAD score after	Percentage
1	0-10	0	0	17	56.6666667
2	10-25	2	6.66667	8	26.6666667
3	25-50	22	73.3333	3	10
4	>50	6	20	2	6.6666667

➤ **OUTCOME**

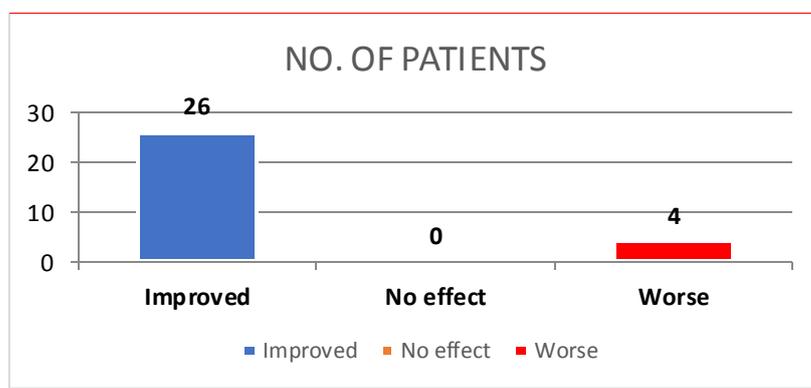


Fig 4 Bar Diagram of Outcome

Statistical Analysis Of Data

As our data was normally distributed and scale of measurement was in intervals, and we compared two sets of data before and after therefore, paired 't' test was used for statistical analysis. It was found that at 29 degree of freedom (Sample size of 30), and 5% significant limit of 't' was 2.045229642. The observed value of 't' was 8.081437372 which showed calculated t value is greater than tabulated 't' value.

Hence, there was no doubt that Quality of life of AD patients improved significantly by Homoeopathic medicine. Hence, we accepted the Alternate Hypothesis that Quality of life in AD cases improved significantly by assessing the result of CDLQI scores with the help of statistical analysis.

Also, on analysing SCORAD index at 29 degree of freedom, 5% significant limit of 't' is 2.045229642. The observed value of 't' is 7.805151922 which showed calculated t value is greater than tabulated t value. Hence, there was no doubt that Symptom severity of AD patients improved significantly by Homoeopathic medicine.

Hence, we accepted the Alternate Hypothesis that symptomatology in AD cases improved significantly by assessing

the result of SCORAD scores with the help of statistical analysis.

CONCLUSION

- It was observed that majorly girls were affected as compared to boys in the age group of 14 to 16 years.
- There was associated hypersensitivity to different allergens, like fatty food, egg, milk, cold drinks, allopathic medicines, dust, cold air, sun heat, meat, gluten, brinjal, and boiled rice, change of weather, cabbage, sweets and wheat in AD children.
- Many AD children had past history of jaundice, chronic diarrhoea, pneumonia, typhoid, aphthae, high fever, TB lungs, URTI, tonsilitis, delayed closure of fontanels, slow learning to walk, asthma, similar skin complaint.
- It was observed that children had history of family atopy, like dust allergy, eczema, allergic rhinitis, TB, bronchial asthma, other chronic diseases in family members like heart complaint hypertension, diabetes mellitus, hypothyroidism, malignancy, chronic liver disease, osteoarthritis, rheumatoid arthritis.
- Many homoeopathic medicines around 20 were prescribed on the basis of

individualization. Out of which Rhus Toxicodendron, Natrium Muriaticum, Pulsatilla Nigricans, Arsenicum Album were given in maximum cases that in 12 cases, 3 cases each, Natrium Muriaticum showed improvement in all 3 cases. Majorly 30, and 200 potencies in centesimal scale showed good result. Mainly there was no change of medicine but in some cases either same medicine with same potency was repeated and in some higher or some acute medicines was prescribed at start or in follow ups.

- Medicines were also changed in cases which became worse.
- There was improvement in general symptoms that is physicals, mental, quality of life and also in particular symptoms of the disease.
- The CDLQI and SCORAD scores improved.
- Overall significant improvement was seen in 26 patients and condition worsened in 4 cases.
- Since, statistically significant result for the CDLQI score was obtained, therefore Alternate Hypothesis i.e., significant improvement in the quality of life in children with atopic dermatitis when treated with homoeopathic medicines was accepted.

This study was a successful one in terms of fulfilling the objectives set for the study. This was the modest effort to find the role of individualistic homoeopathic medicine in the management of AD & the response in this study was quite satisfactory.

Limitation And Recommendation

- Since AD is a chronic relapsing disease therefore follow up of 4-5 months is not sufficient to conclude for the cure of the cases. Therefore, a long-time study is needed to complete the study in a more scientific way.
- In this study patients with AD with age group of only 4 to 16 years was taken, while children in the infant age and toddlers were excluded, this study can be conducted on large sample size, and even including toddlers, and infant.
- Moreover, this was an observational study, in future comparative studies with control groups and those on conventional medicines could be conducted.

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