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EFFECTIVENESS OF HOMOEOPATHIC MEDICINES IN CASES OF TINEA CORPORIS - A RANDOMIZED SINGLE BLIND PLACEBO CONTROLLED STUDY

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ABSTRACT –

Objective: - This study is done to assess the effectiveness of Homoeopathic medicines as compared to placebo in the treatment of *Tinea Corporis* on the basis *Dermatology life quality index* (DLQI) and to assess the miasm in cases of *Tinea Corporis.*

Material and Methodology:

A Randomized single blind placebo-controlled study to assess the effectiveness of homoeopathy in cases of Tinea corporis was conducted at Dr. Girendra Pal Homoeopathic Hospital & Research Centre, Collegiate Hospital of Dr. Madan Pratap Khunteta Homoeopathic Medical College, Hospital, Homoeopathic University Saipura, Sanganer Jaipur during the period of August 2018 to July 2019. 70 cases of Tinea corporis, selected as per inclusion and exclusion criteria, were randomly allocated to the two treatment groups. In Group A (n=35 cases) cases were treated with individualized homoeopathic medicines on the basis of the totality of the symptoms. In Group B (n=35cases) cases were prescribed Placebo. Both groups were advised appropriate lifestyle and hygiene measures. Assessment and reassessment were done using score Dermatology life quality index (DLQI).

Results: Observations and results show that among the 70(Group A= 35; Group B= 35) cases enrolled in the study, Tinea corporis was more common in age group 18-24 years [Group A 13(37.14%) and in Group B15 (42.86%) cases]. Males were more commonly affected than females. More cases were from married group A 21(60%) Group B 20 (57.14%). In the study population more cases were from rural area of residence i.e.in

Group A 17(48.57%) cases and Group B 24(68.57%) cases. Commonly middle socio-economic status 48(68.57%) people were affected. The predominant miasm was Psora in both groups with 30 (85.71%) cases in Group A and 28 (80 %) cases in Group B.

In Group A (Homoeopathic treatment group) Mean DLQI score was 10.58±4.969 (Mean±SD) before treatment and it reduced to 6±3.929 (Mean±SD) after treatment, while in Group B (Placebo Group) Mean DLQI Score was 9.88±4.663 (Mean±SD) before treatment and reduced to 8.62±4.314 (Mean±SD) after treatment. Homoeopathic medicines had significantly improved DLQI score *Tinea corporis* after treatment of 3 months with the mean difference of M = -2.800, SE = .980 as compared with placebo. Overall, there was significant difference between outcomes in the two treatment groups, Group A showed more significant decrease in DLQI score as compared to Group A.

Conclusion: The present study demonstrates that Homoeopathy can offer significant relief in cases of Tinea corporis.

Keywords – Tinea corporis, Homoeopathy, KOH

INTRODUCTION-

Tinea corporis is the infection of glabrous (non-hairy) skin which may result from extension of the infection from scalp, groin or beard region. The erythematous raised lesions, annular, sharply marginated single or multiple plaques.[1]Skin is man's front-line protective barrier between internal structures and the external environment. Because it interfaces with environment, skin plays a key role in protecting us against pathogens and thus it is also prone to various diseases.[2]Tinea corporis is commonly seen with annular/arcuate lesions with relative clearing in the center and an active periphery. Infection of the glabrous skin, except palms, soles, and groins.[3]

The conventional medicines make the usage of external application like ointments, fungicides etc, which leads to suppression or palliation. So, the disease tends to recur often and becomes a chronic disease. The disease is usually chronic and the course extends over months to years. Eczematisation and Lichenification may become the complicating features of chronic cases.[4]

The proposed study was conducted to assess the effectiveness of homoeopathic medicines as compared to placebo in relief to the cases of tinea corporis by using Dermatology Life Quality index [5] to assess the response to treatment. Another objective of the study was to ascertain the predominant miasm in cases of Tinea corporis.

MATERIALS AND METHODOLOGY-

The study was conducted at Dr. Girendra Pal Homoeopathic Hospital and Research Centre, a collegiate hospital of Dr. Madan Pratap Khunteta Homoeopathic Medical College & Hospital, Homoeopathic University Saipura, Sanganer Jaipur. The study was done for a period of 12 months out from August 2018 to July 2019. Each case was followed up for 3 months. Seventy samples were selected and randomised into two groups.

Group A- Interventional Group –Homoeopathic Medicine = 35 cases

Group B – Placebo Group- Placebo = 35 cases

Inclusion criteria –

- Patients giving informed consent to participate in the study.
- Age >18 years
- Both sexes

Exclusion criteria-

- Cases with complication of Tinea Corporis like lichenification & eczemitization.
- Patients having Tinea Corporis which is secondary to Diabetes mellitus, Hypertension, complication of diabetes mellitus (Gangrene) should be excluded.
- Females, who want to conceive, or pregnant or lactating.

Drop outs:

- Patients not reporting back after first or second visit
- Poor compliance of the patient.
- Patients not taking regular medicines.

STUDY DESIGN – Randomized single blind placebo-controlled study.

a. Intervention Group A: Homoeopathic medicines

1.Selection of medicine: The similimum was selected on the individualization of the patient as per the reportorial result, in consultation with the Materia Medica.

2.Potency selection: as per case

3.Repetition: as per Dr. Hahnemann Guidelines

4.Procurement of medicine: The medicines were procured from the pharmacy having the Good Manufacturing Practices certificate and approved by the Scientific Advisory Committee of the Council.

b. Intervention Group B – Placebo

1.Repetition: Three times a day

2.Procurement of medicine: The medicines were procured from the pharmacy having the Good Manufacturing Practices certificate and approved by the Scientific Advisory Committee of the Council.

4.5.c Cointervention for both groups- Both groups were advised appropriate lifestyle and hygienic measures as per disease diagnosis of Tinea corporis

Outcome Assessment –

I. *Dermatology life quality index* (DLQI) -

Percentage change from baseline calculation =

Score before treatment – Score after treatment / Score before treatment x 100

- Cure = 100% Change
- Improvement = 25 to < 100%
- Status quo = < 25 %
- Worse = Increase in Post treatment Score

II. Photographic Evidence

Statistical Tool-

In order to accomplish the Objective 1, two samples (Group A and Group B) each with size 35 were collected. The statistical tools used to achieve objectives are paired t-test and t-test for difference of two means for independent samples respectively. The analysis has been done on IBM SPSS 20.0.

In this study sample size 70 was taken, degree of freedom (n_1+n_2 -1) is 68 and level of significance is α= 0.05.

Table 1 - Baseline Profile - Group wise

Baseline Characteristics of cases of *Tinea Corporis* in Group A and Group B			
Variables	**Total cases (n= 70)**	**Group A (n= 35)**	**Group B (n= 35)**
Age (in years)			
18-24	28(40%)	13(37.14%)	15(42.86%)
25-31	15(21.43%)	6(17.14%)	9(25.71%)
32-38	14(20%)	8(22.86%)	6(17.14%)
39-45	7(10%)	5(14.29%)	2(15.71%)
46-52	6(8.57%)	3(8.57%)	3(8.57%)
Gender			
Female	33(47%)	9(25.71%)	24(68.57%)
Male	37(53%)	26(74.29%)	11(31.43%)
Area of Residence			
Rural	41(58.57%)	17(48.57%)	24(68.57%)
Urban	29(41.43%)	18(51.43%)	11(31.43%)
Socio-economic status			
Upper	2(2.86%)	2(5.71%)	0(%)
Middle	48(68.57%)	28(80%)	20(57.14%)
Lower	20(28.57%)	5(14.29%)	15(42.86%)
Occupation			
Student	30(42.86%)	15(42.86%)	15(42.86%)
Housewife	9(12.86%)	4(11.43%)	5(14.29%)
Teacher	6(8.57%)	3(8.57%)	3(8.57%)
Shopkeeper	5(7.14%)	3(8.57%)	2(5.71%)
Private job	4(5.71%)	2(5.71%)	2(5.71%)
Labor	3(4.29%)	2(5.71%)	1(2.86%)
Farmer	3(4.29%)	3(8.57%)	0(%)
Businessman	1(1.43%)	0(%)	1(2.86%)
Painter	3(4.29%)	0(%)	3(8.57%)

Accountant	2(2.86%)	2(5.71%)	0(%)
Advocate	1(1.43%)	1(1.43%)	0(%)
Property dealer	1(1.43%)	0(%)	1(1.43%)
Security guard	1(1.43%)	0(%)	1(1.43%)
Tailor	1(1.43%)	0(%)	1(2.86%)
Marital status			
Married	41(58.57%)	21(60%)	20(57.14%)
Unmarried	29(41.43%)	14(40%)	15(42.86%)
Past history			
Tinea	4(12.90%)	3(21.43%)	1(5.26%)
Piles	5(16.13%)	(%)	5(26.32%)
Renal calculi	2(6.45%)	2(14.29%)	(%)
Jaundice	3(9.68%)	(%)	3(15.79%)
Appendectomy	3(9.68%)	(%)	3(15.79%)
Eczema	5(16.13%)	3(21.43%)	2(10.53%)
Typhoid	4(12.90%)	2(14.29%)	2(10.53%)
Dengue	1(3.23%)	(%)	2(5.26%)
T. B	1(3.23%)	1(7.14%)	0
Urticaria	3(9.68%)	3(21.43%)	0
Associated complaints			
Bleeding gums	1(2.27%)	1(4.43%)	0
Burning in eyes	1(2.27%)	1(4.35%)	0
Flatulence	6(13.64%)	4(17.39%)	2(9.52%)
Piles	5(11.36%)	4(17.39%)	1(4.76%)
Hair fall	6(13.64%)	5(21.74%)	1(4.76%)
Pain in head	8(18.18%)	5(21.74%)	3(14.29%)
Pain in tooth	2(4.55%)	5(21.74%)	3(14.29%)
Running nose	2(4.55%)	2(8.70%)	0
Burning after stool	1(2.27%)	0	1(4.76%)
Burning in soles	2(4.55%)	0	2(9.52%)

Pain in abdomen	2(4.55%)	0	2(9.52%)
Pain in legs	3(6.82%)	0	3(14.29%)
Pain in throat	2(4.55%)	0	2(9.52%)
Vertigo	1(2.27%)	0	1(4.76%)
Weakness	2(4.55%)	0	2(9.52%)
Family history			
Tinea Corporis	17(33.33%)	9(33.33)%	8(33.33)%
Tinea Cruris	14(27.45%)	5(18.52%)	9(37.50%)
Arthritis	2(3.92%)	2(7.41%)	0
Cholelithiasis	2(3.92%)	2(7.41%)	0
Eczema	1(1.96%)	1(3.70%)	0
Hypertension	3(5.88%)	1(3.70%)	2(8.33%)
Hypothyroidisim	2(3.92%)	2(7.41%)	0
Migraine	3(5.88%)	2(7.41%)	1(4.17%)
Tubercilosis	1(1.96%)	1(3.70%)	0
Vitiligo	2(3.92%)	2(7.41%)	0
Asthma	2(3.92%)	0	2(8.33%)
Diabetes	1(1.96%)	0	1(4.17%)
Renal Calculi	1(1.96%)	0	1(4.17%)

Table -2 - For Indicated Medicine in Group A

Distribution of cases of *TineaCorporis* according to "Medicine Prescribed" in Group A	
Name of medicine prescribed	**Number of patient**
Sulphur	9 (25.71%)
Mercurius solubilis	6 (17.14%)
Lycopodium clavatum	5 (14.28%)
Natrummuriaticum	3 (8.57%)
Sepia succus	3 (8.57%)
Nux vomica	2 (5.71%)
Belladonna	1(2.86 %)

Kali phosphoricum	1(2.86 %)
Lachesis	1(2.86 %)
Bacillinum	1(2.86 %)
Petroleum	1(2.86 %)
Pulsatillanigricans	1(2.86 %)
Rumexcrispus	1(2.86 %)

Table – 3 - Result Obtained in Group A and Group B

RESULT	TOTAL	GROUP A	GROUP B
CURE	2	2 (5.71%)	0
IMPROVED	35	27 (77.14%)	10(28.57%)
STATUS QUO	18	3(8.57%)	16(45.71%)
WORSE	12	3(8.57%)	9(25.71%)

Paired sample t- test result, (Table – 4) to show the effect of Homoeopathic medicine and Placebo.

Table – 4 – Statistical Analysis – Paired Sample t- Test of Both Groups

Group A (N=35)	Before	After	Group B (N=35)	Before	After
Mean	10.43	5.80	Mean	9.83	8.60
S.D.	4.913	3.947	S.D.	4.605	4.251
SEM	.830	.667	SEM	.778	.719
t- Value	7.302		t- Value	2.488	
Df	34		Df	34	

(S.D. - Standard Deviation; SEM – Standard error of mean; df- degree of freedom)

Table- 5 shows independent t- test indicated equal variances (F = .031, p = .000) df = 68. There is significant (p = .000) decrease in DLQI score in cases of Tinea corporis with homoeopathic medicines (GROUP A) (M = 5.80, S.D. =. 3.947) than Placebo (GROUP B) (M = 8.60, S.D. =4.251), t(70) = -2.856, p = 0.000, the mean difference between the groups being M =--2.800, SE =.9.80

Table – 5 – Statistical Analysis – Independent Sample t- Test of Both Groups

Independent Samples Test										
		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	T	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
Score	Equal variances assumed	.031	.860	-2.856	68	.006	-2.800	.980	-4.757	-.843
	Equal variances not assumed			-2.856	67.628	.006	-2.800	.980	-4.757	-.843

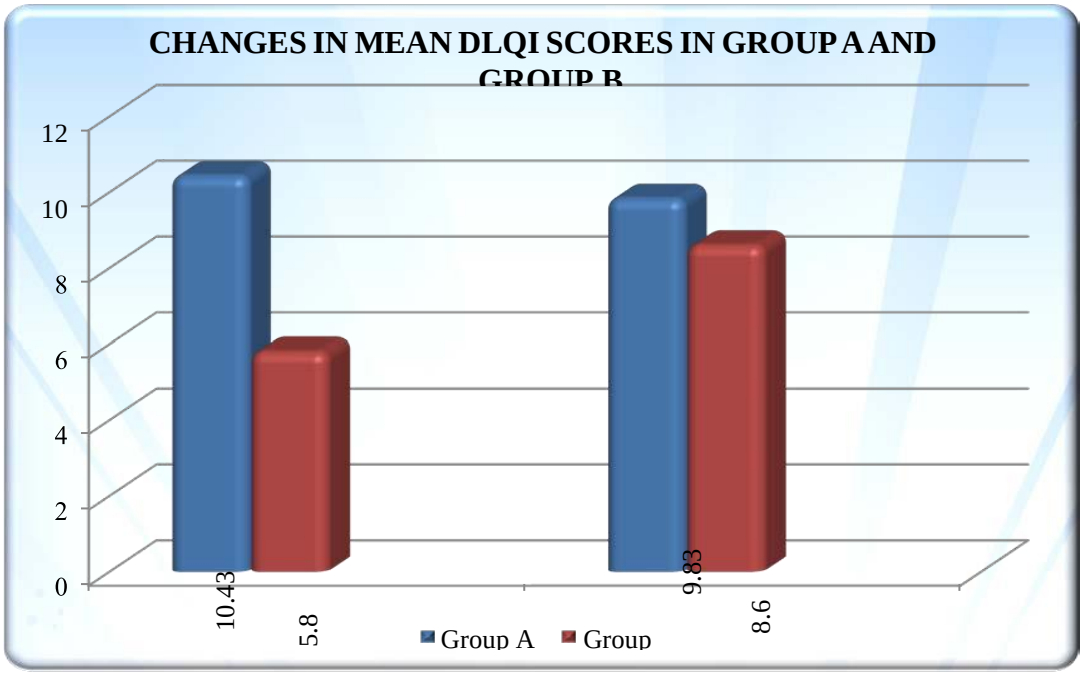

Fig. 1: Graphical presentation of Distribution of cases of *Tinea Corporis* according to "Changes in Mean DLQI scores in Group A and Group B"

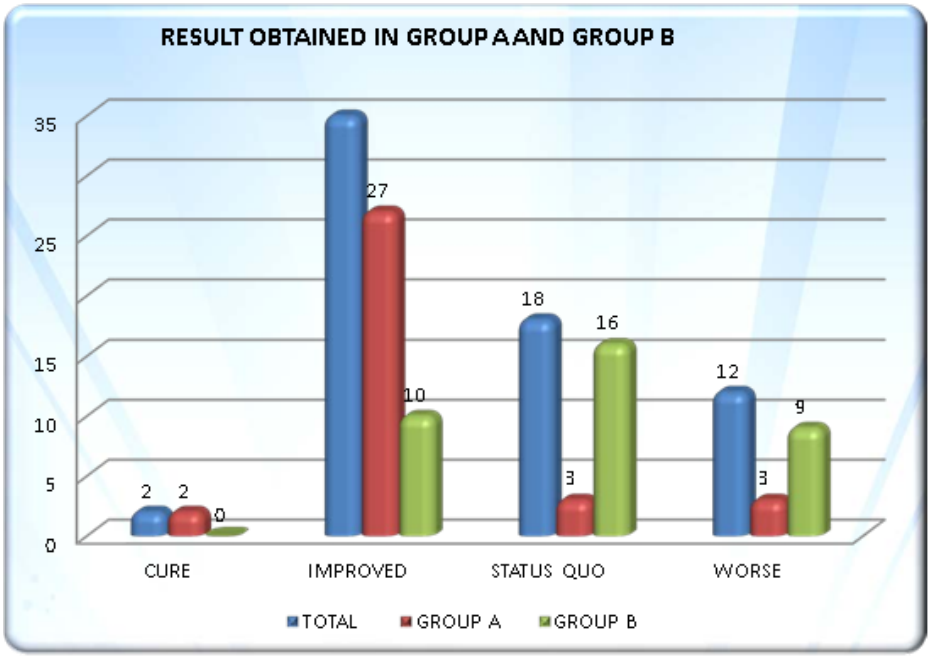

Fig 2: Graphical presentation of Comparative Distribution of Cases of Tinea Corporis according to "Result obtained in Group A and Group B"

DISCUSSION-

In this study 70 cases were taken by random allocation sampling methods. The cases were randomly allocated to two treatment groups:

- Group A-Homoeopathic medicines–35
- Group B – Placebo – 35 cases

A discussion on the interpretations derived from the study has been given below:

Analysis of baseline characteristics (Table 1) showed:

a. Age incidence: In this study it was observed that the maximum incidence of *Tinea corporis* was seen in the age group of 18-24 years [Total 28(40%); Group A-13(37.14%) Group B 15(42.86%)] followed by age group of 25-31 years [Total 15(21.43%); Group A- 6 (17.14%); Group B- 9(25.71%)].This observation is similar to a study where maximum cases of *Tinea corporis* was the most predominant clinical type reported in all age groups but a higher incidence was observed in the 21-30 and 31-40 age groups.[6]

b. Gender: In this study in spite of random allocation both groups differed in gender distribution. However overall, it was seen that cases of were higher in males than in females

[Female 33(47%) and males 37(53%)] which similar with findings from other studies which shows dermatophytosis was more common in males (62%) than in females (38%).[7]

c. Area of Residence: In this study it was observed that maximum cases of *Tinea corporis* were from rural area 41(58.57%) than urban area of residence 29(41.43%). Similar to this other studies which shows that Tinea were more common in rural area.[8]

d. Socio-Economic Status: Maximum cases in this study belonged to Middle socio economic 48(68.57%) followed by Lower socio economic status20(28.57%).

e. Occupation: Maximum cases in this study were students 30(42.86%) followed by Housewives.

f. Marital Status: In this study it was found that married persons were more affected than unmarried.

g. Past History- Patients presented a wide variety of disorders in past history like Piles, Renal calculi Jaundice, Appendectomy, Eczema, Typhoid, Dengue, T .B, Urticaria. 4(12.90%) cases (Group A: 3(21.43%); Group B: 1(5.26%)) had past history of Tinea

h. Family history- Among the study population 17 cases [Group A-9(33.33) %; Group B 8(33.33) %] had family history of **Tinea corporis** and **14 cases** [Group A-5(18.52%); Group B-9(37.50%)] had family history of **tinea cruris.**

i. Associated complaints: Patients presented with a wide range of associated complaints like Bleeding gums, burning in eyes, Flatulence, Piles, Hair fall, Pain in head, Pain in tooth, Running nose, Burning in anus after stool, Burning in soles, Pain in abdomen, Pain in legs, Pain in throat, Vertigo, Weakness. However, the frequencies were less to analyses.

1. **Predominant Miasm:** In this study the miasmatic analysis of cases was done. In maximum cases Psora was found as predominant miasm in cases *Tinea corporis*. The most common factor in development of Tinea is excessive perspiration, which may be due to occupation or lifestyle or due to constitutional factors. Literature review showed that miasmatic analysis of clinical features of Tinea corporis show psora and Sycosis as predominant miasm.
2. **Medicine prescribed**: *Tinea corporis* was treated with medicine in Group A. most Effective medicines found were *Sulphur* in 9 (25.71%) cases; *Mercurius solubilis* in 6 (17.14%) cases; *Lycopodium clavatum* in 5 (14.28%) cases; *Natrum muriaticum* and *Sepia* in 3 (8.57%) cases each; *Nux vomica* in 2 (5.71%) cases; and *Belladonna*, *Kali*

phosphoricum, Lachesis, Bacillinum, Petroleum, Pulsatilla nigricans and *Rumex crispus* in 1(2.86 %) case each.

3. **Changes in mean DLQI scores**- In Group A (Homoeopathic treatment group) Mean DLQI score was 10.58±4.969 (Mean±SD) before treatment and it reduced to 6±3.929 (Mean±SD) after treatment, while in Group B (Placebo Group) Mean DLQI Score was 9.88±4.663 (Mean±SD) before treatment and reduced to 8.62±4.314(Mean±SD) after treatment.
4. **Statistical analysis** - Independent t- test indicated equal variances (F = .031, p = .000) df = 68. There is significant (p = .000) decrease in DLQI score in cases of *Tinea corporis* with homoeopathic medicines (GROUP A) (M = 5.80, S.D. =. 3.947) than Placebo (GROUP B) (M = 8.60, S.D. =4.251), $t_{(70)}$ = -2.856, p = 0.000, the mean difference between the groups being M =--2.800, SE =.9.80. Homoeopathic medicines had significantly improved DLQI score *Tinea corporis* after treatment of 3 months with the mean difference of M = -2.800, SE = .980 as compared with placebo. Hence a Significant difference was seen between the two treatment groups. So it is inferred that Homoeopathic medicines are more effective than placebo. Hence, we are failing to accept Null hypothesis.
5. R**esult obtained**- As shown in above figure, among the 70 cases of *Tinea corporis*, in Group A, 2 (5.71%) cases were cured and 27 (77.14%) cases were improved, 3(8.57%) cases were status quo and 3(8.57%) cases became worse after treatment. In Group B 10(28.57%) cases were improved, 16(45.71%) cases were status quo and 9(25.71%) cases become worse. The results show that although appropriate hygienic measures can help to improve the symptomatology of *Tinea corporis* but Homoeopathic treatment can provide significantly more relief and also cure the patients of *Tinea corporis.*

CONCLUSION:

From this study it can be concluded that Psora is the predominant miasm lying in the background in the patients suffering from Tinea corporis. The study also demonstrated that individualized Homoeopathic medicines are helpful in lowering DLQI score.

LIMITATION OF THE STUDY:

- Tinea corporis is clinical diagnosis on the basis of characteristic symptoms. However for research purpose Skin KOH test for Tinea should be done. Skin KOH of patient was beyond the scope of this study. It is advisable that further research on Tinea corporis should focus on laboratory testing also.
- The time duration of 1 year with follow up of only 3 months was a Limitation of the study. Hence, it is advisable that further research with longer follow-up should be done on the Tinea corporis.
- The sample size undertaken in the study was small. It is advisable that further research should be done with larger sample size.

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Conflict of Interest: - Nil

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