



A randomized clinical study to assess the efficacy of external application of “chrysarobinum” vis-à-vis internal administration of “chrysarobinum” in centesimal scale in the cases of tinea corporis”

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ABSTRACT:

Background: Tinea corporis is a superficial dermatophyte infection characterized by either inflammatory or noninflammatory lesions on the hairless skin (i.e., skin regions other than the scalp, groin, palms, and soles).

Objective- “A Randomised Clinical Study to Assess the Efficacy of External Application of “*Chrysarobinum*” vis-a-vis Internal Administration of “*Chrysarobinum*” in centesimal scale in the cases of tinea corporis”

Study Design:- Randomized, Comparative, Interventional Study.

Methods:- 60 cases of Tinea corporis were randomly allocated to the two treatment groups. In Group A (n=30 cases) homoeopathic medicine predefined medicine *Chrysarobinum* was selected on the basis of their totality and given in Group A (n=30) external application and Group B (n=30 cases) homoeopathic medicine *Chrysarobinum* centesimal (CH) potency was selected internal application. Assessment at baseline and reassessment after 3 months was done using Tinea corporis DLQI scale.

Results:- Tinea corporis was found more common in the middle age group, males as compared to females; among more in reported more in Middle socioeconomic status people. Common warts was the commonest clinical type. In group A 15 cases (30%) showed marked improvement while 6 cases (20%) showed moderate improvement, 5 cases (16.66%) showed mild improvement 1 cases had status quo (3.33%) while 1 case (3.33%) show. In group B, 18 cases (60%) showed marked improvement, 4 cases (13.33%) showed moderate improvement, 2 cases (6.66%) showed mild improvement followed by 3 cases (10%) had status quo followed by (0%) of non-significant improvement

An Independent t-test was conducted to compare the effect of two approaches in Group A and Group B. There is statistically no significant difference in the scores of group A (M =5.96, S.D. = 5.900.), and Group B (M =5.82, S.D. =7.325) conditions; where $t(\text{cal}) = -.214$, $p = 0.831$. These results suggest that there is no significant difference seen in predefined Homoeopathic medicine *Chrysarobinum* External application and centesimal potency in the management of cases of Tinea corporis. Hence Alternate Hypothesis is accepted.

Conclusion:- Both External application (ointment) and Centesimal (CH) potency of *Chrysarobinum* are found effective in the management of Tinea corporis.

Keyword:– Tinea corporis, Centesimal potency, External Application(Ointment), Centesimal, Chrysarobinum

INTRODUCTION:

Tinea corporis is a fungal/ dermatophyte infection on outer covering of skin, having clear lesion with clear center with vesicopapule and scaling ring. It is infection on whole body except that of scalp, groins, palms and thigh and soles. It is a mycosis (any disease caused by fungus) and is caused by three anamorphic (asexual or imperfect) genera cause dermatophytosis namely Trichophyton, Epidermophyton and Microsporum.^[1,2] The most common causative organism for Tinea Capitis is Trichophyton tonsurans and the second most common to caused tinea corporis followed by Microsporum canis which is third most common cause of Tinea corporis.^[3]

The most common infective dermatophyte throughout the world is Tinea rubrum (caused by Trichophyton Rubrum) and is responsible for 47% of Tinea corporis cases. Dermatophytes are major public health issue in school age children especially in low-and middle-income countries and tropical areas. The predisposing factors for the infection is hygiene, high humidity, and low socioeconomic factors^[4]. In India, Rajasthan has dry climate, and in summer, temperature exceeds even 46°C with high humidity during the monsoon season. In therapeutic approach, medicine is selected on the basis of characteristic indication. Local measures prove, Ointment (external application) of “*Chrysarobinum*” can be applied in night and morning. “*Chrysarobinum*” has special indication for ringworm, and ointments clear up case quickly. The ointments have drawback of intense staining.^[5]

So “*Chrysarobinum*” can be used locally as well as internally to treat the cases of tinea. Not much characteristic indications are available for its selection but it is reported to be effective locally and hence can be used internally on the basis of symptom similarity.

RESEARCH QUESTION:

Does *Chrysarobinum* provide relief to patients of Tinea corporis when administered in centesimal scale or as external application?

RESEARCH HYPOTHESIS:

NULL HYPOTHESIS: There is no significant difference between effects of external application of “*Chrysarobinum*” vis-a-vis internal administration of “*Chrysarobinum*” in centesimal scale in the cases of Tinea corporis”

ALTERNATE HYPOTHESIS: There is significant difference between effects of external application of “*Chrysarobinum*” vis-a-vis internal administration of “*Chrysarobinum*” in centesimal scale in the cases of Tinea corporis”

MATERIALS & METHODS:

(1) STUDY SETTING :-

Cases from the O.P.D. of Dr. Girendra pal Homoeopathic Hospital& Research Centre, Saipura, Sanganer, Jaipur.

(2) STUDY DURATION :-

The study will be undertaken for a period of 12 months out of which cases will be registered in first nine month so that minimum three visits/ observations can be obtained from the last case, will be follow up for a period of 3 months of each follow-up 7/15 days.

(3) SAMPLE SIZE:-

At 77.8% prevalence of Tinea corporis in Jaipur and assuming improvement in 50% patients from homoeopathic approaches[8]the sample size for the study will be approx. 60 participants ingroup.

Group A- 30 cases – to be treated with *chrysarobinum* external application (Ointment)

Group B 30 cases – to be treated with internal administration of *Chrysarobinum* internal in centesimal potency scale.

(4) INCLUSION / EXCLUSION CRITERIA INCLUSION CRITERIA:

- Patient suffering from sign and symptoms suggestive of tinea corporis on the basis of clinical history and exam finding.
- Previously Diagnosed cases of Tinea corporis reoccurring, with other medicine with no avail. Patient's age -18 years to 70 years and both the sexes will be considered.
- Patients who give their consent willingly will be included in the study.
- Patient having at least three symptoms of *Chrysarobinum* from the symptom checklist
 - a. Vesicular or squamous lesions.
 - b. Foul smelling discharge and crust formation
 - c. Violent itching in the thighs legs and ears.
 - d. Dry scaly eruptions.
 - e. Eczema behind the ears.
 - f. Ringworm.

EXCLUSION CRITERIA:

1. Cases with complication of tinea corporis like lichenification & eczematization.
2. Patients having Tinea Corporis which is secondary to diabetes mellitus ; hypertension; complication of diabetes mellitus (Gangrene) should be excluded.

DROP OUTS: When Patient Discontinues the treatment during the course of study and required Emergency treatment during the study.

(5) STUDY DESIGN

Interventional clinical trial

(6) SELECTION OF TOOLS

- I. Case Taking Proforma (appendix I): Case taking Proforma will be filled at the commencement of research study; follow-ups will be taken at 7 days of intervention.
- II. Dermatology life quality index (DLQI) scale (appendix II): It will be filled at the commencement and after 4 weeks of the intervention.
- III. Patient information sheet –Appendix III, V
- IV. Patient consent form- Appendix- IV, VI
- V. Individualized homeopathic medicines

(7) DATA COLLECTION

- I. Data was collected after proper follow-ups and maintained in soft and hard copy. A complete history, examination and required investigation were done.
- II. Case taking proforma: A special case taking proforma was designed for the study with the approval of guide. Case taking: Detailed case taking for every screened case was done on especially designed case taking proforma, based on homoeopathic principles.
- III. Diagnostic criteria: Clinical examination and relevant investigation were carried out to establish the diagnosis.
- IV. Follow-ups: All the cases were reviewed at the interval of 7-15 days and data was recorded for minimum 6 follow-ups.
- V. Record: Centralized data was recorded in approved master chart in proper excel format.
- VI. Auxilliary measures: Patients were advised to maintain proper hygiene and avoid wearing of wet clothes. Body should be properly wiped after bathing and all clothing should be properly dried in sunlight. No medicated creams or ointments to be used during the period of study. All other treatments for the same infection is to be avoided.

(8) DATA ANALYSIS

According to the scoring based upon DLQI scale (appendix – ii) using SPSS and Excel

9.9 STATISTICAL TECHNIQUE:

I. Paired t-Test and independent t test to assess score of DLQI pre and post treatment and compare response between the two group

II. Data analysis was done using Microsoft excel sheet on the basis of symptom score before treatment and after treatment using the DLQI Score.

III. Following parameters (Result Criteria) were fixed according to the type of the response obtained after the treatment:-

The percentage changes of symptoms score from baseline to end of treatment were calculated by using following formula:

$$\text{Percentage} = \frac{\text{Score at Baseline} - \text{Score at the end} \times 100}{\text{Score at Baseline}}$$

- Marked Improvement: 76-100 Status %.
- Moderate Improvement: 51-75 Status %.
- Mild Improvement: 26-50 Status %.
- Not Significant Improvement: 1-25 Status %.
- Status Quo: No change in status%.

10. STATISTICAL TECHNIQUES: Data was analyzed on the basis of t test (Paired t test) of statistical technique using IBM SPSS 20.0 version.

- To compare pre and post treatment scores of all the patients in the study. Paired t test was applied for pre and post DLQI scores.

Paired T-test:

$$t = \frac{\bar{x}}{Sd\sqrt{n}}$$

- \bar{x} = Standard error of the mean difference
- Sd = Standard deviation
- n = sample size

11. Consent & Confidentiality

- Patient Information Sheet:- was given to each & every patient where they were sensitized about the study. (Appendix-III).
- Consent form:- Informed consent was obtained from every recruited patient including adequacy of the information being provided to the subjects and confidentiality of identity was maintained. (Appendix - III).
- All the evaluation forms, reports and other records related to the study were kept confidential.

12. ETHICAL CLEARANCE

- Institutional Ethics Committee (IEC) ethical clearance was obtained.

OBERVATION AND RESULTS:-

Tinea corporis was found more common in the middle age group, males as comparison to females; among more in reported more in Middle socioeconomic status people. Common Tinea corporis was the commonest clinical type .In group A 15 cases (30%) showed marked improvement while 6 cases (20%) showed moderate improvement, 5 cases (16.66%) showed mild improvement 1 cases had stat quo (3.33%) while 1 case (3.33) show. In group B, 18 cases (60%) showed marked improvement, 4 cases (13.33%) showed moderate improvement, 2 cases(6.66 %) showed mild improvement followed by 3 cases (10%) had status quo followed by (0%) of non-significant improvement .

An Independent t-test was conducted to compare the effect of two approach in Group A and Group B. There is statistically no significant difference in the scores of group A (M =5.96, S.D. = 5.900.), and Group B (M =5.82, S.D. =7.325) conditions; where $t(\text{cal}) = .214$, $p = 0.831$. These results suggest that there is significant viii difference is seen in preidentified Homoeopathic medicine *Chrysarobinum* External application and centesimal potency in the management of cases of Tinea corporis.

DISCUSSION& CONCLUSION :

From the study various epidemiology, clinical and therapeutic observations have been made. 60 cases have been studied with their types, manifestation, complication, associated conditions etc. various epidemiology, clinical and therapeutic observations have been made. 55cases were studied with their manifestation, associated conditions etc. Homoeopathic medicine *Chrysarobinum* were prescribed after detailed case taking and case processing

From the results of this study, the conclusion can be drawn that individuals suffering from Tinea corporis showed effective improvement by homoeopathic medicine selected via both approaches. Medicines are effective not only in the patches of Tinea corporis, but also in their quality of life.

Homoeopathic medicine '*Chrysarobinum*' was prescribed after detail case taking. From the results of this study, the conclusion can be drawn that individuals suffering from Tinea corporis showed effective relief by homoeopathic medicine '*Chrysarobinum*' not only in the patches of tinea corporis, but also in their quality of life Which treatment group A and group B in effective extent of improvement was better in Chrysarobinum External application and centesimal (CH) than therapeutic approach.

REFERENCES:

1. Khanna N. Illustrated synopsis of dermatology and sexually transmitted diseases. 4th ed. New Delhi: Elsevier; 2011.
2. Najem M. Diagnostic and biological study for some dermatophytes isolated from patients in Thi-qar province [B. Sc.]. College of Science, University of Thi-Qar; 2015.
3. Sharma M, Sharma M, Saxena V. Spectrum of derematophytoses in Jaipur, India. African Journal of Microbiology Research [Internet].2014 [citeds10November 2019];8(3):237-243. Available form: <https://www.researchgate.net/publication//272726591-Spectrum-of-dermatophytoses-in-jaipur-india>
4. Ananth Narayasn R. JayaramPainker C.K. Textbook of Microbiology. 7th Edition. Chennai: orient Longman Pvt Ltd; 2005. Pg no 606.
5. Clarke J. The Prescriber. Delhi: B. Jain Publishers Pvt. LTD.; 1996

DLQI- PRE	GROUPS	N	MEAN	Std. deviation	Std. Error Mean
	Group A	27	21.19	2.403	0.462
	Group B	28	21.43	3.048	0.576
DLQIPOST	Group A	27	5.96.	5.900	1.135
	Group B	28	5.82	6.056	1.144

Table : Group Statistics

In group A Paired sample t-test result, to assess the effect of chrysarobinum External Application post treatment (M =5.96, S.D. = 5.900), compared to pre-treatment (M = 21.19, S.D. = 2.403) by DLQI Scale lower the Score indicate Tinea corporis cases were improved by chrysarobinum CH potency, difference of mean=15.222, t (30) = 13.484, P=0.000

In group B Paired sample t-test result, to assess the effect of Chrysarobinum CH post treatment of (M = 5.82, S.D. =6.056) compared to pre treatment (M =21.43, S.D.=3.048) by DLQI Scale. Lower the score indicate Tinea corporis cases were improved by Chrysarobinum Potency, Difference of mean =15.607, t (40) = 11.275, P =0.001

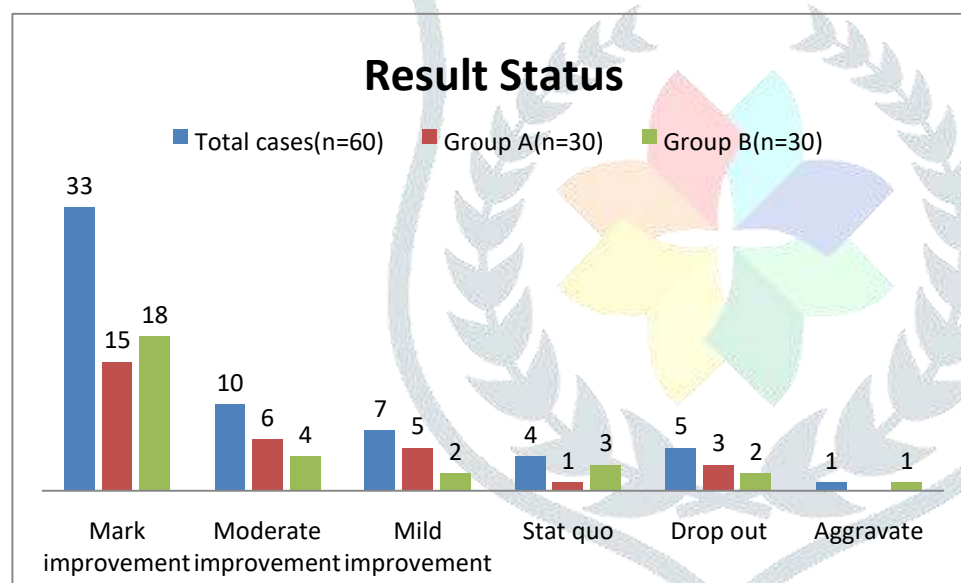


Fig. Graphical comparative representation of 60 cases of Tinea corporis according to “Status of Patients” in Group A and Group B Interpretation of above data:

In group A 15 cases (30 %) showed marked improvement while 6 cases(20%) showed moderate improvement, 5 cases (16.66%) showed mild improvement 1 cases had stat quo (3.33%) . In group B, 18 cases (60 %) showed marked improvement, 4 cases (13.33 %) showed moderate improvement, 2 cases(6.66 %) showed mild improvement followed by 3 cases (10 %) had status quo and 1case aggravate(.30%)

In Group A and Group B of treatment by using “chrysarobinum”, the outcome of the study was better than that of treatment of the patients using Group B using according to DLQI scale.