

Research Article

Effectiveness of Homoeopathy in Tinea corporis and Tinea cruris – A Prospective, Longitudinal Observational Study

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Abstract Dermatophytoses refers to superficial fungal infection of keratinized tissues caused by keratinophilic dermatophytes. According to observations worldwide, dermatophytoses are the most common of the superficial fungal infections. It is common in tropics and may present in epidemic proportions in areas with high rates of humidity. This prospective, longitudinal, observational study was conducted at SKHMC, Jaipur for a period of 1 year (April 2018 to March 2019), aiming to ascertain the effectiveness of homoeopathic medicines in the treatment of Tinea corporis and Tinea cruris. In this study, 65 cases of Tinea Infection (33 cases of Tinea cruris & 32 cases of Tinea corporis) were treated with homoeopathic medicines prescribed on the basis of totality of the symptoms. Treatment outcomes were assessed using Clinical Symptom Score, designed for this study & approved by Institutional Ethical Committee. Out of 65 patients, 41 patients (63.1%) got improved; 19 patients (29.2%) were at status quo and 05 patients (07.7%) became worse. Maximum patients were found to be in the age group of 11-40 years (n=50; 76.9%). Males were observed to be affected more as compared to females. Paired t-test was conducted on the Clinical Symptom Scores obtained before and after treatment and the result showed that p value is < 0.05 & value of t (11.623) is greater than the tabulated value in t-table at df = 64 (1.997), which was statistically significant and which also concluded that homoeopathic medicines were effective in treating Tinea corporis and Tinea cruris.

Keywords Homeopathy; Dermatophytoses; Fungal infection; Observational study

Introduction

Dermatophytoses, also known as ringworm or Tinea is a chronic fungal infection of the skin, hair, and nails. Dermatophytoses refer to superficial fungal infection of keratinized tissues caused by keratinophilic dermatophytes. Tinea varies with the site of infections and fungal species involved. Tinea corporis is the term, when whole body is involved and Tinea cruris is the term, when only groin region is involved [1]. Dermatophytes invade keratin only, and the inflammation they cause is due to metabolic products of the fungus or due to delayed hypersensitivity. In general, zoophilic fungi (those transmitted to humans by animals) cause a more severe inflammation than anthropophilic ones (spread from person to person) [2]. According to World Health Organization (WHO), the prevalence rate of superficial mycotic infection worldwide has been found to be 20-25%. Its prevalence varies in different countries. Tinea corporis (78.1%) was the commonest clinical presentation, followed by tinea cruris (10.1%), tinea manuum (2.5%), tinea faciei (1.8%), and tinea pedis (0.7%). Similar findings were observed in the study by Mishra et al., and Goldstein et al. It is more prevalent in tropical and subtropical countries like India where the heat and humidity is high for most part of the year [3]. In order to determine the extent and causative agent of ringworm infections in Jaipur, a study was done in outdoor patient department of skin, SMS Hospital, Jaipur in 2006. Out of 196 diagnosed cases, Tinea corporis was observed in 69 patients (35.2%). The second most common clinical type is Tinea cruris, reported in 44 patients (22.4%) followed by Tinea Capitis (11.2%) [4].

There is a veritable epidemic of steroid modified Tinea in India. Topical antifungals used for this condition are most often in combination with potent topical steroids and antibacterials. The most common combination in India at present is clobetasol propionate, ornidazole, ofloxacin, and terbinafine. They are often bought over the counter, suggested and sold by the pharmacist or prescribed by the general practitioners. Moreover, they are used erratically, often only for symptom control and that too without any instructions or supervision. People often stop using them when the itching and redness are mitigated and begin to apply again when the symptoms reappear. The cutaneous inflammatory response that the skin mounts to resist or limit the fungal infection is majorly suppressed by topical as well as systemic steroids [5].

Homoeopathy is a method of curing the sufferings of a person by the administration of drugs which have been experimentally proved to possess power of producing similar sufferings in a healthy human being. Homoeopathy implies a particular way of applying drugs to diseases according to a specific principle, known as "Similia Similibus Curentur (let likes be treated by likes); and implies as well the theories of vital force, of chronic miasms and of dynamisation of drugs [6]. Scope of modern medicine is limited in cases of Tinea infections, the oral anti-fungal medicines or topicals only suppress the condition, leading to recurrence of infection with more intensified symptoms.

Considering the rising incidence of Tinea infection & suppression of the same by mainstream medicines, this study has opted to ascertain the effectiveness of homoeopathic medicines in cases of Tinea corporis & Tinea cruris. The Alternate Hypothesis considered in this study was that there will be improvement in cases of Tinea corporis and Tinea cruris by prescribing homoeopathic medicines according to symptoms similarity. The objectives of this study was to clinically assess treatment outcome in cases of Tinea corporis and Tinea cruris using Clinical Symptom Score designed for this study & approved by Institutional Ethical Committee, as well as to observe the incidence of Tinea corporis and Tinea cruris in Jaipur and to prepare therapeutic compendium of homoeopathic medicines for the treatment of Tinea corporis and Tinea cruris.

Materials & Methods

Study setting-This study was undertaken at the O.P.D. of Swasthya Kalyan Homoeopathic Medical College & Research Centre, Jaipur.

Study duration-The duration of study was 12 months (April 2018 to March 2019), out of which first 6 months were for enrolment of the patients and last 6 months were for follow up fortnightly. Patients were screened on their first visit as per inclusion/exclusion criteria. If the patient fulfilled the inclusion criteria, he or she was enrolled in the study.

Sample Size-By taking standard size of 0.4 at 90% power, sample size including drop out was 68.

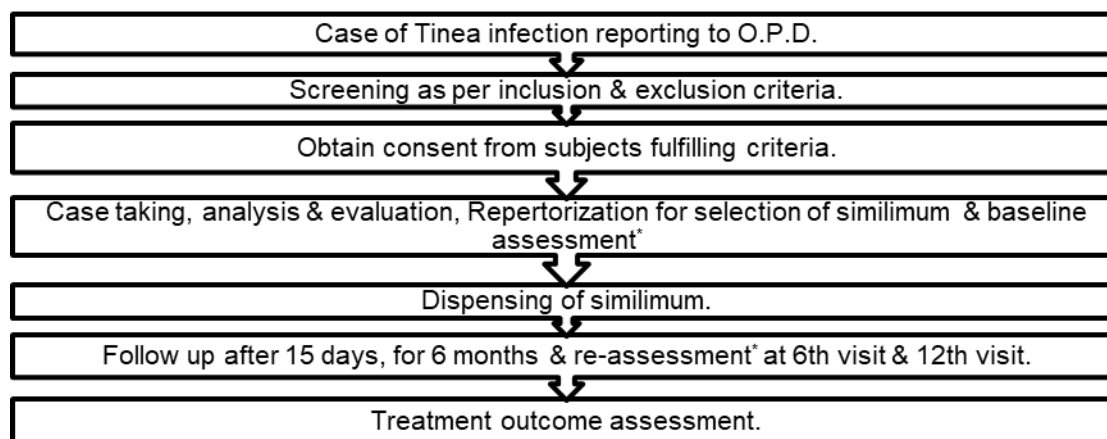
Selection of samples-Selection of cases was done randomly through coin toss method (heads-included; tails-not included) from college OPD, and written consent was taken from patients.

Inclusion Criteria- 1. Newly diagnosed cases of Tinea corporis and Tinea cruris seeking homoeopathic treatment & cases taking treatment from other systems of medicine with no relief.
2. All age group of both sexes.

Exclusion Criteria- 1. The case without proper follow-up and discontinuation of treatment in between the study. Such cases were dropped out. 2. Cases with complication like lichenification and eczema. 3. Patient having Tinea infection secondary to other auto-immune disorders, systemic diseases or patients on immune-suppressive therapy.

Study design- Prospective; Longitudinal; Observational study.

Brief of Procedure-



*Baseline Assessment & Re-assessment:

- Clinical assessment of Tinea corporis & Tinea cruris (Clinical Symptom Score).
- Re-assessment was done at 6th visit and 12th (last) visit.

Intervention-

1. **Selection of the Medicine:** - Homoeopathic Medicine was selected according to the totality of the symptoms as per the repertorial result and confirmed from Materia Medica.
2. **Change of Remedy:** - In case of acute exacerbation of symptoms or appearance of any other acute disease condition, the medicine selected was either a continuation of preselected medicine, or one of the better- indicated medicines. Case was reanalysed to make further prescription.

3. **Doses and potency:** - Selection of doses and potency were done as per the need of the case, depending on the susceptibility of patients. Medicine was administered orally.
4. **Repetition:** - Medicines were repeated depending on the frequency, intensity and duration of symptoms till perceptible changes appeared. Appearance of any change was immediately followed by placebo/change in potency/change in remedy, depending upon the response. In case where no signs of improvement noticed, potency was raised. Even if no change was observed, reanalysis of the case was done.
5. **Procurement of medicine:** - The medicines were procured from the pharmacy having the Good Manufacturing Practices certificate.
6. **Ancillary Measure:** - Avoid going into swimming pools and communal baths. Avoid sharing personal items like towel, bathe soap, comb, etc. Avoid tight under occlusive garments. Regular and thorough bathing with soap and water, with special attention to drying moist areas to maintain personal hygiene. Apply coconut oil on the affected area to reduce itching and to avoid exposure to moisture.
7. **Restrictions:** - Medicines of other streams were restricted during the treatment. Any topical antifungals like clobetasol propionate, ornidazole, ofloxacin, and terbinafine which can be bought over the counter, suggested and sold by the pharmacist were strictly restricted during the treatment. Any homoeopathic topical ointment was also restricted.

Selection of tools-

1. Homoeopathic Case Taking Performa specially designed for this study.
2. RADAR 10.5 (Synthesis 8.1) was used for repertorization.
3. A Clinical Symptom Score was developed to clinically assess the treatment outcome in cases of Tinea corporis and Tinea cruris.

Table I: Clinical Assessment of Tinea corporis and Tinea cruris.

Score	Pruritus	Papular Eruptions	Erythema	Scaling
0	Absent	Absent	Absent	Absent
1	Mild, occasionally disturbing daily activities	Mild, scarcely distributed	Mild redness	Mild, scarcely visible only in some areas
2	Moderate, often disturbing daily activities	Moderately distributed	Moderate redness	Moderate, visible in some areas
3	Severe, frequently disturbing daily activities and sleep	Severe, densely distributed and/or presence of plaques	Severe, bright redness easily visualized	Severe, thick covering large area

Note: Clinical symptom score was calculated before treatment as well as after treatment and was compared to assess the effectiveness of homoeopathic medicines. Following outcomes was assessed:

- **Improvement:** If the score was reduced by 4 or more, after the treatment.
- **Status Quo:** If the score remained the same or was reduced by less than 4, after the treatment.
- **Worse:** If the score was increased even after the treatment.

Data collection-Data were recorded in Homoeopathic Case Taking Proforma specially designed for this study. Data were collected after proper follow-ups. Data were maintained in both soft and hard copy.

Data analysis & Statistical techniques-Demographic data & other observations were presented using Descriptive Statistics i.e. mean, median, percentage, etc. Treatment outcomes were analysed using Paired t-test by using IBM SPSS 25.0.

Need of investigations-The diagnosis of the cases was done clinically by eliciting cases history and clinical findings on physical examination.

Parameter for analysing the outcome/result of this study-All the patients were followed-up for a period of 6 months, at an interval of 15 days and score obtained from 'Clinical assessment of Tinea corporis and Tinea cruris' was assessed before, at 6th visit and after treatment. Following parameters were fixed according to the type of response after the treatment:

Improvement-If the score was reduced by 4 or more after the treatment, with relief in all signs and symptoms.

Status quo-No change in the score or score was reduced by less than 4 after treatment and no specific relief in any complaints in spite of taking the medicine.

Worse-Increase in the score after treatment and no improvement in the condition of the patient, instead he / she got worse.

Ethical Issues-A written consent was obtained from each participant. The study was approved by the Institutional Ethical Committee.

Results, Discussion and Conclusion

A total of 68 patients were enrolled in this study, out of which 03 patients were dropped-out due to irregular follow-up. Observations and statistical analysis was done on 65 patients as per protocol. Out of 65 patients, maximum incidence was observed in the Age group of 21-30 years (n=26; 40%). Majority of the patients belonged to age group of 11-40 years (n=50; 76.9%). In a study conducted by Jain et al. [4] in Jaipur, it was found that tinea infections are more common in the age group of 21-30 (26.0%) followed by 31-40 (18.8%), 11-20 (16.3%). It was also observed that males (n=43; 66.1%) were more affected than females (n=22; 33.9%). Brigida S and Muthiah NS, [7] reported that out of 151 Tinea corporis patients, 84 were males and 67 were females & out of total 138 Tinea cruris patient reported, 62 were males and 76 were females.

In this study, it was observed that Tinea corporis (n=32; 49.2%) and Tinea cruris (n=33; 50.8%) were found to be equally affecting the population. Jain et al. [4] reported that Tinea corporis was the most common clinical type reported from all age groups. Tinea cruris was the second most common clinical type. 19 homoeopathic medicines were used in this study according to totality of symptoms after repertorization and confirmation from Materia Medica. These medicines were considered in the therapeutic compendium for tinea infection.

Table II: Homoeopathic Medicines used in the study

S.No.	Remedy	Total No. of Cases	Improvement	Status Quo	Worse
1.	Sulphur	18 (27.7%)	13 (72.2%)	04 (22.2%)	01 (5.6%)
2.	Bacillinum burnett	12 (18.6%)	06 (50%)	05 (41.7%)	01 (8.3%)
3.	Natrium muriaticum	06 (9.2%)	01 (16.7%)	04 (66.6%)	01 (16.7%)
4.	Tuberculinum	05 (7.7%)	03 (60%)	01 (20%)	01 (20%)
5.	Sepia officinalis	04 (6.2%)	04 (100%)	00 (0%)	00 (0%)
6.	Arsenicum album	02 (3.1%)	02 (100%)	00 (0%)	00 (0%)
7.	Calcarea carbonica	02 (3.1%)	01 (50%)	00 (0%)	01 (50%)
8.	Chrysarobinum	02 (3.1%)	02 (100%)	00 (0%)	00 (0%)
9	Dulcamara	02 (3.1%)	01 (50%)	01 (50%)	00 (0%)
10.	Mercurius solubis	02 (3.1%)	00 (0%)	02 (100%)	00 (0%)
11.	Nux vomica	02 (3.1%)	02 (100%)	00 (0%)	00 (0%)
12.	Baryta carbonicum	01 (1.5%)	00 (0%)	00 (0%)	01 (100%)
13.	Lachesis mutus	01 (1.5%)	01 (100%)	00 (0%)	00 (0%)
14.	Medorrhinum	01 (1.5%)	01 (100%)	00 (0%)	00 (0%)
15.	Natrium sulphuricum	01 (1.5%)	01 (100%)	00 (0%)	00 (0%)
16.	Pulsatilla pratensis	01 (1.5%)	01 (100%)	00 (0%)	00 (0%)
17.	Rhus toxicodendron	01 (1.5%)	00 (0%)	01 (100%)	00 (0%)
18.	Tellurium metallicum	01 (1.5%)	00 (0%)	01 (100%)	00 (0%)
19.	Thuja occidentalis	01 (1.5%)	01 (100%)	00 (0%)	00 (0%)
Total		65 (100%)			

A Clinical Symptom Score was developed specially for this study and was approved by the Institutional Ethical committee, which was used in this study to assess the treatment outcome in cases of Tinea corporis & Tinea cruris. A total of 65 patients were assessed before and after treatment, using Clinical Symptom Score. 41 patients (63.1%) showed improvement in Clinical Symptoms Score and relief in all complaints; 19 patients (29.2%) were at status quo, showing no change in score or difference less than 4 in Clinical Symptoms Score after treatment with no specific relief in symptoms and 05 patients (07.7%) became worse, showing an increase in Clinical Symptoms Score along with worsening of symptoms.

The statistical test used to analyze the scores was Paired t-test. The analysis was done on IBM SPSS 25.0. So, Sample size (per protocol) is 65, for which degree of freedom (n-1) = 64 and level of significance is $\alpha = 0.05$.

Paired t-test:
$$t_{(ca)} = \frac{\bar{d}}{sd/\sqrt{n}} \sim t_{(n-1)}$$

$$\bar{d} = \frac{1}{n} \sum_{i=0}^n d_i \text{ and } s_d = \sqrt{\frac{1}{n-1} \sum_{i=0}^n (d_i - \bar{d})^2}$$

$df = n-1 = 65-1 = 64.$

$n =$ Total number of patients i.e. 65.

$d =$ Mean of samples.

Table III: Mean & Standard deviation of the samples

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Score(before t/t)	8.78	65	0.893	0.111
	Score(after t/t)	4.00	65	3.349	0.415

Table IV: Paired t-test

Paired Samples Test									
		Paired Differences			95% Confidence Interval of the Difference				Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper	t	df	(p)
Pair 1	Score(before t/t) - Score(after t/t)	4.785	3.319	0.412	3.962	5.607	11.623	64	0.000

Paired t-test (Table IV) was conducted to assess the effectiveness of Homoeopathic medicines in the treatment of Tinea corporis and Tinea cruris. The result (Table IV) showed that p value is < 0.05 & value of t (11.623) is greater than the tabulated value in t-table at df = 64 (1.997), which was statistically significant, which justifies the effectiveness of homoeopathic medicines in treating cases of Tinea corporis and Tinea cruris. Thus, homoeopathic medicines can be useful in treating chronic, recurrent fungal infections of skin, but it will require a sound knowledge of Repertory, Materia Medica and Organon of Medicine.

There are also some limitations of this study. The study design was observational which cannot be considered as the standard research design as randomized control trials along with single or double blinding is considered as the ‘gold standard’ in the field of medical research. Since, the sample size was also small in this observational study, so generalizing the result and conclusions of this study need to be done very cautiously.

Globally, there was no specific scale found for the assessment of the treatment outcome in case of Tinea infection. So, the results of this study cannot be generalised to any population. The findings of this study warrant further evaluation using better study designs with large sample size and enhanced methodological rigor. Hence, further more extensive studies will be required with better statistical tools to establish the outcome results of this observational study.

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Conflicts of Interest

There are no conflicts of interest.

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