

Original Research Article

Clinical Evaluation of Thelkoduksu Chooranam (Heliotropium Indicum) in the Treatment of Scabies

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ABSTRACT

To determine the efficacy and tolerability of the topical and systemic effects of Siddha herbal preparation *Thelkoduksu Chooranam (Heliotropium indicum)*, we conducted the open labeled non-comparative prospective clinical study focused on the patients of either sex in the age group between 13 to 60 years irrespective of socio economic status with diagnosis of scabies. After baseline assessment, a total number of 50 patients with scabies were treated with *Thelkoduksu Chooranam (TKC)* orally at the dose of 500 mg twice a day with milk after food and for external use; the fresh leaf paste was applied over the affected area twice a day for one month. Clinical assessment of scabies lesions based on clinical grading score, itching intensity were assessed at weekly intervals for four weeks. The pre and post treatment score was compared statistically and recorded. From the result it was observed that oral and topical administration of TKC significantly reduced all the signs and symptoms after one month treatment. As compared to baseline, TKC treatment significantly reduced clinical grading score and itching grading score from 3.02 ± 0.08 and 2.04 ± 0.099 to 0.08 ± 0.03 and 0.04 ± 0.03 respectively ($P < 0.001$). Complete disappearance of scabies lesions was observed in all patients. No adverse effect has been noticed during the study period. Hence it is concluded that *Thelkoduksu Chooranam* exhibits scabidical activity and is a promising Siddha herbal preparation which has effective and safe anti scabies agent.

Keywords: Scabies, *Thelkoduksu Chooranam*, *Heliotropium indicum*, Siddha, herbal preparation.

INTRODUCTION

Scabies is a widely spread and a highly contagious disease throughout the world. ^[1] The agent responsible is *Sarcoptes scabiei* var. *hominis*, is a mite which colonizes the horny layer of the human epidermis causing a very itchy and contagious dermatitis and by its ability to

produce a wide variety of clinical manifestations, many of them atypical, whose recognition can be difficult for the general physician and even for the dermatologist experienced. ^[2] The organism being oval in shape has four legs in front ending in suckers and four hind legs ending

in spines. The length of the female and male is about 0.15mm respectively. The female parasite after becoming gravid lays about 2-3 eggs per day in burrows in stratum corneum of epidermis. The larval acari develop in about 3-4 days from the eggs and come to the surface and moult thrice thereby becoming adult. This life cycle is repeated in about 10-17 days. ^[3]

Scabies is transmitted by skin-to-skin contact, as demonstrated in classical studies by Mellanby. ^[4] Infection is mainly acquired by very close and long continued contact. This infection is usually acquired from another infected person which has established close contact, can be from a child, a friend or family member. It is also important to treat all family members or community who live with the patient. Thus, it is a disease of overcrowding and poverty rather than a reflection of poor hygiene. ^[5] It has been estimated that 300 million people suffer from scabies infestation at any one time. ^[6]

Several demerits faced in allopathic treatment of scabies is mainly the resistance developed by *Sarcoptes scabiei*, side effects of medicines used, unaffordable cost and the long residual properties of the available medicines in the market urge to search for alternative approaches to combat scabies, thereby controlling the mite. One such approach could be the use of herbal preparations from the ancient Siddha system of medicine that might be useful to cope with scabies disease on human. The treatment history for scabies is found prevalent in Siddha system of medicine which is widely practiced.

For a long time, during the process of controlling diseases, the Tamil people have used many methods of curing by using Siddha medicines. Many Siddha medicines are made from plants that are easy to grow and as a result the cost is low.

One of the promising herb mentioned in Siddha system of medicine for scabies is *Thelkodukku Chooranam* (*Heliotropium indicum*, Family: Boraginaceae) commonly known as Indian Heliotrope, Erysipelas plant, Scorpion weed, Indian turnsole. It is an old saying that the inflorescence of these plants seem to turn towards the sun and hence the name derived. The meaning of 'Helios' in Greek is 'sun' and 'tropicin' from where the word 'tropium' is derived means 'to turn'. ^[7] Numerous studies have been conducted for its various therapeutic potentials.

Heliotropium indicum has its application in several traditional systems of medicine including Ayurveda and Siddha. ^[8,9] This plant contains various chemical compounds such as pyrrolizidine alkaloids, heliotrine, ^[10] indicine, indicinine ^[11] and several triterpenes and steroids. Traditionally the plant has been reported to have anti dote, wound healing, anti rheumatic, anti allergic and scabidical properties. ^[12-14]

As per the ethno pharmacological survey, *Heliotropium indicum* widely used to treat poisonous bites, skin infections, stomach problems and nervine disorder traditionally in Tamilnadu. ^[15] Some African countries widely use this plant in the treatment of malaria and also believed to be useful in treating dermatitis and abdominal pain. ^[16] Decoction of the whole plant is administered orally to cure fever, ulcers, sore throat and venereal diseases. It is also used as an abortifacient and applied over rectal sores. ^[17] Some of the folk remedies include the use of decoction in the treatment of fevers ^[18] and for insect bites, skin rashes, urticaria and menstrual disorder. Decoction of the leaves when given in large doses act as an abortifacient and as an emmenagogue when administered in small doses. ^[19] When the decoction of leaves is macerated with sugarcane juice, it can be applied externally

for scorpion-stings. To cure Rheumatism, poultice of the leaf is applied externally as a traditional practice at Rayalseema in Andhra Pradesh ^[20] and for skin infections in Nicaragua. ^[21] The poultice of leaf and root is applied externally for scorpion sting bites and bug bites traditionally in Amazon. ^[22] Keeping in view the above medicinal properties of *Heliotropium indicum* against different diseases, the present study was designed to evaluate the topical and systemic effects of Siddha herbal preparation *Thekkodukku Chooranam* (*Heliotropium indicum*) clinically for the treatment of scabies.

MATERIALS AND METHODS

The open labeled non-comparative prospective clinical study focused on the patients of either sex in the age group between 13 to 60 years irrespective of socio economic status with diagnosis of scabies. A total number 50 patients in which 16 females and 24 males were included in the present study in the period of 10 months from August 2011 to May 2012 at Government Siddha Medical College Hospital, Arumbakkam, Chennai. The protocol of this present clinical study was approved by the Institutional Ethical Committee and conducted according to the guidelines of the Declaration of Helsinki. ^[23]

Scabies is a highly contagious disease and hence to reduce the chances of reinfestation, ^[24] family members of the subjects were encouraged to participate in the study. Family data and demographic profile were gathered through interview using a questionnaire. Before enrolling the study, all the patients were informed about the trial, properties of the trial drug, benefits, mode of treatment, duration of treatment and their rights. Written informed consent both in international and regional language were obtained before entry into the study.

Pre-study screening and baseline evaluation

Before subject enrolled in the study, history and thorough head to toe skin examination especially the webs of fingers, hands, wrists and elbows were done initially. The diagnosis of scabies usually arises through the classic symptoms and the presence of characteristic skin lesions characterized by itching, mostly nocturnal. A baseline questionnaire compiling the information of the lesions such as burrows, erythematous papules in the fingers of hands and inguinal area, papules and vesicles on the webs of fingers, upper extremities and lower extremities, pustules on palms and soles was prepared. Baseline questionnaire was used to determine the common lesions found in scabies to evaluate the degree of lesion like burrows (slightly elevated, grey linear lines in the skin), erythematous papules on the hands/fingers and inguinal area, vesicles and papules on the webs of fingers, pustules on palms and soles, papules on upper and lower extremities.

Severity of lesions was clinically graded on a scale of 0 to 4. ^[25] Grade 0 - no lesion, Grade 1 – one to ten lesions (mild), Grade 2 – eleven to twenty lesions (moderate), Grade 3 – twenty one to thirty lesions (severe) and Grade 4 – more than thirty lesions (very severe or generalized). Itching was also graded on a scale of 0 to 3 on the basis of severity. Grade 0 - no itching, Grade 1 - mild itching, Grade 2 - moderate itching, Grade 3 - severe / intense itching.

However, the diagnosis was also confirmed by one drop of sterile mineral oil was applied to the area of the skin lesion. Then the sample was taken by scraping with scalpel for microscopic analysis to confirm the presence of the parasite, eggs and other droppings if any. Ink test was also performed to confirm the diagnosis by drawing a line with a blue marker pen on a suspected area of lesion and then washed. If

groove is present, the ink will penetrate and visible.

Inclusion criteria

Clinical diagnosed scabies such as classical burrow, papules, nodules or vesicles at classical site with nocturnal itching, history of similar signs and symptoms in family members or close contact and or microscopically diagnosed scabies such as presence of egg, larvae, mite and other droppings were included the study.

Exclusion criteria

Patient < 12 years of age, pregnant and breast feeding, taking any medication, treatment for scabies within one month, other skin diseases, renal, hepatic and cardiac dysfunctions, HIV infection, CNS disorders and other clinically abnormal findings aside from scabies determined during the entry level were excluded from the study.

Drug formulation and dosage regimen

Preparation of trial drug

The plant *Thelkodukku* (*Heliotropium indicum*) was collected from in an around Chennai. After collection, the plant was identified and authenticated by the Department of botany and Gunapadam dept. The voucher of specimen sample of the plants was kept in the department for future reference. Then the plant was cleaned well and dried for a week in the shadow. The purified plant was made into a fine powder form Chooranam. It was filtered by white cloth (*Vasthirakayam*). This powder was further purified as per the procedure given in the Siddha literature.^[26] Then the drug *Thelkodukku Chooranam* (TKC) was stored in a clean, dry glass container, since the life time of *Chooranam* is only three months, the prepared *Chooranam* was used for three months only. Every three months the trial drug TKC was prepared in this same fashion.

Internal administration

TKC was administered orally at the dose of 500 mg twice a day with milk after food.

External application

For external use the fresh leaf paste was applied over the affected area in the morning and night.

Health educations and prevention standards

Many therapeutic failures are due to an absence or mistreatment of bedding and clothing. Hence, all the enrolled patients and their family members were instructed to do the following hygienic practices and housekeeping.

All patients should be treated and isolated 48 hours. All bedding and clothing and other washable items must be disinfected by washing at 60 ° C in boiling water. Anything that cannot be washed at this temperature should be placed in a trash bag sealed and stored for 5-7 days. The mite does not survive more than 4 days without human contact. Other contaminated objects should be treated with a pesticide disinfectant aerosol. Patients were instructed to avoid any topical and oral treatment during the study period without consulting the doctor.

Clinical assessment

The clinical grading score was assessed initially, after one week, two weeks, three and four weeks of drug administration. Improvement was analysed based on the following formula.

$$\frac{\text{pre-treatment score} - \text{post-treatment score}}{\text{pre-treatment score}} \times 100\%$$

Itching score was also assessed and recorded as per the above formula. Clinical photos were obtained before and after treatment.

Adverse reaction or side effects

Safety of the TKC and topical application of leaf paste was monitored carefully at each visit and recorded. No serious adverse events or side effects were observed by the researcher or reported by the patients. There were some occasional reports of abdominal discomfort, diarrhea and nausea.

Statistical Analysis

Statistical analysis were calculated and analysed by Student' paired t test. P values ≤ 0.05 was considered as statistically significant.

RESULTS AND DISCUSSION

A total number of 54 patients were enrolled in the present study based on the pre study screening and baseline evaluation. During the trial period 4 of them

discontinued from the study after one week due to secondary skin infection which required anti biotic treatment. Total number of 50 patients were completed the study successfully.

The study patients were within the range of 13 - 60 years and females were 20. Majority of the patient came from slums with low income (34 patients) and only 16 patients from middle income groups.

Table No.1. Baseline profile of the patient with scabies (n=50)

Baseline features	Male	Female	Total
Age			
13-20	12	6	18
21-40	14	10	24
41-60	4	4	08
Socio-economic status			
Poor	21	13	34
Lower middle	6	8	14
Higher middle	1	1	02
Rich	0	0	00
Possible source of infection			
Relatives	15	12	27
Hostels	06	03	12
Hotels	02	00	02
Previously affected	05	04	09
Unknown	02	01	03

Table 2. Area wise distribution of scabies

Area of skin with scabies	No of patients with % (n=50)
Scalp / Neck / Face	04 (08 %)
Chest	16 (32 %)
Back	19 (18 %)
Axilla	14 (28 %)
Arms	21 (42 %)
Forearms	17 (34 %)
Wrist / Hand / Finger webs	34 (68 %)
Abdomen	29 (58 %)
Inguinal area	25 (50 %)
Buttocks	28 (56 %)
Legs	24 (48 %)
Feet	07 (14 %)

Table No.3. Comparison of signs and symptoms between Pre and Post evaluation of *Theilkodukku Chooranam*

Signs and Symptoms (n=50)	Before treatment	After treatment	% of improvement
Itching	50	0	100
Sleep disturbance	42	2	95.24
Burning sensation	24	2	91.70
Classical form of scabies	42	0	100
Atypical form	06	0	100
Norwegian form	02	1	50
Skin scrap test (+ve)	50	0	100

Table 4. Itching grade score (Statistical comparison between Pre and Post treatment).

Period of treatment	Pre treatment score (Mean \pm SEM)	Post treatment score (Mean \pm SEM)
0 day	2.04 \pm 0.099	---
1 week	2.04 \pm 0.099	1.50 \pm 0.09 ***
2 weeks	2.04 \pm 0.099	0.80 \pm 0.08 ***
3 weeks	2.04 \pm 0.099	0.24 \pm 0.06 ***
4 weeks	2.04 \pm 0.099	0.04 \pm 0.03 ***

Values are expressed in Mean \pm SEM (n= 50) Student's t test for paired values. Where P *** represents extremely statistically significant at $P < 0.001$.

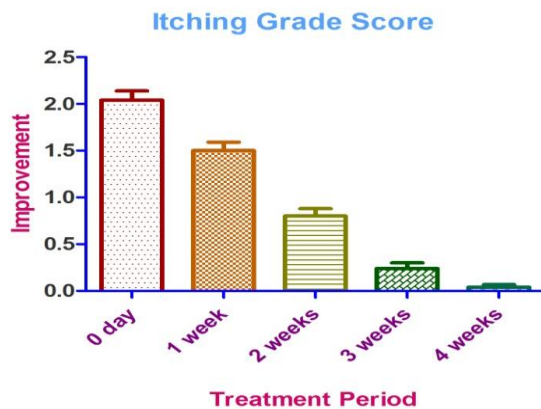


Figure.1. Showing the improvement in itching grading score.

Among the 50 patients 15 patients had scabies through their relatives, 06 of them from hostels and 2 of them from hotels. 05 patients were previously affected with scabies and 02 of them had scabies with unknown origin. Most commonly affected sites were the hands, back and buttocks (34, 29 and 28 patients respectively).

Among the 50 patients who have been in present study, all patients had

itching, and 42 patients reported disturbance in sleep due to nocturnal itching. 42 patients had classical form of scabies, 06 patients

had atypical form and 02 patients were Norwegian form of scabies.

Table 5. Clinical grading score (Statistical comparison between Pre and Post treatment).

Period of treatment	Pre treatment score (Mean ± SEM)	Post treatment score (Mean ± SEM)
0 day	3.02 ± 0.08	---
1 week	3.02 ± 0.08	2.26 ± 0.10 ***
2 weeks	3.02 ± 0.08	1.10 ± 0.10 ***
3 weeks	3.02 ± 0.08	0.42 ± 0.07 ***
4 weeks	3.02 ± 0.08	0.08 ± 0.03 ***

Values are expressed in Mean ± SEM (n= 50) Student's t test for paired values. Where P *** represents extremely statistically significant at P<0.001.

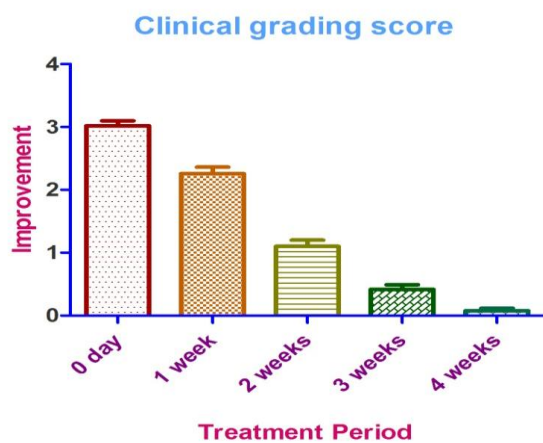


Figure.2. Showing the Clinical grading score.

Table No.6. Gradation of result

Sl.no.	Level of improvement	No. of patients (n=50)	Percentage (%)
1	Marked	46	92
2	Moderate	03	06
3	Mild	02	04
4	Poor	00	00

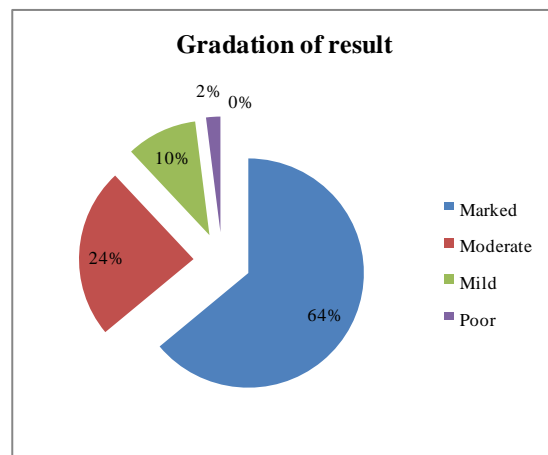


Figure 3. Effect of *Thelkodukku Chooranam* on scabies.

Burning sensation was observed in 24 patients. Skin scrap test was found positive in all the enrolled patients. All the patients concluded the 4-week study duration and the efficacy and safety of the trial drug *Thelkodukku Chooranam* and external application of leaf paste were analysed.

At baseline, mean itching grade score was 2.04 ± 0.099. As compared with baseline itching grade score, treatment period of one week, two weeks, three weeks and four weeks were analysed and found that the improvement in grading score with itching reduced significantly in all weeks. 49 patients out of 50 patients were completely free from itching at 4th week.

As compared to clinical grading score at baseline (3.02 ± 0.08), the treatment period at week 1, week 2, week 3 and week 4 was significantly reduced (P<0.0001). Complete disappearance of scabies lesions was observed in all patients.

At the end of the study, 92 % (46 patients) had marked improvement, 06% (12 patients) had moderate improvement and 2% (4 patients) had mild improvement. Poor improvement was not observed in any patient (0%). Mild response from 4 patients may be due to poor hygienic conditions.

From the above result showed that the Siddha herbal drug *Thelkodukku Chooranam* is effective in the treatment of scabies. It produces rapid and complete disappearance of itching due to their anti

histaminic effect. Clinical grading score was extremely significant after drug therapy

indicated that the drug *Thelkodukku Chooranam* possess scabicial activity.



Figure.4. Clinical improvement of scabies after *Thelkodukku Chooranam* treatment.

CONCLUSION

The main objective of this present study is to assess the compliance of the treatment of scabies in adults with Siddha herbal drug *Thelkodukku Chooranam*. The result clearly showed that systemic and topical application of *Thelkodukku Chooranam* and leaf paste have potent scabicial and anti histaminic activity and appears to be the most effective treatment for scabies. No adverse effect has been noticed during the study period. This study

should lead to propose the treatment of scabies in multicentre clinical programs.

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Declaration of interest: The authors declare that they have no conflicts of interest in relation to this article.

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