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Siddha herbo-mineral drug Kandhaga Rasayanam in the treatment of Dermatophytoses (Padarthamarai)

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Abstract---The symptoms of dermatophytosis goes congruent with the disease entity *Padarthamarai* in Siddha medicine. *Kandhaga Rasayanam* (KR) is a Siddha herbo-mineral formulation indicated for *padarthamarai.* In recent times, treatment of dermatophytosis challenge to dermatologists. The present study was carried out to clinically evaluate the efficacy of KR as a trial drug for Dermatophytosis. The objective of the present study was to study the efficacy of the drug KR in giving mycological and clinical cure. This was an open-label, non-randomized, single -arm clinical study in which 51 patients of either gender diagnosed with *padarthamarai* were included. The trial was registered in Clinical trials registry India with CTRI number CTRI/2012/01/002362. The treatment period was 45 days. Out of the 51 participants enrolled in this study, 45 participants were included in the final analysis based on their adherence to the conditions. 66.67% showed skin scraping negative for dermatophytes. There was a significant reduction in the clinical signs after the treatment without any adverse reactions. This trial has brought to limelight the efficacy of the Siddha drug *Kandhaga Rasayanam* in treating *padarthamarai* . Further, randomized controlled clinical trials are necessary to substantiate the traditional claim and make KR a plausible treatment option for Dermatophytosis.

Keywords---dermatophytosis, Kandhaga Rasayanam, clinical trials, clinical parameters, hematological parameters.

Introduction

Superficial fungal infections which are limited to human hair, nails, epidermis, and mucosa account for 20-25% of global mycotic infections. Although these infections are seldom life threatening, their worldwide distribution, frequency, transmission makes it crucial for study. The three most common types of superficial fungal infections include Dermatophytosis (tinea or ringworm), pityriasis versicolor (formerly tinea versicolor), and candidiasis (moniliasis). Trichophyton, Epidermophyton and Microsporum genera cause the Tinea infections of skin. These diseases can be effectively treated with oral or topical antifungal agents depending on the nature and severity of the infection. Treatment in the 1950s included griseofulvin (Williams DI et al., 1958) an oral antifungal agent followed by broad-spectrum oral imidazoles, especially ketoconazole 1981 (Botter AA et al.,1979). Due to their hepatotoxicity, they are substituted with triazoles, fluconazole, itraconazole, allylamine and terbinafine as they exhibited broad spectrum of activity against dermatophytes, nondermatophytes, and yeast with better efficacy, enhanced patient compliance and safer adverse effect profile. Additionally, they remain active in the skin, hair, and nails for a period after the cessation of the therapy (Aditya KG et al.,2005).

The triazoles, fluconazole and itraconazole, and the allylamine, terbinafine, are antifungal agents with a broad spectrum of activity against dermatophytes, nondermatophytes, and yeast. These antimycotics have an improved efficacy, a safer adverse event profile, and increased patient compliance as compared with the older agents, griseofulvin and ketoconazole. Furthermore, fluconazole, itraconazole, and terbinafine remain active in the skin, hair, and nails for a period after the cessation of the therapy. In recent times, the rate of dermatophytosis infections have changed drastically in India in terms of frequency, acuteness, clinical features, response to treatment in addition to unreasonable use of antifungal drugs, steroid usage and also to the poor socioeconomic status (Das S et al.,2020) which may be due to high relative humidity and therefore emerged as epidemic. The infection is in a rising pattern in tropical countries like India where the relative humidity is high and has emerged as an epidemic (Verma S & Madhu R, 2017). In Spite of the increase, dermatologists witnessed incomplete mycological cure and treating dermatophytosis effectively still remains a challenge (Singh S & Shukla P, 2018). A suitable dose and duration of treatment to get a complete mycologic cure and prevention of recurrence of infection remains indefinable. Though many newer antifungals are discovered, the cost effectiveness remains a big question posing financial burden on the individual (Porter G & Grills N, 2016).

Siddha system of medicine, one of the indigenous medical systems in South India has innumerable remedies for skin diseases. The symptoms of the disease dermatophytosis can be correlated to the symptomatology of *Padarthamarai* or *Pundareega kuttam* in Siddha literature (Kuppuswamy Mudhaliyaar, 2016). The treatment with *Kandhaga Rasayanam* (KR) was a sincere attempt to fill in the existing gaps. The drug KR has been proved to be non-toxic in both acute and chronic toxicity studies in rats (Meena R & Ramaswamy RS, 2018). In our earlier report, we used *Kandhaga Rasayanam* (KR) as a plausible drug for dermatophytosis over one single patient and the response observed was positive.

Itching and erythema reduced and the newly appeared lesions of Tinea corporis vanished with no relapse in the follow up period (Meena R & Ramaswamy RS, 2019). This has motivated us to validate this formulation on an increased number of patients. This pilot open label clinical trial was attempted to study the Siddha formulation *Kandhaga Rasayanam* in *Pundareega Kuttam*. As there are no previous clinical trials with KR, a pilot trial was attempted. Firstly, this study was to study the efficacy of the drug KR in giving mycological cure and to study the clinical cure. Secondly, to study the safety of the drug and improvement in the quality of life of the participants.

Methodology

Patients and methods

This was an open labeled single arm non randomized pilot study to study the efficacy of the Siddha drug KR in *Padarthamarai* (Dermatophytosis). The patients who attended OPD of National Institute of Siddha were screened for *Padarthamarai*. The patients including male and female gender between the age 18 to 60 years who were clinically diagnosed to have tinea infection and also whose skin scrapings were found to be positive for dermatophytes were included in the trial. Pregnant women or nursing mother, patients who used other topical or oral antifungal drugs, immunosuppressive drugs, anthelmintic drugs either currently or during the 2 weeks preceding initiation of drug trial, patients having history of allergy or hypersensitivity of any component of the drug were excluded from the trial. Clinical case of eczema, psoriasis, lichen planus, pityriasis versicolor, drug-induced eruptions, urticaria, intertrigo, *Tinea unguium* and diabetic patients were excluded from the trial. The patients who fulfilled the inclusion criteria and were willing to participate in the trial were provided the informed consent form in vernacular language and the consent was obtained from all the trial participants. The Ethics Committee of National Institute of Siddha, Chennai reviewed and approved the study protocol. The trial was registered in Clinical trials registry India and the CTRI number is CTRI/2012/01/002362

Treatment regimen

The trial participants were administered with KR at the dose of 2 gram twice a day after food, continuously for 45 days. Each dose of the *Kandhaga Rasayanam* (2gm) was dispensed to participants in a zip lock cover to make it airtight. The trial participants were instructed to bring unused drugs on their next visit. They visited the hospital once every 7 days. At each clinical visit, clinical assessment was done and prognosis was noted. The lesion size was measured using a thick chart where squares were drawn for each centimeter. Laboratory investigations and skin scraping tests were done on the 0th day and 46th day of the trial. Identification of dermatophytes was based on standard methods using macro and microscopic colonial characteristics. The patients were advised to have regular follow-up for next 2 months. No laboratory investigations were carried out at the end of follow up. The patients were watched for any recurrence of symptoms for 2 months. The patients who failed to collect the trial drug on the prescribed day but wanted to continue in the trial from the next day or two were allowed to continue, but the defaulters of 1week and more were not allowed to continue in

the trial and were withdrawn from the study. Survival data of the withdrawn subjects were recorded and maintained for 2months. All the patients were evaluated for any ADE/ADR.

Evaluation of efficacy

Siddha based physical assessments include the body constitution, the land they live, season, *gunam* (character) of the patient, affection of sense organs, motor organs, *kosangal* (sheath), affected humour, complexion of the person, voice, eyes, palpation of skin, nature of stools, *neerkuri, neikuri* (nature of urine and oil on urine sign) and seven *thathus* (seven somatic components). General examination, vital organs examination, systemic examination, clinical examination of skin (shape, size, border, pustules, vesicles, ooze, scaling, clearance), palpation, clinical features like erythema, scaling, itching, burning sensation, round lesion with well demarcated margin, colour of the lesion, concentric rings were recorded. The clinical symptoms were assessed and recorded on each visit i.e, $0^{th}/1^{st}$ day, 7^{th} day, 15^{th} day, 23^{rd} day, 31^{st} day, 39^{th} day and 46^{th} day (after treatment period). A pruritus scale was designed and the intensity of itching was determined accordingly. The Quality of life was assessed using Dermatology Life Quality Index or DLQI (Finlay AY and Khan GK 1994).

Statistical Data analysis

This study being a pilot study was started with 85 OPD patients and the result data were analyzed with the statistical software Statistical Package for Social Sciences (SPSS) v13.

Results and Discussion

This study was aimed to find a Siddha based alternative to the existing drugs based on the previous reports that showed Siddha medicine to be effective in skin disorders. The primary objective of the study was to measure the mycological cure after 45 days of treatment. Mycological cure is defined as a negative culture for dermatophytes and an absence of hyphae and / or conidia in a potassium hydroxide preparation. Our previous report on a single case study showed significant results in treating the condition and hence this clinical trial was designed with 85 patients who visited the OPD of National Institute of Siddha. Based on the inclusion criteria, and compliance to clinical trials a total of 51 patients were included in the trial regimen. Trial drug KR was dispensed once every 7 days to the participants along with general and dietary instructions who were on periodic visits. Laboratory and clinical assessments were conducted on the 0th day and 46th day. After 46 days, 45 patients adhered to all the instructions given, completed the trial and follow up studies while 6 patients were excluded due to poor drug compliance and irregular follow up. No adverse event was reported during the study period. The details with respect to age and gender of trial participants are given in the bar graph (Fig. 1).

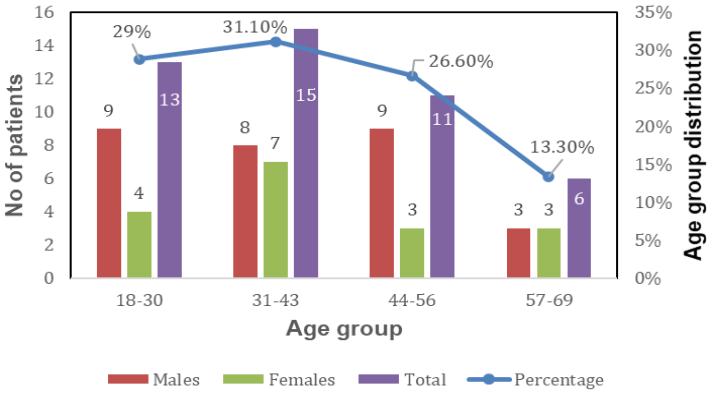

Fig 1. Patient information

Among the 45 trial participants, there were 29 males and 16 females with minimum age to be 19 and maximum age to be 60. 60% of the trial participants were illiterate. 30 (66.67%) of them belonged to a low socio-economic group. 20% of patients fall under the category middle income group. Only 13.33 % were high income group people. The maximum number of patients (n=28, 62.22%) had the lesions in groins. This shows that the common site of affection is groins in this study. 60% of the trial participants were illiterate. Sweating pattern was specifically observed in the patients as moist conditions facilitate the growth of dermatophytes. It has been observed that sweating was normal in 46.66% of patients (n= 21). Decreased sweating was not seen in any of the trial participants. 53.33% of patients (n= 24) had profuse sweating. This shows that dermatophytoses was more common in the patients who sweat profusely. Sweating has been well recognized as a menace for increasing the occurrence of dermatophytosis as it is generally referred to as Jock's itch, Dhobis itch, and athlete's foot. Sweating along with poor hygiene could possibly increase the rate of dermatophytosis. A report by Ranganathan et al. (1995) demonstrated that people in occupation involving increased sweating (58.9%) showed enhanced rate of dermatophytosis in comparison to those not involved in such kind of occupation.

Evaluation of efficacy
Distribution of *Naadi*

The distribution of the pulse is shown in Fig 2. *Vatha pitha naadi* was the predominant naadi (55.56%, n=25) of the trial participants. The second common *naadi* was *Pitha vatha naadi* (22.22%, n=10). *Vatha kaba naadi* was reported in 15.56% patients (n=7). *Pitha kaba naadi* and *Kaba vatha naadi* were seen in 4.44% (n=2) and 2.22% of patients (n=1) respectively. Siddha's way of assessing the body constitution showed that 53.33% (n=24) of patients had *Vatha* udal. The remaining patients had *Pitha* udal (20%, n=9), *Kaba* udal (17.78%, n=4) and *Thondha* udal (8.89%, n=8). Among the 45 patients the maximum number of patients (n=30, 66.67%) had *Thamo gunam*. 26.67% patients (n=12) had *Rasatha gunam* and *Sathuva gunam* was seen in only 6.67% of patients (n=3). Among the trial participants 53.33% of participants reported profuse sweating.

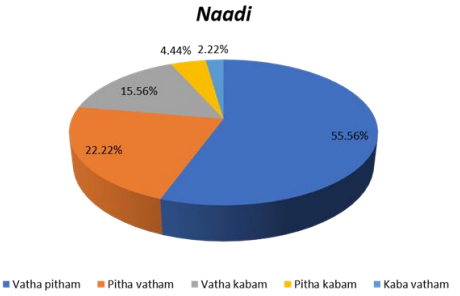

Fig 2. Naadi distribution

Clinical parameters

Differentiating dermatohpytes from non-dermatophytes is based on appropriate clinical presentation and disease manifestation. The ideal and most commonly used method is to examine the clinical material qualitatively and quantitatively. Skin scraping examinations offer ideal results in this identification and hence this test was carried out before and after treatment and the results are provided in Table 1. The results of skin scraping before and after treatment showed that 66.67% showed skin scraping negative for dermatophytes indicating significant therapeutic effect of *Kandhaga Rasayanam* (KR) on dermatophytosis. A statistical analysis also revealed the P value to be zero stating that the result is statistically significant. Skin scraping test is considered to be the most reliable test for dermatophytosis based on expert consensus and also considered to be simple, inexpensive, swift and efficient screening method (Kurade S et al., 2006; Pihet M & Le Govic Y, 2017).

Some of the most common symptoms of dermatophytosis infection include itching, burning sensation, erythema, pustule, vesicle, ooze, scaling and pruritus (Hainer BL, 2003). Therefore, an assessment of these symptoms was carried out before and after treating the patients with KR and statistical validation was carried out (Table 3). Itching was initially reported (day 0) by all the patients making it the most common symptom but after treatment with KR (day 45), 36 people stated no itching clearly stating the positive effect of KR. Burning sensation and erythema was reported on day 0 by 21 patients only of which only 2 people showed these symptoms after treatment. Pustules were reported by 7 patients of which 6 were cured completely. Oozing was reported by 9 patients of which 7 were cured. Vesicles were observed in only 2 patients of whom one patient still showed this condition. Scaling was noticed in 6 patients of whom 5 got cured after treatment. Pruritus score, though not an exact measure for itching, was also calculated using the 5D itch scale (Elman S et al., 2010) for all the 45 patients before and after treatment. 22 patients displayed a score of 4, 19 patients displayed a score of 3 and 4 patients displayed a score of 2 at the beginning of the trial. After 45 days, only 9 patients still showed some signs of itching but with a less score or 1 and 2. A significant transition was observed in the score where one patient each moved from 4 to 3 and 3 to 1, while 2 patients each moved from 4 to 2 and 3 to 2. 16 patients moved from a score of 3 to 0 and 4 patients from 2 to 0. This change in score clearly indicates the positive effect of KR in successfully reducing the symptoms in many patients.

Table 1
Clinical parameters assessment – statistical analysis

Clinical Parameter	Day 0		Day 45		t-value	P value
	Mean	SD	Mean	SD		
Skin scraping	1	0	0.33	0.47	9.381	0
Itching	1	0	0.2	0.405	13.266	0
Burning sensation	0.47	0.505	0.04	0.208	5.67	0
Erythema	0.47	0.505	0.04	0.208	5.67	0
Pustule	0.16	0.367	0.02	0.149	2.602	0.013
Vesicle	0.04	0.208	0.02	0.149	1	0.323
Ooze	0.2	0.405	0.04	0.208	2.347	0.007
Scaling	0.13	0.344	0.02	0.149	2.345	0.024
Pruritus Score	3.4	0.654	0.33	0.739	23.132	0
QoL score	28.22	3.866	1.56	5.203	29.665	0
Lesion size in cm	4.27	1.514	2.22	2.021	12.166	0
Lesion score	2.38	0.490	1.82	0.650	7.416	0

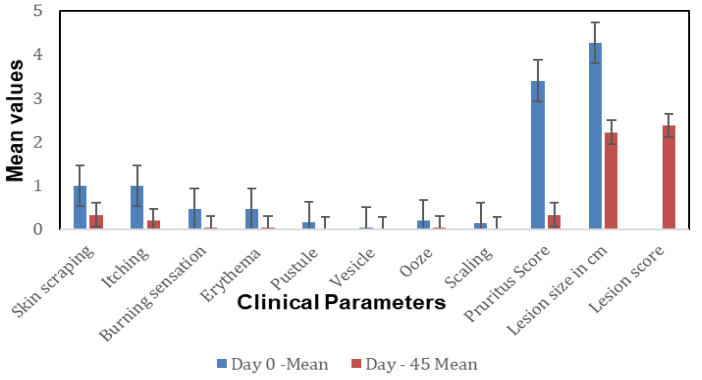

Fig 3. Mean values for Clinical parameters

A statistical analysis was carried out using paired t test for the clinical assessment parameters to find the significance of the test (Table 1 and Fig 3) and it was observed that the p value for itching, burning sensation, erythema, pruritus score was less than p=< 0.001 while the p value for quality-of-life score was p<=0.000. The p value was less than 0.01 for the variable pustule (p<=0.013) and ooze (p<=0.007). The p value was less than 0.05 for scaling (p<=0.024). Every t-value has an associated p-value. A p-value from a t test is the probability that the results from the data occurred by chance and is an indicator of the strength of the results (Krzywinski M. & Altman N, 2013). Dermatophytosis can have a significant effect on a patient's economic and psychosocial life. Knowledge on the quality of life (QoL) in patients with dermatophytosis is not well studied (Mushtaq S et al.,2020). Therefore, Dermatology Life Quality Index (DLQI) scores were developed to have an understanding on the quality of life and the same was employed in this study. DLQI score ranges from 0-30 (Narang T et al., 2019) and in the present study the mean value was found to be 28.22 on day 0 while the value was 1.56 on day 45. The higher the score, the more quality of life is

impaired. A score higher than 10 indicates that the patient's life is being severely affected by their skin disease. As is evident from the data obtained, this disease condition dermatophytosis seems to have a huge impact on the social wellbeing of the person initially but the effect of KR on this condition and significant improvement noticed in patients have led to a massive reduction in the DLQI value to 1.56 which is considered to be almost no effect on the social wellbeing of the patient.

The effect of KR on lesions was assessed before and after treatment by measuring the lesion size in cm and calculating the lesion score based on the size. Grade 1 pertains to lesions with size in the range 0 cm that is absence of lesions, grade 2 is where the size is 1 - 4 cm and grade 3 is where the size is 5 to 8 cm. 28 patients belonged to grade 2 while the remaining 17 patients belonged to grade 3 before KR treatment. After the treatment period, 14 patients showed grade 1 lesions, 25 patients showed grade 2 lesions and 6 showed grade 3 lesions clearly stating significant therapeutic effect of KR. The erythematous lesions showed improvement compared to longstanding lesions with hyperpigmentation Complete disappearance of the lesion is noted in only 31.11% of patients. Statistical analysis using t test showed p values to be 0 for lesion size and score demonstrating the validity and significance of the result obtained.

Hematological parameters

Several hematological parameters like HB, RBC, ESR 1/2HR, ESR 1HR, total WBC, Polymorph, Lymphocytes, Monocytes, Eosinophils, Basophils, Platelets (lakh cell / Cu mm), Fasting Sugar, Post Prandial Sugar, Serum Cholesterol, HDL, LDL, VLDL, TGL, Blood urea, Serum creatinine, Serum uric acid, Total bilirubin, Direct bilirubin, Indirect bilirubin, Serum total protein, Serum albumin, Serum globulin, Fibrinogen, Serum calcium, Serum phosphorus, Serum glutamic-oxaloacetic transaminase, Serum Glutamic Pyruvic Transaminase and Alkaline phosphatase were tested for the patients before and after treatment. The results are provided in Table 2. It was observed that there is not much variation in these parameters except for increase in total RBC, blood glucose fasting and postprandial and the lipid profile in the post treatment report in some patients and decrease in eosinophils, ESR, uric acid and indirect bilirubin in some patients. Paired t test was employed to analyze the hematological data before and after treatment and based on P value it was found to be statistically significant.

Table 2
Hematological parameters – Statistical analysis

Hematological parameters	Day 0		Day 45		t-value	P value
	Mean	SD	Mean	SD		
Haemoglobin	13.84	1.478	14.082	1.2392	-3.989	0
Total RBC	5.17	0.523	5.22	0.47	-3.363	0.002
ESR ½ hr	4.98	7.415	2.82	2.879	3.08	0.004
ESR 1 hr	9.87	15.883	5.02	3.401	2.573	0.014
Total WBC	7573.33	1303.562	7571.33	1195.335	0.041	0.967
Polymorphs %	63.33	5.452	63.22	10.111	0.083	0.934

Lymphocytes %	31.16	5.435	31.71	4.98	-1.012	0.317
Monocytes %	0.11	0.487	0.02	0.149	1.274	0.209
Eosinophils %	5.78	2.915	3.96	1.261	5.783	0
Basophils %	0	0	0	0	0	0
Platelet	2.764	0.7367	2.756	0.6931	0.473	0.638
Glucose – F	88.29	7.988	91.51	7.178	-4.614	0
Glucose -PP	102.82	7.714	105.73	8.672	-2.835	0.007
Serum Cholesterol	168.56	15.773	175.18	12.879	-7.902	0
HDL	37.84	4.112	38.82	4.266	-2.826	0.007
LDL	89.93	13.949	94.76	13.809	-5.262	0
VLDL	20.56	5.93	23.11	5.47	-7.06	0
TGL	113.96	18.238	120.44	17.769	-5.444	0
Urea	19.64	3.419	19.67	2.558	-0.78	0.938
Creatinine	0.79	0.083	0.77	0.087	1.78	0.082
Uric acid	4.62	0.98	4.54	0.926	2.475	0.017
Total bilirubin	0.65	0.167	0.63	0.145	1.53	0.133
Direct bilirubin	0.21	0.073	0.22	0.073	-1.345	0.185
Indirect bilirubin	0.43	0.132	0.41	0.116	2.271	0.028
Total Protein	6.79	0.525	6.78	0.497	0.443	0.66
Albumin	4.06	0.517	3.98	0.452	1.226	0.227
Globulin	2.64	0.581	2.74	0.417	-1.151	0.256
Fibrinogen	0.26	1.488	0.03	0.073	1.052	0.299
Calcium	11.49	12.172	9.94	0.488	0.844	0.403
SGOT	13.33	5.339	13.6	4.351	-0.752	0.456
SGPT	17.36	6.579	17.96	4.411	-0.932	0.356
Alkaline phosphatase	6.98	1.865	7.22	1.731	-1.229	0.226

KR is a classic Siddha drug mainly used in treatment of skin diseases, urinary tract infections, diarrhea, venereal diseases, piles, peptic ulcer and arthritis. The effectiveness and safety of Siddha drugs is evident in literature but a scientific experimental validation would open avenues in the treatment of several disorders. This is a herbo-mineral drug with sulphur as the sole mineral constituent with several medicinally important herbs as constituents (Meena et al 2014). Tenia infections have been found to be on the rise currently and accounts to 63.27% *Tinea corporis* infections, 48.95% *Tinea rubrum* infections and 44.75% *Tinea mentagyrophyte* infections. The commonly affected age group is between 21–40 years (Naglot A et al., 2015).

The effect of *Kandhaga Rasayanam* has been demonstrated by us in our earlier studies where we tried to assess the physico-chemical properties (Meena et al, 2014), long term toxicity effect in rats (Meena R & Ramaswamy RS, 2018), in vitro antifungal studies in dermatophytes (Meena R et al., 2018) and single case study using KR as a treatment for dermatophytosis against one patient (Meena R & Ramaswamy RS, 2019). The positive results demonstrated by all these studies have instigated us to carry out clinical trials in patients suffering with dermatophytosis. The results obtained in our study are similar to the findings of Surendran et al. (2014) who also reported that males were affected more compared to females. Also, this study reported that 53.33% of participants also

reported increased sweating which might have created a favourable condition for the growth of the organism. *Uttinavayu*, bitterness in tongue, loss of taste are symptoms of vitiated *azhal* which is also a reason for profuse sweating. The improvement noticed in the patients may be attributed to pharmacological activities of phytocompounds in *Kandhaga Rasayanam* (Meena R & Ramaswamy RS, 2015).

In the present pilot study, a complete mycological cure was observed in recent infections and reduction of clinical signs in chronic cases. No obnoxious adverse effects were observed and the drug KR was found safe and fairly well accepted by the patients. The laboratory values were also within the limits. These results clearly indicate the efficacy of *Kandhaga Rasayanam* in the treatment of dermatophytosis. Several other considerations in the clinical trials like blinding, randomization, increase in patient number, using a control group, control medication and increased time of treatment depending on chronicity of infection with a follow up period can further shed light into the effectiveness of KR as a treatment option for dermatophytosis.

Conclusion

In this pilot study, the trial drug *Kandhaga Rasayanam* showed greater improvement in the clearance of newer lesions compared with chronic lesions in dermatophytosis patients. Additionally, there was a marked improvement in clinical signs of dermatophytosis. The drug was found to be safe and well tolerated by all the patients. In the light of real-world evidence on the safety and effectiveness, the Siddha herbomineral drug *Kandhaga Rasayanam* can be considered a potent therapeutic choice for *Padarthamarai* (Dermatophyosis). Randomized Controlled clinical Trials are warranted to substantiate the results of the present study.

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Statements and declarations

Competing interest
None

Data Sharing Statement

Relevant data are available in the manuscript. Further any datasets will be provided only on request due to privacy/ ethical restrictions, and can be requested from Dr. R. Meena – meenaprakashphd@gmail.com

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Ethical approval

The Ethics Committee of National Institute of Siddha, Chennai reviewed and approved the study protocol. The trial was registered in Clinical trials registry India and the CTRI number is CTRI/2012/01/002362. Written Informed consent was obtained from the trial participants.

Authors' Contribution

RM: Conducted the pilot clinical trial, Conceived and designed the analysis, wrote the manuscript.
RSR: Guided and supervised the clinical trial, corrected and proof read the manuscript before final submission.

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