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A CLINICAL STUDY OF A TOPICAL NONPHARMACOPEAL OINTMENT IN THE MANAGEMENT OF DERMATOPHYTIC INFECTION

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ABSTRACT

Introduction: Dermatophyte is a group of superficial mycosis produced by dermatophytes, of which belonged to Genera of Epidermophyton, Trichophyton and Microsporum. Cutaneous dermatophytic infection is limited to the superficial layer of the epidermis. Warm and humid climate is a favourable environment for the organisms causing the superficial dermatophytic Infection. The dermatophytes which infect only keratinized structures such as skin, hairs and nails. **Material Methods:** Study was conducted on 100 patients of dermatophytic infection attending the Skin OPD of the A, K, T, C, and Hospital A.M.U Aligarh, during the period from July 2017 to June 2019. Before the clinical trial ethical clearance was obtained from the Ethics committee. The patients were selected on the basis of history, physical examination, and investigations. The diagnosis was confirmed on the basis of KOH examination of skin. **Results:** In group A, itching was found to have improved in 32 patients, while in group B the itching was found to have improved in 34 patients out of 50 patients in each group. In which 40 patients of group A reported improvement while in group B 37 patients reported improvement in erythema. Both the drugs were equally effective in the management of dermatophytosis. **Discussion:** The findings of the clinical study demonstrated that the topical application of the test drug i.e. ointment in the patients of dermatophytosis produced significant effect. The symptomatic relief was observed in almost all patients, while 70% recovery was found in KOH examination. After the complete treatment 66% patients of the test group and 74% patients of standard group were found KOH negative after the completion of treatment duration. **Conclusion:** The test drug in the form of the ointment is effective in the management of dermatophytosis. It is able to ameliorate the signs and symptoms of dermatophytosis including itching, erythema, vesicles, papules, and scaly successfully.

KEYWORD: Dermatophytic Infection, KOH Examination, prevalence rate.

INTRODUCTION

Skin is in intimate contact with the environment and as such very much exposed to infective agents like bacteria, fungi and viruses. Dermatophytes are a group of parasitic fungi that live at the expense of the keratin in the skin, nails and hairs.[1] They are generally confined to the stratum corneum of the epidermis and skin appendages, especially in the moist areas of the body, such as the regions between the toes, groin and below the breasts,[2] It has a high prevalence rate and has been estimated to infect 20-25% of the population.[3,4] Over all the fungal infections are the fourth leading disease of all skin problems. Further, a steady rise in the incidence of contentious fungal infection and almost equally increasing rate of the treatment failure has been reported.[5] Therefore, the dermatophytosis poses a considerable worldwide health problem.[6] Although the fungal infection is not a new problem, as it has been described under the term Qooba in Unani literature centuries back and a number of medicines have been described to be effective in the management of this superficial infection however, it has become a threatening problem because of its widespread prevalence and unavailability of safe and effective drug in conventional medicine. Furthermore, the recurrence of the disease and its resistance against many available

drugs have emerged as the major cause of failure of antifungal therapy. The reports of recurrences are associated both with the discontinuation of therapy, and also the clinical resistance in case of antifungal drugs.[7]

Qooba(Dermatophytosis) is commonly designated as 'Tinea' or Ringworm. The causative dermatophytes which are the groups of taxonomically related fungi have been classified into three genera, viz. Trichophyton, Epidermophyton and Microsporum. They cause dermatophytic infection and are capable of infecting keratinized tissue such as stratum corneum of epidermis, nail and hair.[1] By their metabolic activity they produce inflammatory response in the form of erythema, scaling, postulation and micro-abscess formation giving rise to itching and discomfort. Central clearing is sometimes seen particularly in Tinea corporis. This results in formation of a classic "ringworm" lesion. However, the clinical signs may vary, depending on the part affected. Dermatophytes commonly grow only on the keratinized tissues; but the fungus usually stops spreading when it comes in contact with the living cells or area of an inflammation. Unani physicians have recommended many drugs and preparations for effective treatment of Qooba and other diseases. These drugs are in use since long and have been described to be useful in the management of dermatological disorders including fungal infection.

Three important drugs viz. Kamela (Mallotus philippinensis), Neela Thotha (Copper sulphate) and Murdar sang (Led oxide) are commonly used as a single drug by Unani physicians in the management of fungal infection. These agents have been described to be effective in Qooba and other related skin problems as they possess ability to act against Ajsame Khabisa (pathogenic organisms) and hasten the drying and healing of affected part, and that is why these agents have been the ingredients of a number of topical preparations.[8,9] In the present study these three drugs have been used in combined form as an ointment in white petroleum jelly base. This combination has been proposed by Qarshi (2011) in his book Jameul Hikmat.[9] Further, the ingredients of the compound formulation have been reported in certain recent studies to be effective in cases of ring worms, freckle, pityriasis and bacterial infection etc.[8,10,11,12,13] The description and practices of Unani medicine of the compound formulation and the available scientific reports about its ingredients suggest that the test drug possesses good therapeutic potential in the management of fungal infection. The patients were selected on the basis of the strict inclusion and exclusion criteria and the diagnosis was confirmed by KOH examination of skin scraping of the affected part. Various parametric and non parametric statistical measures were used to determine the level of significance and arrive at a conclusion.

MATERIAL METHODS

The present study was conducted on 100 patients of the superficial dermatophytic infection (Qooba) attending the Jild-wa-Zohrawia OPD of the Ajmal Khan Tibbya College and Hospital A.M.U Aligarh, during the period extending from Jul 2017 to June 2019. Before starting the clinical trial, the research protocol was submitted to the ethical committee of A.M.U Aligarh and ethical clearance was obtained from the committee. The patients were selected on the basis of history, physical examination, and investigations. The diagnosis was confirmed on the basis of KOH examination of skin. All the findings were recorded on the case record proforma, designed for the study. The patients who did not fulfill the inclusion criteria were excluded from the study. All the Good Clinical Practice (GCP)-ICMR guidelines were followed.

Inclusion Criteria for Selection of Subject

- Diagnosed case of Tinea corporis, Tinea cruris, Tinea faciei (where there is normal keratin turnover time) with +ve KOH smear.
- Above mentioned case not on concomitant therapy or left the treatment at least 10 days before the trial.

Exclusion Criteria

- Patients with Tinea capitis, Tinea unguium, Tinea pedis, Tinea manuum.
- Patient having Diabetes Mellitus.
- Patients on concomitant therapy.
- Immuno-compromised patients.

Method of Collection of Data

Subjective parameters

Circumscribed lesion with erythematous papules, tiny vesicles, pustules around a scaly variable pigmented patch and pruritus.

Objective parameter

KOH examination of skin scrapings.
Photography of the affected site.

Study design

The study was designed as randomized single blind with standard control.

Sample size

The sample size was fixed to 100 patients using thumb rule. 50 patients in the test group (Group A) and 50 in the control group (Group B).

Duration of the protocol and follow up

The duration of the treatment was fixed to 6 weeks for both the groups. Patients were advised to visit every week. Follow up was also done after the completion of treatment i.e., at 8th week.

Withdrawal criteria

a. Failure to follow the protocol.
b. Any adverse reaction or adverse event.

c. Drug defaulter.

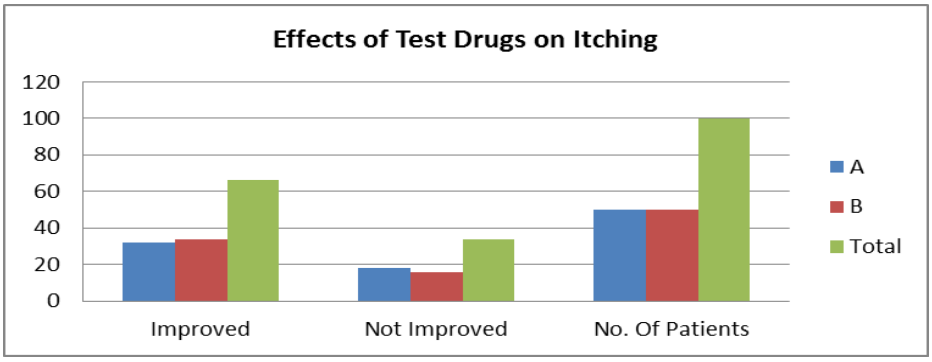
Adverse drug documentation
Adverse events or reactions were kept in consideration.

Statistical analysis
Chi Square Test was used for statistical analysis of the data**.**

RESULTS
All the patients irrespective of their groups had itching problems. In group A, this symptom was found improved in 32 patients, while no improvement was reported by 18 patients after the treatment of the test drug. In the patients of group B who received the standard treatment (Luliconazole cream), the itching was found to have improved in 34 patients but no improvement was reported by 16 patients. The significance was tested statistically by Chi-square test (X^2 –Test) and the findings the two groups were found to be significant, as the X^2 was found to be 0.18 ($p>0.05$ (Table 1 and Graph 1).

Table 1: Effects of Test Drugs on Itching.

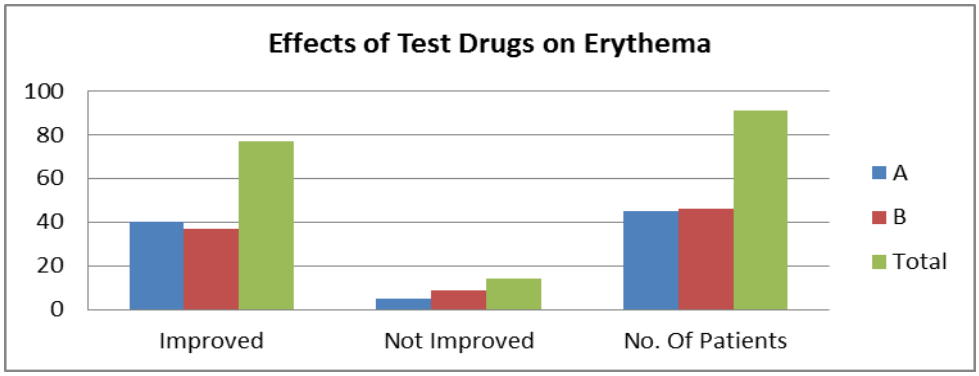
Itching	Improved	Not Improved	No. of Patients	
A	32	18	50	**X^2= 0.18**
B	34	16	50	**P > 0.05**
Total	66	34	100	



45 patients in group A and 46 patients in group B had the complaint of erythema. In which 40 patients of group A reported improvement while 5 patients did not reported such an improvement. Similarly in group B 37 patients reported improvement while 9 patients continued with erythema after treatment with Luliconazole cream. The level of significance was tested by Chi-square test (X^2 – Test) the findings in both the groups were found to be significant ($p>0.05$) which is insignificant. i.e. both the test drugs and control drugs are same in erythema (Table 2 and Graph 2).

Table 2: Effects of Test Drugs on Erythema.

Erythema	Improved	Not Improved	No. Of Patients	
A	40	5	45	**X^2= 1.2**
B	37	9	46	**P > 0.05**
Total	77	14	91	

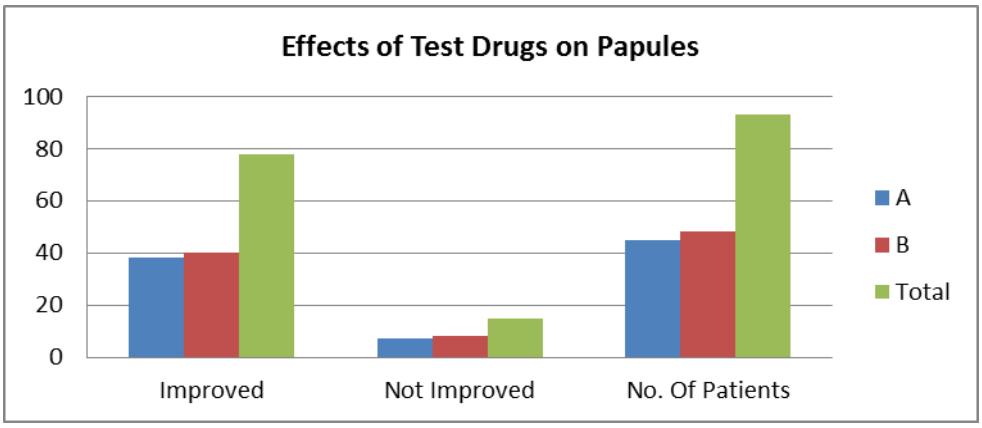


45 patients in group A and 48 patients in group B had the complaint of being afflicted with papules. An

improvement in 38 patients and 37 patients was recorded in two groups, respectively. The improvement was found significant statistically (p>0.05) (Table 3 and Graph 3).

Table 3: Effects of Test Drugs on Papules.

Papules	Improved	Not Improved	No. Of Patients	
A	38	7	45	**X^2= 0.02**
B	40	8	48	**P > 0.05**
Total	78	15	93	



Scaling was found in 39 patients of group A, and 37 patients of group B. It disappeared in 36 patients of group A, who received the Unani treatment (p< 0.05). The standard drug also produced almost similar responses as 32 patients reported improvement (p<0.05) (Table 4 and Graph 4).

Table 4: Effects of Test Drugs on Scaling.

Scaling	Improved	Not Improved	No. Of Patients	
A	36	3	39	**X^2= 0.68**
B	32	5	37	**P > 0.05**
Total	68	8	76	

Graph-4

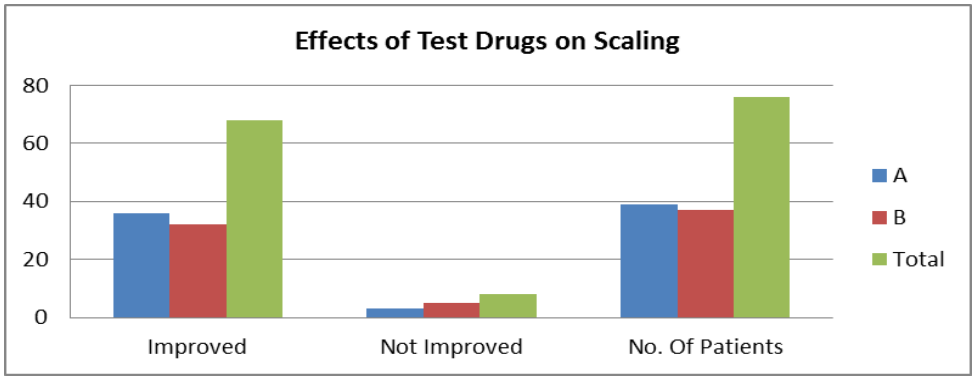


Table 5 and Graph 5 show the effect of the drugs with reference to fungal scraping i.e. KOH test. Before the treatment all the patients of both the groups were found to be KOH positive, as it was taken as objective criteria for the inclusion of the patients in the study. After the complete treatment 33 (66%) patients in group A, and 37 (74%) patients in group B, were found to be KOH negative.

Table 5: Effects of Test Drugs on KOH.

Groups	Positive	Negative	Total No. of Patients	Improved Percent (%)
A	50	33	50	66.0
B	50	37	50	74.0
Total			100	70.0

Graph. 5

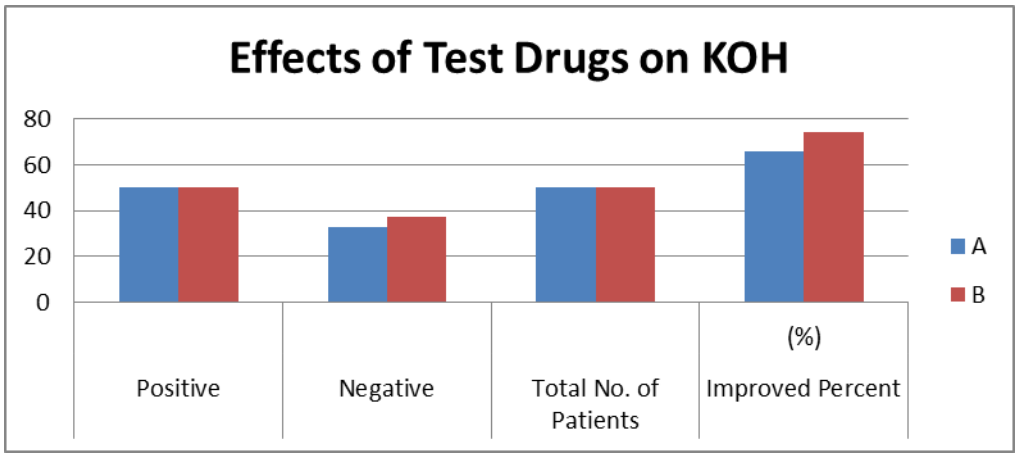
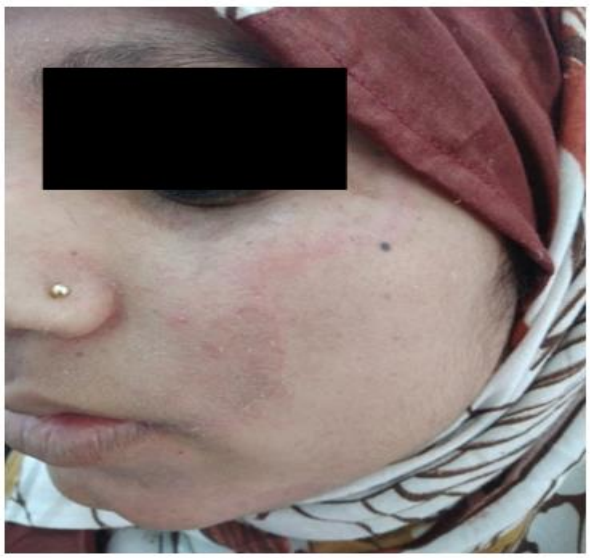


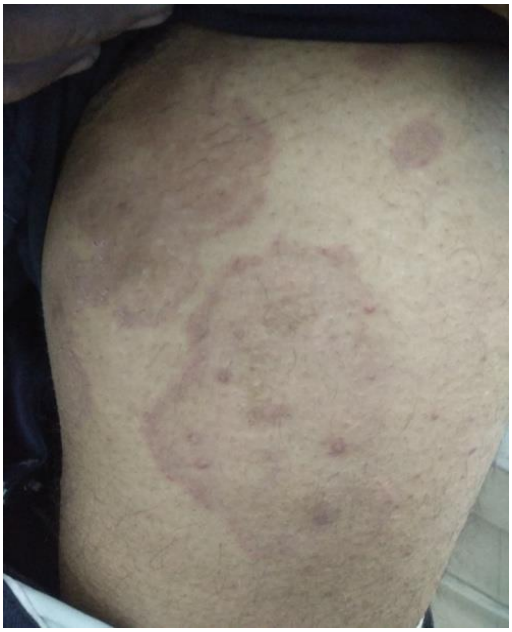
Fig ( ) Test drugs on Tinea faciei



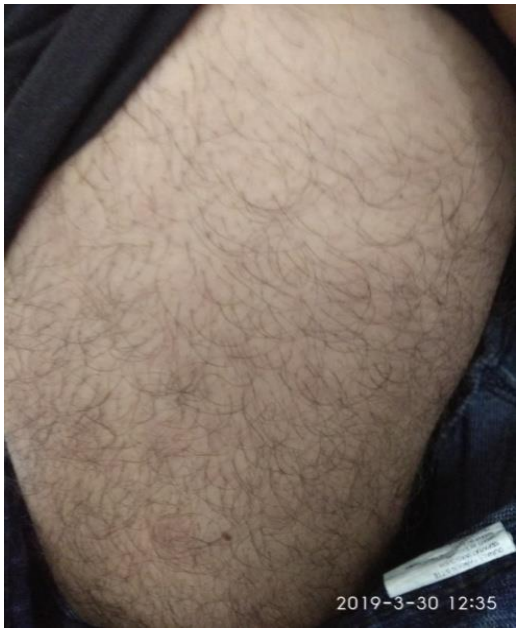
Before Treatment

After Treatment

Test drug on Tinea cruris



Before Treatment



After Treatment

DISCUSSION

The present work was designed to study the efficacy of a Unani Pharmacopoeial drug in a topical dosage form in the management of Qooba (Dermatophytosis). The study was conducted in the patients who visited the OPD of Skin & venereal of AKTC Hospital A.M.U., Aligarh. The test drug contained three different single drugs of plant and mineral origin along with the base in which it was prepared in the form of ointment. The ointment was applied over the affected area of the skin and its efficacy was determined at a regular interval for a period of 6 weeks.

The findings of the clinical study demonstrated that the topical application of the test drug i.e. ointment in the patients of Qooba (Dermatophytosis) produced significant effect. Symptomatic relief was observed in almost all patients, while 70% recovery was found in KOH examination. In the present study however an ointment was used to manage the cases of Qooba. The study showed that the test drug is effective in most of the cases but it was also recorded that some of the patients does not respond to the treatment and recurrence was observed in few patients.

Itching is one of the cardinal symptoms of dermatophytosis. All the patients included in the study had itching at the time of fist presentation. Itching was found in accordance with the other reports and also with the description contained in Unani literature. In a study published in 2011, itching was observed in all the patients at the time of the first visit.[14] Unani physicians such as Ajmal Khan and Gulam Jilani etc have also mentioned that the disease is characterised by intense itching.[15,16] The severity of itching is directly proportional to abnormal khelt-e-raqeeq.[17] It was also evident from the findings that the patients having more oozing had presented with more severe itching. After the treatment a significant improvement in itching was found in both the test and control groups. Complete improvement in itching was found in 32 (64%) patients in Group A and 34 (68%) in Group B, suggesting that the test drug produced significant anti itching effect which was almost equal to the standard treatment, as the test statistic X^2= 0.18 was not found significant (p>0.05). Itching in some patients was associated with burning and pricking sensation which may also be due to the excess of khelt-e- raqeeq.[17] Erythema an important sign of Qooba was evidenced in the present study, as 91% of the patients presented with erythema at their first visit. However, in a previous study erythema was observed only in 66.6% of the patients[14] Association of erythema with Qooba has also been described in Unani literature. It has been mentioned that when the redness in the lesions of Qooba is more, the response to the treatment is delayed.[18] Unani treatment caused a relief from erythema in 80% of the patients, which was little better than the effect produced by standard treatment as only 74% patients got relief from erythema. Though the effect produced by the two drugs was not significant statistically when compared with each other however it was better in absolute treatment. During the current study papules were seen in 93% of the patients. A previous study published in Indian Journal of Traditional Knowledge has found papules in a relatively higher percentage of patients (100.0%).[19,20] Presence of eruption has been described in various Unani manuscripts in cases of Qooba.[15, 21, 22] The test drug produced significant effect as the improvement in 76% of cases which was almost equal to the effect produced by the test drug. At the first visit, 76.0% patients were found to have scaling. In a previous study a higher percentage has been reported.[14] Unani physicians were well acquainted with the appearance of scaling in patients of Qooba. After the treatment, the scaling was subsided in 72.0% and 64.0% of the patients in the Group A and Group B, respectively. The disappearance of scales indicates that the process of progression of fungal infection is arrested. Both the drugs in the present study significantly reduced the scaling showing that they possess antifungal activity. The test drug appears to produce an effect which is equal to that of the standard drug as in comparison the effect produced by the two drugs was not found significant (p> 0.05).

KOH test is a reliable measure of the fungal infection as the final diagnosis is made on the basis of the result of potassium hydroxide test. The efficacy of the test drug was therefore objectively assessed on the basis of negative results in the patients who were tested positive at the time of the first visit to the hospital and enrolled for the study. 66% patients of the test group and 74% patients of standard group were found KOH negative after the completion of treatment duration. The test drug was found effective in treating the patients of dermatophytosis significantly however, there is a wide scope of improvement because despite almost complete symptomatic relief about one third of the patients were not found cured as the most important outcome measure (KOH test) was not found negative in all the patients. Therefore, as suggested by Unani medicine certain other therapeutic agents for the oral administration are required along with local application of the test drug.

The test drug formulation which comprised of Kamela, Neelathotha, Murdar Sang and the base i.e. petroleum jelly appears to be comprehensive as the different components have been included in commensuration of different signs and symptoms and the presentation of the disease. Kamela has been described to be effective in different types of skin affections as it promotes healing.[23,24] as such and also because of having antibacterial and antifungal activity.[25] Unani scholars have also described it to possess antifungal along with antipruritic effect.[26,27,28] It appears to be responsible for antifungal and healing property which caused relief to the patients of the dermatophytosis.

Neelathotha (Copper sulphate) has been reported to have strong antifungal and antibacterial effects. Many in vitro,

in vivo and clinical studies have demonstrated that it has fungus killing properties.[29] it has been shown to especially effective in athlete foot caused by fungal infection.[30] In a study it has been shown that the soldiers who wore the shocks containing it their fungal infection was improved and the signs such as erythema, papules vesicles and scaling were improved.[19] It also possesses anti inflammatory, antipruritic effect and vermicidal activity.[27,31]

Murdar sang is attributed to have cicatrizing, antipruritic and insecticide effects. A compound drug containing Murdar sang as an ingredient has been shown to possess antifungal antipruritic and healing effect.[27, 31]

Petroleum jelly itself has the shooting effect. This may partially be effective in inducing symptomatic relief. Therefore it can be said that the test drug because of having different components which were useful to undermine the different symptomatic presentation of the disease was able to successfully treat the majority of cases of dermatophytosis.

CONCLUSION

The test drug in the form of the ointment is effective in the management of Qooba (Dermatophytosis). It able to ameliorate the signs and symptoms of Qooba including itching, erythema, vesicles, papules, and scaly successfully. The test drug was able to produce almost similar degree of effect as that produced by the standard drug Luliconazole suggesting that it can be used as an alternate option for the allopathic drug, as it is cased effective and safe. This is one of the earliest reports in which the test drug has been demonstrated to possess the antifungal activity through both in vitro and clinical studies. Since it was able to render only 66% of the patients KOH negative therefore finding of the study warrant that in chronic and non responding cases it should be given along with another drug which may be used orally as described the physicians.

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