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Original Article

A Randomized Active Controlled Clinical Trial to Evaluate Safety and Efficacy of a Topical Unani Formulation Marham Kharish Jadeed in the Management of *Qūbā* (Tinea Corporis)

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ABSTRACT

Introduction: *Qūbā* (Tinea Corporis) is a very common disease widely prevalent worldwide. 20 – 25 % individuals suffer for this stubborn disease. Unani System of Medicine offers its treatment. There are many pharmacopoeial formulations indicated for various types of dermatophytic infections. In this study clinical efficacy and safety of the topical Unani formulation Marham Kharish Jadeed (a compound drug in the dosage form of an ointment) was assessed and compared with a standard conventional medicine.

Materials and methods: A clinical study was conducted on 60 participants of *qūbā* randomized into test and control groups (n=30 in each group). The participants were clinically diagnosed and confirmed by microscopy of skin scrapings. The efficacy of the Unani formulation was assessed in terms of TSS score and elimination of fungal elements from the skin lesions. The data collected were analyzed statistically.

Results and discussion: The study showed that the Unani formulation had comparatively better efficacy clinically than conventional medicine *Terbinafine hydrochloride* 1% cream in terms of reduction of itching, erythema, scaling, peripheral raised margins of the lesion comparing to baseline. In this study, 27 participants in test group and 18 participants in control group were completely cured (≥75% reduction in TSS Score with Mycological Cure) after 4 weeks of treatment. The efficacy of the Unani formulation was found significant statistically. The individual drugs of the formulations having analgesic (*Musakkin*), blood purifier (*Muṣaffi-i-Dam*), demulcent (*Mulaṭṭif*), antifungal (*Qātil-i-fafūndī*), detergent (*Jālī*), refrigerant (*Mubarrid*) and antiseptic (*Dāfi'-i-'Ufūnat*) properties might be responsible for the efficacy of Unani formulation.

Conclusion: The findings of the study suggested that the Unani formulation was found effective and safe in the management of *qūbā*. No local and systemic adverse effect was reported during the study.

Keywords Dermatophytosis, Marham Kharish Jadeed, Terbinafine, Tinea corporis, Unani Medicine

INTRODUCTION

Qūbā (dermatophytosis) is a very common skin disorder encountered in about 50% of the patient visiting dermatology clinic (Poluri, Indugula, & Kondapaneni, 2015). It is characterized by skin lesions having intense itching, erythema, scaling, vesicles, central clearing with peripheral raised margin. 25% of world population is affected by dermatophytic infections (Bhatia & Sharma, 2014). The common dermatophytes *Trichophyton, Microsporum*, and *Epidermophyton* are responsible for infection at hair, scalp, arms, legs, trunk, groin, and nails (Kasper et al., 2015). Tinea corporis refers to the dermatophytic infections involving trunk, arms and legs. The major risk factors of tinea corporis are overcrowding, poor hygiene and low standards of living along with high humidity (Bhatia & Sharma, 2014).

Despite medical advancement, the treatment of *qūbā* is still difficult due to various degrees of resistance and side effects of conventional antifungal medicines. Its recurrence rate is also very high. It produces personality disorder, sleeplessness, anxiety and impacts on quality of life of the patients (H. R. Jerajani et al., 2000; Sumyuktha, Narasimhan, & Ahamed, 2017). In this scenario, there is a need to search a better, safe and effective medicine to treat and manage *qūbā* (tinea corporis).

Qūbā has been treated in unani system of medicine since antiquity. There are a large number of pharmacopoeial formulations indicated for the treatment of *qūbā*. The therapeutic approach in Unani System of Medicine for treatment is quite different from allopathic system of medicine. Unani System of Medicine adopts holistic approach which considerers mind, body and soul together to treat any medical condition. The topical medicines are considered as the best option for the treatment of *qūbā* (tinea corporis). Marham Kharish Jadeed, a Unani pharmacopoeial formulation, is one of the recommended treatments for skin dermatoses (*Qūbā, Kharish, Ḥikka and Fasād al-Dam*) (Anonymous, 1986). In this study safety and efficacy of Marham Kharish Jadeed was evaluated in the management of *qūbā*. This study has paramount importance in the hierarchy of evidence as this study documented the safety and efficacy of this Unani formulation for first time.

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MATERIALS AND METHODS

The study was conducted on 60 participants of *qūbā* (tinea corporis) who visited in Outpatient Department (OPD) of Central Research Institute of Unani Medicine, Hyderabad during June 2018 to May 2019. The first participant was enrolled after getting clearance from Institutional ethics committee (Ref. No. 38-18/2015-16/CRIUM/Hyd/IEC/06/M, dated 07.08.2017) and registration in clinical trial registry of India (CTRI No. CTRI/2017/12/010995, dated 27/12/2017).

This study was design as a randomized, active controlled, parallel group and single blind (Assessor blinded) clinical trial. The participants were randomized into test and control groups (n=30 participants in each group) as per predetermined block randomization scheme generated through a computer software. Four participants were taken in a block. The sequence of the block was concealed in separate opaque envelopes following concealment of allocation rules to minimize bias in the study.

Estimation of sample size

The total sample size was 60 participants taken empirically as it was an academic trial. In total 95 participants were screened for the study. Of them 75 participants were registered for the study after taking signed informed consent form. All the registered participants were randomized into test group (n=39) and control group (n=36). Out of them 30 participants in each group completed the study. The remaining 9 participants in test group and 6 participants in control group dropped out of the study due to non-compliance to therapy, migration of the participants and non-response of therapy.

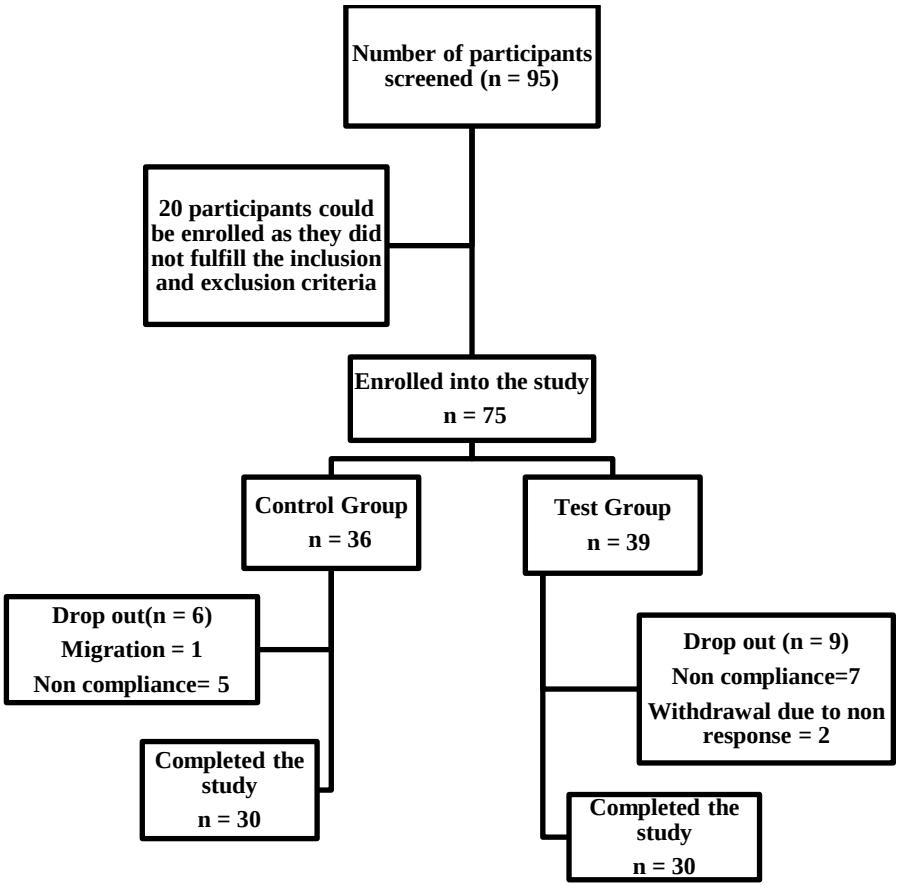

Fig.1. Participants' Flow Chart

Inclusion and exclusion criteria

The participants of any sex, in the age group of 18 to 65 years having skin lesions with itching, erythema, scaling, central clearing with peripheral raised margins and presence of fungal elements in microscopy of skin scrapings were included in the study (Banerjee et al., 2011). Pregnant and lactating women, participants with secondary bacterial infections, diabetes mellitus, hepatorenal dysfunctions, those having treatment history of less than 30 days in case of topical antifungal agent, less than 8 weeks in case of systemic antifungals and less than 30 days in case of systemic corticosteroids were not included in the study. (Lakshmi, Bengalorkar, & Shiva Kumar, 2013)

Intervention

Marham Kharish Jadeed (MKJ), a compound drug in the dosage form of an ointment, was used as a test drug in this study. This drug MKJ was composed of nine animo-herbo-mineral drugs. The composition of the formulation MKJ is given in table 1. This composition of the MKJ is described in the recognized pharmacopoeias of Unani Medicine such as National Formulary of Unani Medicine and *Qarābādīn Majīdi* (Anonymous, 2008; Anonymous, 1986). The MKJ was used in the dosage form of pharmaceutical ointment externally twice daily at the site of the lesion for a maximum period of 28 days.

The botanist and pharmacist of CRIUM, Hyderabad identified and authenticated the single crude drugs used in this formulation. The voucher specimens of the raw drugs used in the formulation had been deposited in the Museum of CRIUM, Hyderabad for future references.; (*Barg-i Ḥinā* - SMPU/CRI-

Hyd. 13556, *Kamilā* -13557, *Kāth Safaid* - 13558, *Kāfūr* - 13559, *Safaidā Kāshgari* -13560, *Sang-i Jarāhat* - 13561, *Gandhak* - 13562, *Murdār Sang* - 13563, *Mom Safaid* - 13564) The Unani formulation MKJ was prepared at the GMP certified pharmacy of the institute in single batch as per standard operating procedure described in Unani Pharmacopoeia *Qarābādīn Majīdi* and preserved in air tight, clean and dry glass jar (Anonymous, 1986).

Table 1. Composition of Marham Kharish Jadeed (MKJ)

S.No	Name	Botanical/ Scientific Name	Quantity
1.	*Barg-i Ḥinā Sā'idā*	*Lawsonia inermis* L.	25gm
2.	*Safaidā Kāshgari*	Zinc Oxide	25gm
3.	*Sang-i Jarāhat*	Magnesium Silicate	25gm
4.	*Kāfūr*	*Cinnamomum camphora Linn.*	25gm
5.	*Kāth Safaid*	*Acacia leucophloea* Willd	25gm
6.	*Kamilā*	*Mallotus philippinensis* L.	25gm
7.	*Gandhak*	Sulphur	50gm
8.	*Murdār Sang*	Litharge	25gm
9.	Mom Safaid	*Wax*	125gm

Terbinafine hydrochloride 1% cream was used as an active control drug in this study. This drug was obtained from the open market which is widely used as an antifungal in superficial skin dermatophytosis that causes fungal cell death due to inhibition of squalene epoxidase resulting in intracellular accumulation of toxic squalene (Sumyuktha et al., 2017). It was used topically twice daily in the participants of control group for 28 days.

Assessment of efficacy of the drugs

The primary end point was to treat a participant of *qūbā* for four weeks or till complete alleviation of the signs and symptoms. The assessment of response to the therapy was measured in terms of reduction in Total Sign and Symptom score (TSSS) and complete elimination of fungal elements in microscopy of skin scrapings at four weeks of treatment in comparison to baseline. The severity of four different sign and symptoms (itching, erythema, scaling of the lesion and central clearing with peripheral raised margins) was rated on four point scale (0= absent, 1=mild, 2=moderate, 3= severe), these score were summed for each patient at each assessment to obtain a total score, with a maximum value of 12 points (Lakshmi et al., 2013) (Jerajani HR et al., 2000). The response of treatment was assessed at 0, 7th, 14th, 21st and 28th days.

Assessment of safety of the drugs

Systemic safety for study and control drugs was assessed comparing base line data with the post treatment data on the parameters haemogram (Hb%, TLC, DLC, ESR), LFT (S. Bilirubin, SGOT, SGPT, S. Alkaline Phosphatase), KFT (Serum Creatinine, Blood Urea Nitrogen), Urine Examination (Routine & Microscopic) and Fasting Plasma Glucose (FPG). Local safety of the drugs was also assessed in terms of itching, erythema, papules, vesicles, burning sensation at the site of application of the study.

Statistical analysis

Descriptive and inferential statistical analysis has been carried out in the present study. As per protocol analysis the data were analyzed using statistical software SPSS 22.0 and R environment ver.3.2.2. Microsoft word and Excel have been used to generate graphs and tables. Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in frequency distribution (%). Student t test (two tailed, dependent) and chi square test have been used to find the significance of the study.

OBSERVATIONS AND RESULTS

This study was conducted to assess and compare the efficacy and safety of Marham Kharish Jadeed in the management of *qūbā*. The clinical and demographic profiles of the participants are given in table 2. Baseline data in both groups were almost comparable. Average age of the participants in test and control groups was 34.63 years and 37.7 years respectively. It was observed that 38.3% participants belonged to 31 to 40 years of age group and 75% participants were female. It was also observed that chronicity of the disease ranged between 3 months to 2.5 years with an average of 8.2 month in test group and 8.1 months in control groups. The temperament of the participants was *Balghamī* (52%) and *Damwī* (48%). 76.7% participants were married in this study.

The study showed that the Unani formulation improved itching, erythema, scaling and peripheral raised margins of the lesions in 91.1%, 93.3%, 98.8% and 77.7% participants respectively in test group at the end of 4 weeks of treatment whereas control drug alleviated itching in 63.33%, erythema in 65.55%, scaling in 77.77% and peripheral raised margins in 56.66% participants (table 3, table 4, table 5, table 6). This study showed that TSS score (mean ± S.D) in test group reduced from 23.6±8.6 to 1.9±2 whereas in control from 24.4±11.6 to1.9±0.408 (table 7). The reduction in TSS score was found statistically significant in both groups while comparing from baseline to at the end of study. The study also revealed that ≥75% reduction in TSS score along with complete elimination of fungal elements was observed in 27 participants in test group (n=30) and 18 participants in control group (n=30) on comparing from baseline. It was also observed that in test group (n=30), 28 participants were declared relieved where ≥75% reduction in TSS Score only was observed after 28 days of treatment whereas in control group (n=30), only 21 participants (70%) were declared relieved in comparison to baseline TSS score of the participants. Two participants in test group and nine participants in control group did not improved at the end of 28 days of treatment where reduction in TSS score was less than 25 % from baseline (table 8). When comparing the efficacy of standard drug at the end of four weeks of treatment, the Unani formulation showed better improvement than that of control drug in alleviation of itching, erythema, scaling and peripheral raised margins of the lesions.

The safety of both test and control drugs was assessed. In this study Unani formulation was found safe. Local as well as systemic toxicity was not observed during the study after application of the Unani formulation for 28 days. No adverse effect (adverse drug reaction or adverse event) was reported during the duration of protocol therapy. In case of control drug terbinafine hydrochloride 1%, no adverse reaction was reported after application of the drug during the course of therapy. Thus the control drug was also found safe.

Table 2. Demographic and clinical profiles of the participants (n=60)

Particulars	Test group (n =30)	Control group (n =30)
No of Male	10	5
No. of Female	20	25
Average Age (years)	34.63	36.7
Average chronicity	8.2 months	8.1 months
No. of lesions in the participants ◆ **<2 lesions** ◆ **2-5 lesions** ◆ **> 5 lesions**	 3.3% 53.3% 43.3%	 3.3% 53.3% 43.3%
TSSS (Mean ±S.D)	23.6±8.6	24.4±11.6

Table 3. Effect of the Unani Formulation and Control Drug on Itching (n=60)

Groups	Mean ± SD, BT	Mean ±SD, DT	Mean ± SD, AT	P value	Percentage Efficacy	Significance
Test Group (n=30)	3±0	1.74±0.47	0.26±0.44	<0.001	91.11%	significant
Control Group (n=30)	3±0	2.02±0.38	1.1±0.90	<0.001	63.33%	significant

BT= Before Treatment, DT= 14th day, AT= After treatment

Table 4. Effect of the Unani Formulation and Control Drug on Erythema (n=60)

Groups	Mean ± SD, BT	Mean ± SD, DT	Mean ± SD, AT	P value	Percentage Efficacy	Significance
Test Group (n=30)	3±0	1.75±0.47	0.2±0.4	<0.001	93.33%	significant
Control Group (n=30)	3±0	1.9±0.408	1.03±0.83	<0.001	65.55%	significant

BT= Before Treatment, DT= 14th day, AT= After treatment

Table 5. Effect of the Unani Formulation and Control Drug on Scaling (n=60)

Groups	Mean ± SD BT	Mean ±SD, DT	Mean ± SD, AT	P value	Percentage Efficacy	Significance
Test Group (n=30)	3±0	1.36±0.56	0.03±0.17	<0.001	98.88%	significant
Control Group (n=30)	3±0	1.66±0.44	0.66±0.78	<0.001	77.77%	significant

BT= Before Treatment, DT= 14th day, AT= After treatment

Table 6. Effect of the Unani Formulation and Control Drug on peripheral raised margin (n=60)

Groups	Mean ±SD BT	Mean ±SD, DT	Mean ± SD, AT	P value	Percentage Efficacy	Significance
Test Group (n=60)	3±0	2.15±0.495	0.66±0.53	<0.001	77.77%	significant
Control Group (n=60)	3±0	2.3±0.41	1.3±1.03	<0.001	56.66%	significant

BT= Before Treatment, DT= 14th day, AT= After treatment

Table 7. Effect of the Unani Formulation and Control Drug on Total Sign and Symptom Score (TSSS) (n=60)

Groups	Mean ± SD (BT)	Mean ± SD (AT)	P value	Difference	Significance
Test Group n=30	23.6±8.6	1.9±2	<0.001	21.700	significant
Control Group n=30	24.4±11.6	7.7±9	<0.001	16.733	significant

BT= Before Treatment, DT= 14th day, AT= After treatment

Table 8. Assessment of overall efficacy at the end of 4 weeks of Study (n=60)

Groups	Relieved*	Not-relieved*	Mycologically cured	Mycologically not cured
Test group n=30	28 (93.3%)	2 (6.6%)	27 (90%)	3 (10%)
Control group n=30	21 (70%)	9 (30%)	18 (60%)	12 (40%)

Cured - ≥75% reduction in TSSS with mycological cured, **Relieved*** **-** ≥75% reduction in TSSS only
Partially relieved - ≤75% reduction in TSSS with mycological cured, **Not-relieved*** **-** ≤25% reduction in TSSS only

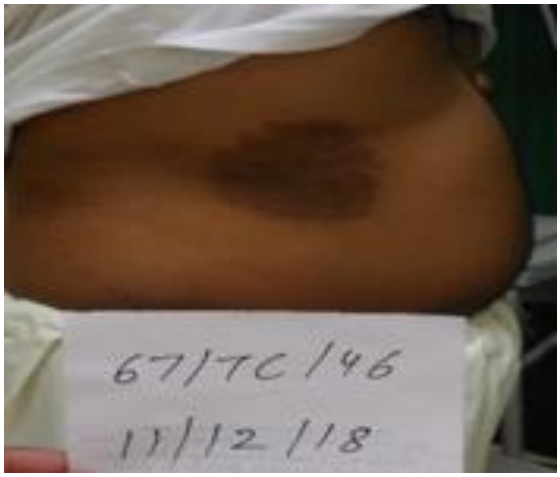

Fig 2. Before treatment

Fig 3. After treatment

Fig. 2 & 3 Showing effect of the Marham Kharish Jadeed on *qūbā* in the participant of test group

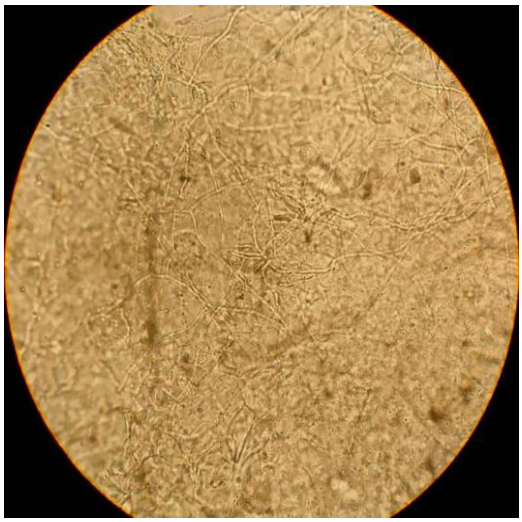

Fig.4 Before treatment

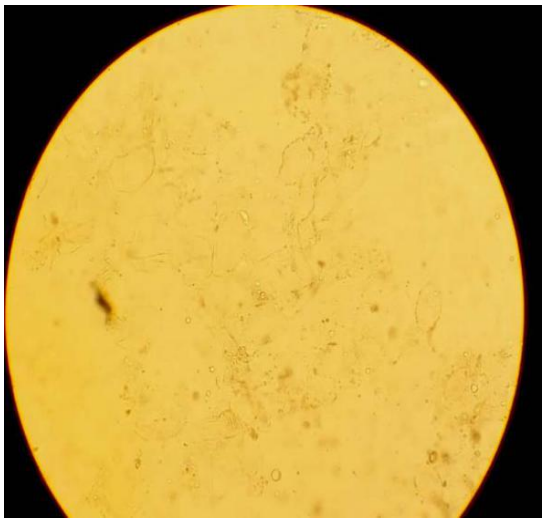

Fig. 5 After treatment

Fig. 4 & 5 Showing effect of the Marham Kharish Jadeed on fungal elements in microscopy (test group)

DISCUSSION

In this clinical study the safety and efficacy of the Unani formulation was assessed and compared with the standard drug *terbinafine hydrochloride 1%* cream. The findings of the study showed that the Unani formulation improved itching, erythema, scaling and peripheral raised margins of the lesions in 91.1%, 93.3%, 98.8% and 77.7% participants respectively in test group at the end of 4 weeks of treatment. In 27 participants ≥75% reduction in TSS score along with complete elimination of fungal elements was observed in the study. It was demonstrated in this study that the Unani formulation MKJ had better efficacy in the management of *qūbā* in comparison to control drug. The efficacy of the Unani formulation MKJ may be explained in terms of actions of the ingredients of the formulation. The possible mechanism of action for the therapeutic efficacy may

be due to desiccant (*Mujaffif)*, demulcent (*Mulaṭṭif)*, healer (*Mudammil),* haemostatic (*Ḥābis ud-Dam)*, muscle grower (*Munbit-i-Laḥm),* analgesic (*Musakkin)*, refrigerant (*Mubarrid)*, astringent (*Qābiḍ)* and antifungal properties of the ingredients of the Unani formulation MKJ which constituted of nine potent animo-herbo-mineral drugs. Berg-i-Hina (*Lawsonia innermis* L), Kamela (*Mallotus philippinensis* L), Safaidā Kāshgari (Zinc Oxide) and Beeswax had been reported to possess antifungal activity in various scientific studies. Suleiman EA and Mohamed EA reported that ethanolic extract of *Lawsonia inermis* L. showed inhibition of the growth of *T. mentagrophyte* and *T. violaceum* (Suleiman & Mohamed, 2014). Afzal *et al.* demonstrated that methanolic extract of shed dried powder of *Mallotus philippinensis* L. showed antifungal activity against *Aspergillus flavus, Aspergillus niger* and *Candida albicans* ((Afzal et al, 2013). Fratini, F et al conducted a study that revealed that Mom (wax) had antifungal property against *T. rubrum, T. mentagrophytes, M. canis* and *E. floccosum* (Fratini, F, et al, 2016). P. Singh reported in a study that Safaidā Kāshgari had antifungal activity against *Aspergillus niger* and *Candida albicans* (Singh & Nanda, 2013)**.** Berg-i-Hina (*Lawsonia innermis* L), Kamela (*Mallotus philippinensis* L), Murdar sang (lead oxide), Gandhak (sulphur) and Kafoor (*Cinnamomum camphora* L) are used as anti-inflammatory drugs (Ghani HN, YNM; Nadkarni AK, 2010). Sang-i-Jarahat (Magnesium Silicate) and Kath safaid (Acacia leucophloea Willd.) are the drugs having desiccant (*Mujaffif),* haemostatic (*Ḥābis ud-Dam)* and healer (*Mudammil)* properties (Kabiruddin, YNM: Hakim, HMA, 2002). The desiccant (*Mujaffif)*, demulcent (*Mulaṭṭif)*, healer (*Mudammil),* haemostatic (*Ḥābis ud-Dam)* and astringent (*Qābiḍ)* properties of constituent drugs may responsible for reduction in itching, resolution of inflammation and healing of the skin lesion. Drug resistance is a common problem in treatment of *qūbā* nowadays. In this study, culture and sensitivity of fungal elements had not been done. So it could not be said that which fungal skin infections could be treated well with the application of MKJ. But clinical efficacy and safety of MKJ may be established in the management of *qūbā* in this study.

The Unani formulation MKJ has been indicated for the treatment of *qūbā* in Unani pharmacopoeias such as National Formulary of Unani Medicine and *Qarābādīn Majīdi*. The outcome of this study validates that MKJ may be indicated for the treatment of *qūbā*. MKJ is a novel preparation that can deliver high concentrations of the drugs to the site of infection may be one of the reasons that this Unani formulation had better efficacy than that of control drug. This Unani formulation may be considered as the drug of choice for skin dermatophytoses.

CONCLUSION

Qūbā (tinea corporis) is a curable disease but difficult to treat due to recurrence, lack of sanitation and personal hygiene and drug resistance. Unani System of Medicine offers its treatment through herbo-mineral pharmacopoeial formulations. In this study Unani formulation Marham Kharish Jadeed had been assessed and compared for its safety and efficacy. The findings of the study suggested that the Unani formulation had better efficacy than control drug. This Unani formulation has widely been used for treatment of *qūbā* and other skin disorders in clinical practice since a long time. This study validates its application in the treatment of q*ūbā* (tinea corporis). Although, this study had several limitations. Small sample size, provision of limited funds and short time period for the study were the limitations of this study. It may be suggested that a better study with large sample size may be conducted to further establish its efficacy so that this Unani formulation could be opted as a drug of choice for the treatment of *qūbā*.

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CONFLICT OF INTEREST

None.

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