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Clinical studies on the treatment of psoriasis in *Unani* system of medicine: A systemic review

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ABSTRACT

Background & Aim: Psoriasis is a chronic inflammatory skin disease. In *Unani* system of medicine, psoriasis is termed as *Da'us Sadaf* or *Taqashshur-i Jild* which has been treated successfully since antiquity with various single and compound drugs. In recent years, various clinical studies have been conducted to validate the claims of *Unani* medicine in the management of psoriasis. The aim of this study was to review the published scientific clinical studies, performed to evaluate the safety and efficacy of *Unani* drugs in the treatment of psoriasis.

Experimental: Author searched four databases for psoriasis, using the terms "*Da'us Sadaf* OR psoriasis", "*Taqashshur-i Jild* OR psoriasis", "*Unani* medicine and psoriasis". Author also hand searched journals available in the library of Central Council for Research in Unani Medicine & Jamia Hamdard (New Delhi) and All India Institute of Medical Sciences (Raipur). All published clinical studies with *Unani* intervention were included in this review.

Results: A total of 58 articles were reviewed; out of them 46 articles based on animal studies, epidemiological reports, studies of general concepts were discarded leading to inclusion of 12 articles. Different Unani drugs were used in the trials. Although each clinical study reported beneficial effect, but there were very few trials that were controlled and randomized.

Recommended applications/industries: Various clinical studies evaluating the safety and efficacy of *Unani* drugs in the treatment of psoriasis have been carried out, but well-designed randomized controlled clinical trials (RCTs) still need to be conducted using standardized tools to scientifically validate the safety and efficacy of *Unani* drugs in the treatment of psoriasis.

1. Introduction

Psoriasis is a chronic skin disease which negatively impact patients' quality of life (QoL). There are reports which suggest that psoriasis can considerably impact QoL, even if relatively limited body surface area (BSA) is affected (De Korte, 2004; Tang, 2013; Augustin, 2014). Psoriasis causes great physical, emotional and social burden (Stem, 2004; Kimball, 2005; Fuji, 2011). Common challenges for people with psoriasis are disfiguration, disability and evident loss of productivity. There is also a significant effect on mental well-being, such as higher rates of depression, leading to negative impact for individuals and society (Russo, 2004; Sampogna, 2012). Prevalence rate is equivalent between men and women irrespective of age and ethnic origin. Psoriasis is major worldwide issue

with prevalence between 0.09% (Gibbs, 1996) and 11.4% (Danielsen, 2013) across different nations. In most developed countries, prevalence is between 1.5 and 5% (Parisi, 2013). The etiology of psoriasis is somewhat unclear, although genetic predisposition is considered as key factor (Harden, 2015). Immune system also plays a major role in its causation. Both external and internal triggers, including mild trauma, sunburn, infections, systemic drugs and stress can precipitate psoriasis (Boehncke, 2015). In modern medicine, treatment of psoriasis is still based on controlling the symptoms. A combination of topical and systemic therapies as well as phototherapy is often used in clinical practice. The need for treatment is usually life-long and is aimed at reducing the remissions (WHO, 2016).

Concept of psoriasis in Unani system of medicine

In Unani system of medicine, psoriasis is termed as Da′us Sadaf (disease of pearl) or Taqashshur-i Jild (peeling of skin) marked by dryness of skin and scale formation similar to the scales of a fish. Taqashshur-wa-Qashaf Jild (peeling and dryness of skin) has been described by renowned Unani physicians like Majusi, Ibne Zuhr, Ibne Hubal Baghdadi, Ibn al-Qaf, Ahmad bin Mohammad Tabari, Akbar Arzani and Azam Khan in their treatises, which closely resembles the clinical picture of psoriasis (Khan, 1289; Arzani, 1875; Zuhr, 1986; Jilani, 1996; Arzani, 2001; Khan, 2006; Hubal, 2007; Majusi, 2010). It is caused by Hirffif o Lazi' Sawda' Muhtaraq (acute and irritant burnt black bile) (Khan, 1289) and Khushk Buraqi Madda (dry alkaline matter) (Hubal, 2007). The principle of treatment in Unani system of medicine for this disease is Talyin-i Jild (to soften the skin), Tartib-i Jild (to moisturize the skin) and Tanqiya-i Badan (evacuation of morbid material from the body) (Khan, 2006). The treatment is specifically aimed at the alteration or removal of morbid material, which is the actual culprit for the genesis of pathology leading to development of the disease. Since the disease, is chronic in nature which cannot be easily overpowered with a unidirectional onslaught. Therefore, Unani physicians adapted a multidirectional approach for the treatment of this disease and the drugs having Musaff-i Dam (blood purifier), Muhallil (resolvent), Mudammil Quruh (healing) properties are being used. Once the morbid matter is removed from the body, inflammation is resolved and proper healing takes places, and chances of recurrence automatically minimizes (Rashid, 2012).

Many renowned *Unani* physicians have recommended various drugs for the treatment of this disease in their treatises. Quite a number of clinical trials have also been undertaken in the light of *Unani* concepts. Thus, the primary objective of this paper was to systematically review the evidences derived from published clinical studies on psoriasis in *Unani* system of medicine.

2. Materials and Methods

Author performed the comprehensive literature searches of relevant articles published, through electronic searches of AYUSH Research Portal, PubMed, SCOPUS, and also through Google Scholar advanced search, using the terms "*Da'us Sadaf* OR psoriasis", "*Taqashshur-i Jild* OR psoriasis", "*Unani* medicine and psoriasis". Author also hand searched journals available in the library of Central Council for Research in Unani Medicine & Jamia Hamdard (New Delhi) and All India Institute of Medical Sciences (Raipur).

After performing an exhaustive search on electronic databases, it was found that there are very few results in main databases. After assessing the resulting lists, all clinical studies were included in the review (Figure 1).

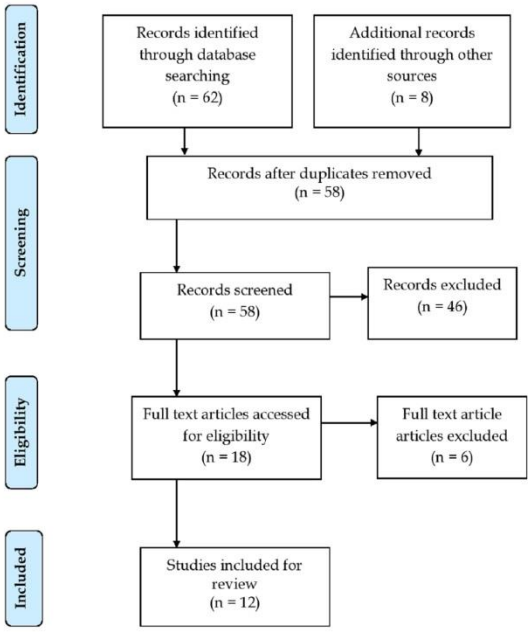

Figure 1: Summarized Methodology

3. Results and discussion

A total of 58 articles were reviewed; out of them 46 articles based on animal studies, epidemiological reports, studies of general concepts were discarded leading to inclusion of 12 articles. Different *Unani* drugs were used in the trials. Although each clinical study reported beneficial effect, but there were very few trials that were controlled and randomized. Summary of these studies is given below in Table 1.

Table 1: Summary of clinical trials

Study ID, Year and Design	Sample size	Interventions & their duration	Results
Lone *et al.* (2011) Randomized single-blind, placebo-controlled study	N=30 Test=20 Control=10	**Test Group** 1. ***Majun Ushba*** (5 gm twice a day) 2. ***Roghan-e-Hindi*** (5-10 ml twice a day) for local application **Control Group** **Placebo drugs** (wheat flour orally and coconut oil topically) **For 2 months**	PASI Score Test group Before treatment=7.75 After treatment=3.25 Placebo Group Before treatment=6.80 After treatment=6.80
Khanna *et al.* (2018) Non-inferiority randomized controlled clinical trial	N=287 Test= 147 Control=140	**Test Group** 1. **UNIM-401** (orally 2 BD capsules of 500 mg) 2. **UNIM-403 oil** once a day, followed by exposure to sunlight **Control Group** 1. **Psoralen plus ultraviolet A (PUVA) sol** (8-methoxsalen in a dose of 0.6 mg/kg on alternate days as a single dose after breakfast) 2. **Petrolatum** (at night) **For 3 months**	PASI reduction / *Unani* group / PUVA sol group Intention-to-treat analysis: n=147, (%) / n=140, (%) <75: 123 (83.7) / 118 (84.3) ≥75: 24 (16.3) / 22 (15.7) <50: 87 (59.2) / 95 (67.9) ≥50: 60 (40.8) / 45 (32.1) Per-protocol analysis: n=84 / n=67 <75: 60 (71.4) / 45 (67.2) ≥75: 24 (28.6) / 22 (32.8) <50: 24 (28.6) / 22 (32.8) ≥50: 60 (71.4) / 45 (65.2)
Rashid (2012) Parallel, randomized, single-blind, observational and comparative study	N=40 Group-A=20 Group-B=20	**Group-A** 1. ***Safuf Chobchini*** (6 mg twice a day) 2. ***Roghan-e-Hindi*** (twice a day) for local application **Group-B** 1 ***Safuf Ushba*** (6 mg twice a day) 2. ***Marham Basaliqun*** (twice a day) for local application **For 45 days**	PASI Score Group- A Before treatment=14.09±1.82 After treatment=7.825±1.22 Group- B Before treatment=20.195±3.038 After treatment=10.465±1.82
Siddiqui *et al.* (2009) Single arm clinical study	N=40	1. ***Safuf Babchi*** (6 gm twice a day as decant water) 2. ***Marham Gulabi*** (once a day) for local application **For 45 days**	An overall clinical improvement of about 77.5% at the end of 45 days treatment.
Mohsin *et al.* (2016) Single arm clinical study	N= 60	1. ***Majun Chobchini*** (6 gm twice a day) 2. **Wet cupping** (fortnightly) **For 2 months**	Palmo-Planter Psoriasis were slow to respond to treatment. The cases of Psoriatic arthritis showed good response and there was drastic improvement seen in swelling of the joints and movements, consequently performance in routine life activities were improved.
Akhtar *et al.* (2011) Randomized single arm pilot clinical study	N= 60	1. ***Itrifal-e-Shahatra*** (6 gm twice a day) 2. ***Roghan-e-Babchi*** (Twice a day) for local application **For 2 months**	Relieve in scaling and itching were 90% and 85% respectively. Burning sensation was relieved in 100% cases at the end of the study. 70%, 90% and 50% relive in plaques, papules

			and pustules. 75% cases relived from erythema. 80% and 70% relief in auspitz sign and woronoff ring due to overall relief in symptoms like scaling, itching and plaquing etc.
Khan (2019) Case Series	N=5	1. ***Majun Ushba*** (10 gm twice a day) 2. ***Marham Safed Kafuri*** (once a day) for local application **For 35 days**	PASI Score Before treatment=27.4 After treatment=14 With significant improvement in symptoms
Siddiqui *et al.* (2019) Case Series	N=6	***Bisfayej***-7gm, ***Post Halela Zard***-10 gm and ***Turbud***-7gm in the form of joshanda (decoction) **For 40 days**	PASI Score Before treatment=6 After treatment=4 With significant improvement in symptoms
Fatima *et al.* (2019) Case Series	N=5	1. ***Majun Mundi*** (5 gm twice a day) 2. ***Qayruti Karnab*** (twice daily) for local application **For 3 months**	PASI Score Before treatment= 20.7±4.6 After treatment= 3.2±1.8 With significant improvement in symptoms
Shiraz *et al.* (2017) Case Study	N=1	**Leech Therapy**	PASI Score Before treatment=14.4 After treatment=3.6 With significant improvement in symptoms
Siddiqui *et al.* (2015) Case Study	N=1	1. ***Safuf Babchi*** (6 gm twice a day as decant water) 2. ***Marham Gulabi*** (once a day) for local application **For 45 days**	Significant improvement in PASI score and other parameters
Qureshi *et al.* (2018) Case Study	N=1	***Sabus Aspaghol*** and **Coconut oil with camphor (**for local application**)** ***Majun Musaff-i* Khas** (6 gm twice a day) ***Musaff-i Ajib*** (30 ml twice daily) For 3 months **Wet Cupping Procedure at the end of treatment**	Effect of medicine was found highly significant on itching, burning and pain with marked improvement in all lesions.

The objective of this systematic review was to combine and summarize the data from various randomized controlled clinical trials performed to evaluate the safety and efficacy of *Unani* drugs in the treatment of psoriasis, but most of such trials were uncontrolled and non-randomized. Only three randomized controlled clinical trials could be found, which also varied in study design, outcome measures, and methodology. However, outcomes of all these studies revealed significant results but these trials are not enough to provide the evidence. Some other single arm/ double arm studies without any control group, case series and case studies were reported and showed good results. But these studies also varied widely in methodology, design, intervention and outcome measures. Different parameters were set by different authors. The meta-analysis of the studies could not be done as no standard scoring system was applied to measure the outcome.

Details of randomized clinical trials

Lone *et al.* (2011) randomly assigned 20 and 10 participants in test and control group respectively. Participants in test group received, a coded *Unani* formulation- *Majun* Ushba (5 gm twice a day) and *Roghan-e-Hindi* (5-10 ml twice a day) for local application, and in control group placebo drugs (wheat flour orally and coconut oil topically) were given. Participants received treatment in both the group for two months and evaluation was carried out by observing the improvement in subjective and objective parameters. Psoriasis Area and Severity Index (PASI) scale was also used for evaluation. Both groups results were compared and analyzed statistically. PASI score in the test group was reduced significantly ($P<0.01$) in comparison with placebo group. No apparent adverse effects were reported in the test group (Lone *et al.*, 2011).

Khanna *et al*. (2018) conducted a clinical trial to find out non-inferiority of *Unani* medications (oral UNIM-401 and topical UNIM-403) vs Psoralen Plus Ultraviolet A (PUVA) sol in treatment of moderate-severe chronic plaque psoriasis (CPP). Patients were randomized into two groups i.e. *Unani* treatment group (147 patients) or PUVA sol treatment group (140 patients) and received treatment for 12 weeks. Percentage reduction in PASI was determined in each patient at 12 wk to establish number of patients who achieved PASI 75 as also to estimate median of percentage reduction in PASI in each group. 12 weeks treatment was completed by 84 of 147 patients in *Unani* group and 67 of 140 patients in PUVA sol group out of total 287 patients. On intention-to-treat (ITT) analysis i.e. attaining PASI 75, it was observed that the response in patients on *Unani* medication was not inferior to those receiving PUVA sol (16.3% in *Unani* group vs 15.7% in the PUVA sol group). PUVA sol group patients showed significantly higher clinical side effects i.e. 16.4% compared to *Unani* group (2%) (Khanna *et al*., 2018).

In Rashid (2012), 20 patients were enrolled in two groups. Group A patients received *Safuf Chobchini* orally and *Roghan-e-Hindi* for local application whereas *Safuf Ushba* orally and *Marham Basaliqun* for local application were given to group B patients. Overall response of *Unani* formulations was accessed by Psoriasis Area Severity Index (PASI). Efficacy of *Unani* formulations administered to group A and B was found statistically significant in the treatment of psoriasis (Rashid, 2012).

A single arm clinical study with sample size (n=40) was conducted by Siddiqui *et al*. (2009) with two *Unani* formulations, *Safuf Babchi* (6 gm twice a day as decant water) and *Marham Gulabi* (once a day) for local application. The duration of the study was 45 days and outcome measured by mean percentage of improvement in symptoms. An overall clinical improvement of about 77.5% at the end of 45 days treatment was observed (Siddiqui *et al.*, 2009).

Another non randomized, single arm clinical study was conducted on 60 participants by Mohsin *et al*. (2016), participants in this study received, *Majun Chobchini* (6 gm twice a day) with wet cupping procedure (fortnightly) for 2 months. Palmo-planter psoriasis was slow to respond to treatment. The cases of psoriatic arthritis showed good response and there was drastic improvement seen in swelling of the joints and movements, consequently performance in daily routine life activities of patients was improved (Mohsin *et al.*, 2016).

Akhtar *et al.* (2011) conducted a randomized single arm pilot clinical study on 60 participants of psoriasis. *Itrifal-e-Shahatra* (6 gm twice a day) and *Roghan-e-Babchi* (Twice a day) for local application was given for two months. Relief in scaling and itching were 90% and 85% respectively. Burning sensation was relieved in 100% cases at the end of the study. There was a 70%, 90% and 50% reduction in plaques, papules and pustules respectively. Erythema was resolved in 75% cases. There was an 80% and 70% relief in auspitz sign and woronoff ring due to overall relief in symptoms like scaling, itching and plaquing etc. (Akhtar *et al.*, 2011).

4. Conclusion

Various clinical studies evaluating the safety and efficacy of *Unani* drugs in the treatment of psoriasis have been carried out, but well-designed randomized controlled clinical trials (RCTs) still need to be conducted to scientifically validate the safety and efficacy of *Unani* drugs in the treatment of psoriasis. Health-care providers and dermatologists should use standardized tools to assess the severity of psoriasis and the impact of the disease on QoL. It is important that the medical community reaches a consensus on using a standardized classification of psoriasis and uniform tools for its evaluation. Tools like Dermatology Life Quality Index (DLQI), Lattice System Global Psoriasis Score (LS- GPS), National Psoriasis Foundation Psoriasis Score (NPF-PS) and Psoriasis Area and Severity Index (PASI) may be used for the assessment of response to treatment.

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