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A systematic review of clinical trials examining the effectiveness of Unani drugs on skin diseases

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ABSTRACT

Background & Aim: Throughout the past three decades, scientific attention has been increased in examining Unani drugs for a potential therapeutic or preventive agent in the management of a number of health disorders in general and skin disorder in particular. The purpose of this systematic review is to analyze and categorize the current state of scientific evidence from clinical studies regarding the efficacy of Unani drugs in skin diseases.

Experimental: Electronic and non-electronic systematic searches were carried out to identify all relevant clinical research on Unani drugs. Reference lists of articles that met the inclusion criteria were searched. Only studies reported in English were reviewed. Studies on single Unani drugs and compound formulations in various skin diseases were included, in accordance with the PRISMA statement that included studies must measure a physiological and/or a behavioral outcome.

Results: The studies that met our inclusion criteria are effects of Unani drugs on Acne (n=5), Melasma (n=2), Pityriasis (n=1), Vitiligo (n=2), Urticaria (n=2), Ring worm (n=2), Psoriasis (n= 3), Eczema (n = 2), and Scabies (n = 1). The data from these studies support the efficacy of Unani drugs as compared to placebo and standard drugs in improving Acne, Melasma, Pityriasis, Vitiligo, Urticaria, Ring worm, Psoriasis, Eczema and Scabies.

Recommended applications/industries: Findings from initial clinical trials suggest that Unani drugs may improve the clinical manifestations of skin diseases. However, larger multi-site clinical trials are needed to extend these preliminary findings.

1. Introduction

Skin represents a status of human body and expresses inner health. It affects more than 60% of the general population in developing countries (Joel *et al.*, 2013). There is high prevalence of dermatological diseases in India, especially mountainous area of North India (Grills *et al.*, 2012). However, world health organisation's report (2001) states that the global

burden of disease indicates that skin diseases are associated with mortality rates of 20,000 in sub Saharan Africa in 2001 (Mathers *et al.*, 2006). Excluding mortality, skin diseases are the fourth leading cause of disability worldwide (Karimkhani *et al.*, 2017). Most common skin diseases are eczema, acne, fungal infection, psoriasis, dermatitis, vitiligo etc. (Al-Hoqail *et al.*, 2013). The common medications for

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oral and topical use include viz. antibiotics, antifungal, corticosteroids, immunosuppressant etc (Stephanie, 2017).

The role of herbal drugs in preventing and treating many diseases has been of interest to several scientific and non scientific communities. Although medicinal plants are used for a wide variety of physical ailments, there is often limited research supporting such practices. Unani medicine is an ancient system of medicine based on the theory of the four humors, whose record can be traced back to ancient Greece. It has been rated as one of the oldest systems of traditional medicine serving mankind for centuries by alleviating ailments through drugs derived from natural resources i.e. plants, minerals and animals (Kalam and Ahmad, 2016). Today it is practiced in India, Bangladesh, Sri Lanka and South Africa under the name of Unani Medicine; in Pakistan as Eastern Medicine and in China as Uyghur Medicine and is considered as a holistic loom (Rahman et al., 2008).

To date, no systematic review has been conducted on the effects of Unani drugs for preventing or treating skin diseases. The purpose of this study is to conduct a systematic review to summarize and critically evaluate the evidence from clinical trials that have examined the effectiveness of a number of Unani single drugs and compound formulations in regards to outcomes related to skin diseases.

2. Materials and Methods

A systematic review was done of all the clinical studies conducted on Unani single drugs and formulations in the management of various skin disorders. A comprehensive bibliographic search was done on classical literature in Unani system of medicine and online published articles on skin disorders. The databases utilized for obtaining information for the current review were MEDLINE, PubMed, Science Direct, and related databases, such as AYUSH Research Portal, Systematic Reviews in Unani, Web of Science, Indus Medicus, and Google Scholar; by consulting existing bibliographies; by using both forward and backward reference chaining techniques; and by tracking recent activities in the field of Unani which is primarily concerned with Unani drugs on skin disorders. We also collected literature on traditional medicine and searched some Indian journals

not included in MEDLINE. The keyword for the search included "skin disorders", "Unani medicine', "Unani drugs" "Acne", "Melasma", "Pityriasis", "Urticaria", "Ring worm", "Psoriasis", "Eczema" and "Scabies". So far we found 20 clinical trials which have been done during the past 10 years and reported the efficacy of Unani drugs in various skin diseases.

2.1 Unani perspective of dermatology

In Unani medicine skin is considered as aaza mutashabihat (Simple organ) which protects the internal organs. Superficial visible part is called as bashra (epidermis) and inner one which is hard is known as adma (dermis) (Maseehi, 2008). In entire human body, skin is most sensitive organ because kaifiyat arba viz. hararat (hotness), baroodat (coolness), ratubat (wetness) and yabusat (dryness) are equally and normally distributed in skin. Skin has pores through which body respires and it is a site from where waste material excreted out (Arzani, 2002, Oarshi, 2011). Unani physicians were well aware of dermatology they were not only described the normal structure and functions of skin but also elaborated the aetiology, clinical presentation, and management of various skin diseases. Moreover ancient physicians have devoted one section of their books on skin diseases as well as drugs used in dermatology are described in detail with the mechanism of action in the literature of Unani pharmacology. According to Greco Arabic physician impurity in the blood is the leading cause of skin diseases. Blood may become morbid by various reasons such as unhealthy food, irregular dietary habit, external environment, stress, lack of sleep, lack of exercise, improper ventilation etc (Tabri, 1997). Unani drugs particularly blood purifying drugs are used successfully in the treatment of skin diseases. Many of the following clinical trials have been done to prove the efficacy of Unani drugs in skin diseases.

2.2 Research studies

2.2.1 Busoore labniya (Acne)

According to classical Unani literature it is described as common dermatological disorder of adolescent period manifest as white eruption over the face. According to Avicenna acne are small white eruptions on the nose and cheeks which resemble a drop of milk (Ibn Sina, 2007).

a) Efficacy of topical application of Safoofe Basoor - a polyherbal formulation

A randomized, single blind, standard controlled study was carried out on 60 patients. The test group was treated locally with formulation containing drugs *viz*. *Cinnamomum zeylanicum*, *Papaver somniferum* and *Euphorbia latex* while control group was treated with topical application of Tretinonin for a period of 8 weeks. The subject was assessed using Cook system of grading. The response of drug was recorded on a five point scale. The result showed that both the groups had significant effect (p<0.001) in ameliorating acne (Quamri *et al.*, 2009).

b) Effect of compound Unani formulation-Zimade Muhasa (ZM)

Another randomized, single-blind, standard controlled trial was conducted to evaluate the efficacy and tolerability of Unani topical anti acne formulation Zimade Muhasa against standard control (5% benzoyl peroxide) which was applied on Acne vulgaris on 48 patients. Content of test drug is Iris germanica, Azadirachta indica, Abrus precatorius, Albizia lebbeck and lake salt. After 6 weeks, both the treatment decreased the acne lesions significantly (P<0.001). Additionally, test drug significantly improved post inflammatory hyperpigmentation (P<0.001), scarring (P=0.025) and complexion (P=0.001). ZM was welltolerated by patients and the efficacy was found to be equivalent to standard drug (Tabasum et al., 2014).

c) Efficacy and safety of a polyherbal formulation

A standard controlled single blind clinical study on 50 patients of acne vulgaris was carried out. The formulation contains *Iris florentina*, *Azadirachta indica*, *Acacia speciosa*, *Abrus precatorious* and Lake Salt.Treatment duration was of 45 days and severity of acne vulgaris and efficacy of the drug was evaluated by employing Cook System of Acne Grading. Result demonstrated that herbal formulation and standard drug were equally effective and statistically significant (p<0.05%). There was no significant difference in efficacy after treatment between the two groups at 5% p level. Further the Polyherbal formulation was found safe and fairly well accepted by the patients (Lone *et al.*, 2011).

d) Efficacy of Marhame Raal and Qurs Musaffie Khoon (Kit Medicine)

Sixty patients with active lesion of acne vulgaris were included in the open clinical trial to evaluate the efficacy of Unani kit medicine viz. Marham Raal (Shorea robusta resin, Cinnamomum camphora, Acacia catechu, oil of Brassica nigra and wax) and Qurs Musaffie Khoon (Berberis artsiata, Zingiber zerumbet, Acacia catechu and Cassia absus). The study shows that Marham Raal and Qurs Musaffie Khoon combination can be effective therapy in I, II and III grade acne vulgaris. In grade IV better results can be obtained if the duration of treatment is to be extended (Ara et al., 2014).

e) Efficacy of local application of a Unani formulation in acne vulgaris

The study was observational self control (before and after treatment) on 40 female patients carried out for one year. *Nigella sativa*, *Ammonium chloride* and Būra Armani mixed with vinegar were applied locally for one month with low calorie index diet. All subjects were assessed on the basis of changes in objective and subjective parameters. The response of test formulation was found to be highly significant (P<0.01). Subjects reported a reduction of 82.6%, 80.9%, and 66.6% in tenderness, itching and irritation respectively (Sultana *et al.*, 2015).

2.2.2 Kalaf (Melasma)

Melasma is one of the common aesthetically displeasing entity continues to be a difficult problem to treat. According to Unani physicians it is caused by sub dermal oozing and accumulation of morbid blood or due to rupture of blood capillaries or congestion (Tabri, 1997).

a) Efficacy of Raphanus sativus and Apium graveolens with vinegar

A single blind, randomized and standard control, clinical study was conducted on 44 patients of melasma. *Apium graveolens* is a blood purifier (Tyagi *et al.*, 2013, Nilugal *et al.*, 2015). In test group ointment containing seeds of *Raphanus sativus* and *Apium graveolens* with vinegar was applied while in control group Azelaic acid, 10% cream was used for 45 days. Both the treatments were found to be equally

effective (P= 0.001) in test and control group (Gauri *et al.*, 2015).

b) Efficacy of Nigella sativa and Sugarcane Vinegar

Another clinical study was done to find out the effect of a paste of *Nigella* sativa and vinegar on melasma. More than 75% improvement was observed in 50% cases and 50-75% improvement in 30% cases. No improvement was seen in 20% cases (Zarnigar *et al.*, 2011).

2.2.3 Bahaq (Pityriasis)

According to a renowned Unani Physician Rhazes (850-923 A.D.) pityriasis is a skin disease characterized by either hypo or hyper pigmentation with formation of scales on skin. Hakeem Ajmal Khan described pityriasis as an infectious or contagious disease characterized by white yellow patches on trunk and neck along with scaling of skin. It may or may not be associated with pruritus. HakeemAkbar Arzani (17th century A.D.) has classified pityriasis into two types, Bahaq Abyaz (white pityriasis) and Bahaq Aswad (Black pityriasis) (Arzani, 2002).

a)Efficacy of polyherbal ointment Zimade Bahaq containing Plumbago zeylanica, Brassica nigra, Centipede minima, Rubia cordifolia, Raphanus sativus and Vinegar.

A randomized, single-blind, standard controlled study was conducted on total 64 patients of Pityriasis. In test group Zimade Bahaq while in control group Sodium Thiosulphate Lotion (20 %) was applied for 30 days daily once. Study revealed that the efficacy of both the formulation is significant (p<0.05) but Unani formulation showed comparatively quicker response than the standard drug (Lone *et al.*, 2012).

2.2.4 Bars (Vitiligo)

Rhazes beautifully described pathophysiology of vitiligo. According to him when there is excessive accumulation of balgham ghaleez (thick phlegm) affected part becomes whitish and molluscs like. Further, the circulating blood is altered on reaching the affected part and becomes phlegmatic, and the area getting such blood cannot be nourished properly (Razi, 1991).

a) Efficacy of Safoof bars containing Psoralea corylifolia, Cassia absus, Ficus hispida, and Cassia tora

A randomized, single blind, placebo controlled study was undertaken to evaluate the efficacy of Safoofe Bars in the management of Vitiligo. The patient was divided in test (30 patients) and control group (10 patients). Duration of trial was 3 months with follow up of every 15 days. Response in test group was found to be statistically (p<0.005) significant (Ahmad *et al.*, 2011).

b) Therapeutic evaluation of compound formulation Majoon Atrilal along with local application of Plumbago zeylanica and Copper sulphate

An observational single blind study was carried out on 20 clinically diagnosed patients of vitiligo. They were given 10 gm of Majoon Atrilal twice daily along with local application of *Plumbago zeylanica* and Copper sulphate, daily once for three months. Vitiligo area study index showed significant improvement (P<0.005). Study revealed that these drugs are efficacious in vitiligo (Mohd *et al.*, 2014).

2.2.5 Shara (Urticaria)

According to Unani literature Urticaria is a disease which is caused by morbid blood. Excessive amount of safra (bile) or balgham shor (abnormal phlegm) may be the factors of such type of disorder. Severe heat of such blood causes abnormality in the nerves which ultimately result in urticaria rash (Tabri, 1997).

a) Therapeutic evaluation of local application of pearl shell and powder of Rauwolfia serpentina

A randomized, single-blind, placebo-controlled study was carried out on 30 patients (Test group included 20 patients and control group 10 patients). Test drug were given for 28 days twice daily. Results showed that the test drug produced significant (p<0.05) effect on itching, wheals, and erythema (Lone *et al.*, 2011).

b) Efficacy of polyherbal formulation prepared by Rauvolfia serpentina, Acorus calamus, Artimisia vulgaris, Fumaria indica, Nardostachys jatamansi, Lavendula stoechas

Unani formulation capsule Pitkriya containing above drugs were tested clinically for its efficacy and safety in the management of urticaria. Patient of urticaria were randomly assigned into two groups. Pitkriya treatment significantly decreased all the symptom score in patient of chronic urticaria. Statistically significant difference (p≤0.01) was observed between two groups. The test formulation found to be safe, none of the

values of haematological and biochemical parameters were outside normal range, and no clinically significant adverse effect was observed during and after 12 week of study (Shamsi *et al.*, 2006).

2.2.6 Qooba (Ring worm)

According to Unani physicians Ring worm is defined as type of roughness appears on the skin as a hyper pigmented patch having edge with itching and devoid of pain. This patch is usually circular in shape (Qarshi, 2011).

a) Assessment of local application of Marhame Qooba along with oral administration of Joshanda Mundi

The study was conducted as a single test drug Marhame Qooba for local application and Joshanda Mundi for oral administration for 60 days; while Fluconazole (150 mg orally and ointment Clotrimazole 1% for local application) were used as standard control for 30 days twice daily. The overall response in both the test and control groups was statistically significant (p<0.05) in the patients of ring worm. The study revealed that the test drug exhibited good response on itching, scaling and erythema (Mobeen *et al.*, 2012).

b) Efficacy of compound oral formulation Majoon Ushba and local application of Marham Gulabi

The efficacy of compound formulation Majoon Ushba and local application of Marham Gulabi was evaluated on 30 patients for a period of 45 days on the basis of improvement in the clinical subjective parameters like itching, scaling etc. The compound formulation had significant effect on itching (Hasan *et al.*, 2011).

2.2.7 Tagasshure Jild (Psoriasis)

Psoriasis is described in Unani literature under the caption "*Taqasshure jild*". Ancient Unani scholars Rofas, Galen, Rhazes, Avicenna, Majoosi, Avenzoar, Ibnul Qaf, and Ibne Hubul described it in detail. According to their description Psoriasisis a common skin disorder characterized by dryness of skin and scale formation like a fish (Qarshi, 2011).

a) Efficacy of local application of Roghane Hindi with orally used formulation, Majoon Ushba

A randomized, single blind, placebo controlled trial was done to assess the safety and efficacy of two pharmacopeial Unani formulations Majoon Ushba and Roghane Hindi in the management of psoriasis on scientific parameters. The duration of the trial was 8 weeks and follow-up was done fortnightly on thirty diagnosed psoriasis patients. The study demonstrated that these Unani formulations produce significant improvements (P< 0.01) in subjective and objective parameters (Lone *et al.*, 2011).

b) Therapeutic evaluation of a compound orally used formulation Itrifal Shahatra along with local application of Roghane Babchi

Another clinical study was designed to evaluate the efficacy of Unani Pharmacopoeal preparation Itrifal Shahatra and Roghane Babchi. Sixty patients were randomly selected and duration of study was 60 days. At the end of the study it was observed that there was improvement in erythema which was reduced up to 75%, burning sensation 100%, and over all well-being and improvement in disfigurement was statistically significant (Akhtar *et al.*, 2011).

c) Effect of Psoralia corylifolia with local application of Marhame Gulabi

The clinical study was conducted on 40 psoriatic patients. Patients were advised to take water of *Psoralia corylifolia* and apply Marhame Gulabi on the lesion once a day for 45 days. Clinical evidences proved the effectiveness of test drugs (Khan *et al.*, 2009).

2.2.8 Naarfaarsi (Eczema)

Eczema is a Greek word comprising two parts "Ec" means 'out' and "Zeo" means 'boil'. The whole word implies to "boil-out". The primary cause of Nar-e-Farsi (eczema) is production of excess quantity of abnormal safra (Yellow bile) mixed with abnormal sauda and sauda-e-muhtariqa (black bile). Therefore all the Unani physicians are of the opinion that its treatment should be started with tanqiyah-e-badan (removal of harmful material from the body) through different means of evacuation like fasd, munzij and mushil etc (Qarshi, 2011).

a) Efficacy of Smilax china with topical application of Murdar sang, Roghane gul, Safeda, Sirka and Kafoor

A randomized, single blind, placebo controlled study was conducted on total fifty patients to find out the efficacy of *Smilax china* with topical application of Unani formulation. *Smilax china* powder was

administered orally along with topical application of ointment comprises of Murdar sang (Litharge), Roghane gul (oil of Rosa damascene), Safeda (white lead), Sirka (vinegar) and Kafoor (*Cinnamomum camphora*) for ninety days. The study reflected that Unani formulation has significant effect in reduction of Six area, six sign atopic dermatitis (SASSAD) severity score (p<0.01) and there was definite reduction in the cardinal symptoms of eczema (Siddiqui *et al.*, 2010).

b) Clinical efficacy of Unani formulation on eczema

The formulation contains Henna (*Lawsonia inermis*) and Black Cumin (*Nigella sativa*) studied on thirty patient of eczema. After the treatment, improvement in macules, papules and vesicles was 75% with improvement in scaling, lichinification, hyper pigmentation and excoriation. The efficacy of test drug on subjective parameter of eczema was found clinically and statistically significant (Nawab *et al.*, 2008)

2.2.9 Jarb (Scabies)

Jarb is a skin disease characterised by intense itching particularly during night. Its aetiology is attributed mainly to the fasade dam (blood impairment) produced by a damvi madda (sanguineous matter) intermixed with a safravi madda (bilious matter) or balghame shor (acidic phlegm) (Tabri, 1997). The actual pathogenesis lies in the production of hiddate dam (abnormal heat in blood) due to which blood becomes more viscous and gets shifted towards the skin leading to the formation of papules/vesicles accompanied with itching and exudation (Qamri, 2008). It is mostly found in those people who take excess of salty and sour food items and poor people including labours who bath after prolonged intervals (Rahman, et al., 2008).

a) Efficacy of polyherbal Unani formulation

An oral administration of formulation containing Fumaria indica, Swertia chirayita, Tephrosia purpurea, Sphaeranthus indicus and Ziziphus jujuba along with local application of Sulphur, Letharg and Cinnamomum camphora was investigated on 30 patients of scabies. After 15 days of treatment, it was observed that out of 30 patients, itching was relieved in 50% cases, pruritic lesions were completely healed in 40 % of cases, skin scrap test was completely negative in 83% cases and burning sensation was relieved in 43% cases (Ali et al., 2006).

3. Results and discussion

Unani drugs tend to be more promising in the field of dermatology as already described by reputed Unani physicians. They have vividly discussed skin diseases, clinical manifestations and treatment in their treatises. The dermatological disorders examined were acne, scabies, eczema, psoriasis, ring worm, urticaria, vitiligo, pityriasis and melasma. In most of the studies Unani medicine was found to be quite effective viz. Acne, (Quamri et al., 2009, Lone et al., 2011, Tabasum et al., 2014, Ara et al., 2014, Sultana et al., 2015), although there were limited studies on pityrasis and scabies (Ali et al., 2006, Lone et al., 2012). None of the studies found that Unani drugs either worsened the condition or had negative effects. Of all outcomes evaluated, the strongest evidence exists to support the efficacy of Unani medicine for improving symptoms of acne. Although the results of our review are encouraging, with most studies displaying a positive effect, the review has several limitations. Though our search strategy involved both electronic and nonelectronic data, we may not have identified all the available trials involving Unani drugs. As noted above, most trials were of short duration (4 to 6 weeks), with relatively small sample sizes (n = 30-40). These factors prevent us from drawing firm conclusions about the effects of Unani medicine on health outcomes related to skin diseases. Other limitations of the studies in this review include a lack of long-term follow-up, use of single self-report outcome measures, reliance on selfreport measures, and lack of moderator analysis. The small sample size most likely precluded the examination of important moderator variables (e.g., gender, age).

In all of the trials included in this review (n=20), among a total of participants, there were no significant adverse events, adding to the safety of Unani medicine. In summary, Unani medicine has vast traditional uses. It has demonstrated efficacy in treating skin diseases; however, a limited number of high-quality clinical trials exist currently. Larger scale randomized controlled clinical trials are needed for better understanding of Unani medicine's potential. Data regarding safety, effectiveness, and mechanisms of action from longer-term trials are needed so that Unani medicine can be widely recommended for the better management of skin diseases and associated disorders.

The commonest used drugs among them were blood purifiers. Blood purifiers are broadly defined as group of drugs that remove toxins and waste matter from the blood by diverse mechanism and have been used in Unani system of Medicine since ancient times for treating numerous diseases including blood, skin, spleen and liver disorders. The medicinal properties of blood purifiers are attributed to its physico chemical properties (hot dry temperament, bitter taste) (Qureshi, 1998) and chemical constituents viz. alkaloids, flavonoids, saponins, tannins etc. present in the drugs, have found which been to have hepatoprotective, antioxidant, anti allergic, microbial, anti septic, anti anaphylactic activity, immunomodulatory, anti fungal, hypoglycemic and anti inflammatory activities (Chauhan et al., 2013).

4. Conclusion

On the basis of above discussion it is concluded that limited studies are carried out in most of the diseases with small sample size short duration and self report measures. Therefore, larger randomized controlled trials are needed equipped with more objective measures to extend these preliminary findings, so that firm conclusions can be made regarding the efficacy of Unani medicine for preventing and treating skin diseases.

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