Effect of a Polyherbal *Unani* formulation in acne vulgaris: A preliminary study

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ABSTRACT

Acne vulgaris is the most common disorder treated by dermatologists. Acne is a disease of pilosebaceous units characterized by the formation of the open and closed comedones, papules, pustules, nodules and cysts. A preliminary trial was conducted in the department of Medicine, National Institute of Unani Medicine, Bangalore, India, to assess the safety and efficacy of a Polyherbal *Unani* Formulation *(PHUF)* in the management of Acne Vulgaris on scientific parameters. Twenty five patients, diagnosed with acne, were included in the study after obtaining their informed consents. All the patients were clinically assessed and diagnosed on the basis of thorough history and dermatological examination. Then, *PHUF* was administered locally once at night for a period of 45 days. The severity of acne and efficacy of treatment was assessed by Cook's acne grading scale. The results showed significant reduction in the Cook's acne grading scores of post-treatment group ($P<0.01$) as compared to pre-treatment scores. Further, *PHUF* was found safe and fairly well accepted by the patients. It was therefore, concluded that *PHUF* can be used safely and effectively for the treatment of acne vulgaris.

Key Words: Acne vulgaris, *Basoore Labaniya*, Polyherbal *Unani* formulation, Cook's acne grading scale

INTRODUCTION

Acne vulgaris is a chronic inflammatory disease of the pilosebaceous units and is characterized by seborrhoea, the formation of comedones, erythematous papules and pustules, less frequently by nodules, deep pustules, or pseudocysts and, in some cases, is accompanied by scarring. [1, 2] It is believed to be the most common disease of the skin. The condition usually starts in adolescence, peaks at the ages of 14 to 19 years and frequently resolves by mid-twenties. Acne develops earlier in females than in males, which may reflect the earlier onset of puberty in females. The most severe forms of acne vulgaris occur more frequently in males, but the disease tends to be more persistent in females. [3]

Acne is a polymorphic disease, which occurs predominantly on the face (99%) and, to a lesser extent, occurs on the back (60%) and chest (15%). Although it is usually a condition of adolescent, acne affects 8% of 25-34 year olds and 3% of 30-44 year old age group. [4, 5]

In *Unani* system of medicine, acne vulgaris is termed as *Basoore Labniya, Mohasa or Keel*. The renowned *Unani* physician, *Ibn Sina* says in his treatise, *Canon of Medicine*, that *Mohasa* are small white eruptions on the nose and cheeks which resemble condensed drops of milk. [6] The etiology is considered to be *Madda Sadeediya* (suppurative material), which comes towards the skin surface due to *Bukharat* (vapours) of the body and is not resolved in the skin due to its viscosity. [6, 7]

The mainstay for the treatment of acne is use of topical and or systemic antibiotics and retinoids but the long term use of these drugs produce significant side effects like erythema, peeling, burning and drying of the skin. Moreover, the development of antibiotic resistance to *Propionibacterium acne* may limit the use of topical antibiotics. Therefore, there is a dire need to develop herbal therapeutic modalities for the treatment of acne. Fortunately physicians of Indian System of Medicine like *Unani* and *Ayurveda*

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have been practicing many herbo-mineral formulations for the treatment of acne since antiquity. Thus, the present study was conducted to validate the safety and efficacy of a *PHUF* (*Zimade Mohasa*) on modern scientific parameters. The formulation was selected for the study from the Hamdard Pharmacopoeia of Eastern Medicine and was procured from the department of Pharmacy NIUM. Its ingredients are *Irsa (Iris florentina), Barghe Neem (Azadirachta indica leaves), Poste Saras (Acacia speciosa bark), Ghungchi Safaid (Abrus precatorius)* and *Namake Sambhar (Lake salt)* 50 grams each. [8] *Zimade mohasa* acts topically as a detergent, astringent, anti-inflammatory and antibacterial agent. In an experimental study, *Azadirachta indica* exhibited antibacterial activity against a variety of micro-organisms such as *Staphylococcus, Enterococcus, Pseudomonas, Escherichia, Klebsiella, Salmonella* and *Mycobacterium.* [9]

MATERIALS AND METHODS

The present study was an open, pre and post evaluation, non-randomized trial conducted at the out-patient departments of National Institute of Unani Medicine (NIUM), Bangalore and Kashmir Tibbiya College, Hospital and Research Centre, Srinagar. A total of 40 patients of acne were registered, among which 15 patients did not fulfil inclusion criteria and were excluded from the study. The remaining 25 patients who were eligible based on the inclusion criteria, were enrolled after obtaining their informed consents. The patients were clinically assessed and diagnosed on the basis of history and dermatological examination. All the findings were recorded on the case record proforma, designed for the study. At the end of study, 5 patients were lost to follow-up and were excluded, leaving behind 20 patients who completed the trial.

Patients of either gender in the age group of 12-30 years were enrolled in the trial. Patients below 12 years and above 30 years, patients with any systemic illness such as diabetes mellitus, patients with other variants of acne like acne fulminans, acne rosacea, acne necrotica and patients suffering from other concomitant diseases like vitiligo, dermatophytosis, psoriasis and eczema were excluded from the study. Similarly, patients who had taken any local or systemic treatment for their disease in the past one month prior to the trial were also excluded.

Routine investigations like complete haemogram, urine and stool examination, Random blood sugar, Liver Function Test and Renal Function Test were done before treatment in order to exclude the other systemic ailments.

All the patients were advised to apply the 6-10 gram of *PHUF* on the affected area once at night and then wash the area with lukewarm water in the morning. The total duration of treatment was 45 days. The *PHUF* was supplied in an individual pack for each patient and their compliance was checked after completion of treatment. No additional medication was allowed.

The primary outcome of this study was pre- and post treatment comparison of efficacy and safety of *PHUF* on Acne Vulgaris. The severity of acne and evaluation of efficacy of *PHUF* was done weekly by employing Cook's System of Acne Grading. [10] The response of the treatment, at the end of study, was recorded on five point scale as follows:

Excellent response was considered as improvement of three basal grades of acne; Good response- improvement of two basal grades; Poor response - improvement of one basal grade only; No response - no change in basal grade at all and Worse response as increase in basal grade at the end of treatment.

The pre- and post-treatment scores were statistically analyzed by using Wilcoxon signed rank test and the level of significant difference was chosen as $P < 0.05$.

Table 1: Baseline demographic and clinical profile of patients

Parameter	No. of patients	Percentage
Age in years	Mean age	18.52 ± 9.12
12-16	5	25
17-21	8	40
22-26	4	20
27-31	3	15
Total	20	100
Gender		
Male	8	40
Female	12	60
Family history		
Present	12	60
Absent	8	40
Socioeconomic status		
Upper	4	20
Upper middle	5	25
Lower middle	8	40
Upper lower	2	10
Lower	1	5
Duration of disease		
1-5 months	2	10
6 months-1 year	4	20
2-3 years	8	40
4-5 years	6	30
Site of lesion		
Face	11	55
Face and chest	3	15
Face and back	4	20
Face and shoulder	2	10

Table 2: Cook's system of acne grading

Grade	Baseline	1st wk	2nd wk	3rd wk	4th wk	5th wk	6th wk
	No of Pts (%)	Pts.	Pts.	Pts.	Pts.	Pts.	No of Pts (%)
0	0	0	0	0	1	3	5 (25)*
2	3 (15)	3	5	8	9	11	12 (60)*
4	10 (50)	10	8	6	7	4	2 (10)*
6	6 (30)	6	6	5	2	2	1 (5)*
8	1 (5)	1	1	1	1	0	0

No = Number, Pts. = Patients, wk = week, Test used: Wilcoxon signed rank -test *$P < 0.001$ very significant with respect to baseline

RESULTS AND DISCUSSION

Demographic data of patients is shown in Table 1. The present study conducted on 25 patients of acne aged between 12-30 years showed the highest incidence (40%) of acne in the age group of 17-21 years, while the least (15%) was seen in the age group of 27-31 years. This finding corroborates with the findings of a pioneer epidemiological study on acne in which a peak was found in the incidence between 14-17 years in case of females and between 16- 19 years in case of males. [11]

Effect of *PHUF* on Cook's acne grading

Cook's acne grading scale is a commonly used grading scale for acne, and it involves the evaluation of the overall severity of acne on 0-8 scale anchored to photographic standards. All patients were clinically assessed weekly and total lesion counts were performed at baseline and at 1, 2, 3, 4, 5 and 6th weeks. At the end of treatment, there was a significant improvement ($P < 0.001$) in acne grading as depicted in Table 2. The overall assessment of efficacy of treatment is shown in Table 3.

This improvement may be attributed to various pharmacological activities of the ingredients of *PHUF*. These herbs possess *Muhalil* (anti-inflammatory), *Jali* (detergent), *Jazib* (absorbent), *Murakhe* (emollient), *Dafe Taufun* (antiseptic and anti- microbial) properties. [12-16] These herbs might have inhibited the proliferation and growth of follicular microflora and resolved the inflammatory process that led to the overall improvement in acne vulgaris at the end of treatment. This is in consonance with the pharmacological actions described in classical Unani literature and in various clinical studies.[14-16] Further, significant and fast improvement in acne flare was noticed implying greater compliance of the treatment. Cutaneous tolerance was evaluated by erythema, scaling, dryness, burning and pruritus. No obnoxious adverse effects were observed and the *PHUF* was found safe and fairly well accepted by the patients.

In the light of above discussion, it may be concluded that *PHUF* is safe and statistically effective in the treatment of acne vulgaris. Although the study showed remarkable

Table 3: Efficacy assessment of treatment

Response	No of patients (%)
Excellent	6 (30)
Good	11(55)
Poor	2 (10)
No Response	1 (5)
Worse	0

response, its limitations include lack of blinding, lack of randomization, small population and no control group studied. Therefore, studies with randomized standard controlled designs on large sample with long duration and long follow-up period need to be carried out for further exploration of efficacy and safety of *PHUF*.

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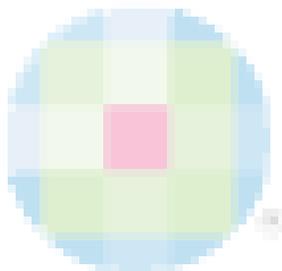
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