

A PRELIMINARY STUDY ON THE EFFICACY AND SAFETY OF TWO UNANI PHARMACOPOEIAL FORMULATIONS (*IṭṛīfalShāhtarah* AND *Sharbat-i-'Unnāb*) IN ADOLESCENT AND YOUNG ADULTS CASES OF ACNE VULGARIS (*BusūrLabaniyyah*): SINGLE ARMED OPEN LABELLED CLINICAL STUDY

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ABSTRACT

Acne vulgaris (*BusūrLabaniyyah*) is an easily recognizable and very common dermatological disease, most often in adolescents. A clinical trial was conducted to assess the safety and efficacy of two Unani Pharmacopoeial formulations *IṭṛīfalShāhtarah* and *Sharbat-i-'Unnāb* in the management of Acne vulgaris. Thirty-six diagnosed patients with acne, were included in the study, clinically assessed and diagnosed on the basis of history and dermatological examination, test drugs were administered orally for 21 days. The severity of acne and efficacy of treatment was assessed by Grading and Visual Analogue Scale (VAS). The results showed significant reduction in the grading and VAS scores of post-treatment group ($P < 0.01$) as compared to pre-treatment scores. The test drugs had not any adverse side-effects and compliance was also good. So we concluded that the test drugs are safe and very effective in the management of Acne vulgaris (*BusūrLabaniyyah*).

KEYWORD: Acne vulgaris, *BusūrLabaniyyah*, Unani, *Sharbat-i-'Unnāb*, *IṭṛīfalShāhtarah*, VAS.

1. INTRODUCTION

Acne vulgaris (AV) is a disease of pilosebaceous units characterized by the formation of the open and closed comedones, papules, pustules, nodules and cysts.^[1] If these become infected, they are associated with fever, swollen lymph nodes, and fatigue. It has a significant physical, emotional and social impact on an individual. It is seen in nearly 100% of individuals at some time during their lives, affecting more than 85 percent of teenagers as well as some adults.^[2] AV commonly known in Hindi *Muhāsah* and in Persian *RūKhārah* and other synonyms like *BusūrLabaniyyah*, *Habb al-Shabāb* *BusūrDuhniyyah*, *Al-Ghudd al-Shāi'* used in Unani System of Medicine (USM).^[3,7] *Ibn Sina* explains *Muhāsah* as small white eruptions on the nose and cheeks which resemble condensed drops of milk whenever squeeze out a yellowish cheesy material *MāddahSadīdiyyah* (*pus*) is not resolved in the skin due to its viscosity.^[8,14] While according to Arzani these are white eruptions which appear on nose and forehead.^[11,12] They are rather more common in adolescents and in early

adulthood, especially in boys. Most common sites for Acne vulgaris are face, neck and chest. Acne vulgaris has been classified according to the predominance of *Khilt* (Humour). These may develop due to the predominance of *Balgham* (phlegm), *Dam* (Blood) or *Safra* (Yellow Bile) and are clearly differentiated on the basis of their features.^[13]

Istifrāgh according to the type of predominant humour, *Tahlīl-o-Taskīn-i-Māddah*, *Mu'addilāt* and *Tasfiyah* through *Musaffiyāt* are the main *Uṣūl-i-'Ilāj* (Principles of treatment) mentioned in the classical literature.^[11,14] This *Uṣūl-i-'Ilāj* is being practiced since long by Unani scholars, however; there are limited scientific data on the efficacy and safety. Keeping this in view, two most common pharmacopoeial formulations viz. *IṭṛīfalShāhtarah* and *Sharbat-i-'Unnāb* are selected for this Single armed Open labelled Clinical Study.

2. MATERIALS AND METHODS

2.1. Study design

The study was an open labelled, pre and post evaluation, non-randomized trial conducted at the out-patient departments of Regional Research Institute of Unani Medicine (RRIUM), Patna. It is started after obtaining ethical clearance from RRIUM Institutional Ethical committee. Clinically diagnosed patients with AV (*BusūrLabaniyyah*) of either sex aged between 15-25 years having comedones, papulo-pustular eruptions over face were selected. A total of 49 patients of AV were registered, among which 13 patients did not fulfil inclusion criteria and 06 patient was dropped out during trial were excluded from the study. The remaining 30 patients completed the study. The duration of study was

1.5 years, (June 2016 to December 2017) with 21 days of test intervention. The subjective and objective parameters were assessed on 0, 7th, 14th and 21th day of follow-up, laboratory investigations were performed at baseline and 21th day of trial i.e. complete blood count (CBC), urine routine and microscopic, stool routine and microscopic, LFT and KFT.

2.2. Study intervention

The results obtained by the observation at base line and after treatment were compared statistically. All the patients were included in this study were given *Itrifal Shahatra* 5 gm and *Sharbat Unnab* 20 ml orally with water in the morning and at bed time.

Table 1: Composition of *Itrifal Shahtara*.^[15]

S. No.	Name of Ingredients	Quantity
1.	Shahtara (<i>Fumaria officinalis</i> L.)	50 gm
2.	Post-e Halela Zard (<i>Terminalia chebula</i>)	50 gm
3.	Post-e Halela Kabuli (<i>Terminalia chebula</i>)	50 gm
4.	Sana (<i>Cassia angustifolia</i>)	10 gm
5.	Gul-e Surkh (<i>Rosa damascene</i> Mill.)	05 gm
6.	Maweez Munaqqa (<i>Vitis vinifera</i>)	350 gm

Table 2: Composition of *Sharbat Unnab*.^[15]

S. No.	Name of Ingredients	Qnt.
1.	Unnab (<i>Ziziphus jujuba</i> Mill.)	500 g
2.	Aab (Water)	Q.S
3.	Qand Safaid	1.5kg

2.3. Assessment of Efficacy

The efficacy of the study drug was assessed on the basis of improvement in *Busoor* (Macules/Papules) on Visual Analogue Scale (VAS). The lesions were evaluated according to Numbers and associated symptoms. Grading was measured according number of lesions present; 0=absent, 1= <10 lesions, 2 =10-15 lesions, 3=>15 lesions. The associated symptoms like erythema, pain and itching were measured on a 10 points Visual Analog Scale (VAS). Total VAS score recorded at baseline and subsequent visits; and pre-treatment and post-treatment score of patients were compared statistically.

2.4. Assessment of Safety

Safety was assessed by the monitoring adverse events and deviation from standard laboratory values done at weeks 0 and 21th day of study, physical examination and vitals checked at every follow up.

3. OBSERVATIONS & RESULTS

During the course of study subjects were divided into four age groups 15-25 years, 26-35 years, and 36-45 years. It was observed that 24(84%) patients belong to 15-25 age group, 5 (16.67%) was from the 26-35 age group and 1(3.33%) was from 36-45 age group were found, among 30 patents 14 (46.67%) were male and 16

(53.33%) female. According to chronicity of disease distributed five groups of months 0-6months 11(36.67%), 7-12months 11(36.67%) patients, 13-18 months chronic 1(3.33%) patient, 19-24 months chronicity 5(16.66) patients and 2(6.67%) patients were found who have *BusūrLabaniyyah* since 2 years or more. The patients were divided into three groups according to their socio-economic status, among this category. The numbers of cases belonging to high income group, middle income group and low income groups were 0 (0%), 17 (56.67%) and 13(43.33%) respectively. According to their occupation, patients were divided into three groups' students, house wife and others. Students are found more vulnerable group 24 (80.00%), house wife and others are 3 (10.00%) and 3(10.00%) cases respectively and all the patients have non vegetarian diets habits 30 (100%).

The patients were distributed according to *Mizāj-i-Damwi* (sanguine) found 7(23.33%), Balghami (Phlegmatic) 6 (20.00%), Safravi (Bilious) 13(43.34%) and Sudavi (Melancholic) found 4(13.33%) respectively. Incidence of AV in adolescent age group shows the disease is most prevailing among the young adults of either sex as on world statistics. Globally around 85% of young adults aged 12-25 years old, approximately 8% of

adults aged 25-35years old and 3%adults aged 35-44 years old experience certain degree of Acne.^[9]

Table 3: Distribution of patients according to demographically characteristics.

Total No. of Patients- 30; Means±SEM of Age : 21 ± 1.19 years		
Characteristics	Treatment Groups	No. of patients (%)
Age (in years)	15-25	24 (80.00)
	26-35	5 (16.67)
	36-45	1 (3.33)
	46-60	-
Gender-wise	Male	14 (46.67)
	Female	16 (53.33)
Duration of Disease (in months)	0-6	11 (36.67)
	7-12	11 (36.67)
	13-18	1 (3.33)
	19-24	5 (16.66)
	>24	2 (6.67)
Socio-economic Status	Higher	-
	Middle	17 (56.67)
	Lower	13 (43.33)
Occupation	Student	24 (80.00)
	House Wife	3 (10.00)
	Others	3 (10.00)
Dietary Habits	Vegetarian	-
	Non-vegetarian	30 (100)
Mizaj (Temperament)	Damvi (Sanguine)	7 (23.33)
	Balghami (Phlegmatic)	6 (20.00)
	Safravi (Bilious)	13 (43.34)
	Saudavi (Melancholic)	4 (13.33)

Table 4: Effect of therapy on clinical parameters.

S. No.	Clinical Parameters	Symptoms	Mean ± SEM		Efficacy (%)	p-value	Significant
			Before Treatment	After Treatment			
1	Macules	Erythema	1.13 ± 0.31	0.53 ± 0.16	52.94	<0.05	S
		Itching	1.03 ± 0.29	0.3 ± 0.11	70.97	<0.01	H.S.
		Pain	0.27 ± 0.13	0.07 ± 0.07	75.00	<0.05	N.S.
2	Papules	Erythema	1.77 ± 0.36	0.83 ± 0.19	52.83	<0.001	H.S.
		Itching	1.37 ± 0.34	0.47 ± 0.13	65.85	<0.01	H.S.
		Pain	0.7 ± 0.2	0.23 ± 0.08	66.67	<0.05	S
3	Pustules	Erythema	2.93 ± 0.38	1.6 ± 0.25	45.45	<0.001	H.S.
		Itching	2.2 ± 0.33	0.93 ± 0.19	57.58	<0.001	H.S.
		Pain	1.67 ± 0.28	0.47 ± 0.14	72	<0.001	H.S.
4	Vesicles	Erythema	0.07 ± 0.07	0.03 ± 0.03	50	<0.05	N.S.
		Itching	0.07 ± 0.07	0.03 ± 0.03	50	<0.05	N.S.
		Pain	0.07 ± 0.07	0.03 ± 0.03	50	<0.05	N.S.
5	Pruritus	Erythema	2.9 ± 0.37	1.37 ± 0.25	52.87	<0.001	H.S.
		Itching	2.57 ± 0.31	1.13 ± 0.18	55.84	<0.001	H.S.
		Pain	1.53 ± 0.29	0.5 ± 0.14	67.39	<0.001	H.S.

H.S.= Highly significant, S=Significant, N.S.=Non-significant.

Table 5: General Therapeutic Response.

	Total	Complete Relieved (90-100 %)	Relieved (60-89 %)	Partially Relieved (30-59 %)	Not Relieved (< 30 %)
No. of Patients	30	1	17	9	3
Percentage (%)	100	3.33	56.67	30	10

4. DISCUSSION

Acne is a chronic inflammatory disease of the pilosebaceous unit resulting from androgen-induced increased sebum production, altered keratinisation, inflammation, and bacterial colonisation of hair follicles on the face, neck, chest, and back by *Propionibacterium acnes*.^[16]

AV is an extremely common condition with a lifetime prevalence of approximately 85% and occurs mostly during adolescence.^[17] There are four factors in acne pathogenesis: Increase of the sebum excretion, Keratinization of infra-infundibulum, Bacterial colonization of the follicle and Inflammation.^[18] Acne has various psychosocial effects that impact patients' quality of life. Treatment of acne in adult women specifically has its challenges due to the considerations of patient preferences, pregnancy, and lactation.^[16] In *Unani* system of medicine, acne vulgaris (AV) is termed as *BusūrLabaniyyah*, *Muhāsah* or *Kīl*.^[19] According to Ibn Sina, *BusūrLabaniyyah* are small white eruptions on the nose and cheeks, which resemble condensed drop of milk.^[20] While according to Arzani these are white eruptions which appear on nose and forehead.^[11] Cause of these eruptions is a *MāddahSadīdiyyah (Pus)* which comes towards skin surface due to *Bukhārāt-i-Badan* (body vapours).^[4] Unani System of Medicine contains treatise of crude and compound formulations that can be administered orally and locally in the treatment of Acne vulgaris. These preparations are useful, effective and well tolerated.^[19]

It is merely observed from results, that *ItrīfalShāhtarah* and *Sharbat-i-'Unnāb* is safe and effective in treating for Acne vulgaris. The results are highly significant for Pustules, Pruritus, Macules, Papules ($P < 0.01$) whereas for vesicle moderately significant ($P < 0.05$). This study is in coincides with the finding of Lone et al (2012), they used a Polyherbal Unani formulation and reported improvement at $P < 0.001$.^[19] Safety parameters assessment showed that they remained in the normal range throughout the treatment. However, a long-term study with a bigger sample size, standard comparator group and multicentre study is needed to further validate pharmacological actions.

5. CONCLUSION

In conclusion above findings, support not only the efficacy of pharmacopoeial formulation *ItrīfalShāhtarah* and *Sharbat-i-'Unnāb* but also the safety of test drug in the management of Acne vulgaris (*BusūrLabaniyyah*), only limitation of these drugs was not suitable for diabetic patients. However further studies especially clinical control trials on the large population needed to rule out the exact efficacy and safety of test drugs.

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