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Research Article

Efficacy of Unani Combination Therapy in the Management of Acne Vulgaris: A Randomised Standard Controlled Study

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A B S T R A C T

Acne vulgaris is one of the common chronic inflammatory diseases of the pilosebaceous unit with multiple pathophysiologies affecting adolescents mainly.

Aims: To evaluate the efficacy of Shahtra (Fumaria indica) orally along with the topical use of Zimad Muhasain and the management of moderate to severe category of acne vulgaris on the Global Acne Grading System (GAGS) scale.

Material & Methods: This was a randomized standard control clinical study. The test group patients were given Shahtra (500 mg), 2 capsules twice daily with a local application of Zimad Muhasa paste once daily; the control group patients were given tablet Azithromycin 500 mg thrice weekly with a local application of Benzoyl peroxide 5% gel once daily for 8 weeks.

Result: In the test group, there was a 77.3% reduction in the GAGS score at the final follow-up with $p<0.0001$; in the control group, there was a 69.8% reduction in GAGS score with $p<0.0001$, showing extremely significant improvement in both groups. The results indicate the superiority of the test group regimen over the control group by at least 7%. Furthermore, adverse effects like burning sensation, dryness, and itching due to Benzoyl peroxide and diarrhoea due to Azithromycin were only reported in the control group whereas the Unani formulations were found to be free of such adverse effects.

Conclusion: The test formulations comprising a dried aqueous extract of Shahtra and Zimad Muhasa were found to be more effective and safe in the management of acne vulgaris in moderate to severe acne, compared to the control combination of Azithromycin and Benzoyl peroxide gel.

Keywords: Acne Vulgaris, Busoor Labaniya, Zimad Muhasa, Shahtra, Fumaria Indica

Introduction

Acne vulgaris is termed as Busoor Labaniya (milky eruptions) in Unani terminology. In the classical Unani text, busoor labaniya is described as a whitish eruption resembling a condensed drop of milk over the face and is more common in the adolescent period.[1] Most of the Unani scholars have recommended the use of topical drugs having Jali (detergent), Mujaffif (desiccant), and Muhallil (anti-inflammatory) effects as the first line of treatment. Some Unani scholars have also encouraged the systemic use of Musaffiyat-e-Dam Adviya (Blood purifier drugs) along with topical drugs.

Busoor labaniya (Acne vulgaris) is the most common as well as universal disease of the skin.[2] It is one of the common chronic inflammatory diseases of the pilosebaceous unit with multiple pathophysiology viz. excessive sebum production, hyper-keratinization, Propionibacterium acnes colonization and inflammation.[2,3] The initial lesions are the microscopic micro-comedones that usually manifest as visible open comedones or closed comedones (blackheads and whiteheads respectively). These comedones subsequently convert into inflammatory papules, pustules, and nodules. Acne most commonly develop on the face/ cheek, lateral aspect of upper arms, back, neck and chest.[4] The prevalence and severity of scarring due to acne have not been well studied, although the current literature mainly acknowledges the severity of acne lesions.[5] The advent of the disease in a psychologically labile and sensitive age, when adolescent people usually want to look their best brings more psychological and social implications.[6,7]

Conventional regimens that are used for the treatment of acne include topical, systemic, hormonal, photodynamic, and combination therapies. Therapeutic agents that are used topically are benzoyl peroxide, antibiotics, and retinoids. Systemic agents in use are antibiotics and isotretinoin. More recently, other oral formulations, including minocycline, doxycycline, azithromycin and trimethoprim, have been frequently used.[4,8] The antimicrobial and antibiotic therapy usually continues for several months and may need to continue even for years. Moreover, these antibiotics are associated with several adverse effects and develop resistance over a time.[9] Regarding the treatment of acne, Oral isotretinoin is supposed to be the best option available currently. Treatment with isotretinoin may induce long-term remission in some individuals, but it is highly teratogenic. Other adverse effects include mucocutaneous symptoms, and in few cases some systemic symptoms like depression, headaches, and myalgia.[10]

Zimad Muhasa is a herbo-mineral topical Unani formulation comprising five ingredients mentioned in Qarabadeen-e-Azam and Qarabadeen Majeedi which is specially formulated for busoor labaniya (acne vulgaris). Shahtra (Fumaria indica) is one of the drugs frequently used orally for many skin diseases including busoor labaniya (acne vulgaris).[11,12,13]

Background

Two published studies on local application of Zimad Muhasa, used alone have demonstrated promising results.[14,15] In another published study, oral administration of aqueous extract of Shahtra (Fumaria indica) alone has shown significant improvement in acne.[16] However, all these studies have not been conducted specifically on moderate to severe acne vulgaris.

Based on the observations of the above published studies on Zimad Muhasa and Shahtra it is hypothesized that combining both of these topical and oral therapies can be an effective and safe treatment regimen in managing the moderate to severe forms of acne vulgaris.

Hence, an open-label, randomized, standard-controlled clinical study was conducted to evaluate the efficacy and safety of Unani formulation Zimad Muhasa (topical use) in combination with aqueous extract of Shahtra (oral administration) on busoor labaniya (Acne vulgaris).

Materials and Methods

This was an open-label, randomized, standard controlled study conducted in the out-patients department of Moalajat (Medicine) in Majeedia Unani Hospital and Skin OPD at HAHC Hospital, Jamia Hamdard, New Delhi. Before enrolment of subjects, Ethical approval was obtained from IEC, Jamia Hamdard, New Delhi, and the trial was registered in CTRI with registration number CTRI/2017/07/009004.

Inclusion and Exclusion Criteria

Subjects of both genders, belonging to the 13 to 35 years age group and willing to sign the informed consent form with moderate to severe acne (GAGS score 19-38) were included. Pregnant and lactating women, patients suffering from PCOD or using hormonal contraceptives were excluded. Subjects suffering from other concomitant skin diseases or using anti-androgenic drugs or have used topical anti-acne medications within the past two weeks or used systemic antibiotics within the past one month or have used isotretinoin within the last six months were also excluded.

Study Medications

Test group subjects were provided Zimad Muhasa in a 50 gm pack and were advised to prepare the paste with sufficient quantity of plain water for local application once daily, and Capsule Shahtra in a pack of 56 capsules to consume 2 capsules twice daily.

Zimad Muhasa consists of fine powder of Barg-e-Neem (Azadirachta indica A. Juss.), Post-e-Siris (Albizia lebbeck (L.)

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Benth.), Bekh-e-Sosan (Iris ensata Thunb), Ghungchi safaid (Abrus precatorius Linn.), and Namak-e-sambhar (Lake Salt) in equal proportion.

Capsule Shahtra was prepared by obtaining a dried aqueous extract of Shahtra (Fumaria indica). 1.5 gm of dried aqueous extract equivalent to 5 gm of Shahtra (Fumaria indica) was filled in 2 capsules.

The control group subjects were provided with 2 Persol AC (Benzoyl peroxide) 5% gel 20 g packs for local application once daily, and 6 tablets Aziwok (Azithromycin 500 mg) per visit to consume 1 tablet thrice weekly. The empty containers/ packets were collected from the subjects at the subsequent visit to determine the compliance to the therapy.

Procurement of Drugs

The ingredients of Zimad Muhasa were procured from M/S. Ahmad Hussain-Ajmal Hussain, Khari Bawli, Delhi. The oral drug Shahtra was procured from Shubham Herbal Trading Company, Sheopur, Madhya Pradesh. After identification from the Department of Botany, School of Chemical & Life Sciences, Jamia Hamdard the drugs were sent to Hamdard Laboratories, Ghaziabad for preparing the finished products Zimad Muhasa (Batch No. SAK/19/11, the manufacturing date 24/6/2017 and Capsule Shahtra (Batch No. SAK/ R&D/ 19/14, manufacturing date 10/7/2017.

Benzoyl peroxide 5% gel was bought from Wallace Pharmaceuticals Pvt. Ltd. with brand name Persol AC 5 gel of the same batch (1302) with printed manufacturing date March 2017 and expiry date February 2019 while Azithromycin 500mg tablets were bought from Wockhardt Limited with brand name Aziwok of the same batch (JS10324) with printed manufacturing date April 2017 and expiry date March 2019.

Duration of Protocol therapy and Follow-up

The duration of the study was 2 years and the duration of Protocol therapy was 8 weeks. The follow-up of the patients was done at 2 weeks interval for GAGS score assessment and dispensing the drugs.

Assessment Parameters

Safety Parameters

CBC with ESR, LFT, KFT, and Urine R/M were done in all patients before and after completion of protocol therapy.

Efficacy Parameters/ Outcome Measures

- GAGS Scale (Global Acne Grading System), scoring was done at each follow-up as shown in Table 1
- Coloured photographs of the lesion with the same magnification, before and after completion of the treatment

No lesion=0, comedones=1, papules=2, pustules=3 and nodules=4.

Table 1.Global Acne Grading System (GAGS) Scale[17]

Location	Factor
Forehead	2
Right cheek	2
Left cheek	2
Nose	1
Chin	1
Chest and upper back	3

Note: Each type of lesion is given a Value depending on Severity

The score for each area (local score) is calculated using the formula: Local score=Factor x Grade (0-4).

The global score is the sum of all local scores, and acne severity was graded using the global score. A score of 1-18 is considered mild; 19-30, moderate; 31-38, severe and

>38, very severe.

Global Acne Grading System (GAGS) Scale is novel system developed by Doshi, A., Zaheer, A., & Stiller, M. in 1997. [17]

Sample Size and Randomization

A total of 107 patients were screened, 80 patients fulfilling inclusion-exclusion criteria were allocated into test and control groups. Finally, 64 subjects completed the protocol therapy (31 in the test group and 33 in the control group) as summarized in Figure 1 (CONSORT).

A computer-generated randomization chart was used for allocating the patients into the test group and control group.

Results & Discussion

Baseline Demographic Findings

The mean age of subjects was 20.7± 0.8 in the test group and 20.8 ± 0.6 in the control group. Maximum 47% patients belong to the 16-20years age group among all 64 patients.

The number of males (40, 62.5%) was higher in our study compared to females (24, 37.5%). This may be due to exclusion of female subjects from the study due to PCOS (17 subjects on USG & 1 subject on raised LH & FSH ratio). The majority of subjects (54, 84.3%) were students and positive family history was present in 42(65.6%) subjects.

Results

The mean GAGS score was calculated for each visit with SEM (Standard Error of Mean). There was a significant change in scale before and after the treatment in both groups. Percentage change and p-value from baseline were calculated at each follow-up which is shown in Table 2 and Figure 2.

Between group analysis Student t test (Unpaired); Within

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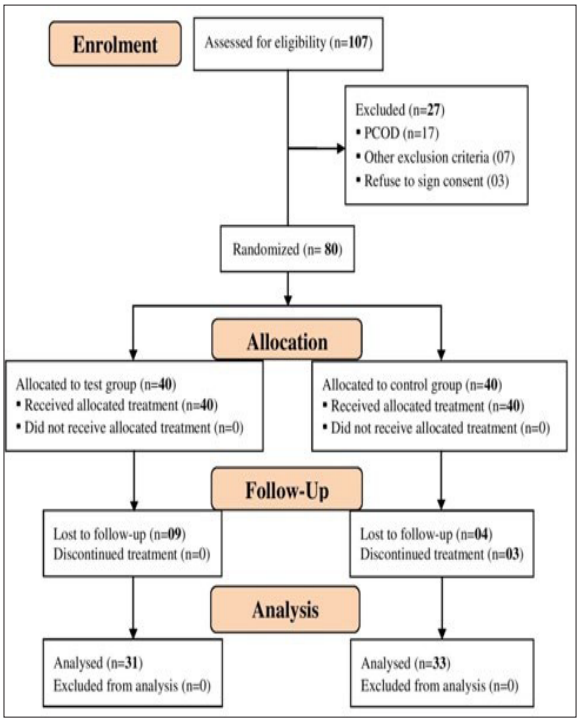

Figure 1.CONSORT Flow Diagram ofStudy Participants

Group- Friedman Test (Non-parametric Repeated Measures ANOVA)[p>0.05,^{NS} p<0.05,^{S} p<0.01,$^{VS.}$ p<0.001.^{ES}

In the test group, GAGS score was reduced by 77.25 % on the 56th day as compared to that of baseline, whereas it was reduced by 69.80 % in the control group.

It is also evident by photographs of the lesions (a few photographs below) that the test formulations comprising of Zimad Muhasa and dried aqueous extract of Shahtra were found more effective to some degree in the management of Acne vulgaris in moderate to severe category compared to control combination drugs.

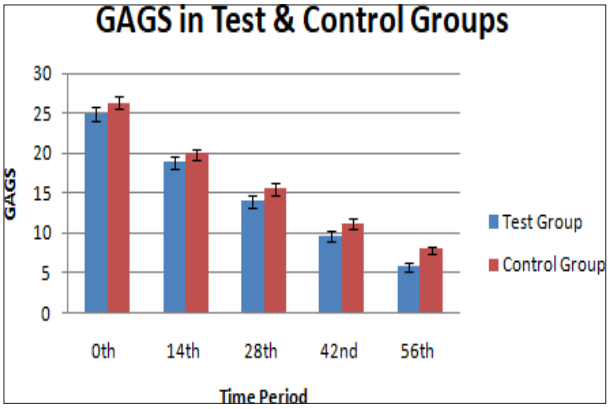

Figure 2.GAGS score in Test & Control Groups

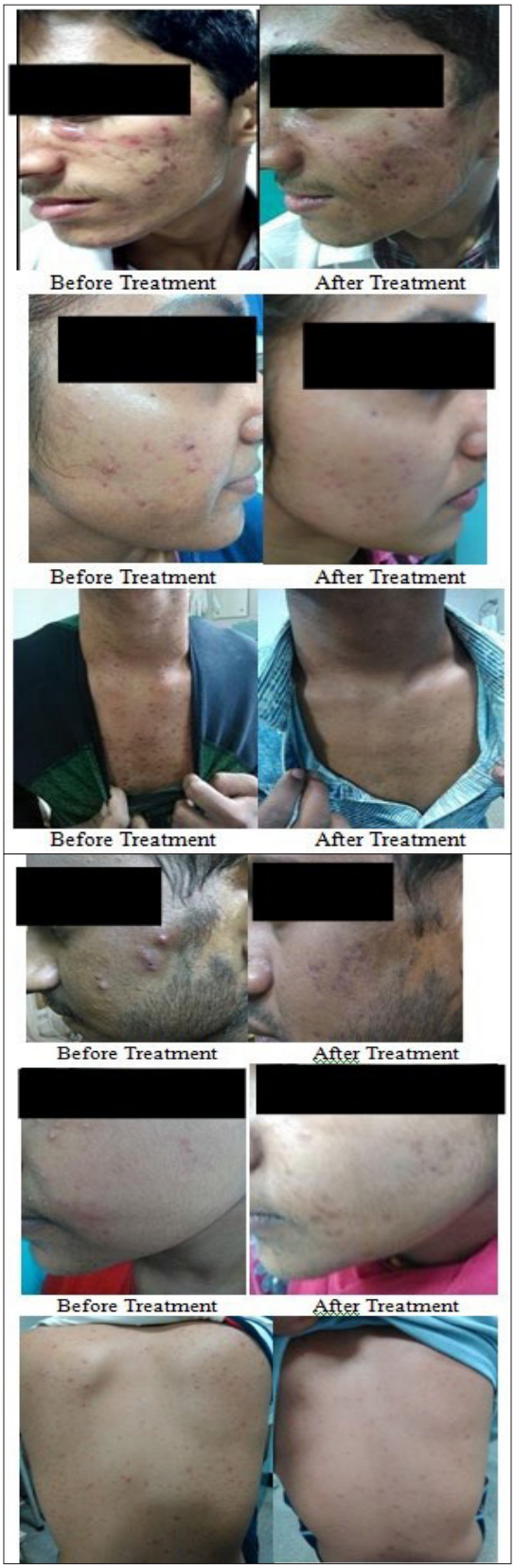

Figure 3.Photograph of lesions of Test GroupBefore and After Treatment

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Discussion

The above mentioned results indicate the superiority of the test group regimen over the control group by at least 7% after completion of protocol therapy (56 days), it was also supported by photographs and unpaired t-test between the groups showing p value=0.0063 (<0.01), which is statistically very significant. Thus, the current study elucidated that the traditional treatment was comparatively more potent than the conventional regimen in alleviating lesions of acne vulgaris.

Table 2.GAGS Score in Test & Control Groups

Follow up	GAGS score (Mean ± SEM)		p-value
	Test Group	Control Group	
Day 0	24.9 ± 0.8	26.3 ± 0.8	0.2117
Day 14	18.9 ± 0.8	19.9 ± 0.7	0.3603
Day 28	13.9 ± 0.8	15.5 ± 0.8	0.1389
Day 42	9.6 ± 0.7	11.2 ± 0.6	0.0702
Day 56	5.7 ± 0.6	7.9 ± 0.5	0.0063
p-value (Day 0 vs Day 56)	<0.001	<0.001	

On looking further into the ingredients of Zimad Muhasa we find that they possess antimicrobial activities particularly Azadirachta indica leaves and Abrus precatorius seeds against Propionibacterium acnes.[18,19] Antibacterial activity against both Staphylococcus epidermidis and Staphylococcus aureus was found in Azadirachtaindica.[20]Antibacterial activity against Staphylococcus aureus was found in Abrus precatorius, Albizzia lebbeck, Iris ensata.[21,22,23] The seeds of Abrus precatorius also possess lipase inhibitory activity which further added to its efficacy in managing acne vulgaris as lipase hydrolyses triglycerides and liberates irritating free fatty acids.[24] Three ingredients possess anti-inflammatory properties namely Azadirachta indica, Abrus precatorius, and Albizzia lebbeck.[25-29] In addition to antimicrobial and anti-inflammatory properties Albizzia lebbeck also has anti-allergic and mast-cell stabilizing properties which may describe its soothing and healing effect and alleviation of itching in acne lesions.[30,31] Recent studies have established the fact that oxidative stress also contributes to the etiology of acne, the squalene in sebum upon oxidation releases irritating peroxides which initiate and maintain inflammation. The seeds of Abrus precatorius, leaves of Azadirachta indica, and bark of Albizzia lebbeck impart antioxidant effect to the formulation.[24,32,33,34] Thus, Zimad Muhasa targets most of the pathogenic factors of acne vulgaris.[35] Likewise, Shahtra is also antibacterial against Staphylococcus epidermidis and Staphylococcus aureus, and possesses anti-inflammatory and anti-oxidant properties as well.

The result of test formulations is supported by the results of previous studies conducted on Zimad Muhasaand Shahtra individually. A comparative study conducted by Tabasum et al. has shown better efficacy of Zimad Muhasa than Benzoyl Peroxide 5% gel using Global Acne Severity Scale (GEA).[15] Similarly, Lone et al. had given Zimad Muhasa in test group (N=20) and benzoyl peroxide group in the control group (N=20) and used Cook's grading scale for grading of lesion and improvement in acne grading was noted on 5 point scale (excellent, good, poor, no response and worse response). The result showed better efficacy of Zimad Muhasa compared to benzoyl peroxide.[36] On the other hand, Fatima et al., have shown the efficacy of dried aqueous extract of Shahtra (Fumaria indica) on 15 subjects. The mean GAGS at baseline was 22.8 and at 6 weeks mean GAGS reduced to 7.8. Hence, there was a 65.5 % reduction in lesions of acne vulgaris on GAGS scale.[16]Thus, the results of combination therapy of Zimad Muhasa for local application along with dried aqueous extract of Shahtra (Fumaria indica) orally as a treatment regimen in acne vulgaris are superior to the results of the same drugs when used individually, and we have also established its specific role in the management of "moderate to severe form of acne" in relatively larger sample size.

The results of the control group are also in consonance with the results of Akter et al., who had also used a combination of oral Azithromycin 500 mg pulse therapy (first 3 days of the week) and daily topical benzoyl peroxide 4% for 12 weeks in 37 subjects. They have shown a 70.7% reduction in Michaelsson Acne Severity Index after 8 weeks (which is almost similar to our results) and an 87% reduction in lesions after 12 weeks.[37] The efficacy of Azithromycin pulse therapy (Azithromycin 500mg thrice weekly) was also established by Sharma et al., in 8 weeks study on 200 subjects having moderate to severe acne (19-38 GAGS score) with total efficacy of 75%, which could be attributed to bigger sample size.[38]

On analysis of pre-treatment and post-treatment safety parameters, it was observed that there was no significant change in any of the parameters in both the groups as summarized in table 3.

Conclusion

It is evident by the GAGS score results and photographs of the lesions that the test formulations comprising of Zimad Muhasa and dried aqueous extract of Shahtra are more effective in the management of moderate to severe acne vulgaris compared to control drugs comprising Azithromycin and Benzoyl peroxide 5% gel. Although subjects found the application of topical formulation cumbersome in the test group, adverse effects like burning sensation dryness and itching due to Benzoyl peroxide, and diarrhea because of the oral drug was only reported in the control group, whereas the Unani formulations were found to be free of such adverse effects.

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Table 3.Results of Safety Parameters

S. No.	Investigations	Test Group			Control Group		
		BT (Mean±SD)	AT (Mean±SD)	p value (paired t test)	BT (Mean±SD)	AT (Mean±SD)	p value (paired t test)
1.	Hb (gm/dl)	13.3± 0.3	13.5± 0.3	0.282	13.9± 0.3	13.6± 0.2	0.069
2.	ESR (mm/hr)	15.5± 1.2	14.1 ± 0.9	0.119	15.2 ± 1.1	15.2 ± 1.1	0.999
3.	TLC (cumm)	7293.6± 263.1	7458.1± 377.3	0.679	7484.7± 369.9	6797± 304.7	0.112
4.	N (cumm)	61.6 ± 1.1	60.8 ± 1.3	0.634	62.9 ±1.3	59.0 ± 1.5	0.385
5.	L (cumm)	32.9 ± 0.9	32.3 ± 1.1	0.640	30.8 ± 1.1	35.2 ± 1.6	0.018
6.	E (cumm)	3.8 ± 0.3	4.2 ± 0.4	0.307	3.7± 1.6	3.4± 1.6	0.4985
7.	S. Bililrubin(mg/ dl)	0.7 ± 0.02	0.6 ± 0.02	0.0415	0.7 ± 0.1	0.7 ± 0.1	0.9999
8.	SGOT (IU/ L)	28.3±1.5	28.5±1.3	0.936	32.2±1.1	35.5±6.0	0.575
9.	SGPT (IU/ L)	28.7 ± 1.4	30.3 ± 1.2	0.338	31.1 ± 1.4	37.7 ± 5.4	0.241
10.	Alk. Phosphatase (IU/ L)	178.5 ± 5.4	176.4 ± 6.2	0.797	177.1 ±6.4	171.3 ± 5.3	0.53
11.	Blood Urea(mg/ dl)	21.7 ± 1.2	21.5 ± 1 .0	0.907	21.9 ± 0.9	24.6 ± 2.3	0.211
12.	S. Creatinine (mg/dl)	0.8 ± 0.03	0.8 ±0.02	0.802	0.8 ± 0.02	0.8 ± 0.02	0.825
13.	S. Uric Acid(mg/ dl)	4.1 ± 0.2	4 ± 0.2	0.646	4.2 ± 0.1	4.4 ± 0.1	0.269

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Conflict of Interest: None

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