

Effectiveness of Unani Drugs, Namely, Oral Tab. *Musaffi* (Kit Medicine) and Local Application of *Kaf-e-darya* (cattle fish bone) + *Badam-e-Talkh* (Bitter Almond) + *Arq Gulab* (Rose Water) in Acne Vulgaris

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Abstract

A clinical trial was conducted on 50 patients of Grade I, II and III Acne Vulgaris with their age range from 10-40 years. The grade IV of the disease was excluded from the study. The already diagnosed patients were given Tab *Musaffi* in the dose of 2 tablets after meals along with local application of a paste of Unani made drugs, namely *kaf-e-darya* (cattle fish bone)+*badam-e-talkh*(bitter almond)+*arq gulab* (rose water) twice daily for 28 days. After completion of therapy, there was a significant recovery in the symptoms of acne vulgaris in grade I and II and little in grade III. The results show that this formulation can be tried in such patients as an alternate. The details have been discussed in the paper.

Key Words: Acne Vulgaris, *Berberis aristata*, *Zinjiber zerumet*, *Cassia absCUS*, *Acacia*, *catechu*, Cattle fish, *Prunus amygdalus*

Introduction

Acne vulgaris is commonly called acne. It is a common skin disorder that affects all persons at least once during life time. It usually affects teenagers but substantial numbers of men and woman between the ages of 20-40 are also affected by this disorder (Cunliffe, 1979). Acne is caused by changes in the pilosebaceous units (skin structures consisting of hair follicles and its associated sebaceous gland). Many factors are rather than a single one combine to cause chronic inflammation of blocked pilosebaceous follicle. In this sebum secretion is increased androgens from the testes, Ovaries and adrenals are the main hormones which stimulate the sebum secretions, increased and abnormal keratinisation at the exit of the pilosebaceous follicle which obstructs the flow of sebum bacteria plays a pathogenic role (Davidson, 1995). The severity of Acne is mainly proportional to the amount of sebum production. The first sign of acne Vulgaris commonly occurs at the time of puberty (Rothman, 1993).

Acne lesions are commonly referred to as Pimples, Spots or it is affecting more than 85% of teenagers and adulthood. Acne vulgaris is polymorphic open and closed comedoes, papules, pustules and cysts are found. Its prevalence is similar in both sexes but the peak age of severity in females is 16-17 years and in male 17-19 years (Lawrence, 2001). Acne may be caused by irritating creams and oils. Pustules on the face can also be caused by tinea infection.

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The lesions occur mainly over the face, neck, upper chest, back, shoulders etc. Comedones are the hall mark of acne vulgaris. Comedones typically are a bit larger and have black material in them. Closed comedones are tiny, fleshy colored non inflamed bumps that give the skin a rough appearance (Lawrence, 2001).

The treatment of acne vulgaris is based on the type and severity of the lesions. Comedones require treatment different from that of pustules and cystic lesions. Comedoes papular acne is managed by local treatment alone, pustular cystic and scaring acne requires local and systemic treatment (Lawrence, 2001). Many topical antibiotics useful in the treatment of acne have been associated with serious short and long term adverse effects (Reisner,1983).

According to Unani System of Medicine, in acne vulgaris disease, the oily glands over work and there secretion increase in quantity. These secretions remain with the cells and do not come out thus results in inflammation and small white or yellowish pustules develop in the skin. These pustules are pointed at the top and there bases are hard. When these pustules mature and when pressed, it releases some pus (Kabiruddin, 2007). The main cause of acne vulgaris are *ghalba-e-khoon*(excess of blood), *fasad-e-khoon*(impurity of blood), *qilatt-e-khoon* (deficiency of blood), *shiddat-e-hararat* and *shiddat-e-baroodat*(excess of heat and cold), *suay-e-hazm*(indigestion),*kasafat-e-jild*(impurity of skin), *kasrat-e-afkar*(excess of mental work), excessive use of *gharam-gezao-wa--masroob* (excess use of hot and spicy foods & drinks), *hamal*(pregnancy), *aam-sehat-ki-kharabi*(general weakness), lack of fresh air, hereditary oily skin, deficiency of Vit C, excess use of oily soaps ,creams, *mardana johar*(male hormone), *shamee ghadood* (oily glands) etc (Azmi,Ynm).

Since there is no specific treatment available in Allopathic System and many patients report at this Institute for alternate treatment, so, this study was undertaken to evaluate the efficacy of this formulation in the patient of acne vulgaris of grades I, II and III in the year 2011. The duration of the therapy was 28 days and duration of the study was 180 days.

Aim of the Study

To provide safe and effective alternate therapy to patients of acne vulgaris.

Inclusion Criteria

1. Age 10-40 years.
2. Both sexes.

3. Acne Vulgaris
4. Sign & Symptoms
 - Burning and itching sensate
 - Local inflammation
 - Comedones, Papules & Pustules
5. Grading
 - Grade I - Mild Acne (non-inflammatory comedones)
 - Grade II - Moderate Acne (comedones and papules)
 - Grade III - Severe Acne (comedones, papules and pustules)

Exclusion Criteria

1. Age below 10 years and above 40 years.
2. Patients having psoriasis, vitiligo and other types of dermatitis.
3. Abnormal thyroid function.
4. Very severe Acne Grade-IV (nodules and cystic acne)

Withdrawal Criteria

1. Failure to follow the protocol.
2. Dropout due to any reason.
3. Any adverse reaction or untoward event.

Materials and Method

A clinical trial was conducted to evaluate the efficacy of the formulation in the patient of acne vulgaris with Grade I, II and III in Out Patients Department of this Institute during the period from April-June, 2011. The duration of the therapy was 28 days. Since the patients were already diagnosed so, no any investigation was conducted on these patients. The treatment was directly started with the formulation. The assessment of the efficacy of the formulation was as per the relief in the signs and symptoms, reduction in local inflammation and in number of comedones and papules, reduction in burning and itching sensation.

50 patients between 10-40 years of age with Grade I, II and III acne vulgaris were selected for the study from the OPD. Out of 50 patients, 20 males and 30 females with female to male ratio of 1.5:1. Among them, 20 patients had grade-I, 24 had grade-II and 6 patients had grade-III acne. The already diagnosed patients were given Tab *Musaffi* in the dose of 2 tablets after meals along with local application of a paste made of Unani drugs, namely *kaf-e-darya* (cattle fish bone) + *badam-e-talkh* (bitter almond) + *arq gulab* (rose water) twice daily for 28 days. Tablet *Musaffi* was given in the dose of 2 Tablets twice a day along with local application of paste on affected area in morning and evening after meals. Weekly follow-ups were made for four weeks and duration of the therapy was 28 days. The patients were asked to avoid spicy, oily food and were asked to take citrus and vitamin-c rich diet and avoid stress.

1. The Composition of Tab *Musaffi*

The composition of Tab. *Musaffi* (kit medicine) prepared and supplied by the CCRUM, New Delhi for such patients and was made available here, has been shown in the Table 1.

2. The Composition of Paste for Local Application

The composition of the paste for local application has been mentioned in Table 2.

Method of Preparation of Paste

Kaf-e-darya and *maghaz-e-badam* (kernel of almond) were powdered or mixed and then *arq-e-gulab* were added as required to make the paste. The paste so prepared was applied over the face two times daily after cleaning of the face.

Observations

It was observed that out of 50 patients, 16 patients were in the age range of 10-20 years, 29 were in the range of 21-30 and 5 were in the age range of 31-40 (Table 3). Out of 50 patients, 20 were male and 30 were female and female to male sex ratio was 1.5:1 which indicates that this disease is more frequently seen in females (Table 3). Out of 50 patients of acne vulgaris, 16 were in the age – group of 10-20 years, 29 were in 21-30 years and 5 patients were in the age group of 31-40 years (Table 3). Among 50 patients of acne vulgaris, 20 patients had acne of grade-I, 24 had grade-II and 6 patients had grade-III of acne vulgaris. It was also observed that out of 50 patients, 20 had non-inflammatory acne (comedones), 24 patients had comedones with papules

and 06 patients had severe acne with comedones and papules with pustules (Table 4).

The Composition of Tab Musaffi

Table 1

S. No.	Unani Names (Botanical /Scientific Names)	Weight	Properties/Actions	References
1.	Rasaut (<i>Berberis aristata</i>)	125 mg.	Blood purifier, anti-inflammatory, blood alternative, vascular astringent, divergent, febrifuge, local analgesic	Ahmed <i>et al.</i> , 2005.
2.	Narkachoor (<i>Zinjiber zerumet</i>)	125 mg	Pimples, boils, skin diseases, anti-inflammatory, hypnotic, digestive	Ahmed <i>et al.</i> , 2005; Nadkarni, 1926
3.	Chaksu (<i>Cassia absus</i>)	125 mg	Blood purifier, anti-inflammatory, alternative, styptic, haemostatic, astringent wound healer	Ahmed <i>et al.</i> , 2005; Nadkarni, 1926
4.	Kattha Safaid (<i>Acacia catechu</i>)	125 mg	Blood purifier, astringent, useful in skin diseases, divergent, bed sores, chronic ulcer	Ahmed <i>et al.</i> , 2005; Nadkarni, 1926

The Composition of Drugs of Local Application

Table 2

S. No.	Unani Names (Botanical /Scientific Names)	Properties/Actions	References
1.	Kaf-e-darya (Cattle fish)	Anti-putrefactive, astringent, irritant	Ahmed, <i>et al.</i> , 2005
2.	Maghaz-e-Badam Talakh (<i>Prunus amygdalus amara</i>)	Anti-hyperpigmentive, black heads, anti-inflammatory, analgesics, detergent	Ahmed, <i>et al.</i> , 2005
3.	Arq-e-Gulab (Rose water)	Exhilarant, anti-inflammatory analgesic, blood purifier, anti-septic, astringent, desiccant styptic, hemostat Divergent, laxatives vascular, astringent	Ahmed, <i>et al.</i> , 2005

Sex and Age wise distribution of the Patients

Table 3

S. No	Age in years	Male (%)	Female (%)	Total	Sex	Female to Male Sex Ratio
1	10-20	7(43.75)	9 (56.25)	16	Male = 20 Female = 30	1.5:1
2	21-30	9(31.03)	20 (68.97)	29		
3	31-40	4(80)	1 (20)	5		
4	Total	20(40)	30(60)	50(100)		

Grade -wise distribution of the disease

Table 4

S. No	Grade	State of Acne	No. of patients
1	I	Mild acne with comedones	20
2	II	Moderate acne with comedones, papules.	24
3	III	Severe acne with comedones, papules and pustules.	6

Treatment Response

Table 5

S. No	Grade	Main features	Mild Response	Moderate Response	Good Response	Excellent Response	No response	Drop out	Total Pts.
1	I	Mild Acne	0	3	7	7	0	3	20
2	II	Moderate Acne	4	5	5	4	4	2	24
3	III	Severe Acne	1	2	0	0	3	0	6
Total			5	10	12	11	7	5	50

Percentage Wise Response of the treatment

Table 6

S. No	Grade	Main features	Mild Response	Moderate Response	Good Response	Excellent Response	No response	Drop out	Total Pts.
1	I	Mild Acne	0%	6%	14%	14%	0%	6%	40%
2	II	Moderate Acne	8%	10%	10%	8%	8%	4%	48%
3	III	Severe Acne	2%	4%	0%	0%	6%	0%	12%
Total			10%	20%	24%	22%	14%	10%	100%

Result-wise distribution of the patients

Table 7

S. No.	Result	Male	female	Total
1	Relieved	11	14	25
2	Partially relieved	5	8	13
3	Not relieved	3	4	7
4	Drop out	1	4	5
5	Total	20	30	50

Results

After completion of the study, it was found that out of 20 patients of grade I acne, 40% response was found in 17 patients, 3 patients were dropout. Out of 24 patients of grade II acne, total 48% response was found in 18 patients, and 4 patients have no response, 2 patients were dropped out. Out of 6 patients in grade III acne, total 12% response was reported and no response was found in 3 patients. Over all out of 50 patients (Table 5 and 6), over all out of 50 patients, 25 patients were cured in which 11 were male and 14 females, 13 patients were partially relieved in which 5 were males and 8 females. 7 patients including 3 males and 4 females showed no response to the treatment. 5 patients had dropped out (Table 7).

Discussion

Acne vulgaris is commonly called acne. It is a common skin disorder that affects all persons at least once during life time. It usually affects teenagers but substantial numbers of men and woman between the ages of 20-40 are also affected by this disorder (Cunliffe, 1979). Acne is caused by changes in the pilosebaceous units (skin structures consisting of hair follicles and its associated sebaceous gland). The first sign of acne vulgaris commonly occurs at the time of puberty (Rothman, 1993). Acne lesions are commonly referred to as pimples, and spots. It is affecting more than 85% of teenagers and adulthood. Its prevalence is similar in both sexes but the peak age of severity in females is 16-17 years and in male 17-19 years (Lawrence, 2001). Acne may be caused by irritating creams and oils. Pustules on the face can also be caused by tinea infection. The lesions occur mainly over the face, neck, upper chest, back, shoulders etc.

According to Unani System of Medicine, in acne vulgaris disease, the oily

glands over work and there secretion increase in quantity. These secretions remain with the cells and do not come out thus results in inflammation and small white or yellowish pustules develop in the skin. These pustules are pointed at the top and there bases are hard. When these pustules mature and when pressed, it releases some pus (Kabiruddin, 2007).

Since there is no specific treatment available in Allopathic and it is routinely managed by oral as well as local treatment (Lawrence,2001). Many topical antibiotics useful in the treatment of acne have been associated with serious short and long term adverse effects (Reisner, 1983).Cysts can be incised and drained under local anesthesia (Davidson 1995). Erythromycin is resistant strains in acne and has also intolerable gastrointestinal side effects in most of the patients (Eady, et al, 1989). In Unani treatment this disease may be treated by *damvi imalaha* (remove the congestion of blood of the affected part), *tanqiya* (detoxification) of body. The affected part can be washed with *jali adviya* (detergent drugs) like *aard-e-karsana*, *post-baizai-e-murg*, *kharya mitti*(calcium carbonate). The application of paste made of anti-inflammatory drugs like *kutki safaid*, *sirka* can be used over affected parts. Due to various side effects of the treatment patients of acne vulgaris has been reporting for alternate treatment of their problem at this Institute. So, this study was undertaken to evaluate the clinical efficacy of this formulation in the patient of acne vulgaris of grades I, II and III in the year 2011. The duration of the therapy was 28 days and duration of the study was 180 days.

After completion of the study, it was found that in Grade-I Acne, 6% of patients had moderate response (reduction in local inflammation, burning and itching sensation in comedones), 14% with good response (reduction in number of comedones, papules and pustules) and 14% with excellent response(reduction in inflammation, burning and itching sensation, reduction in number of comedones, papules and pustules) and 6% cases were dropped out. The total response in Grade-I was 40%. In Grade-II, 8% of patients had mild response (reduction in local inflammation, burning and itching sensation in comedones), 10% moderate response (reduction in number of comedones, papules), 10% good response (reduction in number of comedones, papules and pustules) and 8% excellent response (reduction in inflammation, burning and itching sensation, reduction in number of comedones, papules and pustules), 8% had no response and 4% patients were dropped out. Total response in Grade-II was 48%. Similarly, in Grade-III, 2% of patients had mild response, 4% moderate response and 6% had no response. Total responses in Grade-II was 12 % (Table 5). It was also found that 25 patients were relieved of the symptoms, 13 were partially relieved, 7 were not relieved and 5 were dropped out (Table 7).

Conclusion

It is concluded that the formulation of drugs namely Oral Tab. *Musaffi* (Kit Medicine) and Local Application of *Kaf-e-darya*(cattle fish bone)+*Badam-e-Talkh*(Bitter Almond)+*Arq Gulab*(Rose Water) in Acne Vulgaris can be tried as a safe and an alternate therapy.

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