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Clinical Evaluation of Babchi (*Psoralea corylifolia* Linn) and Chaksu (*Cassia absus* Linn) along with application of Roghan Babchi in cases of Bars (Vitiligo): A Preliminary Clinical Study

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Abstract

Bars (Vitiligo) is a common skin disease in which white spots appear on different parts of the body. It is characterized by completely or partially depigmented milky white areas of varying sizes and shapes. Besides loss of colour there are no other structural changes. It is one of the commonest of all pigmentary disorders. Approximately 1-2% of the world population is believed to be afflicted with it. It does not affect the physical and intellectual capabilities of the individual or the life span. But it certainly inflicts tremendous psycho-sociological stress on the person, particularly in dark skinned individuals it becomes a major emotional problem. With the growing importance of the problem of *Bars*, we have undertaken the preliminary clinical study at the Mohammadia Tibbia College & Assayer hospital Mansoora Malegaon so as to evolve an effective treatment of the disease, certainly without much side effects.

The study was conducted on 40 diagnosed cases of *Bars* (Vitiligo) at Mohammadia Tibbia College & Assayer hospital Mansoora Malegaon. The powder of Babchi (*Psoralea corylifolia* Linn) and Chaksu

(*Cassia absus* Linn) in the doses of 6 grams twice a day on empty stomach and local application of Roghan Babchi were advised and exposed the affected part to direct sunlight for 5-15 minutes (according to the sensitivity to the patient) for a period of 3 months achieved good response in 25%, fair response was in 27.5% of cases, slow response in 22.5%, poor response in 17.5%,cured response in 2.5% and no response in 5% of patients in 3 months duration.

No significant changes were observed in laboratory investigations (Hb%, TLC, DLC, ESR, Blood Sugar, LFT, RFT, Urine and Stool tests) after 3 months of treatment.

In this study it was observed that the response of treatment was good and without any systemic side effects. However, there were some local side effects like itching and blister formation in some patients. Although the treatment offers maximum success but it needs long duration study.

Key Words: Bars, Babchi, Chaksu, Vitiligo, Roghan Babchi.

INTRODUCTION

Bars (Vitiligo) is an acquired pigmentary disorder, characterized by milky, white, hypo-pigmented, sharply demarcated macules. It has been defined by ancient Unani physicians as a skin disease in which white spots appear on different parts of the body. The Unani physicians described the disease in a comprehensive and systemic manner. *Bars* is a disease of great antiquity. The first record of this disease is found in the period of *Aushoorgan* in the history of Iranian Medicine about 2200 BC [1] followed by the *"Ebers Papyrus"* (1550 BC) that two types of disease affecting the color of the skin out of them one was probably Vitiligo. [2]

The term Vitiligo has been described from the latin word "Vitelius" meaning "Calf" was first introduced by the Roman physician "CELSUS" of the second century AD. The characteristic white spots of the disease resembled with that of white patches of a spotted Calf. [3]

"*Fasad-ud-dam* (impairment of blood) and *Burudat-ud-dam* (coldness of blood) are the main causes of *Bars*. If the digestive faculty of the body cannot metabolise the food properly, there is lackness of healthy blood formation which may has cold & moist temperament (Phlegmatic temperament) instead of its normal temperament leads to appear the *Bars*. [4]

Due to excessive accumulation of *balgham-e-ghaleez,* the affected parts become phlegmatic and soft like that of mollusk. Further, the circulating blood is altered on reaching the affected part and become phlegmatic and the area getting such blood cannot be nourished properly. Ibne- Sarabiyoon quoted that "If *Bars* spreads over a large portion of the body or when it becomes highly chronic or when whitish fluid comes out on pricking the *Bars* patches, it is not curable". [5]

Ibn-e-Sina has given another version of *Bars* in his book *Al-Qanoon fit-tib* in which he states that the *Bars* is caused by weakened *quwat-e-mughaiyarah*. The weakened *quwat-e-mughaiyarah* predisposes weakening of *quwat-e-mushabbeha* under the influence of *maddae ghaleeza* and excessive *buroodat.* Further due to the weakness of *quwat-e-dafia*, the *maddae ghaleeza* remain accumulated in the affected part, therefore the nutrients that reached at the affected parts through blood circulation become altered and unable to be a part of the organ so that organ is unable to take its normal appearance because of

weakened *quwat-e- mushabbeha*. At another place, discussing the diseases which can be transmitted from parents to the offsprings and from generation to generation, he stated that there are certain diseases which are transmitted from generation to generation and *Bars* is one of them. [6]

Vitiligo is characterised by completely depigmented milky white macules of varying sizes and shapes. Besides loss of colour there is no other structural changes.[7]

Bars (Vitiligo) is the commonest of all pigmentary disorders. It is a benign cutaneous disorder which does not either affects the physical and intellectual capabilities of an individual or the life span. But it certainly inflicts tremendous psycho-sociological stress on the person. In dark skinned individuals it becomes a major emotional problem. [8]

Bars (Vitiligo) is not a disease exclusively of human beings, probably it occurs in all animals. [9]A similar condition is seen in Chickens and this animal model has opened a new horizon of research in recent year. [10]

The disease is prognostically unpredictable and therapeutically a challenge. In our country *Bars* is one of the major dermatological problems because of its higher incidence. Moreover, complex social stigma arising out of various erroneous notions about the blemishes is attached to the disease in our country. Coincident with the rapid westernization of our society, there is increased cosmetic consciousness. This not only intensifies the predicament of the patients but drive them into despondency. [11]

Bars (Vitiligo) affects approximately 1-4% of the world population. Its prevalence is varying from 0.46 to 8.8 % in India. [12]

The initial symptom of *Bars* is most often a well defined depigmented chalky white macule that may not be noticed by the patient. Lesions can be present at any site of the body, but are usually seen on sites of stretch and pressure, for example, knees, elbows, dorsum of the hands and fingers. Macules are often rounded to oval in shape, variable in size, without scaling and itching. Borders of the macules are sharply demarcated, often convex towards the periphery. [13]

In 17th Century Hakim Akbar Arzani has also given a detailed account of *Bars* in his famous book *Tibb-e-Akbar*. According to him, *Bars* is a whiteness appearing on the skin. When it spreads all over the body it is called *Bars-e-Muntashir* (generalized vitiligo), weakness of *quwat-e-mughayirah* being its cause. Its treatment becomes difficult, if it turns chronic and remains progressive. He has given an account of the prognostic factors in *Bars*. Those lesions where the hairs are not affected and the lesions which become red on rubbing are curable. [14]

Bars is caused by excessive accumulation of *balgham-e-ghaleez* in the blood, *zofe-quwat-e-mugaiyyarah* of skin, *zofe hazm salis*, *akhlat-e-fasida* and *su-e-mizaj barid* of the organ. [15]

In *Bars*, white spots occur on skin surface. These spots are initially small in size then increased gradually. Sometimes it may be idiopathic and/or due to neurogenic disturbance leads to weakened the power of skin and *quwat-e-muggayarah.* [16]

Most of the Unani physicians agreed that the disease occur mostly because of *zofe quwat-e-mughaiyarah and mushabbeha*, the power that brings changes in the nutrients so that these become the part of the

body. This weakness may be because of *Fasad-ud-dam* and *Burudat-ud-dam* or it may be due to collection of *balgham-e-ghaleez* in the whole body or on the affected parts. [17]

METHODOLOGY

The objective of the study is to clinically assess the disease of *Bars* and to find out the therapeutic efficacy of Babchi (*Psoralea corylifolia* linn), Chaksu (*Cassia absus* linn) and local application of *Roghan Babchi* and also to provide cost effective, potent and safe drug in the treatment of *Bars*.

The total 48 diagnosed patients of Vitiligo were selected for the study from Moalejat OPD of Mohammadia Tibbia College & Assayer hospital, Mansoora, Malegaon. The patients fulfilling the inclusion criteria were included in the study after obtaining written voluntary consent, and those patients who come under exclusion criteria were excluded from the study. The total 40 were completed the study protocol.

CRITERIA FOR SELECTION OF CASES

Inclusion Criteria

Patients suffering from *Bars* belonging to both sexes and more than 10 years of age were selected for study. White patches on the surface of the skin neither elevated nor depressed having no exudation or scaling and no itching with hyperpigmented margins were taken as *Bars* patches.

Exclusion criteria

Cases of *Bars* suffering from other systemic diseases like diabetes mellitus and thyroid dysfunctions. Pregnant women, lactating mothers and children of less than 10 years of age were also excluded from the study.

STUDY DESIGN : Observational open clinical Study.

SAMPLE SIZE : The sample size was 40 patients.

PROCEDURE OF STUDY

The patients were selected on the basis of detailed history and clinical examination according to case report form. Special emphasis was paid to local examination while systemic examinations were carried out to ascertain the systemic disease if any. The selected patients were gone through the laboratory investigations that include complete haemogram (Hb%, TLC, DLC, ESR), urine examination, stool examination, Liver function test (LFT), Renal function test (RFT) and Random blood sugar (RBS) to make the proper diagnosis, to exclude the other systemic ailments and to assess the adverse effects of the drug on liver and kidney. The findings were recorded on the prescribed proforma designed for the clinical evaluation.

SELECTION OF DRUGS

Numerous drugs have been described for the treatment of *Bars* in the classical literature of Unani medicine.

Ingredients

1- Babchi (*Psoralea corylifolia* linn) 100 gm.

2- Chaksu (*Cassia absus* linn) 100 gm.

3-Roghan Babchi

METHOD OF PREPARATION, DOGAGE SHEDULE AND MODE OF ADMINISTRATION OF DRUG

Each ingredient was crushed and mixed together in Mansoora Pharmacy to make fine powder. Six grams of the powdered drug was soaked in a cup of 200 ml of lukewarm water over night. It was filtered in the morning and *Zulal* (fiterate) was taken on empty stomach. The same procedure was repeated in the evening at 5 pm daily. The Roghan Babchi applied locally over the patches and the lesions were exposed directly to sunlight for 5-15 minutes. The treatment was given for a period of 3 months for the maximum repigmentation. Clinical follow up was done on every 15 days where as laboratory investigations were done before the start and after the completion of study.

Vitiligo Area Scoring Index (VASI)

The total body VASI is calculated using a formula that includes contributions from all body regions (possible range, 0–100) (1) One hand unit, which encompasses the palm plus the volar surface of all the digits, is approximately 1% of the total body surface area and is used as a guide to estimate the baseline percentage of vitiligo involvement in each body region. The body is divided into five separate and mutually exclusive regions: hands, upper extremities (excluding hands),trunk, lower extremities (excluding feet), and feet. The axillary region is included with the upper extremities while the buttocks and inguinal areas are included with the lower extremities. The extent of residual depigmentation is expressed by the following percentages: 0, 10%, 25%, 50%, 75%, 90%, or 100%.

At 100% depigmentation, no pigment is present;

At 90%, specks of pigment are present;

At 75%, the depigmented area exceeds the pigmented area;

At 50%, the depigmented and pigmented areas are equal;

At 25%, the pigmented area exceeds the depigmented area;

At 10%, only specks of depigmentation are present.

Criteria for Assessment of Response

Response was assessed on the following lines.

1 – Control on the appearance of new white patches or increase in the size of the existing patches.

2 – Repigmentation of the depigmented areas which on assessed as follows.

1. Cured (100% repigmentation)
2. Very good response (91 – 99% repigmentation)
3. Good response - (71 - 90% repigmentation)
4. Fair response (51 – 70% repigmentation)
5. Slow response - (41 - 50 % repigmentation)

6. Poor response - (Below 40 % repigmentation)

7. No response - (no repigmentation)

The complete data of patients were recorded on a case report form (CRF). Response to the treatment was assessed after every 15 days and the findings were noted in terms of percentage of repigmentation of the depigmented patches. Photographs were taken before treatment and after the treatment of those patients who gave their consent for the use of photograph.

OBSERVATION

Table No -1 Age wise distribution of patients n = 40

S.N.	Age group (in yrs)	No. of cases	Percentage
1	11-20	12	30
2	21-30	8	20
3	31-40	16	40
4	41-50	4	10
5	**Total**	40	100

Table No -2 Sex wise distribution of patients n = 40

S. N.	Sex	No. of cases	Percentage
1	Male	16	40.0
2	Female	24	60.0
3	**Total**	40	100

Table No -3 Showing social status of the patients n = 40

S.N.	Social status	No. of cases	Percentage
1	High	2	5.0
2	Middle	26	65.0
3	Low	12	30.0
4	**Total**	40	100

Table No – 4 Showing the dietary habits n = 40

S. N.	Dietary habits	No of cases	Percentage
1	Non vegetarian	26	65
2	Vegetarian	14	35
3	**Total**	40	100

Table No – 5 Classification of Bars patients according to Mizaj n = 40

S. N.	Types of Mizaj	Male	Female	Total	Percentage
1.	Balghami	7	12	19	47.5
2	Safravi	5	7	12	30
3	Damvi	3	5	8	20
4	Saudavi	1	-	1	2.5
5	**Total**	16	24	40	100

Table No – 6 Distributions of patients according to Vitiligo Area Scoring Index (VASI): n=40

S.N.	Depigmentation in percentages	No of patients	Percentage
1	10	20	50.0
2	25	18	45.0
3	50	2	5.0
4	75	-	-
5	90	-	-
6	100	-	-
7	**Total**	40	100

Table No –7 Showing onset of repigmentation n=40

S.N.	Repigmentation in days	No of patients	Percentage
1	11-20	4	10
2	21-30	10	25
3	31-40	12	30
4	41-50	8	20
5	51-60	3	7.5
6	61-70	1	2.5
7	No response	2	5
8	**Total**	40	100

Table No –8: Distribution of patients according to the chronicity of the disease n = 4

S.N.	Chronicity	No of patients	Percentage
1	Up to 2 years	22	55
2	3-5 years	12	30
3	6-10 years	6	15
4	Total	40	100

Table No – 9: Showing the types of Bars lesion n = 40

S. N.	Types of lesion	No of cases	Percentage
1	Focal	18	45
2	Acrofacial	10	25
3	Segmental	8	20
4	Vulgaris	4	10
5	Total	40	100

Table No – 10 : Showing the response of treatment in different types of lesion n=40

S. N.	**Types of lesion**	**No of cases**	**Response of treatment**					
			Cured	**Good**	**Fair**	**Slow**	**Poor**	**No**
1	**Focal**	16	-	4 (25%)	6 (37.5%)	3 (18.7 %)	2 (12.5%)	1 (6.25 %)
2	**Segmental**	5	1 (20%)	2 (40%)	1 (20%)	1 (20%)		-
3	**Acrofacial**	13	-	4(30.7 %)	2 (15.3%)	2 (15.3 %)	4 (30.7%)	1 (7.6%)
4	**Vulgaris**	6	-	-	2 (33.3%)	3(50%)	1 (16.6%)	-
5	**Total**	40	1	10	11	9	7	2

Table No – 11: Showing the side effects n=40

S. N.	Types of side effects.	No of cases	Severity of side effects.		
			Mild	Moderate	Severe
1	Itching	20(50%)	10(50%)	6(30%)	4(20%)
2	Blister	9(22.5%)	5(55.5%)	3(33.3%)	1(11.1%)
3	Erythema	6(15%)	1(16.6%)	2(33.3)	3(50%)
4	Dryness	5(12.5%)	-	4(80%)	1(20%)
5	Total	40	16(40%)	15(37.5%)	9(22.5%)

Table - 12 Showing the total response of the treatment n =40

S .N.	Response	No of patients	percentage
1	Cured	1	2.5
2	Good response	10	25
3	Fair response	11	27.5
4	Slow response	9	22.5
5	Poor response	7	17.5
6	No response	2	5
7	Total	40	100

STATISTICAL ANALYSIS

The data were analyzed statistically by one-way ANOVA (Analysis of variance). The values were significant ($p<0.01$).

RESULTS AND DISCUSSION

Forty patients suffering from *Bars* were treated with powder of Babchi (*Psoralea corylifolia* linn) and Chaksu (*Cassia absus* linn) along with local application of Roghan Babchi for a period of 3 months. Responses were assessed by using Vitiligo Area Scoring Index (VASI).

The maximum number of patients 16 (40%) were in age group of 31-40 years followed by 12 (30%) in age group of 11-20 years (Table 1). The maximum number of patients were male16 (40%) followed by female 24(60%). It indicates that the females are more prone to this disease (Table 2). In this study maximum number of patients 26(65%) were belonged to middle social status and 12(30%) to the low social status group and only 2(5%) were belonged to high social status (Table 3).

In this study out of 40 patients 26 (65%) were non vegetarian and 14 (35%) were vegetarian. This high percentage of non vegetarian patients is quite interesting as according to Unani system of medicine dietary factors are believed to play an important role in the causation and prognosis of the disease. Cold and moist foods, fish, milk, moist vegetables and fruits are described in the list of restricted food items in various classical text book of Unani medicine (Table 4).

Mizaj of the patients was assessed according to the parameters given by Ibne-Sina. Mizaj is one of the important factors that is related with Bars patients. Our study showed that maximum cases were Balghami, followed by Safravi. It indicates that the patients with balghami mizaj were more affected by this disease. This study is in confirmatory as described in Unani medicine. In Unani system of medicine, accumulation of balgham- e- ghaleez is one of important cause of this disease (Table 5).

As evident from the table that maximum 20(50%) patients were 10%, 18(45%) patients 25% and2(5%) patients depigmentation according to Vitiligo Area Scoring Index (VASI). (Table 6).

As evident from the table that maximum 12(30%) patients were started repigmentation with in 31-40 days after starting the treatment followed by 10(25%) patients in whom repigmentation were started within 21-30days, 8(20%) patients had started within 41-50 days, 3(7.5%) patients had started repigmentation within 51-60 days after starting the treatment and 2(5%) patients had no response at the end of the study (Table 7).

In this study the chronicity of the disease varied from 5 months to 10 years, but the maximum number of cases 22 (55%) were having chronicity of up to 2 years followed by12(30%) of 3-5 years. It was observed that the response of the treatment was decrease with the increased chronicity of disease.

Maximum response was achieved in cases having chronicity of up to 5 years and minimum response was achieved in cases having chronicity of 6-10 years (Table 8)

Out of 40 patients 16 (45%) were of focal type, 10 (25%) of acrofacial, 8 (20%) of segmental and 4 (10%) patients of vulgaris (Table 9).

The patients with segmental lesions showed good response in comparison with other types of lesions (Table 10).

The maximum number of patients 20(50%) who had itching at the site of lesion. Out of these 10(50%) patients had mild, 6(30%) patients had moderate and 4(20%) patients had severe itching during the study. There were only 9(22.5%) patients who had blister formation over their lesion, in which 5(55.5%) patients had mild, 3(33.3%) patients had moderate and 1(11.1%) patients had severe blister over the site of lesion. There were 6(15%) patients who had erythema over the site of lesion in which 4(80%) patients had moderate and 1(20%) patients had severe erythema over the site of lesion and only 5 (12.5%) patients who had dryness in which 4(80%) patients had moderate and 1(20%) patients had

severe dryness over the site of lesion. There were 9(22.5%) patients with severe side effect, 15(37.5%) patients of moderate degree and 16(40%) patients of mild degree side effects. But these were local side effects and no systemic side effect was observed. Thus the study indicates that these drugs are effective and safe in cases of Bars. Hence these drugs may be used safely for longer duration (Table 11).

The overall response on 40 Bars patients with achieving good response in 25%, fair response was in 27.5% of cases, slow response in 22.5%, poor response in 17.5%, cured response in 2.5% and no response in 5% of patients in 3 months duration (Table 12)

No significant changes were observed in laboratory investigations (Hb%, TLC, DLC, ESR, Blood sugar-random, LFT, RFT, Urine and Stool tests) after 3 months of treatment. Thus this Unani formulation is suggested to be effective as well as safe for Bars patients.

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